

Final addendum to the
Additional Report
- public version -

**Additional risk assessment provided by the rapporteur Member State
Belgium for the existing active substance**

BENFURACARB

**according to the Accelerated Resubmission Procedure laid down in
Commission Regulation (EC) No. 33/2008**

February 2009

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ANNEX B

Benfuracarb

B.7 Residue data

(Addendum November 2008)

Open point 3(2) in the Reporting Table rev.0 (November 2008): Vol. 3 B.7.1.3 bis Metabolism in cabbage

A) The total radioactive residues in the aqueous phase after partitioning increased up to 51.9 % of the TRR at 4 weeks sampling interval (see Table B.7.1.3 *bis* -2).

On HPLC chromatograms, the radioactivity in the aqueous soluble phase was fractionated into 2 peaks A and B of which one possibly matched with Carbofuran-3-OH-7-phenol but on the TLC plates the total radioactivity remained at the origin and could not be further characterized.

Therefore the aqueous soluble residues fraction was subjected to acid hydrolysis. Organo soluble metabolites released by hydrolysis were extracted from the aqueous phase using partitioning against Dichloromethane (DCM).

These data are reported in the table here below.

Table B.7.1.3 *bis* -2': Acid hydrolysis /DCM partitioning of the aqueous soluble residues of the 4 weeks samples.

Harvest	Combined DCM extracts		Aqueous soluble residues fraction	
	% TRR	mg Benfuracarb equiv./kg ¹⁴ C-	% TRR	mg Benfuracarb equiv./kg ¹⁴ C-
4 weeks samples	31.1	189	17.5	107

31.1 % of the TRR indicated de-conjugation of the organo soluble metabolites.

HPLC analysis: Only one peak was observed both on the DCM extract and the aqueous soluble phase after acid hydrolysis but without any further identification.

TLC analysis in solvent system I:

-TLC analysis of the DCM extract showed 4 peaks of which 3 matched with Carbofuran-3-OH (6.1 % of the TRR) and possibly with carbofuran-3-keto and Carbofuran (2.7 % and 17.2 % of the TRR, respectively).

Those metabolites were assumed to be under their conjugated form in the aqueous soluble phase before the acid hydrolysis treatment.

5.1 % of the TRR remained at the origin of the TLC plate.

-TLC analysis of the aqueous soluble residues fraction after acid hydrolysis showed that one peak was observed at the origin (10.5 % of the TRR) and a peak that had a similar retention time with Carbofuran (7 % of the TRR).

B) RMS agrees with the comment of the notifier.

During the EPCO Expert Meeting 34, the experts considered that the available metabolism study on sugar beet (Haynes L.M., 2003) could address the metabolism of Benfuracarb in brassica crops. The findings were as expected i.e. Benfuracarb largely converted into Carbofuran. The study highlighted a fraction, T1 (composed of 2 minor and 1 major components and not susceptible to beta-glucosidase digestion), which made up 36% of the TRR (0.11 mg/kg) in sugar beet tops/leaves at harvest.

Fractionation and characterization of the fraction T1 in sugar beet tops and leaves extracts were performed (Van Noorloos B., 2007).

The T1 fraction was analysed by TLC and by gel permeation chromatography together with polysaccharides standards in order to estimate the molecular size of the compounds.

It was observed that the polar fraction T1 did not release any Benfuracarb or Carbofuran/3-keto-carbofuran/3-OH-carbofuran upon enzymatic and acid hydrolysis treatments. This fraction contained high molecular weight compounds, indicating incorporation of radioactivity into macromolecules such as polysaccharides.

In conclusion, it is not relevant to include the conjugates of Carbofuran, 3-OH-carbofuran and Carbofuran -3-keto in the residue definition for risk assessment.

Open point 3(7) in the Reporting Table rev.0 (November 2008): Vol 3. B.7.6 Residue trials – Methods

The EFSA comment referred to the study reports BPL 06/063/CL-1 and -2 in the Appendix C in the DAR.

These trials were analysed using validated analytical methods - NOTOX project 434813 (Carbofuran) and NOTOX project 465154 (3-OH-carbofuran).

The LoQ of these methods in the cauliflower seedlings and heads was established at 0.005 mg/kg for each analyte. During the analysis of the residues of 3-OH-carbofuran, this LoQ could not be reached as the sensibility of the LC-MS/MS system was lower than during the validation. Consequently, the LoD was over the LoQ fixed during the validation. The obtained LoD values for the 3-OH carbofuran were:

-for seedlings: 0.0089 mg/kg

-for heads: 0.00551-0.0067 mg/kg.

For Carbofuran, the LoD of these methods was always below the LoQ.

Therefore the LoQ of the methods for the determination of the residues of 3-OH-carbofuran was set at 0.01 mg/kg.

RMS did not consider these trials for MRL setting and consumer dietary risk assessment.

Open point 3(11): Vol 3 B.7.11 Exposure assessment

Carbofuran+ 3-OH-Carbofuran			
Status of the active substance:	Annex I inclusion	Code no.	#N/A
LOQ (mg/kg bw):	0,0045	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,00015	ARfD (mg/kg bw):	0,00015
Source of ADI:	DAR 2008	Source of ARfD:	DAR 2008
Year of evaluation:	2008	Year of evaluation:	2008

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum
7
No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
6,8	NL child	3,1	Cauliflower	1,5	Broccoli	0,9	Head cabbage	1,2
5,6	FR toddler	2,7	Broccoli	2,6	Cauliflower	0,3	Head cabbage	0,3
4,0	SE general population 90th percentile	1,9	Head cabbage	0,6	Chinese cabbage	0,6	Broccoli	2,6
3,6	NL general	1,6	Cauliflower	0,6	Head cabbage	0,6	Kale	0,9
3,5	IE adult	1,4	Broccoli	1,1	Cauliflower	0,6	Brussels sprouts	1,0
3,2	WHO regional European diet	1,4	Cauliflower	1,1	Head cabbage	0,3	Broccoli	1,2
2,8	FR infant	2,0	Broccoli	0,8	Cauliflower	0,0	Brussels sprouts	0,1
2,6	UK Infant	1,7	Cauliflower	0,6	Brussels sprouts	0,3	Head cabbage	0,9
2,0	DE child	0,9	Cauliflower	0,8	Broccoli	0,3	Head cabbage	0,4

1,9	WHO cluster diet D	0,6	Chinese cabbage	0,5	Head cabbage	0,5	Kale	1,4
1,8	PL general population	1,1	Head cabbage	0,6	Cauliflower	0,1	Broccoli	1,2
1,7	WHO Cluster diet F	0,8	Head cabbage	0,5	Broccoli	0,2	Chinese cabbage	1,1
1,7	UK vegetarian	0,8	Cauliflower	0,6	Broccoli	0,3	Head cabbage	0,4
1,6	UK Toddler	0,7	Cauliflower	0,4	Broccoli	0,3	Head cabbage	0,4
1,5	WHO Cluster diet B	0,7	Head cabbage	0,5	Cauliflower	0,3	Chinese cabbage	1,0
1,4	WHO cluster diet E	0,8	Head cabbage	0,5	Broccoli	0,1	Brussels sprouts	0,9
1,2	UK Adult	0,5	Broccoli	0,4	Cauliflower	0,2	Head cabbage	0,3
1,2	LT adult	1,2	Head cabbage		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	1,2
0,9	FR all population	0,6	Cauliflower	0,2	Broccoli	0,1	Head cabbage	0,2
0,8	DK child	0,3	Broccoli	0,2	Cauliflower	0,2	Head cabbage	0,2
0,7	DK adult	0,2	Cauliflower	0,2	Head cabbage	0,2	Broccoli	0,3
0,6	IT adult	0,3	Cauliflower	0,2	Broccoli	0,1	Head cabbage	0,1
0,6	FI adult	0,2	Head cabbage	0,1	Cauliflower	0,1	Chinese cabbage	0,3
0,5	ES adult	0,4	Cauliflower	0,1	Head cabbage		FRUIT (FRESH OR FROZEN)	0,1
0,5	ES child	0,3	Cauliflower	0,1	Head cabbage		FRUIT (FRESH OR FROZEN)	0,1
0,4	IT kids/toddler	0,3	Cauliflower	0,1	Broccoli	0,0	Head cabbage	0,0
	PT General population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
Acute risk assessment /children				Acute risk assessment / adults / general population				

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): 5			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 4			No of commodities for which ARfD/ADI is exceeded (IESTI 1): 4			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 3		
	IESTI 1 *)		**)	IESTI 2 *)		**)	IESTI 1 *)		**)	IESTI 2 *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
440,5	Cauliflower	0,01 / 0	440,5	Cauliflower	0,01 / 0	211,6	Cauliflower	0,01 / 0	211,6	Cauliflower	0,01 / 0	
396,0	Broccoli	0,0102 / 0	282,9	Broccoli	0,0102 / 0	145,0	Broccoli	0,0102 / 0	145,0	Broccoli	0,0102 / 0	
387,6	Kale	0,0086 / 0	276,9	Kale	0,0086 / 0	116,9	Kale	0,0086 / 0	107,1	Chinese cabbage	0,0045 / 0	
157,9	Head cabbage	0,0045 / 0	111,4	Chinese cabbage	0,0045 / 0	107,1	Chinese cabbage	0,0045 / 0	86,8	Kale	0,0086 / -	
111,4	Chinese cabbage	0,0045 / 0	94,7	Head cabbage	0,0045 / -	95,2	Head cabbage	0,0045 / -	57,1	Head cabbage	0,0045 / -	

ANNEX B

Addendum January 2009

Benfuracarb

B.6 Toxicology and metabolism

Introductory note: submitted studies on CARBOFURAN, relevant metabolite of Benfuracarb

At the occasion of the resubmission of **Carbofuran**, the main metabolite of Benfuracarb, an updated Draft Assessment Report was produced by the RMS.

FMC notified the existence of **comparative acute neurotoxicity studies**, conducted after the submission of the original EU DAR.

As RMS suspected that these studies could have an impact on the original reference doses of Carbofuran, these studies were requested and evaluated.

In 2009, EFSA requested the inclusion of these studies in an addendum of Benfuracarb.

Relating documents, including LoEP were modified accordingly.

Section	Study	Reference	page
B.6.6.1.2 Supplementary studies (Annex IIA 5.6.1)	Oral administration of carbofuran on male reproductive system of rat	Chevalier, 2006	
B.6.7.3 Further neurotoxicity studies (Annex IIA 5.7)	Rat, acute neurotoxicity study, gavage, 0.3, 0.6, 1 mg/kg b.w. (range-finding study)	Tyl, 2005a	
	Rat, acute neurotoxicity study, gavage, 0.6 mg/kg b.w. (peak time identification study)	Tyl, 2005b	
	Rat, acute neurotoxicity study, gavage, 0, 0.3, 0.6, 1.0 mg/kg b.w. (main study)	Tyl, 2005c	
	Rat, acute neurotoxicity study, gavage, 0, 0.03, 0.1, 0.3 mg/kg b.w. (range-finding study)	Hoberman, 2007a	
	Rat, acute neurotoxicity study, gavage, 0.0 or 0.1 mg/kg b.w. (peak time identification study)	Hoberman, 2007b	
	Rat, acute neurotoxicity study, gavage, 0; 0.03, 0.1, 0.3 mg/kg b.w. (main study)	Hoberman, 2007c	
	Rat, acute neurotoxicity study, gavage, 0; 0.1, 0.3, 0.6 or 1.0 mg/kg b.w.	Moser, 2007b	
	Rat, acute neurotoxicity study, gavage, 0; 0.1, 0.3, 0.6 or 1.0 mg/kg b.w. in neonate rats (PND 17)	Moser, 2007a,	
	Rat, acute neurotoxicity study, gavage, 0; 0.1, 0.3, 0.5, 0.75 or 1.5 mg/kg b.w. in adult rats	Mc Daniel <i>et al.</i> , 2007	
	Rat, acute neurotoxicity study, gavage, 0.5 mg/kg b.w. in adult rats – time-course study	Padilla <i>et al.</i> , 2007	

B.6.6.1.2 Supplementary studies (Annex IIA 5.6.1)

A new toxicity study was conducted in the SD rat, to see whether the adverse effects in the male reproductive system, observed in a study of the open literature (Pant, 1995) would be reproducible.

- Oral administration of carbofuran on male reproductive system of rat (Chevalier, 2006)

Findings: see table 6.6.1.2-2.

Mortality: no substance-related mortality

Clinical signs:

-none in the dietary groups

-gavage group: top-dose animals experienced transiently (30' following treatment) hypoactivity, tremor and hypersalivation.

Body weight and food consumption: were decreased in the top-dose animals of the dietary groups during the first 4 weeks of treatment (more marked during the first week: -40%). The effect was related to a transient reduction of food consumption.

Clinical chemistry (testicular activity):

In the dietary top-dose group, significantly decreased LDH and increased γ -GT activities were noted. Animals in the gavage group were unremarkable. The study director considered the altered enzyme activities non-adverse, given the slight difference with the controls. However, the differences were significant to highly significant, and for LDH (12016 IU/L at the top-dose, 16400 IU/L in controls) well outside the historical reference values (15658-19007 IU/L), and could also be considered for the determination of the NOAEL.

Organ weight:

No marked treatment-related effects on absolute and relative organ weights were observed. Lower epididymides and testis weights were noted in the top-dose animals, attaining statistical significance in some cases.

Dietary study. The decreased epididymides or testes weight was lower in two ♂, and the finding correlated with both necropsy and histology. The epididymides/testes weights in the remaining top-dose animals were within the range of the control group. The weight changes in other organs were small, insignificant and without histopathological correlate.

Gavage study. Significant decreases in right absolute or relative epididymides/testis weight was noted at the top-dose. The findings were however unilateral, both incidence and severity of histopathological testicular lesions were evenly distributed among control and treated groups (only scored in left organs), and therefore the toxicological significance remains equivocal.

Sperm parameters (epididymal or testicular sperm counts, motility and morphology) remained unaltered, in both the dietary and the gavage group.

Gross necropsy and histopathology:

No major treatment-related findings were observed at macroscopic or microscopic examination of the genital and accessory organs. In 2/10 top-dose animals of the dietary study, both macroscopic sizing and microscopic assessment of testes and epididymides showed reduced presence of spermatozoid precursors, confirming the weight decreases. However, the findings were not observed in the animals where the test article was administered by gavage.

Table 6.6.1.2-1 : carbofuran toxicity study on male reproductive organs.

Dose		Diet				Gavage		
ppm		0	5	30	180	-	-	-
Endpoints	mg/kg b.w./d	0	0.5	3	18	0	0.2	0.8
Clinical signs (incidence /10):								
hypoactivity		-	-	-	-			8
tremor		-	-	-	-			5
hypersalivation		-	-	-	-			3
Body weight (wk 0-4)					↓30%			-
Food consumption					↓			-
Organ weights :								
Final b.w.					↓10%			-
Epididymis (l/r)	a				↓10% / ↓4%			↑5% / ↓13%*
	r				- / ↑5%			- / ↓16%**
Testes (l/r)	a				↓9% / ↓7%		↑8% / ↓6%	↑6% / ↓7%
	r				- / -		↑6% / ↓8%	- / ↓11%*
Seminal vesicles	a				↑6%		-	-
	r				↑16%		-	-
Prostate	a				-		↓5%	↓12%
	r				↑12%		↓7%	↓15%
Necropsy								
testes soft/reduced in size		0	0	0	1/2	1	0	0
epididymes reduced in size		0	0	0	1	0	0	0
Histopathology[§]								
↓n° of tailed spermatids		0	0	0	2 ^(3.5)	-	-	-
↓n° of round spermatids		0	0	0	2 ^(4.0)	-	-	-
↓n° of spermatocytes		0	0	0	2 ^(4.5)	-	-	-
Testicular enzymes:								
γ-GT					↑42%*			-
LDH					↓27%**			-

l/r: left/right; a: absolute; r: relative; § : incidence number and ⁽⁻⁾ mean severity (grades 1..5)

Statistical significant modification: *p<0.05 (Dunnett test) and **p<0.001 (Dunn test)

Conclusion:

The NOAEL's in this study were:

-0.2 mg/kg bw/d, based on clinical signs observed at 0.8 mg/kg bw/d in the gavage phase;

-3 mg/kg bw/d, based on clinical signs and testicular findings, including ↑GGT observed at 18 mg/kg bw/d in the dietary phase.

The subtle testicular findings in the dietary study indicated that at the top-dose, Carbofuran exerted some effects which had also been observed in the previous study. However, the effects were far less pronounced, and occurred only at a systemically toxic dose (18 mg/kg b.w./d), as compared to the original published gavage study (0.2, 0.4 and 0.8 mg/kg b.w./d). In particular, the same histopathological effects were not replicated in the current gavage study. In neither case, morphological nor functional (motility) spermatocyte parameters were altered by the treatment in the current study. It was of note that, comparably to the first study, general toxicity was also much lower (no deaths, no body weight reduction).

The difference in severity was possibly due to the fact that in the first study (Pant, 1995), presumably younger animals were involved, and rats of a different strain were used. Also the batch of Carbofuran used could be different (although from the same company). However, the study is not critical for the establishment of reference doses (see below B.6.7.3 and B.6.10).

Guidelines: No guidelines are of application, as this is a study for clarification of pre-dosing effects in ♂rats, observed in previous developmental studies

GLP status: The study is GLP.

Remark from RMS: it was of note that some differences were observed with the Pant study (2005):

-the rats had a mean bw of about 201 g, and were 35-42d (gavage group) or 42-49d (dietary group) old at the beginning of the study. In the Pant study (1995), the initial bw was about 80g. The exact age was not stated, but presumably they were somewhat younger (about 28-30d);

-the rat strain was different: SD in this study, and Druckrey in the Pant study.

Material and methods:

10 male CD® (Sprague-Dawley) albino rats/group received Carbofuran (purity 97.1%; B.n° 4L14) at doses of:

(i) 0, 5, 30 or 180 ppm in the diet, corresponding with 0, 0.5, 3 or 18 mg/kg b.w./d for 10 weeks, or

(ii) 0, 0.2 or 0.8 mg/kg b.w./d by gavage (dissolved in corn oil; dosing volume 5 mL/kg b.w.) for 60d.

The dietary admixtures were prepared for up to 8d and stored in closed bags at room t°; the dosing suspensions were prepared for up to 9 days and stored in the dark (4°C) Analytical verification of homogeneity was performed at d0 (preparation time) of dietary admixtures dosing solutions (LD, HD). Analytical verification of stability was performed for the dietary admixtures (up to 15-16d for closed bags and up to 8-9d for open feeders) and of dosing solutions (up to d9 storage). It appeared that the homogeneity was satisfactory, with maximal values of CV=5% (dietary admixtures) or CV=8% (liquid dosages), and biases being mostly positive. Also the stability was acceptable. Dietary admixtures were maximally -7% to +10% from nominal, and administered dosage forms were -9% to +2% from nominal.

-Standard parameters including clinical signs, body weight, food consumption were studied.

-In addition, (right) testicular activities including sorbitol dehydrogenase (SDH), LDH, γ-GT, G6PD were measured.

-At termination, seminology included epididymal sperm motility and count, morphology, and testicular sperm count (elongated spermatids and mature spermatozoa).

-Brain, prostate, epididymes, testes and seminal vesicles were weighed wet as soon as possible after dissection.

-Complete gross necropsy was performed.

-The following tissues or representative samples were collected and fixed: adrenal glands, aorta, brain (medulla/pons cerebellar and cerebral cortex), femoral bone with articulation, epididymides, eyes (with Harderian glands), heart, GIT, kidneys, liver, lungs, lymph nodes (mandibular, mesenteric), mammary gland, pancreas, pituitary, prostate, salivary gland (sublingual and submandibular), sciatic nerve, seminal vesicles, skeletal muscle, skin, spinal cord (cervical, thoracic, lumbar), spleen, sternum with bone marrow, stomach, testes, thymus, thyroid/parathyroid, tongue, trachea and urinary bladder.

-Microscopic examination was performed on: macroscopic abnormalities, brain, testis (left), epididymis (left), seminal vesicles, prostate and coagulating glands. Transverse sections of the left testis were specifically stained with PAS for testicular staging. Particular attention was paid to all the stages of testicular spermatogenesis and to the interstitial structure.

The study is accepted.

Table B.6.6.3-2: Summary

Type of test Test species	Test substance purity	Results			References
		NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Symptoms	
60-day rat study, <i>gavage</i> (0.2, 0.8 mkd)	purity 97.1%; B.n° 4L14	NOAEL = 0.2 mg/kg b.w./d	LOAEL = 0.8 mg/kg b.w./d	Clinical signs	Chevalier, 2006
10 week rat study, <i>diet</i> (5, 30, 180 ppm = 0.5, 3, 18 mkd)		NOAEL = 3 mg/kg b.w./d	LOAEL = 18 mg/kg b.w./d	Decreased body weight, slight testicular findings	

B.6.7 Neurotoxicity (Annex IIA 5.7)

At the occasion of the resubmission of Carbofuran, the notifier submitted several oral (gavage) neurotoxicity studies on adult (PND 60) and neonate (PND 11) rats (6 studies). In addition, 2 studies were submitted in order to assess neurotoxicity via dermal administration (2 studies). These studies could be relevant for the establishment of reference doses.

In addition, 2 oral studies, conducted by the EPA, were added for information.

- Rat, acute neurotoxicity study, gavage, 0.3, 0.6, 1 mg/kg b.w. (range-finding study) (Tyl, 2005a, FMC)

Findings: see table B.6.7.3-1.

Mortality: none

Clinical signs:

Following signs progressed over time in all dosing groups: fine tremors, whole body tremors, large head tremors and intermittent tremors, beginning at 2' post dosing, increased dose- and time-dependently in severity and incidence, and were maximal at 10'-19' post dosing. Large head tremors persisted the longest in all dosing groups. The symptoms were unremarkable from 60' post dosing on.

It was of note that other typical carbamate toxicity signs were possibly missed. Some anticipated signs could have been left unremarked. For instance, as the pup eyes were still closed, observation of lachrimation was possibly prevented, and because of the continuous grooming of the pups by their dams observation of salivation and urination/defaecation was difficult.

Body weight: top-dose ♂ were about 15% lighter than ♂ at the lowest dose at termination.

Cholinesterase activity:

-RBC cholinesterase activity was unaffected at any dose.

-Brain cholinesterase was decreased at 0.6 (♂) and 1 mg/kg b.w. (♂,♀) when compared to the lowest dose (0.3 mg/kg b.w.).

Necropsy examination: not examined.

Histopathology: not examined.

Table B.6.7.3-1: neurotoxicity testing of Carbofuran in rat pups: cholinesterase activity (Tyl, 2005a – range-finding)

Endpoint	Dose Level (mg/kg)					
	0.3		0.6		1	
	♂	♀	♂	♀	♂	♀
RBC (U/L)	3307 ± 202	2780 ± 171	3353 ± 217	3393 ± 267	3400 ± 171	3020 ± 40 ¹
Brain (U/g)	7.74 ± 0.03 ###	7.01 ± 0.79	7.06 ± 0.17 **	7.45 ± 0.28	5.47 ± 0.09***	6.37 ± 0.14

Values are the mean ± std error; ¹: N=2 animals due to one blood sample clotting (value was excluded).

Statistically significant modification: ** p≤0.01, *** p≤0.001 (Dunnett's test; compared to the 0.3 mg/kg group).

: p≤0.001 (anova)

Conclusion:

In the absence of moribundity or mortality, rat PND11 pups tolerated a single administration of Carbofuran by gavage up to and including 1 mg/kg b.w.. The treatment caused clinical signs like tremors very shortly after dosage up to 1h post-dose. Brain but not RBC cholinesterase activity was decreased at the mid- and top-dose in the ♂, when compared to the low-dose group. The determination of a NOAEL was not possible in the absence of proper control groups.

GLP status: yes

Guideline: not of application

Material and methods:

Three PND 11 rats/sex/dose (Sprague-Dawley (CrI: CD[®]SD)) received a single administration of Carbofuran (batch n° PL04-0056, purity 99.0%) dissolved in corn oil (dosing volume 5 mL/kg) by gavage at 0.3, 0.6 and 1.0 mg/kg b.w.. The pups were returned to their dams and examined for clinical signs of toxicity at approximately 15', 30', 1h, 1.5h, 2h, 4h and 6h. At 6h post-dosing, each pup was weighed, examined, terminated (CO₂ asphyxiation), and blood collected via cardiac puncture. Each pup brain was removed intact, weighed, transferred to a labelled vial, and placed on dry ice.

Blood and brain samples were transferred to the clinical chemistry laboratory within 20' of collection. The blood samples and brains were processed immediately (preparation of RBC lysates and whole brain homogenisation) and then frozen at –70°C until analysis. The cholinesterase enzyme assays (modified from Ellman et al., 1961) were performed spectrophotometrically (405 nm absorbance) on a COBAS MIRA[®] Plus CC clinical chemistry analyser.

Quantitative continuous data were compared among the treatment groups by the use of Levene's test for homogeneity of variances and in the case of lack of homogeneity of variances ($p \leq 0.05$) robust regression method were used to test all treatment effects. General Linear Model (GLM) analysis was used to determine whether significant dosage effects occurred for selected measured (ANOVA). A Dunnett's two-tailed test was used for all pairwise comparisons to the low-dose group for body weight parameters, and one-tailed test was used for cholinesterase levels.

The study is considered to provide complementary information.

**- Rat, acute neurotoxicity study, gavage, 0.6 mg/kg b.w. (peak time identification study)
(Tyl, 2005b, FMC)**

Findings: see table B.6.7.3-2

Mortality: none

Clinical signs:

-Pups:

Clinical observations on PND11 rat pups started 2' post dosing (1♂ with whole-body tremors). Tremors occurred from 3' (1♂) and 4' (1♂, 1♀), and were maximal in severity and incidence at about 15' post dosing. Triggered tremors (tremors observed when touched or moved) were observed mainly at about 30' post-dosing (start at about 15' and lasted until about 2h post-dosing). As a general remark, it was reported that initially, fine tremors were observed, followed by large whole-body tremors, and then large head tremors. Over time postdosing, the tremors became intermittent, with large head tremors persisting the longest.

-Young adults:

Treatment-related clinical observations in the adult rats started at 6' post dosing in 1♀, with maximal severity and incidence at about 15' post dosing. The main signs were head and face tremors, which were observed up to 1h post dosing. Additional signs observed occasionally were lethargy, salivation, slow respiration, soft faeces, coprophagy and piloerection. Abdominal twitching (1♀, 2h) and piloerection (3♀, 4h) were further observed at later stages.

Body/brain weight:

Significantly increased body weights (♂pups, 90') or decreased (♀pups, 120', 240') were observed but irrelevant in the absence of similar changes at the later time-points. Male adult brain weights were marginally (6%, $p \leq 0.01$) lower at 120' and at 360' but without biological relevance; thus, the treatment was deemed without effect on the body and brain weights.

Cholinesterase activity:

-The RBC cholinesterase activity was considered unaffected by the treatment at any sampling time.

-The brain cholinesterase was maximally inhibited in both the ♂ and the ♀ from the first timepoint (15') on, and showed a time-dependent decrease until the last timepoint (6h).

In the pups, the AChE-inhibition was up to 59% of controls at 15', and persisted until 6h post-dose.

In the adults, the effect was less pronounced, as the inhibition at 15' post-dose amounted up to 38% of controls.

The ♂ adults exhibited a slight brain AChE inhibition at 6h post-dose (–8%), but statistical significance was lacking. In the ♀ adults, the inhibition was statistically significant up to termination (6h), except at 4h post-dose.

In conclusion, this time-course experiment demonstrated that the time-of-peak for both clinical signs and brain AChE inhibition was about 15' after single administration of 0.6 mg/kg b.w. Carbofuran, to both neonates and young rat adults. This kinetics was compatible with the known effects of carbamates as 'reversible' cholinesterase inhibitors, where enzyme binding, inactivation and associated toxicity (signs associated with excessive stimulation of cholinergic receptors throughout CNS and PNS) was limited in time. It was demonstrated that there was no full recovery of brain AChE inhibition in the pups up to 6h post-dose, while marginal effects were observed at the late time-points (4h) in the young adults. The results clearly show that pups were more sensitive to the brain AChE inhibition at peak-time after single Carbofuran treatment than the (young) adults.

The reason why a meaningful brain AChE inhibition was measured, in the absence of such modification in the RBC remained unclear.

Table B.6.7.3-2: neurotoxicity testing in rats: cholinesterase activity after single administration of 0.6 mg/kg b.w. of Carbofuran (Tyl, 2005b – peak time identification study)

a. Rat pups

	Endpoint	Time of sacrifice (minutes post dosing)							
		0	15	30	60	90	120	240	360
Males	RBC (U/L)	3494 ± 295 ##	2988 ± 199 -	3056 ± 96 -	4092 ± 251 -	3052 ± 139 -	3896 ± 87 -	3340 ± 118 -	4320 ± 199 -
	Brain (U/g)	7.33 ± 0.33 ###	3.50 ± 0.29 ↓52%***	4.02 ± 0.33 ↓45%***	4.29 ± 0.25 ↓41%***	5.31 ± 0.39 ↓28%***	4.62 ± 0.18 ↓37%***	5.54 ± 0.52 ↓24%***	6.18 ± 0.05 ↓16%*
Females	RBC (U/L)	3770 ± 336 ###	3100 ± 203 -	3232 ± 227 -	4444 ± 202 -	3048 ± 193 -	3928 ± 133 -	3208 ± 132 -	5064 ± 459 -
	Brain (U/g)	8.38 ± 0.38 ###	3.43 ± 0.32 ↓59%***	4.45 ± 0.41 ↓47%***	4.13 ± 0.25 ↓51%***	4.71 ± 0.57 ↓44%***	4.99 ± 0.37 ↓40%***	6.87 ± 0.52 ↓18%*	6.36 ± 0.20 ↓24%**

b. Young adult rats

	Endpoint	Time of sacrifice (minutes post dosing)							
		0	15	30	60	90	120	240	360
Males	RBC (U/L)	4208 ± 261 -	4332 ± 299 -	4456 ± 390 -	5124 ± 233 -	4228 ± 240 -	4732 ± 297 -	4796 ± 611 -	5164 ± 298 -
	Brain (U/g)	12.98 ± 0.22 ###	8.04 ± 0.55 ↓38%***	8.47 ± 0.39 ↓35%***	11.28 ± 0.17 ↓13%***	10.74 ± 0.12 ↓17%***	11.68 ± 0.26 ↓10%**	11.78 ± 0.39 ↓9%*	12.00 ± 0.32 ↓8%
Females	RBC (U/L)	4760 ± 296 -	4088 ± 400 -	4432 ± 400 -	5272 ± 358 -	4908 ± 366 -	4540 ± 329 -	3856 ± 403 -	4536 ± 173 -
	Brain (U/g)	13.06 ± 0.12 §§§	8.67 ± 0.38 ↓37% ^{ooo}	9.18 ± 0.33 ↓30% ^{ooo}	11.38 ± 0.27 ↓13% ^{ooo}	11.18 ± 0.28 ↓14% ^{ooo}	12.12 ± 0.20 ↓7% ^{ooo}	13.04 ± 0.52 -	12.24 ± 0.20 ↓6% ^{oo}

Values are the mean ± std. error, and concomitant % reduction compared to control group;

Statistically significant modification: *: p≤0.05, **: p≤0.01, ***: p≤0.001 (Dunnett's test); °: p≤0.01; °°: p≤0.001 (t- test) for pairwise comparison with 0' group; ### : p≤0.001 (anova) and §§§: p≤0.001 (Wald χ^2 -test) for treatment effect in regression model (trend).

Conclusion:

The administration of Carbofuran by gavage induced typical carbamate-induced clinical signs very shortly (15') after dosage, which lasted up to 2h post-dosing. Brain but not RBC cholinesterase activity was decreased, when compared to the untreated group. Throughout the experiment, pups showed a stronger reaction than young adults.

Based upon this time-course experiment, the time-of-peak for brain AChE inhibition, after the administration of Carbofuran at 0.6 mg/kg b.w., was 15' after administration. In the pups, a meaningful effect (*ca.* 20% average) was still visible 6h post-dose, while at this time-point, the inhibition was <10% in the young adults. Therefore, the recovery time remained unidentified, and considered >6h overall. It may be expected that the AChE inhibition would be unremarkable by 24h post-dose.

GLP status: yes

Guideline: not of application

Material and methods:

Thirty-five rat pups (PND11)/sex and thirty-five young adult rats (60d)/sex (Sprague-Dawley (CrI: CD[®]SD)) received a single administration of Carbofuran (batch n° PL04-0056, purity 99.0%) dissolved in corn oil (dosing volume 5 mL/kg) by gavage at 0.6 mg/kg b.w.. In addition, 5 pups/sex and 5 young adults/sex remained untreated.

Five treated animals/sex/timepoint were terminated at 15', 30', 1h, 1.5h, 2h, 4h and 6h post-dose, and five untreated animals/sex/timepoint were terminated immediately (at 0') and at 6h. The final control group values were pooled from the 0' and 6h undosed animal values, for both the pups and the adults.

At these times, the animals were examined for clinical signs of toxicity, and were weighed, terminated (CO₂ asphyxiation), and blood collected via cardiac puncture. Each brain was removed intact, weighed, transferred to a labelled vial, and placed on dry ice.

The blood samples and brains were processed immediately (preparation of RBC lysates and whole brain homogenisation) and then frozen at -70°C until analysis. The cholinesterase enzyme assays (modified from Ellman et al., 1961) were performed spectrophotometrically (405 nm absorbance) on a COBAS MIRA[®] Plus CC clinical chemistry analyser.

Quantitative continuous data were compared among the treatment groups by the use of Levene's test for homogeneity of variances and in the case of lack of homogeneity of variances ($p \leq 0.05$) robust regression method were used to test all treatment effects. GLM analysis was used to determine whether significant time effects occurred for selected measured (ANOVA). A Dunnett's two-tailed test was used for all pairwise comparisons to the control group for body weight parameters, and one-tailed test was used for cholinesterase levels.

The study is considered to provide complementary information.

**- Rat, acute neurotoxicity study, gavage, 0, 0.3, 0.6, 1.0 mg/kg b.w. (main study)
(Tyl, 2005c, FMC)**

Findings: see table B.6.7.3-3

Mortality:

One male pup at 0.6 mg/kg was moribund 14' post dosing and was necropsied on schedule at 15' post dosing. The condition was not considered treatment-related as no fatalities were observed at the top-dose.

Clinical signs:

15' sacrifice

-Pups: At 15 minutes post dosing, clinical observations were consistent with the maximum treatment- and dose-related inhibition of brain cholinesterase (predominantly tremors of the head or body or tremors not otherwise specified). Signs were observed at all doses.

-Adults: Tremors were observed at 0.6 mg/kg b.w. and above, and both incidence and severity were maximal at termination. There were no treatment-related clinical signs at any time at 0.3 mg/kg.

12h sacrifice

-For pups sacrificed at 12h, the period of maximum response was 15-30' post-dosing in all treated groups. Treatment-related clinical signs (tremors) were present at 0.6 mg/kg b.w. (2/20) and 1 mg/kg (8/20) at 1h post-dosing (9/10 of these animals with tremors when touched). At 2h, 13/20 top-dose animals showed tremors (12/13 of these animals with tremors only when touched).

-For the adults sacrificed at 12h post dosing, there was a clear, dose-response pattern in increased severity of treatment-related clinical observations, with the time of maximum effect also 15-30' post dosing. The tremors were observed up to 1h post-dosing at 0.3, 0.6 and 1.0 mg/kg.

Body weight:

As pre-dosing body weights of some treatment groups were lower than the controls, the observed (not dose-related) b.w. drops at sacrifice times could not be attributed to the test-article administration.

Cholinesterase activity:

-In the pups, brain AChE activity was highly significantly and dose-dependently reduced at all doses at 15' post-dosing, in both the ♂ and the ♀. No treatment-related inhibition was observed at the 12h-sacrifice time.

-In the adults, the brain AChE was again highly significantly and dose-dependently reduced at all doses at 15' post-dosing, in both the ♂ and the ♀. The inhibition was still present at 12h post-dosing. However, the level of inhibition was only marginal (4-6% decrease), with only a slight dose-dependency observed in the ♀ but less evident in the ♂. Therefore, the biological significance of the residual slight effect on the brain AChE at 12h is uncertain. The notifier considered that the difference in brain acetylcholinesterases were due to variability of this parameter and not residual effects.

It was of note that, as demonstrated in the previous studies, the brain AChE inhibition was apparently more pronounced in the pups (48-65%) than in the young adults (24-44%). However, the notifier considered that, as the *absolute* amount of AChE inhibition at peak-time was greater in the adults than in the pups, (except for the low-dose ♀ pups), there was no increased sensitivity of pups compared to adults.

RMS disagreed with this position, for the following reasons:

- (i) The *relative* decrease (compared to controls) was more important in the pups, and the results of the current study confirmed the findings of the previous time-course study, where the relative decreases were more important in the pups at all time-points. RMS considered that the comparison of *absolute* activity drops was questionable in a situation where control values were so different in the pups and in the adults (e.g. level at 12h: 7.0-7.2 U/g in the pups vs. 13.0-13.3 U/g in the adults). In general, RMS considers it inadequate to make an assessment on absolute levels in enzymology.
- (ii) In addition, the total number of noted clinical signs, during the period 0'-120' (i.e. the period where most signs were seen, taking into consideration both the n° of observations and the n° of animals involved) pointed towards a more marked effect in the pups. At 0/ 0.3/ 0.6/ 1.0 mg/kg b.w., the integrated count was 0/44/42/77 in the pups vs. 0/10/29/70 in the adult animals. The differences were particularly obvious at the two lowest doses.
- (iii) Further, as the observation of the clinical signs in the pups was reported to be possibly hindered by the grooming activity of the dams (see also remarks in range-finding study), it is not excluded that the symptoms had been even underreported in the pups, compared to the adults.
- (iv) Finally, other studies indicated that both RBC and brain AChE were more effectively inhibited in the pups than in the adults.

Table B.6.7.3-3a: neurotoxicity after single administration of Carbofuran in rat pups: cholinesterase activity (Tyl, 2005c – main study)

Sampling time (post-dosing)	Endpoint	Dose Level (mg/kg)							
		0		0.3		0.6		1.0	
		♂	♀	♂	♀	♂	♀	♂	♀
15'	RBC (U/L)	5436 ± 437 -	4782 ± 472 ##	5746 ± 307 -	6672 ± 270 -	4944 ± 449 ¹ -	4646 ± 319 -	5260 ± 357 -	5064 ± 367 -
	Brain (U/g)	6.62 ± 0.14 ###	6.90 ± 0.11 ###	3.47 ± 0.09 ↓48%***	3.56 ± 0.19 ↓48% ^{ooo}	3.13 ± 0.17 ↓53%***	3.27 ± 0.15 ↓53% ^{ooo}	2.53 ± 0.11 ↓62%***	2.42 ± 0.09 ↓65% ^{ooo}
12h	RBC (U/L)	4791 ± 430 ² ###	4558 ± 215 #	4034 ± 287 -	4166 ± 309 -	6093 ± 499 -	5427 ± 471 ³ -	4062 ± 191 -	4092 ± 289 -
	Brain (U/g)	7.03 ± 0.12 ² -	7.17 ± 0.12 -	6.49 ± 0.15 -	6.87 ± 0.17 -	6.55 ± 0.24 -	7.10 ± 0.16 ³ -	6.53 ± 0.16 -	7.20 ± 0.16 -

Values are the mean ± std error, and concomitant % of reduction as compared to control group; N=9 i.o. 10 animals, due to: ¹: insufficient quantity of RBC for 1♂ (value excluded), ²: absence of 5th ♂ pup in one litter, or ³: dosing error in 1♀ pup.

Statistically significant modification:

***: p≤0.001 (Dunnett's test); ^{ooo}: p≤0.001 (t- test) for pairwise comparison with control;

: p≤0.05; ##: p≤0.01; ###: p≤0.001 (anova) and ###: p≤0.001 (Wald χ²-test) for treatment effect in regression model (trend).

Table B.6.7.3-3b: neurotoxicity after single administration of Carbofuran in young adult rats: cholinesterase activity (Tyl, 2005c – main study)

Sampling time (post-dosing)	Endpoint	Dose Level (mg/kg)							
		0		0.3		0.6		1.0	
		♂	♀	♂	♀	♂	♀	♂	♀
15'	RBC (U/L)	4774 ± 515 -	5390 ± 441 -	5110 ± 3353 -	5754 ± 507 -	4880 ± 395 -	4718 ± 267 -	5276 ± 390 -	5200 ± 356 -
	Brain (U/g)	12.46 ± 0.20 ###	12.88 ± 0.18 #	9.22 ± 0.21 ↓26%***	9.84 ± 0.35 ↓24%***	8.44 ± 0.28 ↓32%***	8.54 ± 0.31 ↓34%***	7.01 ± 0.19 ↓44%***	7.16 ± 0.35 ↓44%***
12h	RBC (U/L)	5470 ± 199 ###	5058 ± 291 -	5570 ± 264 -	5146 ± 96 -	5246 ± 267 -	5492 ± 195 -	5910 ± 279 -	6884 ± 237 -
	Brain (U/g)	13.00 ± 0.25 #	13.29 ± 0.20 #	12.29 ± 0.27 ↓5.5%*	12.74 ± 0.15 ↓4.1%	12.41 ± 0.218 ↓4.5%	12.62 ± 0.25 ↓5.0%*	12.18 ± 0.19 ↓6.3%*	12.55 ± 0.17 ↓5.6%*

Values are the mean ± std error, and concomitant % reduction as compared to control group;

Statistically significant modification:

*: p≤0.05; **: p≤0.01; ***: p≤0.001 (Dunnett's test) for pairwise comparison with control;

: p≤0.05; ###: p≤0.001 (anova) for treatment effect in regression model (trend).

Conclusions:

- The administration of Carbofuran by gavage induced clinical signs which were most intense at 15-30' after dosage, and which remained visible 1h-2h post-dosing.
- Brain but not RBC cholinesterase activity was decreased at all doses in both the ♂ and the ♀ when compared to the control group at 15' post-dosing. At 12h post-dosing, the brain AChE inhibition had virtually resolved.
- The intensity of clinical signs and the magnitude of the brain AChE inhibition was relatively higher in the newborn pups than in the young adults.
- Based upon the observed clinical signs (tremors) and the dose-dependent brain AChE inhibition in neonates, the NOAEL was considered <0.3 mg/kg b.w..

GLP status: yes

Guideline: not of application

Remark:

The pups, designated to dosing groups 0.3, 0.6 and 1.0 mg/kg b.w.(15' sacrifice time) and the ♂pups of the 0.3 mg/kg b.w. group (720' sacrifice time), had lower b.w. than control animals at the day of dosing (amounting to 5-14%, attaining statistical significance, except for the mid-dose ♀ pups 15' sacrifice time) following randomisation on t0; hence, the observed b.w. reduction of treated animals was not attributable to the treatment.

Material and methods:

Ten rat pups (PND11)/sex/dose and ten young adult rats (PND60)/sex/dose (Sprague-Dawley (CrI: CD[®]SD)) received a single administration of Carbofuran (batch n° PL04-0056, purity 99.0%) dissolved in corn oil (dosing volume 5 mL/kg) by gavage at 0, 0.3, 0.6 or 1.0 mg/kg b.w.. The pups (which were returned to their dams) and the young adults were examined for clinical signs of toxicity at approximately 15', 30', 1h, 2h, 4h, 6h and 12h post-dose. At 15' or at 12h post-dose (considered as being the time of maximum AChE inhibition, and anticipated time of full recovery, respectively), each pup was weighed, examined, terminated (CO₂ asphyxiation), and blood collected via cardiac puncture. Each brain was removed intact, weighed, transferred to a labelled vial, and placed on dry ice.

Blood and brain samples were transferred to the clinical chemistry laboratory within 20' of collection. The blood samples and brains were processed immediately (preparation of RBC lysates and whole brain homogenisation) and then frozen at -70°C until analysis. The cholinesterase enzyme assays (modified from Ellman et al., 1961) were performed spectrophotometrically (405 nm absorbance) on a COBAS MIRA[®] Plus CC clinical chemistry analyser. The stability and content of active substance in the dosing suspensions was demonstrated to be adequate.

Quantitative continuous data were compared among the treatment groups by the use of Levene's test for homogeneity of variances and in the case of lack of homogeneity of variances (p≤0.05) robust regression method were used to test all treatment effects. General Linear Model (GLM) analysis was used to determine whether significant dosage effects occurred for selected measured (ANOVA). A Dunnett's two-tailed test was used for all pairwise comparisons to the low-dose group for body weight parameters, and one-tailed test was used for cholinesterase levels.

The study is accepted.

The experiments conducted by Tyl et al. were repeated in another laboratory (i.e. a range finding study, a time-course experiment, and a full acute neurotoxicity experiment on rat pups or on young adults).

- **Rat, acute neurotoxicity study, gavage, 0, 0.03, 0.1, 0.3 mg/kg b.w. (range-finding study) (Hoberman, 2007a, FMC)**

Findings: see table B.6.7.3-4.

Mortality: none

Clinical signs:

At the top-dose, 2/5♂ and 2/5♀ had slight to moderate whole body tremors after dosing (at 15' post dose). All other pups survived dosing with no adverse clinical observations.

Body weight: no treatment-related effects.

Cholinesterase activity:

A slight decrease of AChE activity was observed in the RBC at 0.03 mg/kg b.w. and above. The decrease did not attain statistical significance, but was probably treatment-related, given the apparent dose-related pattern in the ♂.

Brain AChE activity was also decreased at 0.03 mg/kg b.w. and above, and the modification was highly significant at 0.1 and at 0.3 mg/kg b.w.. As the magnitude of the modification was about 10% at the lowest dose, and in the light of the clear dose-dependent decrease, the effect at 0.03 mg/kg b.w. was not discounted as irrelevant by the RMS.

Necropsy examination: not examined.

Histopathology: not examined.

Table B.6.7.3-4: neurotoxicity after single administration of Carbofuran in rat pups: cholinesterase activity at 15' post-dosing (Hoberman, 2007a – range-finding)

Endpoint	Dose Level (mg/kg)							
	0		0.03		0.1		0.3	
	♂	♀	♂	♀	♂	♀	♂	♀
RBC (U/mL)	1.874 ± 0.430 ¹	2.024 ± 0.570	1.627 ± 0.145 ↓13%	1.962 ± 0.303 -	1.474 ± 0.287 ↓21%	1.543 ± 0.300 ² ↓24%	1.354 ± 0.274 ↓28%	1.551 ± 0.520 ↓23%
Brain (U/g)	7.173 ± 0.364	7.066 ± 0.964	6.487 ± 0.447 ↓10%	6.303 ± 0.348 ↓11%	4.758 ± 1.189 ↓33%**	4.620 ± 0.156 ↓35%**	2.841 ± 1.074 ↓60%**	3.784 ± 1.564 ↓46%**

Values are the mean ± s.d, and concomitant % reduction compared to control group; ¹:N=3 or ²:N=4 i.o. 5 animals, due to 'samples not meeting the acceptability criteria' (unreproducible replicate sample); Statistically significant modification: ** p<0.01

Conclusion:

The administration of Carbofuran by gavage induced clinical signs 15' after dosage at 0.3 mg/kg b.w.. Brain and RBC cholinesterase activity was decreased at all doses, in both the ♂ and the ♀, when compared to the untreated group.

The NOAEL was 0.03 mg/kg b.w. in this study, based upon the significantly decreased RBC and brain AChE activities at the higher doses. However, this value should be considered with caution, as the number of animals per group was low, and the overall dose-response showed a decreasing trend from the lowest dose on (although the magnitude was <20%, and there was no statistical significance).

GLP status: yes

Guideline: not of application

Remark: part of the pups had a clinical observation 1-9' post-dosing i.o. 15' post-dosing.

Material and methods:

Five PND 11 rats/sex/dose (Sprague-Dawley (CrI: CD[®]SD)) received a single administration of Carbofuran (batch n° PL06-0504, purity 98.8%) dissolved in corn oil (dosing volume 1 mL/kg) by gavage at 0.03, 0.1 and 0.3 mg/kg b.w.. The pups were returned to their dams and examined for clinical signs of toxicity at approximately 1-9' (24/40 pups) and at 15' (16/40 pups) post-dosing. At 15' post-dosing, each pup was weighed, examined, terminated (decapitation), and blood collected. Each pup brain was removed intact, weighed, and homogenised. Brain samples were placed in chilled 0.9% NaCl until analysis.

Blood and brain samples were transferred to the clinical chemistry laboratory within 15' of collection. The cholinesterase AChE enzyme assays (modified from Ellman et al., 1961) were performed spectrophotometrically (? nm absorbance) on a clinical chemistry analyser. The stability and content of active substance in the dosing suspensions was demonstrated to be adequate.

Statistics: Bartlett's test for homogeneity of variances was used to estimate the probability that the groups had different variances.

If nonsignificant, data was compared using the ANOVA test and Dunnett's test was performed for pairwise comparisons.

If Bartlett's Test was significant and $\leq 0.75\%$ of the scores in all the groups were tied, the Kruskal-Wallis Test was used for pairwise comparisons. If Bartlett's Test was significant and $> 0.75\%$ of the scores in any groups are tied, Dunn's Test was used for pairwise comparisons.

The study is considered to provide complementary information.

- Rat, acute neurotoxicity study, gavage, 0.0 or 0.1 mg/kg b.w. (peak time identification study) (Hoberman, 2007b, FMC)

Findings: see table B.6.7.3-5

Mortality: none

Clinical signs: no treatment-related effects.

Body weight: no treatment-related effects.

Cholinesterase activity:

a. Pups:

-The peak effect in RBC AChE inhibition occurred at 15' (♂), and a significant effect was still present up to 1h post-dose. A same trend was also observed in the ♀ pups, although statistical significance was lacking.

-Brain AChE levels were maximally inhibited at 1h post dosing. Significant reductions lasted for 1h (♂)-2h (♀). At 4h post-dose, neither RBC nor brain AChE levels were altered in the rat pups.

b. Adult rats:

-The peak effect in RBC AChE inhibition occurred at 15(♀)-30'(♂).

-The inhibition of brain AChE activity showed a maximal effect 30' post dosing, and decreased at the later time points. This inhibition was time-dependently decreased.

Overall, both RBC and brain AChE inhibition was unremarkable at 6h after single administration of 0.1 mg/kg b.w. in both ♂ and ♀ young adult rats.

Table B.6.7.3-5: neurotoxicity testing in rats: cholinesterase activity after single administration of 0.1 mg/kg b.w. of Carbofuran (Hoberman, 2007b – peak time identification study)

a. Rat pups

	Endpoint	Time of sacrifice (minutes post dosing)						
		0	15	30	60	120	240	360
Males	RBC (U/L)		↓29%**	↓18%	↓21%**	↓9%	-	↑23%
	Brain (U/g)		↓20%**	↓21%*	↓27%**	-	-	-
Females	RBC (U/L)		↓16%	↓8%	↓15%	-	↑35%	-
	Brain (U/g)		↓18%**	↓32%**	↓33%**	↓18%**	-	-

b. Young adult rats

	Endpoint	Time of sacrifice (minutes post dosing)						
		0	15	30	60	120	240	360
Males	RBC (U/L)		↓12%	↓22%**	-	↑15%	↓18%	↓11%
	Brain (U/g)		↓17%**	↓21%**	↓16%*	↓12%**	↓9%**	↓5%
Females	RBC (U/L)		↓17%**	-	↓10%	↓10%	↓12%	↑14%
	Brain (U/g)		↓8%	↓18%**	-	↓9%**	↓6%*	-

Statistically significant modification: *: p≤0.05, **:p≤0.01, (Dunnett's test)

Conclusion:

The administration of 0.1 mg/kg b.w. Carbofuran by gavage induced an inhibition of both RBC and brain AChE activity in both PND11 pups and young adults.

The AChE inhibition was more marked in pups than in the young adults. In the ♂pups, the brain AChE activity was reduced by about 30% at 1h, while the value amounted to about 20% at 30' in the young adults. This observation of differential neurotoxicity confirmed the findings of a previous study (Tyl, 2005c). On the other hand, the duration of the inhibition was slightly shorter in the pups, where AChE levels returned to control levels at about 4h post-administration, compared to adults, showing control levels at about 6h post-administration.

Based on the data from both adults and pups, the time of peak effect for the dose response study was selected at 30', and the recovery time at 4h by the notifier.

GLP status: yes

Guideline: not of application

Material and methods:

Ten rat pups (PND11)/dose/time point and ten young adult rats (60d)/dose/time point (Sprague-Dawley (CrI: CD[®]SD)) received a single administration of Carbofuran (batch n° PL06-0504, purity 98.8%) dissolved in corn oil (dosing volume 1 mL/kg) by gavage at 0 or at 0.1 mg/kg b.w.. Ten animals/dose/timepoint were terminated at 15', 30', 1h, 2h, 4h or 6h post-dose. At these times, the animals were examined for clinical signs of toxicity, and were weighed, terminated (adults: isoflurane, pups: decapitation), and blood collected. Each brain was removed intact, weighed and processed within 15'. Brain samples were placed in chilled 0.9% NaCl until analysis. Blood and brain samples were transferred to the clinical chemistry laboratory within 15' of collection. The cholinesterase AChE enzyme assays (modified from Ellman et al., 1961) were performed spectrophotometrically (? nm absorbance) on a clinical chemistry analyser. The stability and content of active substance in the dosing suspensions was demonstrated to be adequate.

Bartlett's test for homogeneity of variances was used to estimate the probability that the groups had different variances.

If nonsignificant, data was compared using the ANOVA test and Dunnett's test was performed for pairwise comparisons.

If Bartlett's Test was significant and ≤0.75% of the scores in all the groups were tied, the Kruskal-Wallis Test was used for pairwise comparisons. If Bartlett's Test was significant and >0.75% of the scores in any groups are tied, Dunn's Test was used for pairwise comparisons.

The study is considered to provide complementary information.

**- Rat, acute neurotoxicity study, gavage, 0; 0.03, 0.1, 0.3 mg/kg b.w. (main study)
(Hoberman, 2007c, FMC)**

Findings: see table B.6.7.3-6

Mortality: none

Clinical signs: no treatment-related effects.

Motor activity (adults): no treatment-related effects.

Body/brain weight: no treatment-related effects

Cholinesterase activity:

a. Pups

-The RBC AChE activity was slightly inhibited at 0.03 mg/kg b.w.(♀) and above (♂,♀) 30' after dosing. Although the modification showed a dose-dependent trend, the values were not statistically significantly different from controls. At 4h, recovery was mostly complete, except in the ♀ at the top-dose.

-The brain AChE levels were significantly and dose-dependently reduced at 0.03 mg/kg b.w. and above in both the ♂ and the ♀ at 30' post-dosing. Four hours after administration, the brain AChE values were still inhibited in both sexes at 0.1 mg/kg b.w. and at 0.3 mg/kg b.w., but not at the lowest dose.

b. Young adults

-Like in the pups, RBC AChE activity was inhibited at 0.03 mg/kg b.w. (♀) and above (♂,♀) at 30' post-dosing time, but returned to control values at 4h in all dosing groups.

-At 30', also brain AChE activity was inhibited at 0.03 mg/kg b.w. (♂) and above (♂,♀), and recovery was observed at the lowest dose (♂,♀) and above (only ♀) at 4h post-dose.

The AChE values at both 30' and 4h sampling time indicated that PND11 rat pups were more sensitive than young rat adults to the inhibiting potency of Carbofuran, and this confirmed earlier findings (Tyl, 2005b).

It was also of note that the single treatment of Carbofuran up to and including 0.3 mg/kg b.w. was without effect on clinical signs, even when substantial reduction of brain AChE activity was recorded in the pups and young adults. This was in contrast to the study of Tyl (2005b), where tremors had been observed from 0.3 mg/kg b.w. onwards, at least at 1h post-dose.

Table B.6.7.3-6a: neurotoxicity after single administration of Carbofuran in rat pups: cholinesterase activity (Hoberman, 2007c – main study)

Sampling time (post-dosing)	Endpoint	Dose Level (mg/kg)							
		0		0.03		0.1		0.3	
		♂	♀	♂	♀	♂	♀	♂	♀
30'	<i>N</i>	7	8	6	9	8	8	9	9
	RBC (U/mL)	0.826 ± 0.323	0.965 ± 0.448	0.889 ± 0.415	0.808 ± 0.245	0.708 ± 0.291	0.609 ± 0.080	0.617 ± 0.137	0.585 ± 0.119
				-	↓16%	↓14%	↓37%	↓25%	↓39%
	<i>N</i>	9	10	10	10	10	10	10	10
4h	Brain (U/g)	5.996 ± 0.533	6.257 ± 0.545	5.192 ± 0.575	5.020 ± 0.684	3.881 ± 0.891	3.322 ± 0.854	2.771 ± 0.978	2.668 ± 0.918
				↓13%*	↓20%**	↓35%**	↓47%**	↓54%**	↓57%**
	<i>N</i>	9	8	10	9	8	9	9	9
	RBC (U/mL)	0.518 ± 0.154	0.612 ± 0.204	0.468 ± 0.174	0.601 ± 0.228	0.665 ± 0.154	0.589 ± 0.161	0.532 ± 0.185	0.515 ± 0.136
			-	-	-	-	-	↓16%	
<i>N</i>	10	10	10	10	10	10	10	10	
30'	Brain (U/g)	6.226 ± 0.570	6.374 ± 1.091	5.681 ± 0.484	6.049 ± 1.049	5.035 ± 0.575	4.957 ± 0.781	2.935 ± 0.655	3.385 ± 1.242
				↓9%	↓5%	↓19%**	↓22%**	↓53%**	↓47%**

Values are the mean ± s.d. and concomitant % reduction compared to control group;

Statistically significant modification: *:p<0.05; **:p<0.01 (Dunnett's test for pairwise comparison with control).

Table B.6.7.3-6b: neurotoxicity after single administration of Carbofuran in young adult rats: cholinesterase activity (Hoberman, 2007c – main study)

Sampling time (post-dosing)	Endpoint	Dose Level (mg/kg)							
		0		0.03		0.1		0.3	
		♂	♀	♂	♀	♂	♀	♂	♀
30'	<i>N</i>	10	10	10	10	10	10	10	10
	RBC (U/mL)	1.148 ± 0.236	1.077 ± 0.229	1.066 ± 0.120	0.906 ± 0.113	0.815 ± 0.196	0.854 ± 0.144	0.707 ± 0.162	0.664 ± 0.191
				↓7%	↓16%*	↓29%**	↓21%**	↓38%**	↓38%**
	<i>N</i>	9	9	10	10	10	10	10	9
4h	Brain (U/g)	14.834 ± 1.434	15.090 ± 0.900	13.049 ± 1.338	15.124 ± 1.624	10.039 ± 1.179	12.050 ± 1.142	7.504 ± 1.407	8.985 ± 1.002
				↓12%**	-	↓32%**	↓20%**	↓49%**	↓40%**
	<i>N</i>	10	9	10	10	10	10	10	10
	RBC (U/mL)	1.034 ± 0.218	1.162 ± 0.109	1.079 ± 0.172	1.190 ± 0.123	1.167 ± 0.178	1.151 ± 0.160	1.126 ± 0.218	1.114 ± 0.259
			-	-	-	-	-	-	
<i>N</i>	10	10	10	10	10	10	10	10	
30'	Brain (U/g)	15.679 ± 1.358	15.908 ± 1.723	14.557 ± 0.919	15.151 ± 1.631	13.592 ± 1.567	14.897 ± 1.509	13.137 ± 1.407	14.538 ± 1.235
				↓7%	↓5%	↓13%**	↓6%	↓16%**	↓9%

Values are the mean \pm s.d, and concomitant % reduction compared to control group; Statistically significant modification: *:p \leq 0.05; **:p \leq 0.01; ***: p \leq 0.001 (Dunnett's test for pairwise comparison with control);

Discussion:

Thirty minutes after the single administration of Carbofuran by gavage at dose-levels of 0.03, 0.1 and 0.3 mg/kg b.w. to rat pups and young adults, brain (and to a lesser extent RBC) AChE activity was inhibited. The effect was more marked into the pups than into the young adults. The notifier, in contrast considered that the increased sensitivity of pup brain AChE inhibition at the time of maximum inhibition was only "apparent". However, similar differences were observed in the other experiments (Tyl, 2005c; Moser, 2007b, see below).

The inhibition of brain AChE activity subsided at 4h post-administration, at 0.1 mg/kg b.w. and above, but at the lowest dose-level of 0.03 mg/kg b.w., recovery was observed.

Thus, it appears that the brain AChE inhibition is fully reversible within 4h at the lowest dose only.

In this single-dose study, the pup NOAEL is thus considered <0.03 mg/kg b.w., based upon the brain AChE inhibition in rat pups (σ , ρ) shortly after administration. As the decrease was <20% in rats adults, the adult neurotoxicity NOAEL could be established at 0.03 mg/kg b.w..

As there was no dose without effect in the pups, the standard approach would be to apply an assessment factor of 10 \times to approximate a NOAEL. However, the effects seen at 0.03 mg/kg b.w. were at the limit of relevance (just 20% decrease in ρ pups and 12% in the adults 30' after administration). The effect was unremarkable 4h post-dosing in the adults (and <20% in the pups), and no clinical signs were observed.

In principle, a statistically significant decrease by \geq 20% of brain AChE represents a clear toxicological effect and any decision to dismiss such findings should be justified (JMPR, 1998). In the case of the Hoberman study, clinical signs and motor activity impairments were not observed, but a full FOB assessment or motor activity assessment was not conducted in the pups. It is often difficult to observe minor cholinergic clinical signs during a study, especially transient and intermittent signs. FOB tests are designed to measure and observe in detail such neurotoxic impairments.

In order to make an approximation of the NOAEL, RMS considered the determination of a benchmark dose, where advantage is taken of all data in the dose-response curve to estimate a plausible no-adverse effect level.

In such benchmark-dose approach, it is generally considered that a 5-10% response (in this case brain AChE inhibition compared to controls), would be acceptable as a no-adverse-effect (EPA, 2005).

The BMD₁₀ was computed, i.e. the dose corresponding with a 10% brain AChE inhibition in the worst-case group (ρ pups, brain AChE inhibition at 30' post-dosing), using all data in the dose-response curve (Hill-model, assuming a sigmoidal decrease, appropriate for receptor-mediated responses like inhibition of Acetyl Cholinesterase), using the BMDS software from the EPA (v 2.0, 2008).

For the ρ pups, the BMD₁₀ was 0.01739 mg/kg b.w.. The BMDL₁₀ (the one-sided 95% confidence limit of the BMD), was 0.0085 mg/kg b.w.. Although the BMD₁₀ should be taken with caution (a sigmoidal curve-fit using a model with 4 parameters may not be statistically demonstrable with \leq 4 dose-groups), it is fairly comparable with the value obtained by extrapolating in a linear dose-response. As a comparison, assuming a (more simple) linear dose-response for the first three doses, a 10% inhibition would be assumed at 0.021 mg/kg b.w. (corresponding BMDL₁₀= 0.018 mg/kg b.w.). (see also summary data in Annex)

Hence, an AF=2 instead of 10, applied on the LOAEL would support the abovementioned BMD₁₀, and was considered sufficient to derive the NOAEL in this study. Therefore, NOAEL = LOAEL (0.03 mg/kg b.w.) \div 2 = 0.015 mg/kg b.w..

The notifier proposed another value for the NOAEL, and considered that "*the dose of 0.03 mg/kg appears to be a NOAEL for brain and RBC ChE inhibition in both pups and adults as ChE approached, but did not surpass 20% inhibition*".

RMS considers that the decrease is both statistically and biologically significant, and a clear dose-response was observed. Brain AChE activity decreases were also dose-dependent from the lowest dose on in the σ adults, although the decrease at the lowest dose was <20%. It was acknowledged that clinical signs were absent at the lowest dose, but as a full FOB or motor activity assessment would be impossible in the pups, the implication on the neurotoxicological level of the observed brain AChE decrease remained unexplained.

Conclusion:

Neurotoxicity NOAEL (pups) = 0.015 mg/kg b.w.
Neurotoxicity LOAEL (pups) = 0.03 mg/kg b.w., based upon ↓brain AChE inhibition (20%)
Neurotoxicity NOAEL (adults) = 0.03 mg/kg b.w.
Neurotoxicity NOAEL (adults) = 0.1 mg/kg b.w. based upon ↓brain AChE inhibition (≥20%)

GLP status: yes

Guideline: not of application

Material and methods:

Twenty rat pups (PND 11)/sex/dose/time point and twenty young adult rats (PND 65)/sex/dose/time point (Sprague-Dawley (CrI: CD[®]SD)) received a single administration of Carbofuran (batch n° PL06-0504, purity 98.8%) dissolved in corn oil (dosing volume 1 mL/kg) by gavage at 0, 0.03, 0.1 and 0.3 mg/kg b.w.. The experiment was terminated at 30' or 4h post-dose, and the animals were examined for clinical signs of toxicity (15', 30', 1h, 2h or 4h). In addition, motor activity was evaluated 30' post dosing (for the 4h sacrifice adult group only). Motor activity was studied by assessing behaviour during a 1h observation period in a wire-bottomed cage, equipped with a passive IR sensor, the n° of movements and time spent in movement being automatically sampled in 8' intervals. Further, they were weighed, euthanised (adults: isoflurane, pups: decapitation), and blood collected. Each brain was removed intact, weighed and processed. Brain samples were placed in chilled 0.9% NaCl until analysis. Blood and brain samples were processed on the day of sacrifice. The cholinesterase AChE enzyme assays (modified from Ellman et al., 1961) were performed spectrophotometrically (? nm absorbance) on a clinical chemistry analyser. The stability and content of active substance in the dosing suspensions was demonstrated to be adequate. Bartlett's test for homogeneity of variances was used to estimate the probability that the groups had different variances. If nonsignificant, data was compared using the ANOVA test and Dunnett's test was performed for pairwise comparisons. If Bartlett's Test was significant and ≤0.75% of the scores in all the groups were tied, the Kruskal-Wallis Test was used for pairwise comparisons. If Bartlett's Test was significant and >0.75% of the scores in any groups are tied, Dunn's Test was used for pairwise comparisons.

The study is considered to provide complementary information

Reference:

Ellman GL, Courtney KD, Andres V Jr, Featherstone RM. A new and rapid colorimetric determination of acetylcholinesterase activity. Biochem. Pharm. 7:88-95, 1961.

Additional information: reports from the EPA, and data from public literature

The Neurotoxicology Division of the National Health and Environmental Effects Research Laboratory/Office of Research and Development (NHEERL/ORD) of the US-EPA conducted some studies on the acute NT effects of N-Methylcarbamates, a.o. on Carbofuran. Internal Reports and published papers were reviewed by the RMS to obtain additional information upon the neurotoxic effects of Carbofuran after single oral exposure.

Four papers are available. From the published papers (Padilla *et al*, 2007; Mc Daniel *et al*, 2007), only the data on Carbofuran were reported and discussed in this DAR.

- **Rat, acute neurotoxicity study, gavage, 0; 0.1, 0.3, 0.6 or 1.0 mg/kg b.w. (Moser, 2007b, EPA paper)**

Findings: see table B.6.7.3-7

Mortality: none

Clinical signs: not reported; however, in the study report it was stated that there were no cases of 'severe toxicity'.

Cholinesterase activity:

A dose-dependent decrease of AChE activity was observed at 0.1 mg/kg b.w. (pups) and above (pups and adults). No statistical significance was mentioned, but the dose-related pattern and the magnitude (>20% inhibition) indicated that the effects were toxicologically meaningful.

Table B.6.7.3-7: neurotoxicity 40' after single administration of Carbofuran in ♂rat pups and adults: cholinesterase activity (Moser, 2007b)

group	Endpoints	dose level (mg/kg b.w.)				
		0	0.1	0.3	0.6	1.0
pups	RBC	0.871 ± 0.066	0.407 ± 0.129 ↓53%	0.260 ± 0.071 ↓70%	0.139 ± 0.049 ↓84%	0.096 ± 0.044 ↓89%
	Brain	3.382 ± 0.316	2.028 ± 0.299 ↓40%	1.435 ± 0.234 ↓58%	0.993 ± 0.155 ↓71%	0.760 ± 0.212 ↓78%
adults	RBC	0.599 ± 0.055	0.523 ± 0.106 ↓13%	0.307 ± 0.067 ↓49%	0.251 ± 0.085 ↓58%	0.155 ± 0.050 ↓74%
	Brain	6.690 ± 0.351	5.834 ± 0.458 ↓13%	4.786 ± 0.389 ↓28%	4.325 ± 0.322 ↓35%	3.312 ± 0.290 ↓50%

AChE inhibition values expressed in µmol Ach hydrolysed/min/mL (RBC) or /g (brain); values are the mean ± s.d, and concomitant % reduction compared to control group; Statistically significant modification: data not provided

Conclusions:

In this study, the NOAEL is thus considered <0.1 mg/kg b.w., based upon the brain AChE inhibition in ♂rat pups.

GLP status: not reported, but study data were subjected to QA audit at NHEERL

Guideline: not of application

Material and methods:

Eight ♂rat pups (PND 11)/dose and six ♂adult rats/dose (Long-Evans (CrI)) received a single administration of Carbofuran (Chem-Serve, Inc., batch n° 341-41B, purity 99%) dissolved in acetone (2.5% v:v) + corn oil by gavage (dosing volume 2 mL/kg) at 0, 0.1, 0.3, 0.6 or 1.0 mg/kg b.w.. The experiment was terminated at 40' post-dose, and animals were euthanised (decapitation), and blood collected. The blood was processed (RBC lysate preparation) within 15'. Each brain was removed intact and placed on dry ice until analysis. RBC lysates and brain samples were stored at -80°C. The cholinesterase AChE enzyme assays were performed radiometrically (Johnson and Russel, 1975). The stability and content of active substance in the dosing suspensions was demonstrated to be adequate.

No data concerning statistical evaluation was reported.

The study is considered to provide complementary information.

- Rat, acute neurotoxicity study, gavage, 0; 0.1, 0.3, 0.6 or 1.0 mg/kg b.w. in neonate rats (PND 17) (Moser, 2007a, EPA paper)

Findings: see table B.6.7.3-8

Mortality: none

Clinical signs: not reported

Motor activity:

A meaningful decrease in cage movements was observed at 0.3 mg/kg b.w. and above.

Table B.6.7.3-8a: neurotoxicity 15-35' after single administration of Carbofuran in ♂rat pups: motor activity (Moser, 2007a)

Endpoints	dose level (mg/kg b.w.)				
	0	0.1	0.3	0.6	1.0
motor activity	80.5 ± 30.4	93.7 ± 41.1 ↑16%	47.8 ± 18.5 ↓41%	28.6 ± 20.3 ↓64%	3.7 ± 5.4 ↓95%

Motor activity values are the mean ± s.d, and concomitant % reduction compared to control group; Statistically significant modification: data not provided

Cholinesterase activity:

A dose-dependent decrease of both RBC and brain AChE activity was observed at 0.1 mg/kg b.w. and above. No statistical significance was mentioned, but the dose-related pattern and the magnitude (>20% inhibition) indicated that the effects were toxicologically meaningful.

Table B.6.7.3-8b: neurotoxicity 40' after single administration of Carbofuran in ♂rat pups: cholinesterase activity (Moser, 2007a)

Endpoints	dose level (mg/kg b.w.)				
	0	0.1	0.3	0.6	1.0
RBC AChE	0.786 ± 0.261	0.446 ± 0.103 ↓43%	0.243 ± 0.047 ↓69%	0.171 ± 0.045 ↓78%	0.153 ± 0.069 ↓81%
Brain AChE	5.096 ± 0.382	3.684 ± 0.409 ↓28%	2.626 ± 0.418 ↓48%	2.288 ± 0.409 ↓55%	1.811 ± 0.477 ↓64%

AChE inhibition values expressed in µmol ACh hydrolysed/min/mL (RBC) or /g (brain); values are the mean ± s.d, and concomitant % reduction compared to control group; Statistically significant modification: data not provided

Conclusions:

In this study, the NOAEL is thus considered <0.1 mg/kg b.w., based upon the RBC and brain AChE inhibition in ♂rat pups.

GLP status: not reported

Guideline: not of application

Material and methods:

Ten ♂rat pups (PND 17)/dose (Long-Evans (CrI)) received a single administration of Carbofuran (Chem-Serve, Inc., batch n° 341-41B, purity 99%) dissolved corn oil by gavage (dosing volume 2 mL/kg) at 0, 0.1, 0.3, 0.6 or 1.0 mg/kg b.w.. At 15' post-dose, the rats were placed into figure-eight chambers with photocells for a 20' activity assessment. The experiment was terminated at 40' post-dose, and animals were euthanised, and blood collected. The blood was processed (RBC lysate preparation) within 15'. Each brain was removed intact and placed on dry ice until analysis. RBC lysates and brain samples were stored at -80°C. The cholinesterase AChE enzyme assays were performed radiometrically (Johnson and Russel, 1975). The stability and content of active substance in the dosing suspensions was demonstrated to be adequate.

No data concerning statistical evaluation was reported.

The study is considered to provide complementary information.

- Rat, acute neurotoxicity study, gavage, 0; 0.1, 0.3, 0.5, 0.75 or 1.5 mg/kg b.w. in adult rats (Mc Daniel et al., 2007, published)

Findings: see table B.6.7.3-9

Mortality: none

Clinical signs: not reported

Motor activity:

A significant decrease in cage (horizontal and vertical) movements was observed at 0.3 mg/kg b.w. and above. At the lowest dose of 0.1 mg/kg b.w., a slight decrease was notable, and possibly treatment-related (although statistically not significant), given the dose-responsiveness at the higher doses. The authors remarked that the higher doses produced relatively greater decreases in motor activity, with vertical activity significantly more affected than horizontal at the two highest doses.

There was a graded increase in the number of rats showing toxicity as graded by the Tox Score, from 0.5 mg/kg b.w. onwards.

Table B.6.7.3-9a: neurotoxicity 15-35' after single administration of Carbofuran in ♂ adult rats: Tox Scores and motor activity (Mc Daniel, 2007)

Endpoints	dose level (mg/kg b.w.)					
	0	0.1	0.3	0.5	0.75	1.5
Tox Scores[§]	-	-	-	1.1	1.5	2.4
motor activity	209.6 ± 36.2	180.2 ± 36.3 ↓14%	99.3 ± 25.9 ↓53%*	99.1 ± 52.1 ↓53%*	91.0 ± 40.1 ↓57%*	26.4 ± 18.9 ↓87%*

§: average score, on a 1-to-3 scale, graded 1: normal; 2: some effects that were not very obvious; and 3: severe and obvious effects; Values are the mean ± s.d, (N=10/dose) and concomitant % reduction compared to control group; Statistically significant modification: *:p≤0.05

Cholinesterase activity:

A significant dose-dependent decrease of both RBC and brain AChE activity was observed at 0.1 mg/kg b.w. and above. Statistical significance was attained at 0.3 mg/kg b.w. and above, but the dose-related pattern suggested that the effects at the lowest dose were probably also toxicologically meaningful (in the brain, AChE reductions were close to 20% compared to the control levels). It was of note that at each dose-level, the inhibition of brain and RBC AChE inhibition was of comparable magnitude.

In this study, a within-subject Pearson correlation coefficient was calculated between the brain/RBC AChE activity and motor activity, both horizontal (H), and vertical (V). It appeared that all correlations were highly significant (p<0.01), with values attaining for brain ACh 0.750-0.701 (H-V), and for RBC AChE 0.683-0.580 (H-V). These numbers tend to support the assumption that the decreased AChE activities at the lowest dose were adverse.

Further, a comparison between the results in pups and adult clearly indicated that rat pups were more sensitive to the AChE inhibiting properties of Carbofuran than adult rats. Compared to the study controls, the degree of inhibition amounted to 28-48% in the pups, compared to 18-33% in the adults for the dose-levels 0.1-0.3 mg/kg b.w., respectively.

Finally, the authors calculated the BMD₁₀ values, which were considered similar for all endpoints (0.04-0.09 mg/kg b.w., no further details reported).

Table B.6.7.3-9b: neurotoxicity 40' after single administration of Carbofuran in ♂ adult rats: cholinesterase activity (Mc Daniel, 2007)

Endpoints	dose level (mg/kg b.w.)					
	0	0.1	0.3	0.5	0.75	1.5
RBC AChE	0.43 ± 0.043	0.37 ± 0.076 ↓14%	0.32 ± 0.056 ↓25%*	0.30 ± 0.099 ↓30%*	0.25 ± 0.091 ↓41%*	0.14 ± 0.032 ↓67%*
Brain AChE	7.158 ± 0.450	5.895 ± 1.037 ↓18%	4.812 ± 0.441 ↓33%*	4.544 ± 0.637 ↓37%*	4.411 ± 0.645 ↓38%*	2.873 ± 0.677 ↓60%*

AChE inhibition values expressed in µmol ACh hydrolysed/min/mL (RBC) or /g (brain); values are the mean ± s.d, (N=5/dose) and concomitant % reduction compared to control group; Statistically significant modification: *:p≤0.05.

Conclusions:

In this study, the NOAEL is thus considered <0.1 mg/kg b.w., based upon brain AChE inhibition (~20%), and associated decrease of motor activities in ♂ adult rats.

GLP status: not reported

Guideline: not of application

Material and methods:

Ten ♂ adult /dose (Long-Evans (CrI)) received a single administration of Carbofuran (Chem-Serve, Inc., batch n° not reported, purity 99%) dissolved in acetone (2.5% v:v)+corn oil (the vial with this dilution was vortexed every 10' and placed uncapped in a hood during 30' to allow the acetone to evaporate). The test article was administered by gavage (dosing volume 1 mL/kg) at 0, 0.1, 0.3, 0.5, 0.75 or 1.5 mg/kg b.w..

Ca. 10-12' post-dosing, each animal was visually examined and received a score, termed "Tox Score." The Tox Score was a ranked, global description of degree of overt cholinergic signs, including a.o. lachrimation, miosis, fasciculations, smacking, tremors, polyuria, and diarrhea (any of these alone or in combination). Rats were scored as 1: normal; 2: some effects that were not very obvious; and 3: severe and obvious effects. The examiners had no knowledge of the treatment of the animals. Motor activity assessment began 15' after dosing, and the session length was 20'. Activity was monitored in a photocell-based chamber shaped like a figure eight. A set of eight photocells spread throughout the chamber measured horizontal activity, and a bank of photocells placed 14 cm above the flooring measured vertical activity.

The experiment was terminated at 40' post-dose, and animals were euthanised, and blood of 5 animals/dose collected. The blood was processed (RBC lysate preparation) within 15'. The brain of 5 animals/dose was removed intact and placed on dry ice until analysis. RBC lysates and brain samples were stored at -80°C. The cholinesterase AChE enzyme assays were performed radiometrically (Johnson and Russel, 1975). The stability and content of active substance in the dosing suspensions was demonstrated to be adequate.

Statistical analysis: Two-way ANOVA, Dunnett's t-test or paired t-tests were used Benchmark dose modeling software (version 1.4.1; USEPA, 2007) was used to calculate doses estimated to produce a 10% decrease (BMD₁₀; i.e., 90% of control) in each end point. In all cases, the Hill model was used, with a correction for nonequal variances when they were present.

The study is considered to provide complementary information.

**- Rat, acute neurotoxicity study, gavage, 0.5 mg/kg b.w. in adult rats – time-course study
(Padilla et al., 2007, published)**

To compare the toxicity of seven N-methyl carbamates, time course profiles for brain and red blood cell (RBC) cholinesterase (ChE) inhibition were established for each. Adult ♂ Long Evans rats (n=4-5/dose group) were dosed orally with a.o. Carbofuran at 0.5 mg/kg b.w. in corn oil. Brain and blood were taken from 0.5 to 24h after dosing for analysis of ChE activity using two different methods: (1) a radiometric method which limits the amount of reactivation of ChE activity, and (2) a spectrophotometric method (Ellman method using traditional, unmodified conditions) which may encourage reactivation. The time of peak ChE inhibition was similar for all seven N-methyl carbamate pesticides: 0.5-1.0 h after dosing. By 24 h, brain and RBC ChE activity in all animals returned to normal.

Specifically, the dose of 0.5 mg/kg Carbofuran produced 55% inhibition of AChE activity in the RBC and 40% inhibition of cholinesterase activity in the brain by 0.5h after dosing. The time course of recovery was quite protracted for both compartments, with the brain recovering to control levels by 6h after dosing, but the RBC did not recover to control levels until between 6h and 24h after dosing. For Carbofuran, the RBC ChE was slightly (ca. 10-15%) more inhibited than brain ChE throughout the experimental period.

Generally, the spectrophotometric method underestimated ChE inhibition. Moreover, there was a strong, direct correlation between brain and RBC ChE activity (radiometric assay) for all seven compounds combined ($r^2=0.73$, slope 1.1), while the spectrophotometric analysis of the same samples showed a poor correlation ($r^2=0.09$, slope 0.67).

These data indicate that:

- (i) the radiometric method is superior for analyses of ChE activity in tissues from carbamate-treated animals;
- (ii) animals treated with these N-methyl carbamate pesticides are affected rapidly, and recover rapidly, and
- (iii) generally, assessment of RBC ChE is an accurate predictor of brain ChE inhibition for these 7 pesticides.

References:

-Johnson CD and Russell RL, *A rapid, simple radiometric assay for cholinesterase, suitable for multiple determinations, Anal Biochem*, 64(1):229-238, 1975.

- Padilla, S, Marshall, RS, Hunter, DL, Lowit, A, *Time course of cholinesterase inhibition in adult rats treated acutely with carbaryl, carbofuran, formetanate, methomyl, methiocarb, oxamyl or propoxur, Toxicol Appl Pharmacol*, 219 (2-3), 202-209, 2007.

- McDaniel KL, Padilla S, Marshall RS, Phillips PM, Podhorniak L, Qian Y, Moser VC. Comparison of acute neurobehavioral and cholinesterase inhibitory effects of N-methylcarbamates in rat, *Toxicol Sci*, 98(2):552-560, 2007.

B.6.7.3 Summary of neurotoxicity (Annex IIA 5.7)

At the occasion of resubmission, comparative neurotoxicity studies were conducted to establish the lowest relevant neurotoxicity NOAEL in PND11 rats pups or young adult rats. The animals were given a single administration of Carbofuran in corn oil, by gavage, at the dose-range of 0.03 mg/kg b.w. to 1.0 mg/kg b.w. included (tested over two separate experiments). Overall, clinical signs were observed from 0.3 mg/kg b.w onwards. Clinical signs were most intense 15-30' after dosage, and lasted up to 1h in some instances. At the lowest dose of 0.03 mg/kg b.w., AChE activity was meaningfully inhibited in the pup brain at 30' post-dosing, and returned to control levels 4h after the administration. Overall, AChE inhibition was resolved by 24h after administration.

Based upon brain AChE inhibition percentages at peak times throughout the experiments, pups would be on average about 2× more sensitive than young adults.

Although no clinical signs were observed at the lowest dose, it was considered that the neurotoxicity NOAEL in pups was <0.03 mg/kg b.w., mainly based upon the inhibition of brain AChE activity up to 20% ($p \leq 0.01$) at 30' post-dosing. At 4h post-dose, the effect was reversible at the lowest dose, but a significant effect was remanent at 0.1 mg/kg b.w. and above.

Thus, in the key acute neurotoxicity study (Hoberman, 2007c), there was no dose without effect. At 0.03 mg/kg b.w., brain AChE of ♀ pups at 30' post-dosing were significantly decreased by 20%. Both the magnitude of the decrease and the absence of clinical signs and of motor activity failure indicated that the response at this dose-level was at the limit of the toxicological relevance. Whereas in principle, a 20% brain AChE inhibition could not be ignored, RMS was of the opinion that a supplementary assessment factor of 10× to bridge from the NOAEL to NOAEL would be overly conservative. Applying a curve-fitting to estimate the NOAEL using the data in the dose-response curve, and estimating the benchmark dose at the 10% response level (BMD_{10}), gave a value of 0.017-0.021 mg/kg b.w. (assuming either a sigmoidal or a linear dose-response). Therefore, RMS judged that a 2× assessment factor on the LOAEL would well be sufficient to estimate the NOAEL, and a value of 0.015 mg/kg b.w. was proposed. As at 0.03 mg/kg b.w., the adult brain AChE inhibition at 30' post-dosing was <20%, it was considered a NOAEL only for this group.

Table B.6.7.31 Summary of carbofuran neurotoxicity studies

Study type	Batch n° and purity	NOAEL (mg / kg b.w./d)	LOAEL (mg / kg b.w./d)	Symptoms	References
Acute neurotoxicity, rat (pup-juvenile), gavage, 0.3, 0.6, 1.0 mg/kg bw	PL04-0056, 99%	<0.3	0.3	brain AChE inhibition (pups: ↓48%, young adults: ↓25%) at 15', clinical signs (tremor) at 1h post-dosing	Tyl, 2005c
Acute neurotoxicity, rat (pup-juvenile), gavage, 0.03, 0.1, 0.3 mg/kg bw	PL04-0056, 99%	•pups: <0.03 (0.015) •adults: 0.03	•pups: 0.03 •adults: 0.1	brain AChE inhibition (pups and adults: ↓≥20%,) at 30', reversible at 4h post-dosing	Hoberman, 2007c

Further comments from the notifier were evaluated by the RMS :

FMC disagreed with the proposition of the RMS to consider the lowest dose of 0.03 mg/kg b.w./d in the PND11 pups a LOAEL (20% AChE inhibition), to ignore human studies, and to apply a 100× assessment factor for the derivation of the ARfD. Relevant parts of the position paper are cited below and commented by the RMS, and the whole position paper and references were added in Appendix B.

Notifier's statement:

"Brain cholinesterase is the preferred endpoint for risk assessment because it is directly relevant to the mechanism of toxicity. Given that background levels may vary as much as ±10%, the question becomes what degree of ChE inhibition signifies a compound-related effect. To the best of our knowledge, EU guidelines do not specify what level of ChE inhibition constitutes a toxicological relevant effect."

RMS response:

There is a general agreement to consider a statistically significant drop of brain Acetyl Cholinesterase activity by 20% a relevant effect. This threshold was recommended by the WHO, as well as the ACRA working group on acute cholinesterase risk assessment (Carlock, 1999). Therefore, the brain AChE effects were considered relevant.

Notifier's statement:

"The observation of approximately 20% inhibition comes from Hoberman (2007c), and specifically the results in female pups (Table 1). Statistically significant differences were also noted in the same study for male pups and adults, but the degree of inhibition was 13% and 12%, both clearly within the 20% threshold. The question then is whether the 19.8% difference is compound-related or just a chance occurrence of comparing two extremes of the normal range. Fortunately there is a second study by Hoberman (2007a) that can be used to answer the question. The study showed only 11% inhibition of brain cholinesterase for female pups at 0.03 mg/kg/day."

RMS response:

It is of note that the inhibition in the Hoberman (2007c) study was dose-related in the ♀ pups, and that some inhibition was also visible in the ♂ pups (-13%, p<0.05) and in the ♂ adults (-12%, p<0.01), indicating that the effect was not a spurious effect, but definitely substance-related. RMS feels that the results in the range-finder experiment (Hoberman, 2007a) is not necessarily in contradiction with the full study: the AChE activity was indeed only 10-11% (n.s.s.) lower than controls, but the fact that there was a decrease in both experiments in rat pups points toward a consistent effect, which should for this reason not per se be considered irrelevant. However, as already mentioned in the evaluation, RMS agrees that the effect is at the limit of toxicological significance.

Notifier's statement:

"As stated above, the WHO's guidelines state that a statistically significant inhibition less than 20% should be considered on a case-by-case basis including correlation with clinical signs (WHO, 2000a). The rat comparative neurotoxicity studies showed no clinical signs were observed in 0.03 or 0.1 mg/kg/day dosed rats; clinical signs were observed in some 0.3 mg/kg/day dosed groups and only when ChE inhibition was markedly decreased at least about 50% [...]"

A practical real world example of how a 20% decrease in ChE inhibition is considered protective and not reflective of toxicity is the State of California's policy for the protection of workers. [...] This demonstrates that the suppression of 20 to 30% RBC ChE inhibition is a surrogate measure to reasonably protect workers from nervous system toxicity and is not itself an adverse effect, and is consistent with the minimum 20% brain (or RBC in the absence of brain) ChE inhibition guidelines established by the WHO".

RMS response:

It may be argued that the brain AChE inhibition was observed at 0.03 mkg, whereas clinical signs were visible at 0.1 mkg and higher. However, the AChE inhibition could be associated with subclinical effects, not noticeable in the study (and which may even not be measurable in animals). It is worthwhile to highlight that subtle clinical signs could be missed in pups due to the nursing activities of the mothers like reported in some

studies (Tyl, 2005 a-c). On the other hand, it is unclear how to interpret the presence of significant brain AChE inhibition in the absence of clinical signs, as some studies (Carlock, 1999) seem to indicate that in the majority of cases, brain AChE inhibition was as high as 50% at the LOAEL for clinical signs. In half of the studies, there was even a poor relationship between brain AChE inhibition and cholinergic effects, but this does not mean that potential adversity should not be recognised.

Further, the cited 20% criterium for workers protection pertains to RBC AChE inhibition, and not to brain AChE inhibition. This biomonitoring parameter should be interpreted with caution. From the quantitative point of view, the rat pup experiments (Tyl, Hoberman, McDaniel) indicate that, certainly at the higher doses, the AChE inhibition in the brain was systematically higher than that in the RBC, although this was not observed in the Moser studies. From the qualitative point of view, it is well-accepted that an AChE inhibition of the same severity (e.g. 20%) has not the same toxicological impact in the RBC than in the brain.

Notifier's statement:

"An outside expert consultant calculated a BMD₁₀ of 0.033 mg/kg/day for carbofuran rat pup brain ChE inhibition based on the individual study BMD₁₀ estimations at 0.25 and 0.5 hr from several FMC rat ChE inhibition studies (FMC, 2008). US EPA calculated a BMD₁₀ of 0.04 mg/kg/day for rat pup brain ChE inhibition using both FMC's data and their own data (EPA, 2008). These benchmark dose calculations using data from multiple studies are more robust than estimations derived using data from only one of the available studies, and the obtained values are consistent with the judgment that the 0.03 mg/kg/day low dose in FMC's rat ChE inhibition studies is a LOAEL.

As indicated in FMC's paper that was submitted to the RMS along with the rat comparative ChE studies, we believe the collective results show that while pups are more sensitive to ChE inhibition than adults at higher doses, this difference attenuates and practically disappears at the lowest doses, which are the most relevant in risk assessment."

RMS response:

Firstly, the EPA made an estimation of the BMD₁₀ using *all* available FMC data, including the EPA data (i.e. 7 studies), which were put in an exponential model. Notifier made a new estimation, using two studies (the 2005 range finder, and the 2007 full study), but raw data were not submitted.

RMS did its own estimation, using the Hill-model, and using the full studies, to check notifier's assumption of improved robustness using more data at higher doses.

RMS did not obtain the same results as the notifier in a new BMD analysis, because (i) another model was used (we used the preferred Hill model while the notifier used an exponential model); (ii) the dataset was different: notifier used the data of a sighting study (Hoberman, 2007a), as well as the first full study (Tyl, 2005c), basically because both studies measured brain AChE at exactly 15' (however, at comparable doses the values were the same at 15' and at 30', thus pooling was acceptable); (iii) finally, notifier preferred to derive a BMD₁₀ for each dataset separately, and computed an 'overall' BMD₁₀ instead of calculating BMD₁₀ on the pooled data. Surprisingly, including the most relevant second full study (Hoberman, 2007c) in the notifier's model did not change the BMD₁₀, indicating that the exponential model was perhaps not the best one to fit the data, or that the presence of the lowest BMD₁₀ did not influence the 'average' BMD₁₀-value. In any case, no major difference would be expected when calculating the BMD₁₀ based on the pooled results of the Tyl and the Hoberman study in the Hill model, as the Tyl data were obtained with doses at 0.3-0.6-1.0 mg/kg b.w, while the Hoberman data were obtained in the 0.03-0.1-0.3 mg/kg b.w. range. Making the dataset more 'robust' at the high end of the dose-response curve (in the plateau phase) is unlikely to influence meaningfully the interpolation at the low end, which was the dose-range of interest. The result of the RMS estimation was added in Appendix F. As with the extrapolation on the Hoberman data (full study) alone, BMD₁₀ values for ♂ and ♀ pups were 0.014-0.016 mg/kg b.w., confirming the overall conclusion, which was that the probable pup NOAEL was 0.015 mg/kg b.w, i.e. 50% of the LOAEL=0.03 mg/kg b.w.. Most importantly the RMS approach was based upon the rationale that the results in the full Hoberman study were relevant by themselves, and should not be 'levelled out' by a less convincing range-finder with a low number of rats (Hoberman, 2007a), or by data at higher doses (Tyl, 2005a-c).

The RMS' evaluation of differential sensitivity would be that overall, pups are more sensitive to the brain AChE inhibition than adults, although the data also indicate that the difference was less obvious at the lowest dose.

Notifier's statement:

“Most chemical risk assessments are based solely on animal studies extrapolated to humans, since direct assessment of many toxicological endpoints in humans would of course be totally unethical and inappropriate. One advantage of chemicals having cholinesterase inhibition as their mode of action, however, is that human studies may be conducted as long as they are conducted ethically. Indeed, direct measurement of ChE inhibition may be conducted in humans at sufficiently low doses that avoid adverse effects in the volunteers. This provides for increased certainty around the NOAEL and for the overall risk assessment. [...]

... the results any human study to be used in risk assessment must be scientifically relevant. In 1997, USEPA engaged three academic experts to provide their independent views on the suitability of the carbofuran human oral study for scientific risk assessment (EPA, 1997). [...] They concluded that 0.05 mg/kg was the NOEL (one expert judged 0.1 mg/kg to the NOAEL), and that, while there were some technical deficiencies, the human study was acceptable for use in deriving the acute reference dose. USEPA agreed with the experts' assessment and used this human oral study to set the carbofuran acute reference dose for almost a decade (1997-2006).”

RMS Response:

The EU policy in terms of human studies consists of using the data to confirm animal findings. In addition, the oral study was conducted on a very limited number of persons, and was considered insufficiently robust. Therefore, BE still consider the data complementary. Contrarily to the opinion of the notifier, the EPA was not convinced about the validity of the study. In their latest assessment (EPA, 01/2008), it was stated: The (HSRB) panel concluded that there were a number of technical scientific issues regarding the conduct of both the oral and dermal studies which made them deficient and not appropriate for use in risk assessment [...]. Based on the above, the HSRB did not recommend use of any of the oral or dermal studies conducted with Carbofuran in human subjects for the single chemical assessment. [...] This (EPA) assessment takes into consideration the HSRB recommendations and does not rely on these data.”

RMS concurs with this view. While the data apparently indicate that the RBC AChE inhibition was comparable in the rat and the human, the low number of subjects in the human study was not considered sufficient to draw firm conclusion. Moreover, the most critical endpoint appears to be brain AChE inhibition, for which each comparison is lacking.

Notifier's statement:

“The EU guidelines for acute reference dose determination refer to both the traditional 10X inter- and 10X intra-species factors, but also refer to using reduced factors for cholinesterase inhibitors because ChE inhibition is so largely dependent upon toxicokinetic factors (EU, 2001). The magnitude of carbofuran induced ChE inhibition is primarily a function of the maximum blood concentration in the target nervous system tissue in that it has rapid onset, peak effect within 15-30 minutes, and is rapidly reversible. The EU guidelines allow for the use of factors less than 100X for ChE inhibitors.

In a similar fashion, WHO guidelines advocate reduced 5X inter-species and 5X intra-species factors (25X overall) for cholinesterase inhibitors (JMPR, 2002). The previous carbofuran WHO acute reference dose was based on a 5X inter-species factor and a 5X intra-species factor applied to the NOAEL from a dietary study in dogs (JMPR, 2002). The current carbofuran WHO acute reference dose of 0.001 mg/kg/day was also based on a 5X inter-species factor and a 5X intra-species factor applied to the 0.03 mg/kg NOAEL from the rat ChE inhibition studies (JMPR, 2008). In fact, the WHO concluded that the overall 25X safety factor for carbofuran was conservative, and that the carbofuran database provides sufficient evidence to justify a further reduction in the overall safety factor. Other cholinesterase inhibitors that the WHO has used less than a 100X overall factor in their acute reference dose determinations include carbaryl, thiodicarb, acephate, and methamidophos.”

RMS response:

Based upon the arguments above, the discussion of the use of assessment factors should be restricted upon the animal studies (i.e. acute rat NT study).

RMS acknowledges that there is room for discussion concerning the application of assessment factors on the obtained NOAEL. In the EU guidance document (2001) for the establishment of the ARfD, the use of a 10-fold factor for both intra-species and interspecies differences is recommended, unless a convincing scientific case can be made for applying a lower factor (the extent of which has yet to be determined). The notifier is correct in observing that other peer-review boards such as the JMPR adopted a different view on the use of AF in the case of carbamate-induced AChE inhibition. In a general consideration, recently published (JMPR, 2008), the use of a 25× i.o. 100× AF was strongly supported. This was mainly based on the consideration that a reduction of AChE would be highly dependent on the C_{max} parameter (peak concentration following bolus ingestion), which is supposed to be less variable between species than the AUC (area under the curve following to repeated ingestion and subsequent accumulation). RMS acknowledges that this explanation may be plausible, especially for a rapidly reversible event as AChE inhibition, and considers that this may be subject to further discussion at the EU-level. The JMPR highlighted also that, as the pup NOAEL was used to derive the ARfD of Carbofuran, “one component of potential variability has already been taken into account, and the remaining interindividual differences are likely to be less than the default, as they are due to passive processes”. This is correct, although other interindividual differences as a possible higher susceptibility between subjects should not be excluded.

On the other hand, one should also be aware that robust data on intra/inter species comparisons for methylcarbamates are scarce, especially for what brain AChE inhibition is concerned. Whereas frank clinical signs were observed in adults only at levels 10× higher than the lowest dose, the subclinical impact of a 20% brain AChE inhibition in pups is still unknown.

The ARfD of the reviewed carbamates in the EU, including Oxamyl, Methomyl, Thiodicarb, Pirimicarb and Carbaryl were based upon acute neurotoxicity gavage studies; the ARfD of methiocarb was based upon a dietary study, where the NOAEL was marginally lower than the acute oral rat study LOAEL. As an exception, the dietary reference dose of Aldicarb was based upon a human study, which showed the lowest NOAEL. Contrarily to the opinion of the notifier, this could be an indication that in some cases, human could well be more sensitive than the animal. Another example of a possible difference could be found with methomyl, where lower values were observed in humans. For the cited substances it is well worth stressing that no comparative NT study (pups/adults) were conducted, thus possibly the acute NOAEL's would have been lower if the same endpoints would have been assessed in more sensitive assays, as it was with Carbofuran. In any case, the AF applied on the NOAEL at the EU-level was always a factor of 100, contrarily to the situation at the WHO, where lower AF were deemed appropriate.

Conclusions:

- (i) ***Brain AChE inhibition and clinical signs:*** the statistically significant brain AChE inhibition of 20% in the PND11 pups was considered a toxicologically relevant effect, and should be taken into account even if it may be highlighted that clear clinical effect were only observed at higher dose-levels, as these may be missed in the pups, and subclinical effects are not excluded.

- (ii) **Sensitivity of rat pups:** overall, it was observed that the level of brain AChE inhibition was higher in the pups than in the adults. This may be counterbalanced by a possible more rapid elimination rate of pups vs. adults, although the latter was not confirmed in one study. RMS recognises that this age-related difference in sensitivity was obvious at the higher dose-levels, but considers that it should be taken into account at the level of the NOAEL by precaution. In a BMD analysis, a no-effect level (10% decrease) was detected at 50% of this LOAEL, confirming the proposed 2× factor in order to extrapolate from a LOAEL to a NOAEL. The inclusion of data at the highest dose-levels is inappropriate and does not meaningfully alter this conclusion.
- (iii) The **human oral study** may be considered as complementary information, as it was considered of insufficient power to invalidate the lower NOAEL's in the rat studies, both because of the small number of subjects used and because the rat studies addressed brain AChE.
- (iv) **Safety factors:** RMS agrees that the choice of lower AF than the default 100× could be discussed, as the JMPR proposed a value as low as 25×, mainly based upon considerations of low inter/intra species variability for C_{max} effects, which are readily reversible. However, a precautionary approach was preferred in a first step.

Reference:

Regulating and assessing risks of cholinesterase-inhibiting pesticides: divergent approaches and interpretations, Carlock LL, Chen WL, Gordon EB, Killeen JC, Manley A, Meyer LS, Mullin LS, Pendino KJ, Percy A, Sargent DE, Seaman LR, Svanborg NK, Stanton RH, Tellone CI, Van Goethem DL, J Toxicol Environ Health B Crit Rev, 2(2):105-160, 1999.

B.6.10 Summary of mammalian toxicology and proposed ADI, AOEL and drinking water limit of CARBOFURAN(Annex IIA 5.10)

B.6.10.2 Acceptable daily intake (ADI) of CARBOFURAN

Initial proposal (before resubmission):

The ADI should be based on the highest dose at which no adverse effect is observed in the most appropriate study in the most sensitive species. Carbofuran has been tested in rats, mice and dogs in several sub chronic and chronic studies. Dogs and rats were found to be of quite similar sensitivity. The lowest NOAEL of 0.1 and 0.25 mg/kg bw/d were seen in the 1-year dog studies. In these studies, at the LOAEL, clinical signs (miosis and soft stool) and inhibition of AChE were reported at 1 mg/kg bw/d in one study and testicular degeneration was seen at 0.5 mg/kg bw/d in the second study. The choice of 0.1-mg/kg bw/d is further supported by NOAEL of 0.1 mg/kg bw/d in a published study from Pant et al (1995) in which, rats exposed for 60 weeks by gavage, showed testicular damage and toxic effects on sperm at 0.2 mg/kg bw/d. It was of note that the effects observed at 0.2 mg/kg b.w./d in the published Pant study (1995) were not replicated in a more recent study conducted by the notifier (Chevalier, 2006) (albeit with rats of a different strain, which were possibly older, and with Carbofuran of potentially another specification). However, the absence of similar findings in the rat did not discount the effects observed in the dog.

Initially, this NOAEL of 0.1 mg/kg b.w./d was considered an appropriate point of departure to establish an ADI, taking into account an assessment factor of 100×, which was then 0.001 mg/kg bw/d.

During re-submission however, newly submitted studies were evaluated, which were considered relevant for the estimation of the reference doses. Acute neurotoxicity studies were performed where AChE inhibition was measured in RBC and in the brain of neonate and adult rats. Administration of Carbofuran in neonate and adult rats at 0.03 mg/kg b.w. induced brain AChE inhibition by about 20% and 12% in neonate and adult rat, at 30' post-administration, respectively (Hoberman, 2007c). Neither clinical signs or impaired motor activity was observed at this low dose (LOAEL for decreased motor activity in adult rats, associated with mild brain AChE inhibition was 0.1 mg/kg b.w., Mc Daniel, 2007).

The establishment of a reference dose on this LOAEL, with a supplementary 10× assessment factor would certainly be overly conservative. A benchmark dose approach would approximate a bridging from LOAEL to NOAEL taking into consideration a decrease by 10% (BMD₁₀) compared to controls. The calculation of a benchmark dose for a 10% decrease of brain AChE by the RMS provided a value of 0.017 mg/kg b.w. in the ♀pups (dose group with the largest decrease at the LOAEL). Therefore, an AF of 2× was deemed acceptable and sufficient. In addition, a 100× AF was applied to account for the intraspecies and interspecies extrapolation.

ADI (Carbofuran) = LOAEL (acute NT) ÷ 2 ÷ 100 = 0.03 mg/kg b.w. ÷ 200 = 0.00015 mg/kg b.w./d

It was considered that the long-term exposure of the consumer would be covered by this reference dose. Taking into account the rapid reversibility of the adverse effect (within 4h), a chronic effect due to life-long ingestion of the residus in the food, will actually be covered by the effect due to the repeated daily single exposure, without an accumulating effect, as demonstrated by toxicokinetic data and repeated toxicity studies.

B.6.10.3 Acute reference dose (ArfD) of Carbofuran

Initial proposal (before resubmission):

The acute and sub chronic oral toxicity database for carbofuran indicates that carbofuran elicits toxic manifestations of central and peripheral nervous system origin by over stimulating muscarinic and nicotinic receptors.

The acute oral LD50 study with rats showed mortality at 5-13 mg/kg bw.

Although the duration of inhibition was short, RBCs, brain and plasma cholinesterases activities were inhibited after a single low dose of 2-3 mg/kg bw in rats. Quite similar effects were observed in short term

toxicity studies. Testicular and sperm toxicity were reported in the open literature after exposure during lactation or during gestation at doses of 0.2 mg/kg bw/d. Clinical signs of neurotoxicity were reported in dams developmental studies at doses higher than 0.3 mg/kg bw/d.

A NOAEL of 0.1mg/kg bw/d was observed in developmental rat studies. In this study, at 0.3 mg/kg bw/d, neurotoxic signs were noted in mothers.

Initially, this study was selected to derive the ArfD, accounting an assessment factor of 100×, thus calculating 0.001 mg/kg bw/d.

Initial Dianica proposal: cholinesterase inhibition can be considered as the most appropriate endpoint in determining the ARfD. Because the ADI is base on acute effects, the acute reference dose should be the same as the ADI = 0.002 mg/kg bw/d.

Initial FMC proposal: in the absence of a suitable short term study for carbofuran, it is proposed to use the ADI of 0.002 mg/kg bw/d on the basis of the 4-week dog study for AChE inhibition in RBCs.

During resubmission, this value was revised, taking into account the studies as described above (ADI).

Hence, **ARfD** = LOAEL (acute NT) ÷2 ÷100 = 0.03 mg/kg b.w. ÷200 = **0.00015 mg/kg b.w./d**

RMS thus considered appropriate to derive the ARfD on the same basis as for the ADI, where effects were observed after one ingestion. As it was derived in pups, being about 2× more sensitive than the adults, this reference dose was protective for the most sensitive population, as required by the criteria.

B.6.10.4 Acceptable Operator Exposure Level (AOEL) of Carbofuran

The proposed acceptable operator exposure level should be established on the basis of the highest dose at which no adverse effect is observed in relevant studies in the most sensitive species.

Initial proposal (before resubmission):

On the basis of the data available, the initial AOEL was derived from an overall NOAEL of 0.1 mg/kg bw/d resulting from the sub chronic feeding studies in dogs, and published studies in rats. Considering the toxicological profile of carbofuran, for the determination of the AOELs a safety factor of 100 is considered adequate. As the oral absorption reached 92% of the dose within 96h, no correction is necessary, and AOEL was 0.001 mg/kg bw/d.

Dianica proposed to use the NOAEL established in the 28-day dog study (0.22 mg/kg bw/d).

FMC proposed the setting of 2 AOELs: the first is derived from the human volunteer study. Based on effects on RBCs AChE, using a safety factor of 100, gives an AOEL = 0.005 mg/kg bw/d. the 4-week dog study was also considered appropriate, giving an AOEL = 0.002 mg/kg bw/d.

During resubmission, this value was revised taking into account the studies as described above.

The effects observed in the acute neurotoxicity study in the rat was a convenient point of departure for the establishment of the AOEL.

However, at the lowest dose of 0.03 mg/kg b.w., brain AChE inhibition of 20% was only observed in the ♀pups. At the next-higher dose of 0.1 mg/kg b.w., the effect was obvious for both the pups and the adult rats. Therefore, RMS proposed to consider the dose of 0.03 mg/kg b.w./d a NOAEL only for the adult animals, which represent the relevant population for operator risk assessments.

Hence, the AOEL was calculated on this basis, using the standard AF of 100×. As the substance is well absorbed, no correction for incomplete absorption is necessary.

Hence, **AOEL** = NOAEL (acute NT) ÷100 = 0.03 mg/kg b.w. ÷100 = **0.0003 mg/kg b.w./d**

General remark concerning the choice of the assessment factors.

Notifier proposed another assessment factor instead of the default 100×, and put forward following arguments:

“The lowest NOAEL for rat pups is 0.03 mg/kg in study A2006-6137 (Hoberman, 2007c). In this study there was some statistically significant brain ChE depression at this dose, but this

depression never reached 20% (19.8%) when compared to a control group. In addition, no clinical signs of toxicity were observed at 0.03 or 0.1 mg/kg in the FMC-sponsored studies.

Although the human study was limited, it supports the fact that rat and human have about the same sensitivity in term of carbofuran RBC ChE inhibition, especially at the lower dose levels more applicable for risk assessment. This is consistent with the fact that the ChE enzyme is highly conserved among mammalian species, including rats, mice, dogs, and humans.

Due to the rapid reversibility of the carbofuran-induced ChE inhibitory effect, there is no more toxicity after repeated dose than after a single dose. Therefore it is appropriate that the ADI and ARfD have the same value.

As far as assessment factor is concerned, the measured ChE depression in brain and RBC is more a direct consequence of the carbofuran level in this compartment, and is therefore highly dependent on toxicokinetics. Toxicodynamic inter- and intra-species variability is only minimally involved in this end-point. According to the IPCS EHS 210 (1999), inter-species and intra-individual variability are further divided into (2.5 and 4.0) and (3.16 and 3.16) for toxicokinetics and toxicodynamics, respectively. It is most appropriate, therefore, to only take into account the toxicokinetic factors in determining an assessment factor for carbofuran-induced ChE inhibition. The toxicokinetic inter- and intra-species factors are 4 and 3.16, respectively, giving an assessment factor of 12.6. Based on these considerations, the ARfD/ADI for carbofuran from these studies is $0.03 \text{ mg/kg/day} / 12.6 = 0.0024 \text{ mg/kg/day}$.

The human carbofuran acute oral study indicating that RBC ChE inhibition is of equal magnitude in humans and rats supports removing a factor for inter-species variation. It is interesting to note that a similar ARfD/ADI is obtained using the traditional intra-species factor of 10, and a inter-species factor of 1 based on the similar sensitivity of humans and rats to carbofuran-induced RBC inhibition [$0.03 \text{ mg/kg/day} / 10 = 0.003 \text{ mg/kg/day}$]

Consequently, the previously determined ARfD of 0.001 mg/kg for carbofuran will more than safely cover potential acute effects in adults as well as in infants and children. As previously said, the effects are reversible in few hours, normally less than four, especially for the low doses, and any effect occurring during a sitting will have completely resolved before the next one. For this reason, this ARfD should be compared to the residues contained in the portion absorbed during a sitting instead of the portion absorbed during a whole day.”

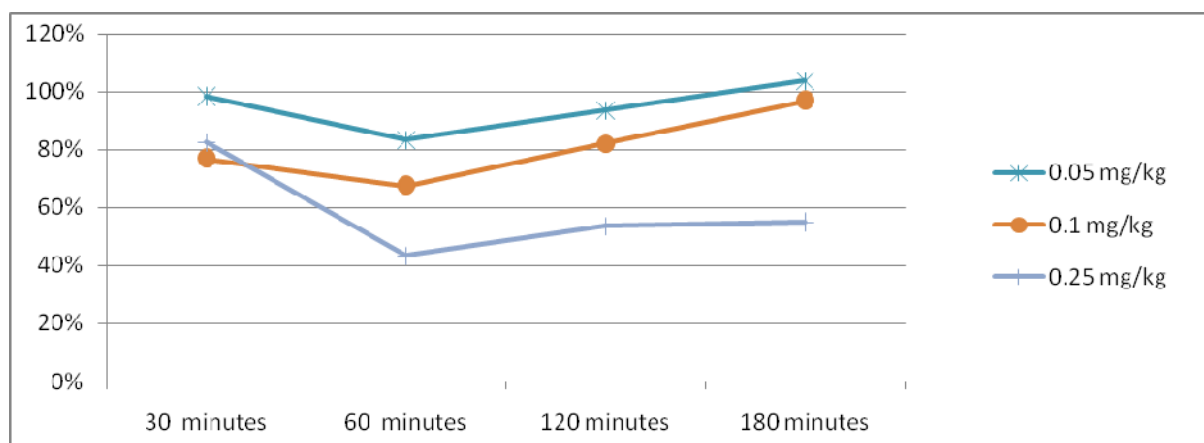
Further explanation underpinning Notifier justification to reduce the standard interspecies AF of 10× was extracted from the study performed on human volunteers (Arnold, 1976, please refer to B.6.8.2 Supplementary studies):

“In this study nine volunteers were administered carbofuran orally at the dose of 0 (one volunteer), 0.05 (two volunteers), 0.1 (two volunteers) and 0.25 (four volunteers) mg/kg bw. Dose was given after a standard breakfast. Plasma and RBC ChE were measured pre-dose and after 30, 60, 120, 180, 360 minutes and after 24 hours.

The value of this study is limited due to the poorly detailed methodology and test procedures, and to the low number of studied subjects. However, these results can be used to estimate relative sensitivity of rat vs. human.

In this study the maximum inhibition of RBC ChE was obtained after one hour, with 32 and 54% RBC ChE depression observed at 0.1 and 0.25 mg/kg, respectively; and less than 20% inhibition at 0.05 mg/kg, which was judged to be a NOAEL (Fig. 14).

Fig. 14: RBC ChE over time (in minutes) after single similar doses in human.



The comparison of maximum RBC ChE depression between rat and human demonstrates a similar degree of sensitivity (Table 2). At 0.25 mg/kg, humans showed a slightly greater depression than 0.3 mg/kg dosed rats. RBC ChE depression at 0.1 mg/kg was comparable between rats and humans. When comparing the peak effect obtained with the lowest doses (0.03 mg/kg in rat and 0.05 mg/kg in human), which are the most relevant for risk assessment, results indicate a similar response of human and rat RBC ChE depression.

Table 2: Comparison of maximum RBC ChE depression between human and rat: Mean RBC ChE value as percent of controls.

Doses (mg/kg)	Rat	Human	
	Mean	Mean	Range / n
0.03 (Rat) / 0.05 (Human)	88.5% ¹	83.4%	[87.2%-76.6%] / n=2
0.1	80.6% ²	67.6%	[80.8%-54.4%] / n=2
0.3 (Rat) / 0.25 (Human)	62.3% ³	43.6%	[52.7%-32.9%] / n=4

¹ mean of one study: A2006-6137 (combined male and female rat mean value)

² mean of four studies: 6137, 6136 and the two EPA studies by Moser et al.

³ mean of three studies: 6137 and the two EPA studies by Moser et al

Although the human study was limited in terms of quality of reporting methodology and low number of subjects, it is sufficient to indicate that the usual 10X assessment factor to extrapolate between animal and human is not necessary, in this case."

RMS position:

- (i) Due to the low number of human volunteers/dose, and the overall poorly reported study, RMS considered it inappropriate to draw conclusions from the quantitative comparison between rat and human RBC cholinesterase inhibition. In addition, human results would also not enable the risk assessor to draw conclusion on possible interspecies differences in sensitivity of brain AChE inhibition of Carbofuran.
- (ii) The mechanism of action of acetylcholinesterase in the brain is well known. It is possible that, since the AChE functionality is well conserved, inter- or intraspecies variability would be minimal, casually reducing the toxicodynamic assessment factor to 1. However, scientific evidence for such a statement is scarce, and without further corroborating data, cannot be considered for risk assessment of Carbofuran.

- (iii) Because of these uncertainties, RMS considered that from a precautionary point of view, the default 100× assessment factor, in order to bridge both interspecies and interindividual variability should be maintained and applied to the lowest relevant NOAELs, detected in the acute rat neurotoxicity study, in order to estimate the appropriate Reference Doses ADI, ARfD and AOEL. However, the choice of an assessment lower factor (such as 25×, as proposed by the JMPR) could be defensible (see position paper of the notifier, discussed under B.6.8).

B.6.16 References relied on

B.6.16.1 Toxicology and metabolism of the Carbofuran (Annex IIA 5)

Arysta

Annex point reference number	Author(s)	Year	Title Source Company GLP Published or not	Data protection claimed (Y/N)	Owner
IIA 5.6.3/09 <i>added in november 2008</i>	Guillaume Chevalier	2006	60-day or 10-week toxicity study by oral administration (gavage or dietary admixture) in male rats 17.03.2006 Arysta LifeSciences SAS CIT study No. 30129 GLP – Unpublished	Y	FMC
II A 5.7/02	Tyl RW, Marr MC and Myers CB	2005a	Acute range-finding study of Carbofuran Technical (CAS No. 1563-66-2) administered by gavage to postnatal day 11 male and female CD® (Sprague Dawley) rat pups. RTI International, Research Triangle Park, USA Report No. A2005-5983 September 30, 2005 GLP - Unpublished	Y	FMC
II A 5.7/03	Tyl RW, Marr MC and Myers CB	2005b	Acute time-course study of Carbofuran Technical administered by gavage to adult and postnatal day 11 male and female CD® (Sprague Dawley) rats. RTI International, Research Triangle Park, USA Report No. A2005-5982. November 07, 2005 GLP – Unpublished	Y	FMC
II A 5.7/04	Tyl RW, Marr MC and Myers CB	2005c	Acute dose-response study of Carbofuran Technical administered by gavage to adult and postnatal day 11 male and female CD® (Sprague Dawley) rats. RTI International, Research Triangle Park, USA Report No. A2005-5981 November 07, 2005 GLP – Unpublished	Y	FMC

Annex point reference number	Author(s)	Year	Title Source Company GLP Published or not	Data protection claimed (Y/N)	Owner
II A 5.7/05	Hoberman A.M.	2007a	Acute oral (gavage) dose range-finding study of cholinesterase depression from Carbofuran Technical in juvenile (Day 11) rats. Charles River Laboratories Preclinical Services, Worcester, MA, USA Report No. A2007-6135. May 31, 2007 GLP – Unpublished	Y	FMC
II A 5.7/06	Hoberman A.M.	2007b	Acute Oral (Gavage) Time Course Study of Cholinesterase Depression from Carbofuran Technical in Adult and Juvenile (Day 11 Postpartum) Rats Charles River Laboratories Preclinical Services, Worcester, MA, USA Report No. A2007-6136. May 31, 2007 GLP – Unpublished	Y	FMC
II A 5.7/07	Hoberman A.M.	2007c	Cholinesterase Depression in Juvenile (Day 11) and Adult Rats Following Acute Oral (Gavage) Dose of Carbofuran Technical. Charles River Laboratories Preclinical Services, Worcester, MA, USA Report No. A2007-6137. May 31, 2007 GLP – Unpublished	Y	FMC
II A 5.7/08	G. Moser	2007a	Report on Cholinesterase Inhibition Study of Carbofuran. PND17 Rats. Neurotoxicology, Division (MD B105-04) NHEERL/ORD US EPA. RTP, NC 27711 29 June 2007 Non GLP – published	N	Published
II A 5.7/09	G. Moser	2007b	Report on Cholinesterase Comparative Sensitivity Study of Carbofuran. Adult and PND11. Neurotoxicology Division (MD B105-04) NHEERL/ORD US EPA. RTP, NC 27711 14 November 2007 Non GLP – published	N	Published
II A 5.7/10	N Ledirac and PG Pontal	2008	Relative sensitivity of rat pups and adults to RBC & brain cholinesterase inhibition induced by carbofuran CEHTRA, 43 rue Laroque, 33560 Sainte Eulalie, France 22 August 2008 Non GLP – Unpublished	N	FMC

Toxicology and metabolism of the active substance – Open literature (Annex IIA 5)

Annex point(s) 91/414/EEC	Author (s)	Title Generated by (company or organization), Submitted by (company (ies) or organization), Report/File n°. Of submitting company Date of report: For publication: reference	Data protection claimed:	GLP /GEP	Published or not
IIA 5.7	Padilla, S, Marshall, R.S., Hunter, D.L. and Lowit, A	Time course of cholinesterase inhibition in adult rats treated acutely with carbaryl, carbofuran, formetanate, methomyl, methiocarb, oxamyl or propoxur. Toxicol. Appl. Pharmacol. 219: 202-209, 2007	No	No	Yes
IIA 5.7	McDaniel KL, Padilla S, Marshall RS, Phillips PM, Podhorniak L, Qian Y, Moser VC.	Comparison of acute neurobehavioral and cholinesterase inhibitory effects of N-methylcarbamates in rat. Toxicol Sci, 98(2):552-560, 2007.	No	No	Yes

Appendix A:

Benchmark-dose calculation and graphs based upon the data of Hoberman et al., 2007c.

(♂+♀ pup and ♂adult brain AChE inhibition at peak-time following acute oral administration of Carbofuran to rats).

A curve-fitting model is applied on the mean values \pm standard deviations in order to estimate the BMD₁₀ and BMDL₁₀-values, i.e. the interpolated dose where a 10% decrease of brain AChE is expected. Both the Hill-model on the 4 doses or a linear model on the three first doses are used.

(calculations made by RMS)

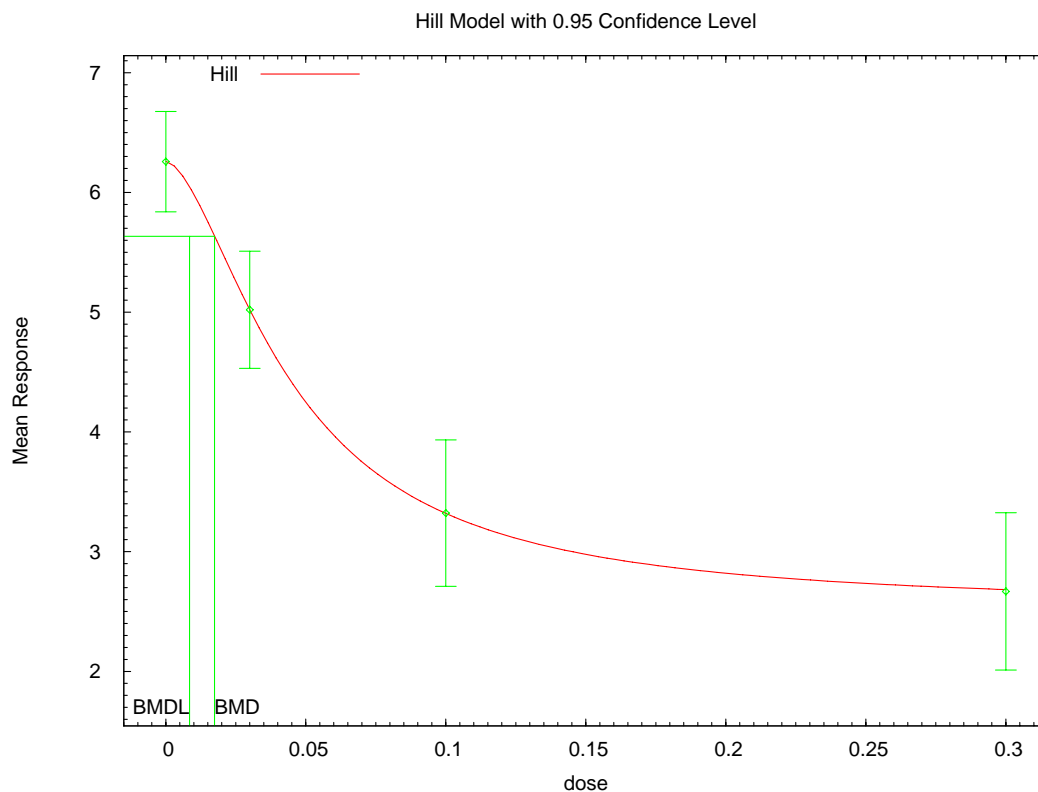
Benchmark dose estimation brain AchE decrease (Hoberman, 2007c)

Female pups, 30' sampling time (Hill-model)

Specified effect = 0.1
Risk Type= Relative risk
Confidence level = 0.95

BMD = 0.01739

BMDL = 0.00847484



14:16 08/26 2008

Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	9	6.26	6.26	0.545	0.541	-0.0152
0.03	10	5.02	5.02	0.684	0.618	0.0241
0.1	10	3.32	3.32	0.854	0.792	0.0215
0.3	9	2.67	2.68	0.918	0.9	-0.0398

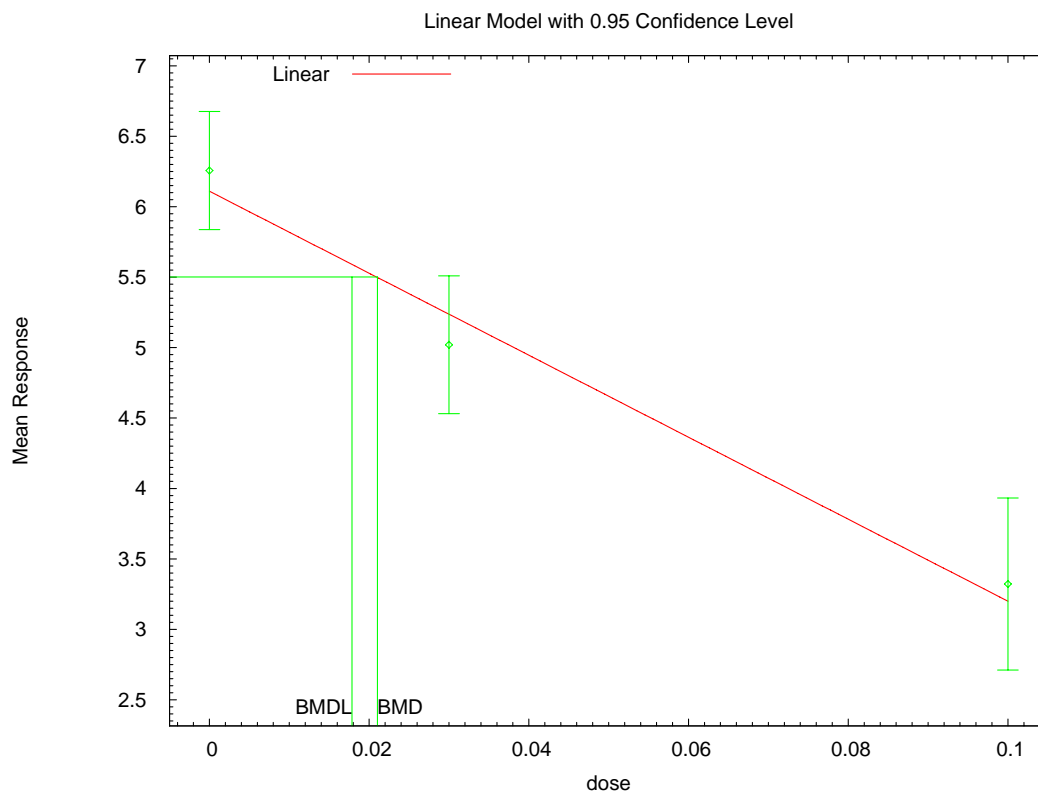
Benchmark dose estimation brain AchE decrease (Hoberman, 2007c)

Female pups, 30' sampling time (linear extrapolation)

Specified effect = 0.1
 Risk Type= Relative risk
 Confidence level = 0.95

BMD = 0.021039

BMDL = 0.017853



15:28 08/26 2008

Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	9	6.26	6.11	0.545	0.579	0.749
0.03	10	5.02	5.24	0.684	0.632	-1.11
0.1	10	3.32	3.21	0.854	0.836	0.434

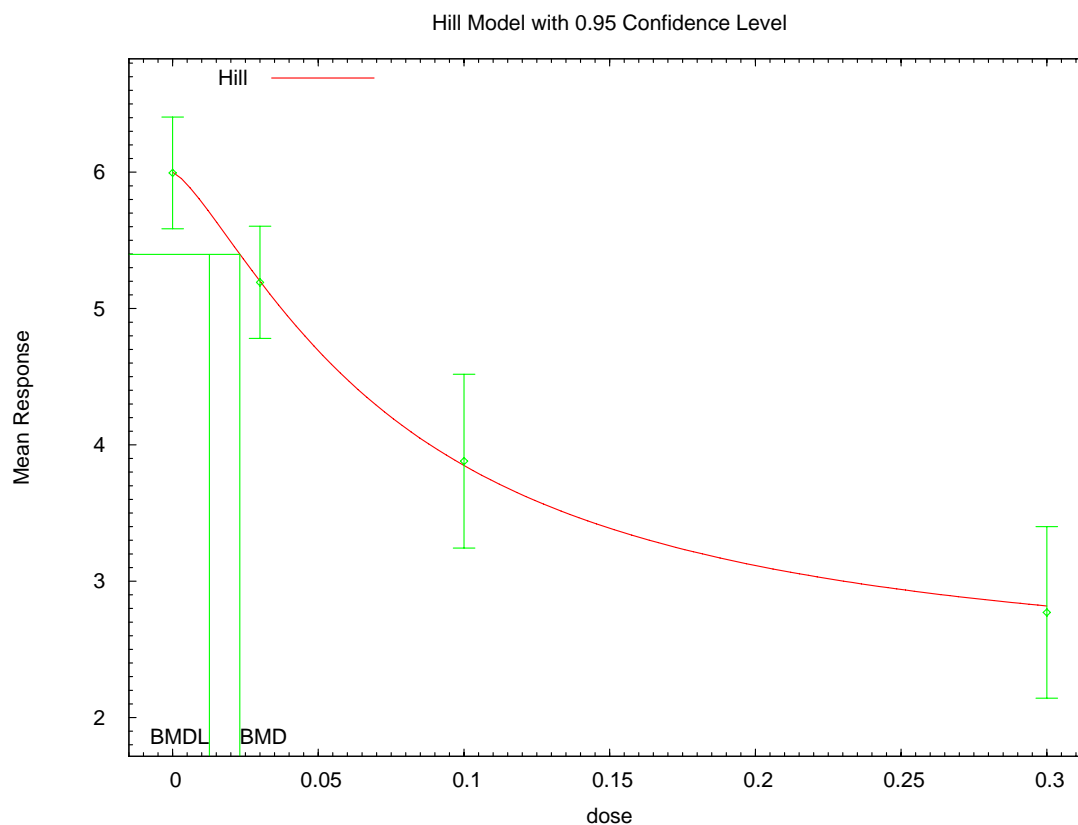
Benchmark dose estimation brain AchE decrease (Hoberman, 2007c)

Male pups, 30' sampling time (Hill model)

Specified effect = 0.1
Risk Type= Relative risk
Confidence level = 0.95

BMD = 0.0230417

BMDL = 0.0126075



15:03 08/26 2008

Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	9	6	6	0.533	0.518	-0.012
0.03	10	5.19	5.2	0.575	0.578	-0.0297
0.1	10	3.88	3.84	0.891	0.728	0.16
0.3	10	2.77	2.81	0.879	0.925	-0.146

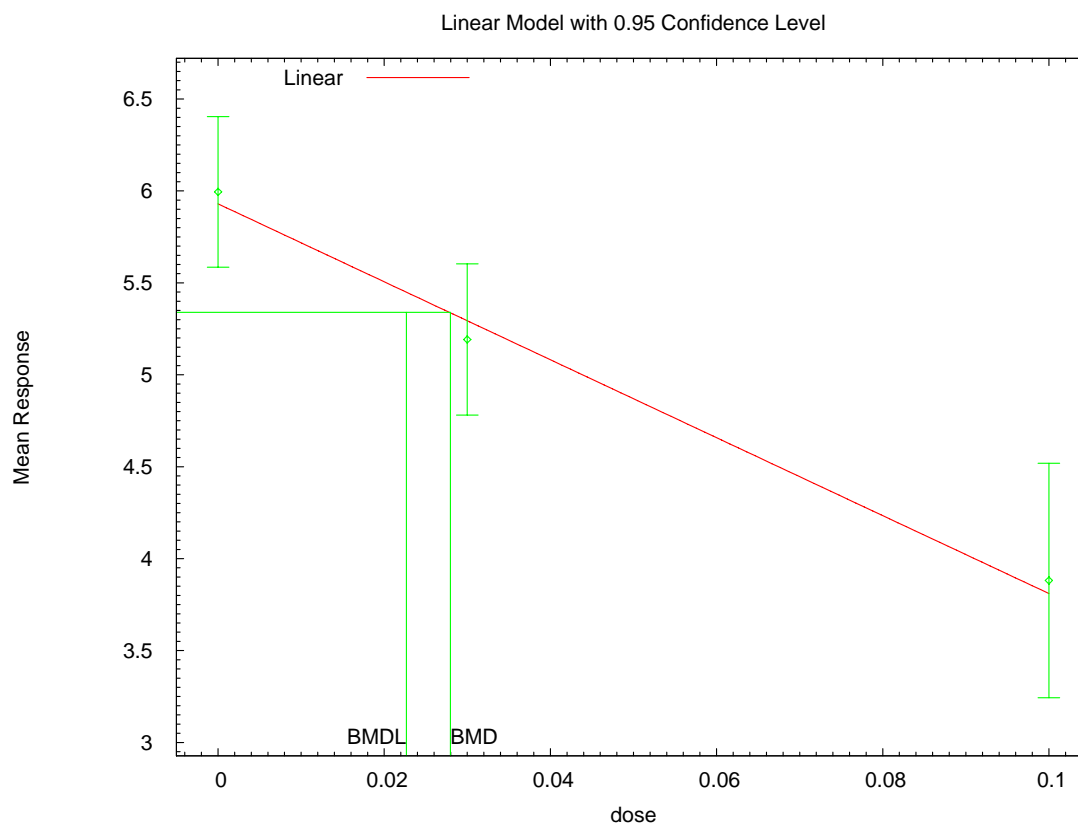
Benchmark dose estimation brain AchE decrease (Hoberman, 2007c)

Male pups, 30' sampling time (Linear model)

Specified effect = 0.1
Risk Type= Relative risk
Confidence level = 0.95

BMD = 0.0279676

BMDL = 0.022666



15:55 08/26 2008

Table of Data and Estimated Values of Interest

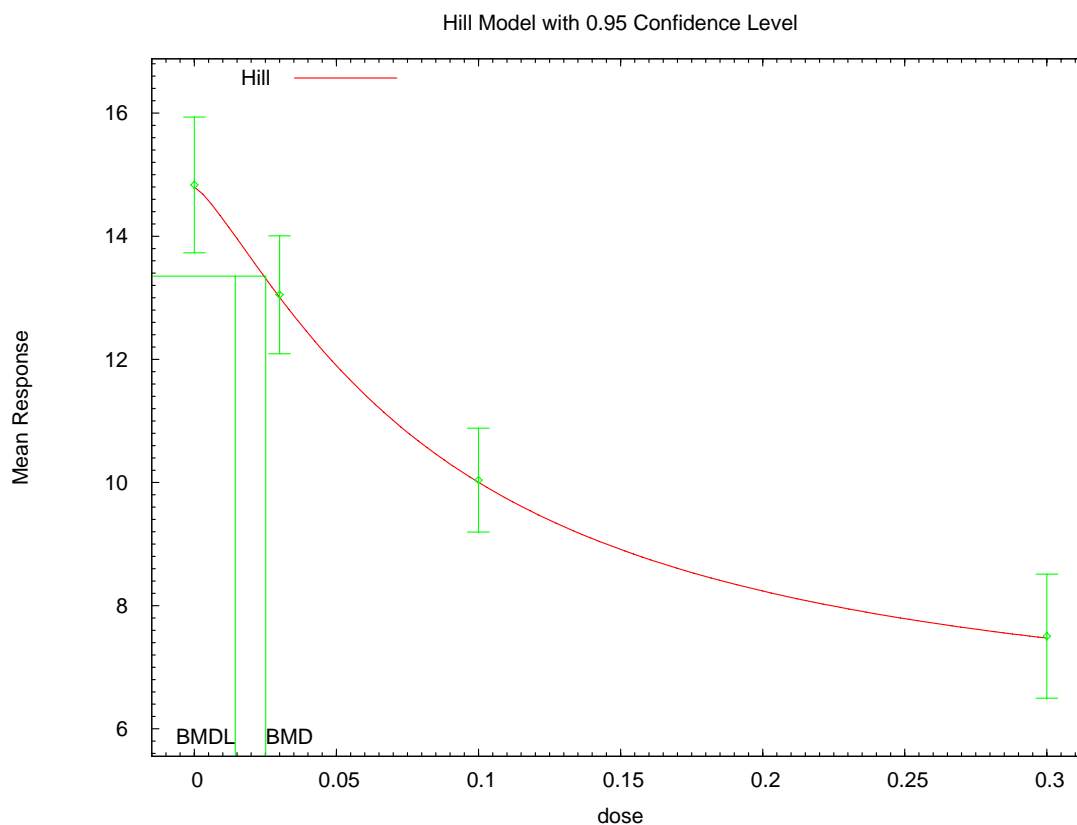
Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	9	5.99	6	0.533	0.497	0.374
0.03	10	5.19	5.3	0.575	0.569	-0.582
0.1	10	3.88	3.81	0.891	0.843	0.26

Benchmark dose estimation brain AchE decrease (Hoberman, 2007c)

Male adults, 30' sampling time (Hill model)

Specified effect = 0.1
 Risk Type= Relative risk
 Confidence level = 0.95

 BMD = 0.025132
 BMDL = 0.0143936



16:37 08/26 2008

Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	9	14.8	14.8	1.43	1.27	-6.93e-008
0.03	10	13	13	1.34	1.27	-2.96e-009
0.1	10	10	10	1.18	1.27	5.2e-007
0.3	10	7.5	7.5	1.41	1.27	-6.47e-008

Benchmark dose estimation brain AchE decrease (Hoberman, 2007c)

Male adults, 30' sampling time (Linear model)

Specified effect = 0.1
 Risk Type= Relative risk
 Confidence level = 0.95

BMD = 0.0314294

BMDL = 0.0269837

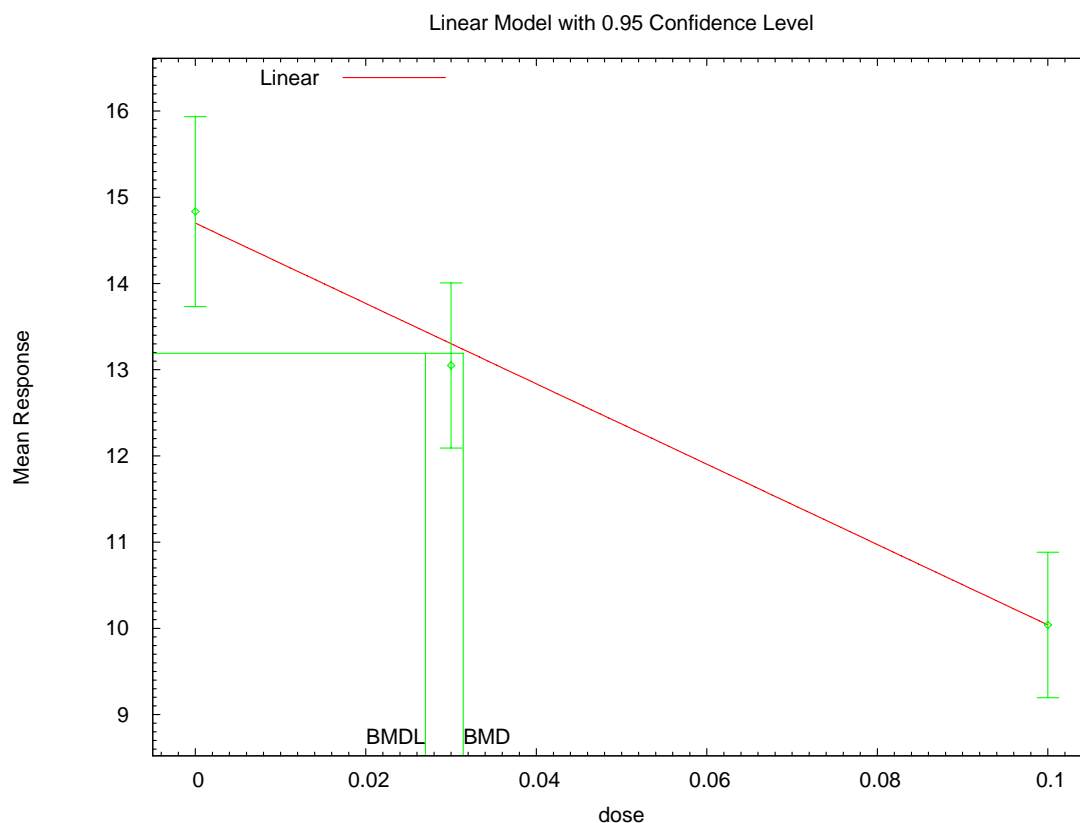


Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	9	14.8	14.7	1.43	1.36	0.394
0.03	10	13	13.3	1.34	1.29	-0.508
0.1	10	10	9.99	1.18	1.12	0.132

Appendix B: Notifier's statement

(Added in November 2008 at the occasion of the second resubmission-)

17Oct08

FMC Corporation's Comments on the Proposed Revised Carbofuran Toxicology DAR (September, 2008)

Carbofuran is a carbamate insecticide, which was registered in the EU for many years and was resubmitted to the EU for registration earlier this year. As with all carbamate insecticides, carbofuran's mode of action results from rapidly reversible cholinesterase (ChE) inhibition.

On August 26th of this year, FMC submitted at the request of the RMS, comparative neurotoxicity studies in rats which compared the relative sensitivity of rat adults and pups to carbofuran ChE inhibition. These are not standard studies in the EU, but nevertheless contain information relevant to establishing the point of departure for an acute reference dose. The RMS has provided an initial draft assessment of the key study of Hoberman (2007c), which interpreted the lowest dose of 0.03 mg/kg/day as a LOAEL rather than a NOAEL, and which suggested a NOAEL or point of departure at half that dose or 0.015 mg/kg/day based upon a benchmark dose analysis of pup brain ChE inhibition.

Differing views on the interpretation of toxicological results is not unusual among scientists, but in most cases, individuals can reach consensus through sharing these views openly. We believe the determination of the point of departure and safety factors for carbofuran are examples of where a common view might be developed by sharing differing interpretations of the evidence. It is in that spirit that FMC offers the following observations for consideration and discussion on 1) the point of departure for carbofuran exploring cholinesterase inhibition, clinical signs of toxicity, and differential response between adults and neonates, 2) the value of the carbofuran human oral study in risk assessment, and 3) appropriate safety factors for carbofuran. We trust our comments will contribute meaningful insights for achieving the ultimate goal of establishing a sound basis for determining carbofuran consumer risk.

Cholinesterase Inhibition

There is general agreement that the critical toxicological effect of carbofuran results from the inhibition of acetylcholinesterase (AChE). Short-term and long-term toxicology studies in laboratory animals and in humans demonstrate that protection from acute toxicity of carbofuran also protects from any effects associated with long term exposure. Protection from significant inhibition of nervous system AChE will protect from clinical signs of toxicity.

Brain cholinesterase is the preferred endpoint for risk assessment because it is directly relevant to the mechanism of toxicity. Given that background levels may vary as much as $\pm 10\%$, the question becomes what degree of ChE inhibition signifies a compound-related effect. To the best of our knowledge, EU guidelines do not specify what level of ChE inhibition constitutes a toxicological relevant effect. Therefore, a reasonable set of criteria to apply are those of the World Health Organization (WHO) as these might be considered the most broadly applicable and commonly accepted set of criteria because presumably they represent a large cross-section of toxicologists from many nations (WHO, 2000a). Here we observe that the inhibition of brain AChE activity and clinical signs are the primary end-points of concern in toxicological studies on compounds that inhibit acetylcholinesterase. The guidelines further state that a statistically significant inhibition of brain acetylcholinesterase of 20% or more represents a clear toxicological effect, and that statistically significant inhibition less than 20% should be considered on a case-by-case basis including correlation with clinical signs. The selection of a 20% threshold for a compound-related effect is a wise choice as it eliminates the possibility of attributing inhibition to the chance occurrence of a control measurement at one end of the normal range (+10%) and a compound-related measurement at the other end (-10%). Based on the recent summary report (JMPR, 2008), it appears that when WHO applied these criteria to the FMC comparative neurotoxicity studies, it judged 0.03 mg/kg/day to be a NOAEL for carbofuran. In other words, 0.03 mg/kg/day did not elicit a toxicological effect in rat because the level of cholinesterase depression did not exceed 20% (although close to the limit) and there was no evidence of clinical signs of toxicity at this dose (Table 1).

The RMS review also acknowledged that "...no clinical signs were observed at the lowest dose...", but appears to have placed greater weight on the fact that the observed 19.8% cholinesterase inhibition was statistically significant at $p < 0.01$, suggesting that the NOAEL was lower than 0.03 mg/kg/day. The observation of approximately 20% inhibition comes from Hoberman (2007c), and specifically the results in female pups (Table 1). Statistically significant differences were also noted in the same study for male pups and adults, but the degree of inhibition was 13% and 12%, both clearly within the 20% threshold. The question then is whether the 19.8% difference is compound-related or just a chance occurrence of comparing two extremes of the normal range. Fortunately there is a second study by Hoberman (2007a) that can be used to answer the question. The

study showed only 11% inhibition of brain cholinesterase for female pups at 0.03 mg/kg/day. Therefore, the results of Hoberman (2007a) failed to confirm the level of inhibition in female pups in Hoberman (2007c). This lack of concordance in the two studies would argue that the 19.8% brain cholinesterase inhibition of Hoberman (2007c) falls within the expected range of $\pm 10\%$ variation. Thus, consideration of the relevant data from the two studies leads to the conclusion that there was no compound-related toxicological effect at the 0.03 mg/kg/day dose and that 0.03 mg/kg/day is a NOAEL.

Clinical Signs

As stated above, the WHO's guidelines state that a statistically significant inhibition less than 20% should be considered on a case-by-case basis including correlation with clinical signs (WHO, 2000a). The rat comparative neurotoxicity studies showed no clinical signs were observed in 0.03 or 0.1 mg/kg/day dosed rats; clinical signs were observed in some 0.3 mg/kg/day dosed groups and only when ChE inhibition was markedly decreased at least about 50% (Table 1). Thus, for carbofuran, clinical signs (neurotoxicity) are exhibited at a dose an order of magnitude greater than the dose at which statistically significant but less than 20% ChE inhibition is observed (0.3 versus 0.03 mg/kg/day) providing an additional built-in safety factor for risk assessment.

A practical real world example of how a 20% decrease in ChE inhibition is considered protective and not reflective of toxicity is the State of California's policy for the protection of workers. The State of California has adopted RBC (red blood cell) ChE inhibition as an endpoint for protecting workers potentially exposed to ChE inhibiting crop protection chemicals (California, 2002). As the state has explained, the inhibition of RBC ChE is monitored to ensure no adverse effects will occur, incorporating an adequate margin of safety. California has concluded that no action at all is warranted until RBC ChE is decreased by 20%, and workers are not reassigned to tasks without exposure potential until a RBC ChE decrease of 30% is measured. These guidelines apply to both carbamates and organophosphates. Importantly, enzymatic inhibition from the organophosphates is not rapidly reversible as it is with the carbamates, yet even for organophosphates, no action is mandated at ChE inhibition levels of less than 20%. This demonstrates that the suppression of 20 to 30% RBC ChE inhibition is a surrogate measure to reasonably protect workers from nervous system toxicity and is not itself an adverse effect, and is consistent with the minimum 20% brain (or RBC in the absence of brain) ChE inhibition guidelines established by the WHO.

Sensitivity of Rat Pups and Adults to Carbofuran

In the draft assessment, the RMS utilized a benchmark dose estimation of a NOAEL because the RMS's initial assessment judged the low 0.03 mg/kg dose to be a LOAEL. The RMS estimated a benchmark dose at the 10% response level (BMD10) of 0.0017-0.021 mg/kg/day for pup brain ChE inhibition, and on this basis, assigned a 2X assessment factor to the 0.03 mg/kg/day LOAEL to estimate a NOAEL of 0.015 mg/kg/day. The RMS appears to have used the data from the Hoberman (2007c) study to estimate the BMD10 value.

An outside expert consultant calculated a BMD10 of 0.033 mg/kg/day for carbofuran rat pup brain ChE inhibition based on the individual study BMD10 estimations at 0.25 and 0.5 hr from several FMC rat ChE inhibition studies (FMC, 2008). US EPA calculated a BMD10 of 0.04 mg/kg/day for rat pup brain ChE inhibition using both FMC's data and their own data (EPA, 2008). These benchmark dose calculations using data from multiple studies are more robust than estimations derived using data from only one of the available studies, and the obtained values are consistent with the judgment that the 0.03 mg/kg/day low dose in FMC's rat ChE inhibition studies is a LOAEL.

As indicated in FMC's paper that was submitted to the RMS along with the rat comparative ChE studies, we believe the collective results show that while pups are more sensitive to ChE inhibition than adults at higher doses, this difference attenuates and practically disappears at the lowest doses, which are the most relevant in risk assessment (Ledirac and Pontal, 2008). Based on these observations, the above observations on ChE inhibition from the previous section, and coupled with the fact that the carbofuran rat ChE inhibition studies did direct measurement of brain ChE inhibition in rat pups in addition to adult rats, it would be reasonable to conclude that no additional safety factor is required for protection of infants and children.

Table 1
ChE Inhibition (% of Control) in Rats 15 or 30 Minutes
After Receiving a Single Oral Dose of Carbofuran

Carbofuran:	0.03 mg/kg			0.1 mg/kg			0.3 mg/kg		
	Brain ChEI	RBC ChEI	Clinical Signs	Brain ChEI	RBC ChEI	Clinical Signs	Brain ChEI	RBC ChEI	Clinical Signs
Tyl et al, 2005c									
Male Pups							52.4*	106	Tremors
Female Pups							51.6*	140	Tremors
Male Adults							74.0*	107	None
Female Adults							76.4*	107	None
Hoberman, 2007a:									
Male Pups	90.4	86.8	None	66.3*	78.6	None	39.6*	72.3	Tremors (2/5)
Female Pups	89.2	96.9	None	65.4*	76.2	None	53.5*	76.6	Tremors (2/5)
Hoberman, 2007c:									
Male Pups	86.6*	107.6	None	64.7*	85.7	None	46.2*	74.8	None
Female Pups	80.2*	83.8	None	53.1*	63.1	None	42.6*	60.6	None
Male Adults	88.0*	92.8	None	67.7*	71.0*	None	50.6*	61.6*	None
Female Adults	100.2	84.2*	None	79.9*	79.4*	None	59.5*	61.6*	None

Brain ChEI = % of control (control = 100%) brain cholinesterase inhibition

RBC ChEI = % of control (control = 100%) red blood cell cholinesterase inhibition

Note: Maximum inhibition of cholinesterase was observed at 15 min post-dose in the range-finding studies (Tyl et al, 2005b & Hoberman, 2007b)

* Statistically significant difference

Carbofuran Human Study

Most chemical risk assessments are based solely on animal studies extrapolated to humans, since direct assessment of many toxicological endpoints in humans would of course be totally unethical and inappropriate. One advantage of chemicals having cholinesterase inhibition as their mode of action, however, is that human studies may be conducted as long as they are conducted ethically. Indeed, direct measurement of ChE inhibition may be conducted in humans at sufficiently low doses that avoid adverse effects in the volunteers. This provides for increased certainty around the NOAEL and for the overall risk assessment.

Many years ago, FMC sponsored a previous study in which nine volunteers were administered carbofuran orally at 0 (one volunteer), 0.05 (two volunteers), 0.1 (two volunteers), and 0.25 (four volunteers) mg/kg (Arnold, 1976). RBC ChE and other measurements were taken pre-dose, and after 30, 60, 120, 180, 360 minutes and after 24 hr. At 0.25 mg/kg, clinical signs and cholinesterase inhibition were observed. At 0.1 mg/kg, borderline cholinesterase inhibition was observed and no effects were observed at 0.05 mg/kg.

The RMS previously reviewed FMC's carbofuran human oral study (EU, 2004), and concluded the dose of 0.25 mg/kg induced symptoms analogous to those usually attributed to cholinesterase inhibition, and that these symptoms occurred in conjunction with a substantial reduction in RBC AChE activity. The human study was accepted as additional information, but no judgment regarding whether any of the dose groups represented a NOAEL was reported.

We would like to elaborate below why FMC believes this human oral study is of value for use in carbofuran risk assessment. First and foremost, any human study absolutely must be conducted in an ethical manner. The EU's draft guidance document for setting acute reference doses states the requirement that the ethical status of studies in humans must be established before they are taken into consideration (EU, 2001). The carbofuran human study was conducted in an ethical manner according to the criteria in place at the time the study was conducted,

and according to JMPR's criteria for using human studies in their pesticide evaluations (WHO, 2000b). In addition, the USEPA submitted the carbofuran human oral study to the HSRB (Human Studies Review Board) in 2006 in support of the carbofuran US risk assessment. The HSRB concluded that there was no evidence the human oral study failed to fully meet the ethical standards in place at the time the study was conducted, nor was the study fundamentally unethical.

Second, the results any human study to be used in risk assessment must be scientifically relevant. In 1997, USEPA engaged three academic experts to provide their independent views on the suitability of the carbofuran human oral study for scientific risk assessment (EPA, 1997). The experts involved were Stephen Brimijoin, Ph.D.: Department of Pharmacology at the Mayo Clinic in Rochester, Minnesota; Janice Chambers, Ph.D., DABT: William L. Giles Distinguished Professor, College of Veterinary Medicine, Mississippi State University in Starkville, Mississippi; and Carey Pope, Ph.D.: Associate Professor and Director, Division of Toxicology, Northeast Louisiana University in Monroe, Louisiana. They concluded that 0.05 mg/kg was the NOEL (one expert judged 0.1 mg/kg to the NOAEL), and that, while there were some technical deficiencies, the human study was acceptable for use in deriving the acute reference dose. USEPA agreed with the experts' assessment and used this human oral study to set the carbofuran acute reference dose for almost a decade (1997-2006). In addition to the three academic experts and USEPA, the WHO, a wide body of international scientists, has also concluded that 0.05 mg/kg is the NOAEL in the human study (JMPR, 2008). The NOAEL in the human study, and the similarity of ChE activity among species gives additional support to concluding that the low 0.03 mg/kg dose in the rat ChE studies is also a NOAEL.

Safety Factors

In many cases, acute reference doses are based on the lowest NOAEL determined in animal studies divided by a 10X factor for inter-species variation and divided by another 10X factor for intra-species variation (100X overall factor). Indeed, the current carbofuran acute reference dose of 0.001 mg/kg/day is based on the NOAEL of 0.1 mg/kg/day based on clinical effects in dog and rat studies divided by a 100X factor (EU, 2004).

The overall 100X factor is typically used with toxicology endpoints other than ChE inhibition, and when only animal studies are used. However, we would like to remind the RMS of the many precedents for reduced inter-species and intra-species factors for acute reference dose determinations for cholinesterase inhibitors, especially when ethical human data are available.

The EU guidelines for acute reference dose determination refer to both the traditional 10X inter- and 10X intra-species factors, but also refer to using reduced factors for cholinesterase inhibitors because ChE inhibition is so largely dependent upon toxicokinetic factors (EU, 2001). The magnitude of carbofuran induced ChE inhibition is primarily a function of the maximum blood concentration in the target nervous system tissue in that it has rapid onset, peak effect within 15-30 minutes, and is rapidly reversible. The EU guidelines allow for the use of factors less than 100X for ChE inhibitors.

In a similar fashion, WHO guidelines advocate reduced 5X inter-species and 5X intra-species factors (25X overall) for cholinesterase inhibitors (JMPR, 2002). The previous carbofuran WHO acute reference dose was based on a 5X inter-species factor and a 5X intra-species factor applied to the NOAEL from a dietary study in dogs (JMPR, 2002). The current carbofuran WHO acute reference dose of 0.001 mg/kg/day was also based on a 5X inter-species factor and a 5X intra-species factor applied to the 0.03 mg/kg NOAEL from the rat ChE inhibition studies (JMPR, 2008). In fact, the WHO concluded that the overall 25X safety factor for carbofuran was conservative, and that the carbofuran database provides sufficient evidence to justify a further reduction in the overall safety factor. Other cholinesterase inhibitors that the WHO has used less than a 100X overall factor in their acute reference dose determinations include carbaryl, thiodicarb, acephate, and methamidophos. The evaluations may be viewed on JMPR's website.

The importance of toxicokinetics on ChE inhibition is clearly demonstrated with the carbamate methomyl. In which rat acute neurotoxicity studies conducted with methomyl, a four-fold higher NOAEL for acute effects following dietary administration was observed compared the NOAEL for acute effects following gavage administration (JMPR, 2001). Unfortunately, we do not have similar comparative data for carbofuran. These observations suggest that ChE gavage studies provide an additional built-in safety factor (4X in the case of methomyl), since dietary administration is the route of exposure of humans to pesticide residues. Because cholinesterase inhibition is so highly dependent upon toxicokinetic factors, WHO believes reduced safety factors still offer acceptable protection in risk assessment.

Human ChE inhibition data from ethically-conducted studies allow the reduction or even removal of the inter-species factor because the measurement is made directly in humans. We observed that in six of seven WHO acute reference dose evaluations for carbamates and organophosphates based on human study results, WHO used a 2X inter-species factor for an overall safety factor of 10X (5X for intra-species and 2X for inter-species). The six compounds were oxamyl, chlorpyrifos, dimethoate, fenitrothion, malathion, and phosmet. For one carbamate (methomyl), WHO used an inter-species factor of 1X for an overall factor of 5X. The evaluations may be viewed within JMPR's website.

With regard to carbofuran, the US EPA utilized a 30X overall safety factor (3X inter-species, 10X intra-species) when it used the human study for the risk assessment of carbofuran from 1997 to 2006 (EPA, 1997). In 2006, US EPA submitted the carbofuran human oral study to the Human Studies Review Board (HSRB) in support of the carbofuran US risk assessment, since at the time, EPA opined on the basis of both rat and human studies that a rough estimate of the inter-species extrapolation factor for carbofuran was 1X. This is contained in EPA's Weight of Evidence Report (EPA, 2006), which indicated:

The Arnold (human oral) study "provides useful information into the sensitivity of RBC AChE inhibition of rats compared to humans", and "The Agency is in the process of analyzing both the rat and human BMD10 data to determine the central estimate and 95% confidence interval for use as the interspecies extrapolation factor for carbofuran may be made by comparing the RBC BMD10 values for the rat and human from Table [] above. This ratio is approximate 1X" (emphasis added).

However, the HSRB advised not to use the study for the inter-species extrapolation for technical reasons (i.e., small number of subjects, variable ChE results, etc.), and although the HSRB opinion is advisory only, the US EPA elected to ignore its own long-standing scientific assessment and that of its independent experts and deferred to the HSRB.

Aldicarb is a carbamate with similar rapid onset and disappearance of ChE inhibition to carbofuran. Human aldicarb studies have been conducted, and even though aldicarb is more acutely toxic than carbofuran, the overall safety factor for aldicarb advocated by USEPA is 20X based on a 1X inter-species factor (EPA, 2007). The EU also initially based the acute reference dose of aldicarb based on a 1X inter-species factor (EU, 1996 and EFSA, 2006).

Although the carbofuran human oral study may not be robust enough to use for setting the carbofuran acute reference dose in and of itself, it does confirm that carbofuran ChE inhibition is similar among humans, rats, and dogs, and is therefore sufficiently informative to comfortably reduce the inter-species safety factor for the carbofuran acute reference dose. The above precedents indicate that a 1-3X inter-species factor based on the human study would be more than appropriate.

As explained above, decreases in rat brain ChE inhibition were observed at a carbofuran dose an order of magnitude lower than the dose at which clinical signs/neurotoxicity were observed. This represents another built-in 10X safety factor for clinical signs/neurotoxicity in addition to a built-in gavage to dietary exposure extrapolation (4X in the case of methomyl), on top of the inter- and intra-species factors assigned to the ChE inhibition effects.

Finally, we wish to re-emphasize that the carbofuran rat ChE inhibition studies involved direct measurement of brain ChE inhibition in rat pups in addition to adult rats. Therefore, no additional safety factor is required for protection of infants and children, since actual ChE inhibition measurements were made in the target tissue for carbofuran neurotoxicity in juvenile animals.

As indicated above, the current carbofuran EU acute reference dose of 0.001 mg/kg/day was based on NOAEL of 0.1 mg/kg/day for neurotoxicity effects observed in dogs and rats with a 100X overall factor (EU, 2004). It is interesting to note that the WHO derived the same current 0.001 mg/kg acute reference dose by determining that the low 0.03 mg/kg dose was a NOAEL and dividing by a conservative 25X overall factor (5X inter-species factor and 5X intra-species factor; JMPR, 2008). Assuming that the low 0.03 mg/kg dose in the rat ChE inhibition studies is a NOAEL, the above precedents would fully support an acute reference dose of 0.003 mg/kg/day based on a 2X inter-species factor and a 5X intra-species factor.

We believe that consideration of all the above observations, coupled with the lack of a sex difference in carbofuran rat brain cholinesterase inhibition (Table 1), and the comparable results of the rat, dog and human carbofuran studies provide a reasonable basis for concluding that 0.03 mg/kg/day is a NOAEL for rat ChE inhibition, and that an appropriate overall safety factor is 10-30X.

FMC would like to thank the RMS for the opportunity to comment on the draft carbofuran toxicology assessment, and look forward to discussing our comments with the RMS in the near future.

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Appendix C:

Benchmark-dose calculation and graphs based upon the pooled data of Tyl et al., 2005c and Hoberman et al., 2007c.

(♂+♀ brain AChE inhibition at peak-time –15' or 30' – following acute oral administration of Carbofuran to rats). A curve-fitting model is applied on the mean values \pm standard deviations in order to estimate the BMD₁₀ and BMDL₁₀-values, i.e. the interpolated dose where a 10% decrease of brain AChE is expected. The Hill-model on the 6 doses are used.

(calculations made by RMS)

Benchmark dose estimation brain AchE decrease
(pooled data Tyl, 2005c and Hoberman, 2007c).

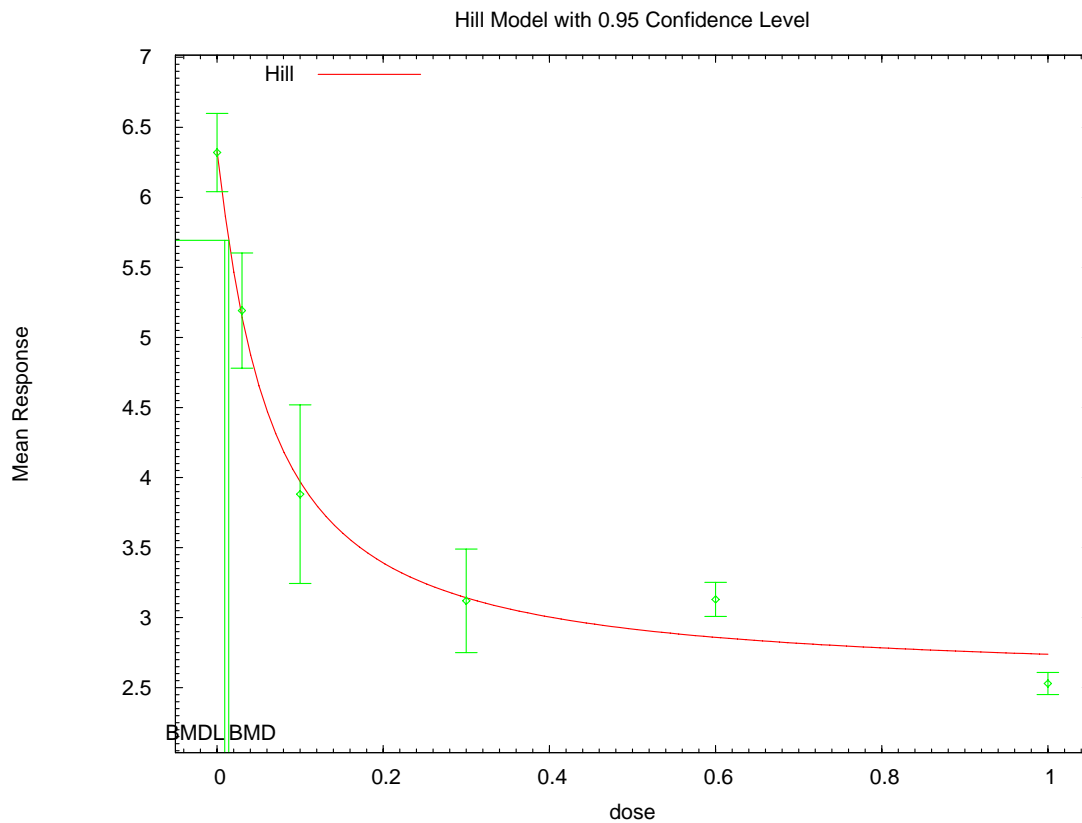
Male pups, 15' or 30' sampling time (Hill Model)

Specified effect = 0.1

Risk Type = Relative risk

Confidence level = 0.95

BMD = 0.014081
BMDL = 0.00918498



16:20 10/29 2008

Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	19	6.32	6.32	0.58	0.668	-0.00597
0.03	10	5.19	5.13	0.575	0.623	0.331
0.1	10	3.88	4.01	0.891	0.575	-0.704
0.3	20	3.12	3.14	0.79	0.601	-0.113
0.6	10	3.13	2.85	0.17	0.514	1.74
1	10	2.53	2.7	0.11	0.505	-1.08

Benchmark dose estimation brain AchE decrease
(pooled data Tyl, 2005c and Hoberman 2007c).

Female pups, 15' or 30' sampling time (Hill Model)

Specified effect = 0.1

Risk Type = Relative risk

Confidence level = 0.95

BMD = 0.0155047

BMDL = 0.0070757

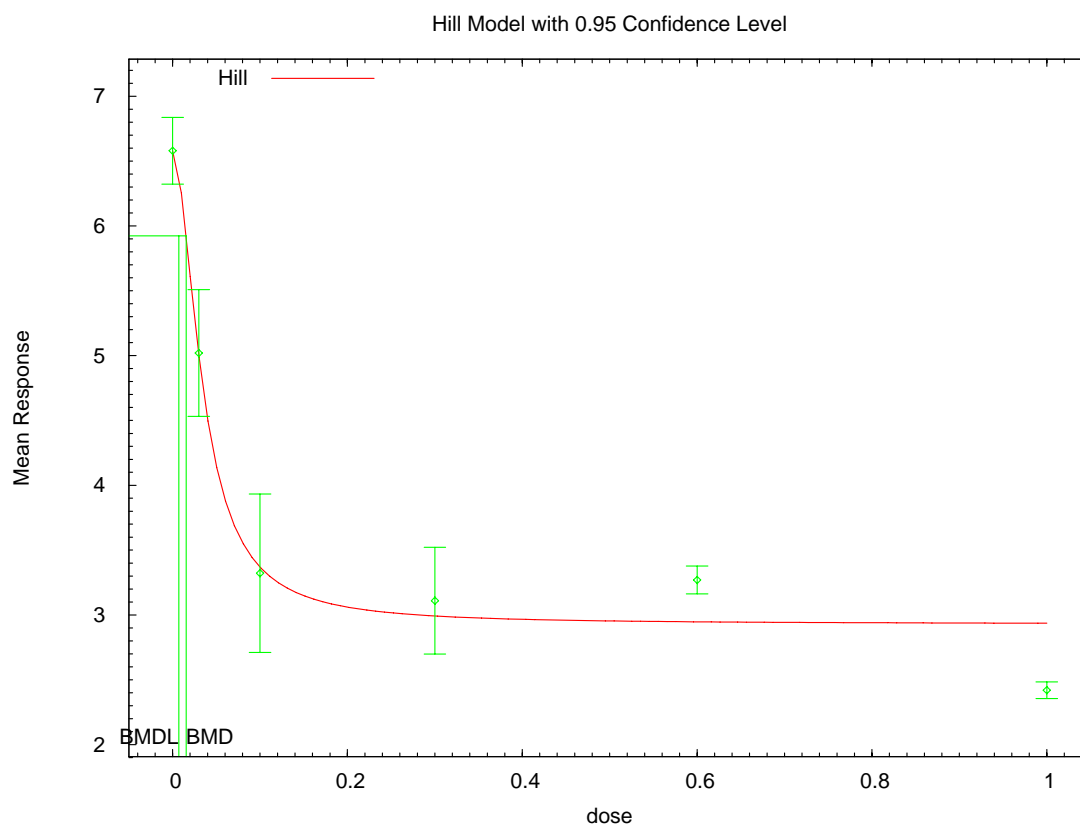


Table of Data and Estimated Values of Interest

Dose	N	Obs Mean	Est Mean	Obs Std Dev	Est Std Dev	Scaled Res.
0	20	6.58	6.58	0.55	0.56	-0.0194
0.03	10	5.02	5.01	0.684	0.611	0.0718
0.1	10	3.32	3.37	0.854	0.692	-0.226
0.3	20	3.11	2.99	0.88	0.719	0.726
0.6	10	3.27	2.95	0.15	0.722	1.41
1	10	2.42	2.94	0.09	0.723	-2.26

ANNEX B

Benfuracarb

B.7 Residue data

(Updated Addendum January 2009 after PRAPeR Expert Meeting TC 5)

Open point 3(1) in the Reporting Table rev.0 (November 2008): Vol.3 B.7.1.3 bis Metabolism in cabbage

EFSA asked for further clarification on the statement made by RMS with respect to the high variability observed in the recovered total radioactive residues in the seedling leaves.

RMS: The statement referred to the observation that the total radioactive residues increased from 4.2 mg/kg after 3 days to 319 mg/kg after 2 weeks and decreased again to 188 mg/kg after 3 weeks. Unexpectedly, the residue levels were higher again in the PHI 4 weeks' samples. The variability in those results was assumed to be due to the homogenisation of only a small amount of seedlings leaves.

The second point highlighted in the DAR was the unrealistic high recovery of radioactivity in the acetonitrile/n-Ethylmaleimide extraction phase of the PHI 3 day-samples (173 % of the TRR-7.3 mg/kg). According to the notifier, the high recovery in this sample was probably related to the very low radioactivity of the samples hampering accurate measurement of the total radioactivity in those extracts.

Open point 3(2) in the Reporting Table rev.0 (November 2008): Vol. 3 B.7.1.3 bis Metabolism in cabbage

A) The total radioactive residues in the aqueous phase after partitioning increased up to 51.9 % of the TRR at 4 weeks sampling interval (see Table B.7.1.3 bis -2).

The aqueous and organic phases were analysed by HPLC and TLC for further characterization and identification. On HPLC chromatograms, the radioactivity in the aqueous soluble phase was fractionated into 2 peaks A and B of which one possibly matched with Carbofuran-3-OH-7-phenol but on the TLC plates the total radioactivity remained at the origin and could not be further characterized.

Therefore the aqueous soluble residues fraction was subjected to acid hydrolysis. Organo soluble metabolites released by hydrolysis were extracted from the aqueous phase using partitioning against Dichloromethane (DCM).

These data are reported in the table here below.

Table B.7.1.3 bis -2': Acid hydrolysis /DCM partitioning of the aqueous soluble residues of the PHI 4 weeks samples.

Harvest	Combined DCM extracts		Aqueous soluble residues fraction	
	% TRR	mg Benfuracarb equiv./kg ¹⁴ C-	% TRR	mg Benfuracarb equiv./kg ¹⁴ C-
4 weeks samples	31.1	189	17.5	107

31.1 % of the TRR indicated de-conjugation of the organo soluble metabolites.

HPLC analysis: Only one peak was observed both on the DCM extract and the aqueous soluble phase after acid hydrolysis but without any further identification.

TLC analysis in solvent system I:

-TLC analysis of the DCM extract showed 4 peaks of which 3 matched with Carbofuran-3-OH (6.1 % of the TRR) and possibly with carbofuran-3-keto and Carbofuran (2.7 % and 17.2 % of the TRR, respectively).

Those metabolites were assumed to be under their conjugated form in the aqueous soluble phase before the acid hydrolysis treatment.

5.1 % of the TRR remained at the origin of the TLC plate.

-TLC analysis of the aqueous soluble residues fraction after acid hydrolysis showed that one peak was observed at the origin (10.5 % of the TRR) and a peak that had a similar retention time with Carbofuran (7 % of the TRR).

B) RMS agrees with the comment of the notifier.

During the EPCO Expert Meeting 34, the experts considered that the available metabolism study on sugar beet (Haynes L.M., 2003) could address the metabolism of Benfuracarb in brassica crops. The findings were as expected i.e. Benfuracarb largely converted into Carbofuran. The study highlighted a fraction, T1 (composed of 2 minor and 1 major components and not susceptible to beta-glucosidase digestion), which made up 36% of the TRR (0.11 mg/kg) in sugar beet tops/leaves at harvest.

Fractionation and characterization of the fraction T1 in sugar beet tops and leaves extracts were performed (Van Noorloos B., 2007). The results were included in the revised DAR (August 2008).

The T1 fraction was analysed by TLC and by gel permeation chromatography together with polysaccharides standards in order to estimate the molecular size of the compounds.

It was observed that the polar fraction T1 did not release any Benfuracarb or Carbofuran/3-keto-carbofuran/3-OH-carbofuran upon enzymatic and acid hydrolysis treatments. This fraction contained high molecular weight compounds, indicating incorporation of radioactivity into macromolecules such as polysaccharides.

In conclusion, it is not relevant to include the conjugates of Carbofuran, 3-OH-carbofuran and Carbofuran -3-keto in the residue definition for risk assessment.

Open point 3(3) in the Reporting Table rev.0 (November 2008): Vol 3. B.7.3.1 Residue definition

EFSA disagreed with the RMS statement “None of the metabolite formed [...] was of particular toxicological concern as they were generally also produced by the rat”.

RMS: It is known that Carbofuran together with 3-OH-carbofuran are the active intermediates of Benfuracarb and show an acute toxicity much higher than Benfuracarb.

RMS agrees that this statement should be rephrased as follows: “All the metabolites of Benfuracarb recovered in the available plant metabolism studies were also recovered in the rat metabolism and their toxicity is therefore covered by the studies provided in the Mam Tox section and performed both with Benfuracarb and Carbofuran.”

Open point 3(6) in the Reporting Table rev.0 (November 2008): Vol 3. B.7.6 Residue trials – Methods

EFSA asked RMS to clarify whether or not the analytical methods do determine free and potential conjugated residues.

In the revised DAR (August 2008), the extraction patterns of all the available analytical methods used to determine the residues of Benfuracarb, Carbofuran and 3-OH-carbofuran in the brassica crops were reported. None of the reported analytical methods included an analytical step (acid hydrolysis, enzymatic digestion) in order to extract all the residues of carbofuran and 3-OH-carbofuran in both free and conjugated forms.

Open point 3(7) in the Reporting Table rev.0 (November 2008): Vol 3. B.7.6 Residue trials – Methods

The EFSA comment referred to the study reports BPL 06/063/CL-1 and -2 in the Appendix C in the DAR.

These trials were analysed using validated analytical methods - NOTOX project 434813 (Benfuracarb, Carbofuran) and NOTOX project 465154 (3-OH-carbofuran).

The Limits of Quantification of these methods in the cauliflower seedlings and heads were established at 0.005 mg/kg (Benfuracarb), 0.0015 mg/kg (Carbofuran) and 0.005 mg/kg (3-OH-carbofuran). During the analysis of the residues of 3-OH-carbofuran, the Limit of Detection (LoD) was over the Limit of Quantification (LoQ) due to the fact that on the days of analysis, the sensibility of the LC-MS/MS system was lower than during the validation period.

The obtained Limits of Detection for the 3-OH carbofuran were:

-for seedlings: 0.0089 mg/kg

-for heads: 0.00551-0.0067 mg/kg.

For Carbofuran, the LoD of these methods was always below the LoQ.

Therefore the LoQ of the methods for the determination of the residues of 3-OH-carbofuran was set at 0.01 mg/kg.

The residue trials included in the first DAR (July, 2004) were not considered for the MRL proposals since these were generated by the analytical methods (Howie, 1998) and (Parsons E. & Beale R., 2002) characterized by a higher Limit of Quantification for Carbofuran and 3-OH-carbofuran.

The trials referenced BPL 06/063/CL-1 and -2 (revised DAR, August, 2008) were not considered both for MRL setting and for the consumer dietary risk assessment.

B.7.6.1-1(revised): Overview of the residue database for the different supported uses and MRL proposals.

Crops	Analytes determined	Residue values (mg/kg)	Recommendations	MRL proposal
Cauliflower (Flowering brassica)	<i>Northern EU</i>			
	Benfuracarb	3x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	3x<0.0045	Residue database is complete.	0.01*
	<i>Southern EU</i>			
	Benfuracarb	<0.005-<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	<0.0065 ⁽¹⁾ -<0.0045	Residue database is complete.	0.01*
Broccoli (Flowering brassica)	<i>Northern EU</i>			
	Benfuracarb	2x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	<0.0045-0.0102	Residue database is complete.	0.01
	<i>Southern EU</i>			
	Benfuracarb	2x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	2X<0.0045	Residue database is complete.	0.01*
Head cabbage (Head brassica)	<i>Northern EU</i>			
	Benfuracarb	3x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	3x<0.0045	Residue database is complete.	0.01*
	<i>Southern EU</i>			
	Benfuracarb	4x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	4x<0.0045	Residue database is complete.	0.01*
Kale (Leafy brassica)	<i>Northern EU</i>			
	Benfuracarb	3x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	2x<0.0045-0.0086	Residue database is complete.	0.01
	<i>Southern EU</i>			
	Benfuracarb	/	Further trials are not required	0.05*
Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	/	0.01*		
Leafy cabbage (Leafy brassica)	<i>Northern EU</i>			
	Benfuracarb	/	Further trials are not required	0.05*
Carbofuran + 3-OH-	/	0.01*		

	carbofuran as Carbofuran equiv.			
	<i>Southern EU</i>			
	Benfuracarb	3x<0.05	Residue database is complete.	0.05*
	Carbofuran + 3-OH-carbofuran as Carbofuran equiv.	3x<0.0045	Residue database is complete.	0.01*
<p>Remarks:</p> <p>⁽¹⁾: This residue value is the sum of the LoQ of the analytical methods n° 434813 for carbofuran (0.0015 mg/kg) and the LoQ of the analytical methods n° 465154 for 3-OH-carbofuran (0.005 mg/kg) – Trial n° TRC-06-11.</p> <p>-The residue values taken into account in this table were highlighted in bold and underlined in the summary sheets here after.</p> <p>-Based on the available storage stability data, RMS concluded that the residues of Benfuracarb, Carbofuran and 3-OH-carbofuran were stable over a period of 10 months in cauliflower and cabbage and 6 months in maize. All the trials used for MRL setting were characterized by a maximum period of frozen storage of 56 days.</p>				

Conclusion:

Although the current guidance document SANCO 7525/VI/95 rev.8 mentioned that at least 2 residue trials should confirm the situation of no residue, RMS agreed on the following statement provided by the notifier: Comparable residue profiles (i.e situation of no residue) in head, flowering and leafy brassicas for Benfuracarb, Carbofuran and 3-OH-Carbofuran have been demonstrated between the North and the South of Europe.

Moreover, Benfuracarb is applied prior to sowing, i.e. before any edible parts of the crop are present. Residues in plants are therefore only dependant on the uptake of residues through the roots at the early stages of development.

RMS considers that the residue database for flowering, head and leafy brassica are complete for enforcement purposes and dietary risk assessment.

Supervised residue trials summary sheets

<i>Added in the revised DAR (August 2008)</i>														
BPL 06/063/CL-1 (analyse: 473928) trial no.: BPL 06/063/CL-1. F- 49320 LUIGNE (Northern area)	Cauliflow er / Aviso	1/ 10- July-06 (Planting) 3/ 06-Oct- 06	Micro- granulator	Not applicab le	Not applicab le	0.991 (11.13 kg product/ ha)	10-July- 06	BBCH 13	Seed- lings	na na na na na	0.0203 0.0292 0.669 1.070 0.2030 0.0325	0.0153 0.0183 0.313 0.577 0.144 0.0469	1 DAT 3 DAT 7 DAT 14 DAT 21 DAT 28 DAT	[6] HPLC- MSMS analytical method was validated in the respective NOTOX Projects 434813 and 465154.

BPL 06/063/CL-2 F-80170 Beaufort En Santerre (Northern area)	Cauliflower / Aviso	1/ 04- Aug-06 (Planting) 3/ 12- Dec-06	Micro- granulator	Not applicab le	Not applicab le	0.933	04-Aug- 06	BBCH 13	Seed- lings	na na na na na	0.0641 0.8390 6.2600 0.0839 <LOQ 0.00647	0.00828 0.4250 1.3800 0.1170 <LOQ <LOQ	1 DAT 3 DAT 7 DAT 14 DAT 21 DAT 28 DAT	HPLC- MSMS analytical method was validated in the respective NOTOX Projects 434813 and 465154.
									Heads	na	<0.005*	<0.01*	130 DAT	
TRC05-20; trial no.: TRC05-20R1 SP - 46192 MONSERRAT (Valencia)	Cauliflower / Arizona	1/ 03- Aug-05 (Planting)	Grain scatterer	Not applicab le	Not applicab le	1.032	03-Aug- 05	BBCH 13	Seed- lings	<0.5* <0.5* <0.5* <0.005* <0.005* <0.005*	0.104 0.495 0.009 <0.0015* <0.0015* <0.0015*	na na na na na	3 DAT 7 DAT 14 DAT 21 DAT 28 DAT 35 DAT	Analytical method validated under NOTOX project n° 434813
Heads	<u><0.005*</u>	<0.0015*	<u>na</u>	85 DAT										

Trial no.: TRC-06-11 Catarroja (Valencia), Spain	Cauliflower /Arizona	1. 11-07-06	Grain scatterer	Not applicable	Not applicable	1.032	11-07-06	BBCH 13	Seedlings	na na na na na	0.0105 0.136 0.0180 <0.005* <0.005* <0.005*	<0.01* 0.105 0.0585 <0.01* <0.01* <0.01*	1 DAT 3 DAT 7 DAT 14 DAT 21 DAT 28 DAT	Analytical methods validated under NOTOX project n° 434813 and n°465154.
									Heads	na	<u><0.0015*</u>	<u><0.005*</u>	harvest	
Trial no.: AF/12035/OT-1, Shepshed, Leicester, England	Broccoli/Marathon	1.06-06-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 06-06-2007	BBCH 12	Seedlings	< 0.05* < 0.05* nd nd nd nd nd	0.00238 0.047 0.540 0.972 1.713 0.193 < 0.0015*	< 0.003* 0.0129 0.192 0.579 1.165 0.190 < 0.003*	0 3 7 14 21 28 42	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369 Storage stability data ?
									Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	
Trial no.: AF/12035/OT-2, Audeville, France (North)	Head cabbage, var. Eton	1.19-06-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 19-06-2007	BBCH 13-14	Seedlings	< 0.05* < 0.05* nd nd nd nd nd	< 0.0015* 0.912 0.124 < 0.0015* < 0.0015* < 0.0015* < 0.0015* 0.0169#	< 0.003* 0.332 0.207 0.00588 < 0.003* < 0.003* < 0.003* < 0.003*	0 3 7 14 21 28 42	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369 # this results seems an outlier,
									Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	
									Earth-worms	< 0.05* < 0.05* < 0.05*	< 0.0015* 0.00278 < 0.0015*	< 0.003* < 0.003* < 0.003*	3 7 14	

										< 0.05*	< 0.0015*	< 0.003*	21	however it was included in the RA birds/mammals as worst-case.
Trial no.: AF/12035/OT-3, Hemmington, Leicestershire, England	Head cabbage, var. Stanton F1	1.05-06-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 05-06-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12035/OT-5, Audeville, France (North)	Cauliflower/ Amsterdam	1.12-07-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 12-07-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12035/OT-6, St. Hilaire St Mesmin France (North)	Broccoli/Belstar	1.13-07-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 13-07-2007	-	Mature crop	<u><0.05*</u>	<u>0.00708</u>	<u>0.00319</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12035/OT-7,	Head cabbage/ Calomera	1.05-06-2007 2.-	Micro-granulator	Not applicable	Not applicable	1.000	1 05-06-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen

Germany		3.-												E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12035/OT- 8, Germany	Cauliflow er Ceveline	1.06-06- 2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicable	1.000	1 06--06- 2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12035/OT- 9, Wilson, Derbyshire, England	Cauliflow er/ Flamenco F1	1.22-06- 2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicable	1.000	1 22-06- 2007	BBCH 14	Earth- worms Mature crops	<0.05* <0.05* <0.05* <0.05* <0.05*	0.504 0.417 0.0255 0.00284 <u><0.0015*</u>	0.0576 0.0349 <0.003* <0.003* <u><0.003*</u>	3 7 14 21 Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12036/OT- 1, Montauban (82) France (South)	Cauliflow er/ Nautilus	1.03-07- 2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicable	1.000	1 03-07- 2007	BBCH 12	Seed- lings Mature crop Earth- worms	<0.05* <0.05* <0.05* <0.05* <0.05* <0.05*	<0.0015* 0.176 1.286 0.0317 <0.0015* <0.0015* <0.0015*	<0.003* 0.0843 0.893 0.123 <0.003* <0.003* <0.003*	0 3 7 14 21 28 42 Harvest 3 7 14	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369 Storage stability data ?

Trial no.:	Broccoli/ Partenon	1. 21-09- 2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicab le	0.960	1 21-09- 2007	BBCH 13	Seed- lings	<0.05*	<0.0015*	<0.003*	21	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
AF/12036/OT- 2, Utebo Spain									Immat ure crops	<0.05*	<0.0015*	<0.003*	0	
										<0.05*	<0.0015*	<0.003*	3	
										<0.05*	0.168	0.0242	7	
										<0.05*	0.0169	0.035	14	
										<0.05*	0.640	0.593	21	
										<0.05*	0.146	0.200	28	
										<0.05*	<0.0015*	<0.003*	42	
										<0.05*	<0.0015*	<0.003*	118	
										Mature crop	in progress	in progress	in progress	
										Earth- worms	<0.05*	<0.0015*	<0.003*	3
<0.05*	<0.0015*	<0.003*	7											
<0.05*	<0.0015*	<0.003*	14											
<0.05*	<0.0015*	<0.003*	21											
Trial no.:	Head cabbage Rigoletto	1. 09-08- 2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicab le	2.000	1 09-08- 2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.:	Broccoli/ Partenon	1. 13-09- 2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicab le	0.995	1 13-09- 2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369

Trial no.: AF/12036/OT-5, Remolinos Spain	Broccoli/ Chevalier	1. 11-09-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 11-09-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12036/OT-6, Granaloro Italy	Head cabbage Green cup	1. 10-08-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 10-08-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12036/OT-7, Budrio Italy	Head cabbage/ Green cup	1. 14-08-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 14-08-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12036/OT-8, Budrio Italy	Head cabbage/P rodusa	1. 24-08-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	1.000	1 24-08-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369

Trial no.: AF/12037/OT-1, Lancashire England	Kale/Winterbor F1	1. 25-07-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	0.860	1 25-07-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12037/OT-2, Audeville France (North)	Kale/Prover	1. 12-07-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	0.878	1 12-07-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12037/OT-3, Dampierre en Burly France (North)	Kale/Prover	1. 13-07-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	0.860	1 13-07-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u>0.00718</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12038/OT-1, Blagnac (31) France (South)	Leafy Cabbage/Rigoletto	1. 30-07-2007 2.- 3.-	Micro-granulator	Not applicable	Not applicable	0.860	1 30-07-2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369 Storage

														stability data ?
Trial no.: AF/12038/OT-2, Canals (82) France (South)	Leafy Cabbage/ Alaska	1. 14-09-2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicable	0.860	1 14-09- 2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369
Trial no.: AF/12038/OT-3, Zaragosa Spain	Leafy Cabbage/ Temprosa	1. 31-08-2007 2.- 3.-	Micro- granulator	Not applicab le	Not applicable	0.860	1 31-08- 2007	-	Mature crop	<u><0.05*</u>	<u><0.0015*</u>	<u><0.003*</u>	Harvest	Analytical method (Baltussen E., 2007) validated under NOTOX project n° 485369

nd = not determined

* = denotes LOQ

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date	8 Portion analyzed	9 Residues (mg/kg)			10 PHI (days)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH- CF		
BPL 05/014/CL; trial no.: BPL 05/014/CL – 1. F- 30840 MEYNES (Southern area)	Cauliflower / White passion	1/ 29- Mar-05 (Planting)	Micro- granulator (localised application in plant- hole)	Not applicab le	Not applicable	1.016	29-Mar-05	BBCH 14	Seed- lings	- - - -	0.0339 0.238 8.79 24.00 0.738	nd nd nd nd nd	1 DAT 3 DAT 7 DAT 14 DAT 28 DAT	-Results for BFC not valid because of low procedural recoveries (0.45- 22.53%) -trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) Analytical method (Baltussen E., 2005) validated under NOTOX projects n° 434813 and n°436782

BPL 05/014/CL; trial no.: BPL 05/014/CL – 2. F- 80170 ROSIERES EN SANTERRE (Northern area)	Cauliflower / Aviso	1/ 25- May-05 (Planting)	Micro- granulator (localised applicatio n in plant- hole)	Not applicab le	Not applicable	1.161	25-May-05	BBCH 14	Seed- lings	0.0069 <0.005 * <0.005 * <0.005 * <0.005 * <0.005 *	0.813 3.56 17.80 2.03 0.212 0.0237	nd nd nd nd nd	1 DAT 3 DAT 7 DAT 14 DAT 21 DAT 29 DAT	-Results for BFC indicative because of low procedural recoveries (44- 45%) -trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) Analytical method (Baltussen E., 2005) validated under NOTOX projects n° 434813 and n°436782
BPL 05/014/CL; trial no. : BPL 05/014/CL – 3. F- 30620 BERNIS (Southern area)	Cauliflower / Aviso	1/ 30- May-05 (Planting)	Micro- granulator (localised applicatio n in plant- hole)	Not applicab le	Not applicable	1.099	30-May-05	BBCH 14	Earth- worms	<0.02* <0.02* <0.02* <0.02* *	<0.005 * <0.005 * <0.005 * <0.005 *	nd nd nd nd	1 DAT 7 DAT 14 DAT 28 DAT	trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) Analytical method (Baltussen E., 2005) validated under NOTOX projects n° 434813 and n°436782

BPL 05/014/CL; trial no. : BPL 05/014/CL – 4. F- 80170 ROSIERES EN SANTERRE (Northern area)	Cauliflow er / Aviso	1/ 09-Jun- 05 (Planting)	Micro- granulator (localised applicatio n in plant- hole)	Not applicab le	Not applicable	1.077	09-Jun-05	BBCH 14	Earth- worms	<0.02* <0.02* <0.02* <0.02*	<0.005 * <0.005 * <0.005 * <0.005 *	nd nd nd nd	1 DAT 7 DAT 14 DAT 27 DAT	trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) Analytical method (Baltussen E., 2005) validated under NOTOX projects n° 434813 and n°436782
BPL 06/063/CL (analyse: 473928) trial no.: BPL 06/063/CL–2. F- 80170 BEAUFORT EN SANTERRE (Northern area)	Cauliflow er Aviso	1/ 04- Aug-06 (Planting) 3/ 12- Dec-06	Micro- granulator	Not applicab le	Not applicable	0.933 (10.49 kg product/ ha)	04-Aug-06	BBCH 13	Seed- lings	nd nd nd nd nd	0.0641 0.839 6.26 0.0839 <0.005 * 0.0065	<0.01* 0.425 1.38 0.117 <0.01* <0.01*	1 DAT 3 DAT 7 DAT 14 DAT 21 DAT 28 DAT	HPLC-MSMS analytical method was validated in the respective NOTOX Projects 434813 and 465154. -LOQ 3-OH-CF was set at 0.01 mg/kg. (see remark under paragraph 4.4) -2 nd planting outside normal planting period for that area due to crop failure. Retarded growth and results not representative for GAP.

									Heads	nd	<0.005*	<0.005*	130 DAT	-2 rd planting outside normal planting period for that area due to crop failure. Retarded growth and results not representative for GAP. [6]
TRC05-19; trial no.: TRC05-19R1 SP - 46192 MONSERRAT (Valencia)	Cauliflower / Arizona	1/ 03-Aug-05 (Planting)	Direct to the transplanting hole (localised application in plant-hole)	Not applicable	Not applicable	1.032	03-Aug-05	BBCH 13	Seedlings	<0.5* <0.5* <0.5* <0.005* <0.005* <0.005*	8.88 20.1 3.36 0.091 0.0189 <0.0015*	nd nd nd nd nd	3 DAT 7 DAT 14 DAT 21 DAT 28 DAT 35 DAT	- LOQ BFC set at 0.5 for certain samples because of poor recoveries at 0.005. - trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow)
									Heads	<0.005*	<0.0015*	nd	85 DAT	Analytical method (Baltussen E., 2006) validated under NOTOX project n° 434813

TRC05-21; trial no.: TRC05-21 Spain CATARROJA (Valencia)	Cauliflower / Arizona	1/ 03- Aug-05 (Planting)	Broadcast applicatio n	Not applicab le	Not applicable	1.032	03-Aug-05	BBCH 13	Seed- lings	<0.5* <0.5* <0.5* <0.005 *	0.121 0.141 0.006 <0.001 5*	nd nd nd nd nd nd	3 DAT 7 DAT 14 DAT 21 DAT 28 DAT 35 DAT 85 DAT	- trial not relevant for intended use (broadcast application instead of homogeneous distribution in furrow) Analytical method (Baltussen E., 2006) validated under NOTOX project n° 434813
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Open point 3(8) in the Reporting Table rev.0 (November 2008): Vol 3. B.7.6 Residue trials – Methods

For MRL setting and consumer dietary risk assessment, RMS considered all the trials performed using the analytical method-NOTOX report 485369 intended for post-registration control and monitoring of Carbofuran and 3-OH-carbofuran at the validated LoQs of 0.0015 mg/kg and 0.003 mg/kg, respectively for Carbofuran and 3-OH-carbofuran.

In the table B.7.6.1-1 in the DAR, the residue values of 0.0043 mg/kg must be corrected into 0.0045mg.kg. This table was revised and discussed under open point 3(7) in this addendum.

Open point 3(11): Vol 3 B.7.11 Exposure assessment

The dietary intake risk assessment to the residues of Carbofuran and 3-OH-carbofuran generated by the use of Benfuracarb on brassica crops was performed considering the following input parameters in the EFSA PRIMo:

- HR (LoQ of the validated analytical method (report n° 485369)) for Benfuracarb: 0.05 mg/kg for all brassica crops.
- HR (LoQ of the validated analytical method (report n° 485369)) for the sum of Carbofuran and 3-OH-carbofuran: 0.0045 mg/kg for head cabbage and leafy cabbage.
- HR value for cauliflower: 0.0065 mg/kg.
- HR value for broccoli: 0.0102 mg/kg.
- HR value for kale: 0.0086 mg/kg.
- Revised Carbofuran toxicological end points: ADI/ARfD: 0.00015 mg/kg bw/day (Acute rat neurotoxicity study, Assessment factor: 200) (cf. Carbofuran DAR – Mam Tox section, revised in November 2008).

Carbofuran+ 3-OH-Carbofuran			
Status of the active substance:	Annex I inclusion	Code no.	#N/A
LOQ (mg/kg bw):	0,0045	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,00015	ARfD (mg/kg bw):	0,00015
Source of ADI:	DAR 2008	Source of ARfD:	DAR 2008
Year of evaluation:	2008	Year of evaluation:	2008
Chronic risk assessment			
TMDI (range) in % of ADI minimum - maximum			
6			
No of diets exceeding ADI:	---		

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)
5,7	NL child	2,0	Cauliflower	1,5	Broccoli	0,9	Head cabbage	1,2
4,7	FR toddler	2,7	Broccoli	1,7	Cauliflower	0,3	Head cabbage	0,3
3,8	SE general population 90th percentile	1,9	Head cabbage	0,6	Chinese cabbage	0,6	Broccoli	2,6
3,1	IE adult	1,4	Broccoli	0,7	Cauliflower	0,6	Brussels sprouts	1,0
3,0	NL general	1,0	Cauliflower	0,6	Head cabbage	0,6	Kale	0,9
2,7	WHO regional European diet	1,1	Head cabbage	0,9	Cauliflower	0,3	Broccoli	1,2
2,6	FR infant	2,0	Broccoli	0,5	Cauliflower	0,0	Brussels sprouts	0,1
2,0	UK Infant	1,1	Cauliflower	0,6	Brussels sprouts	0,3	Head cabbage	0,9
1,9	WHO cluster diet D	0,6	Chinese cabbage	0,5	Head cabbage	0,5	Kale	1,4
1,7	WHO Cluster diet F	0,8	Head cabbage	0,5	Broccoli	0,2	Chinese cabbage	1,1
1,7	DE child	0,8	Broccoli	0,6	Cauliflower	0,3	Head cabbage	0,4
1,6	PL general population	1,1	Head cabbage	0,4	Cauliflower	0,1	Broccoli	1,2
1,5	UK vegetarian	0,6	Broccoli	0,5	Cauliflower	0,3	Head cabbage	0,4
1,4	WHO cluster diet E	0,8	Head cabbage	0,5	Broccoli	0,1	Brussels sprouts	0,9
1,4	WHO Cluster diet B	0,7	Head cabbage	0,3	Cauliflower	0,3	Chinese cabbage	1,0
1,3	UK Toddler	0,5	Cauliflower	0,4	Broccoli	0,3	Head cabbage	0,4
1,2	LT adult	1,2	Head cabbage		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	1,2
1,1	UK Adult	0,5	Broccoli	0,3	Cauliflower	0,2	Head cabbage	0,3
0,7	FR all population	0,4	Cauliflower	0,2	Broccoli	0,1	Head cabbage	0,2
0,7	DK child	0,3	Broccoli	0,2	Head cabbage	0,2	Cauliflower	0,2
0,6	DK adult	0,2	Head cabbage	0,2	Broccoli	0,2	Cauliflower	0,3
0,5	FI adult	0,2	Head cabbage	0,1	Chinese cabbage	0,1	Broccoli	0,3
0,5	IT adult	0,2	Cauliflower	0,2	Broccoli	0,1	Head	0,1

0,4	ES child	0,2	Cauliflower	0,1	Head cabbage		cabbage FRUIT (FRESH OR FROZEN)	0,1
0,4	ES adult	0,3	Cauliflower	0,1	Head cabbage		FRUIT (FRESH OR FROZEN)	0,1
0,3	IT kids/toddler	0,2	Cauliflower	0,1	Broccoli	0,0	Head cabbage	0,0
	PT General population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
Acute risk assessment /children				Acute risk assessment / adults / general population				

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): 5			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 4			No of commodities for which ARfD/ADI is exceeded (IESTI 1): 4			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 3		
	IESTI 1 *)		**)	IESTI 2 *)		**)	IESTI 1 *)		**)	IESTI 2 *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
396,0	Broccoli	0,0102 / 0	286,4	Cauliflower	0,0065 / 0	145,0	Broccoli	0,0102 / 0	145,0	Broccoli	0,0102 / 0	
387,6	Kale	0,0086 / 0	282,9	Broccoli	0,0102 / 0	137,6	Cauliflower	0,0065 / 0	137,6	Cauliflower	0,0065 / 0	
286,4	Cauliflower	0,0065 / 0	276,9	Kale	0,0086 / 0	116,9	Kale	0,0086 / 0	107,1	Chinese cabbage	0,0045 / 0	
157,9	Head cabbage	0,0045 / 0	111,4	Chinese cabbage	0,0045 / 0	107,1	Chinese cabbage	0,0045 / 0	86,8	Kale	0,0086 / -	
111,4	Chinese cabbage	0,0045 / 0	94,7	Head cabbage	0,0045 / -	95,2	Head cabbage	0,0045 / -	57,1	Head cabbage	0,0045 / -	

Conclusion:

There is no chronic intake concern when the different categories of consumers are exposed to residues of Carbofuran and 3-OH-carbofuran produced by Benfuracarb application on brassica crops.

The acute dietary risk assessment showed an exceedance of the ARfD of 0.00015 mg/kg bw/day (new RMS proposal) both for children (396 % of ARfD for broccoli) and for adults (145 % of ARfD for broccoli).

RMS considers that the acute risk assessment is still acceptable since the use pattern of Benfuracarb on brassica is not expected to leave detectable residues on edible parts of the crops and all the metabolites of Benfuracarb recovered in the plant metabolism studies were also recovered in the rat metabolism and therefore covered toxicologically by the available studies provided in the “Toxicology and Metabolism” section.

Open point 3(12) in the Reporting Table rev.0 (November 2008): Vol. 3 B 7.13: Proposed MRLs

Revised MRLs proposals.

Crops	Expression of the residue	MRLs (mg/kg)
Flowering brassica	Benfuracarb	0.05*
	Carbofuran (Carbofuran + 3-OH-carbofuran expressed as Carbofuran equivalents)	0.01
Head brassica	Benfuracarb	0.05*
	Carbofuran (Carbofuran + 3-OH-carbofuran expressed as Carbofuran equivalents)	0.01*
Leafy brassica	Benfuracarb	0.05*
	Carbofuran (Carbofuran + 3-OH-carbofuran expressed as Carbofuran equivalents)	0.01

Open point 3(13) in the Reporting Table rev.0 (November 2008): Vol. 3 B 7.15: Summary and evaluation of residue behaviour

RMS proposes to delete the sentence: “The contribution of animal products was not considered since no residue definition was proposed” and to replace by the following sentence: “No residue of Benfuracarb and its metabolites carbofuran and 3-OH-carbofuran are expected in the animal matrices. Their contribution to the consumer dietary intake risk assessment is not considered”.

In the available goat metabolism study (Spare W.C., 1983), the Limit of Detection of the method was:

0.16 (Low dose)-2.0 (high dose) mg/kg (muscle/fat);

0.051 (LD)-0.74 (HD) mg/kg (liver, kidney, brain, heart).

Open point 3(14) in the Reporting Table rev.0 (November 2008): Vol 3, B.7 Appendix C, Residue trials

See open point 3(7) above.

JMPR report 2007**Plant metabolism data:****-Potatoes:**

Experimental design: Greenhouse grown potatoes were treated with (phenyl)¹⁴C Carbofuran in a single direct application to the soil surface at 7.4 kg a.s./ha after plant emergence. Immature vines were sampled after 56 days and mature tubers harvest after 104 days.

The samples were assayed for total radioactivity by combustion and Liquid scintillation counting.

Extraction procedure:

The extraction of immature vine and mature tubers was carried out with Methanol/water followed by partitioning against Methylene chloride to provide the organosoluble and aqueous soluble phases. The aqueous phase from the methylene chloride partitioning was sequentially incubated with B-glucosidase and hydrolysed with 0.25 N HCl and 2 N HCl in order to release organosoluble compounds from their conjugated form.

The parent compound and the metabolites were identified or characterized by reverse-phase HPLC and normal-phase TLC. Tentative identifications were confirmed by GC-MS.

Findings:

Compound	Mature tuber (104-day PHI)		Immature foliage (56-day PHI)	
	% of TRR	Mg/kg	% of TRR	Mg/kg
TRR (mg/kg)	100	0.80	100	30.5
Methanol/water extraction phase	Not given		Not given	
Methylene chloride organosoluble phase	22	0.176	6	1.83
Aqueous soluble phase	61	0.488	87	26.53
14C released by enzymatic digestion (B-glucosidase)	7.9	0.063	51	15.55
14C released by 0.25 N HCl	32	0.256	14	4.27
14C released by 2 N HCl	9.4	0.075	13	3.96
Metabolites identification				
Carbofuran	nd	nd	3.5	1.071
3-OH-carbofuran	2.9	0.023	22.6	6.906
3-keto-carbofuran	-	-	1.1	0.324
7-phenol	45.3	0.361	6.7	2.044
3-OH-7-phenol	13.4	0.107	5.4	1.658
3-keto-7-phenol	6.6	0.052	9.4	2.858
5-OH-carbofuran	-	-	34.4	10.522
Total identified	68.2 (2.2% unconjugated)	0.543	83.1 (4.6% unconjugated)	25.383
Others	3.7	0.029	2.6	0.807
Polar residues	23.3	0.185	11.0	3.354
Unextractable residues	4.9	0.039	3.3	1.002
Total residues	100.0	0.80	100.1	30

-Soya beans:*Experimental design:*

Sandy loam soil was treated with Carbofuran uniformly labeled with ¹⁴C in the phenyl ring at 5.5 kg a.s./ha (USA). The test substance was applied deep furrow. Immediately after application, soya bean seeds were sown in a single row and covered with untreated soil. The soya beans were grown outdoors and samples of forage (PHI: 45 days), beans (PHI: 139 days) and hay (PHI: 139 days) were collected.

Extraction procedure:

The samples were assayed for total radioactivity by combustion and Liquid scintillation counting.

Samples were sequentially extracted with Methanol/water and with 0.25 N HCl. The extracted samples were extracted with Methylene chloride and the residual solids were sequentially hydrolysed with 0.25 N HCl, cellulose, B-glucosidase, amyloglucosidase, pectinase, protease, 6N HCl and 2N NaOH. The solid residues from the hay samples after solvent extraction were solubilized with dioxane-water to release lignin. After each hydrolysis the aqueous extracts were adjusted to pH 2 and extracted with acetonitrile to recover organosolubles.

The methanol/water and acid-refluxed methanol/water extracts were analysed by reversed-phase HPLC.

Confirmation was by normal-phase TLC and the main metabolites were identified by GC-MS.

Unknown compounds separated by TLC and HPLC were investigated by HPLC-MS.

Findings:

Compound	Total radioactive residues expressed as % of TRR and mg/kg ¹⁴ C Carbofuran equiv.											
	Forage				Soya beans				Hay			
	Methanol extract		Acid-refluxed extract		Methanol extract		Acid-refluxed extract		Methanol extract		Acid-refluxed extract	
	% TRR	Mg/kg	% TRR	Mg/kg	% TRR	Mg/kg	% TRR	Mg/kg	% TRR	Mg/kg	% TRR	Mg/kg
Carbofuran	11.6	7.3	11.4	7.2	-	-	0.42	0.001	0.30	0.11	0.62	0.22
3-keto-carbofuran	1.7	1.1	1.6	1.0	-	-	5.3	0.02	0.41	0.15	-	-
3-OH-carbofuran	10.6	6.6	28	18	0.56	0.002	1.5	0.005	3.2	0.50	7.8	2.8
7-phenol	-	-	1.4	0.90	0.38	0.001	4.0	0.013	0.67	0.24	0.72	0.26
3-keto-7-phenol	1.6	1.0	13	8.1	0.71	0.002	9.2	0.030	4.3	1.6	9.8	3.5
0-glucoside conjugate of 3-OH or 3-keto-7-phenol	16	9.9	3.4	2.1	11	0.036	-	-	3.6	1.3	-	-
2-OH-methyl-3-keto-carbofuran	-	-	3.6	2.2	-	-	0.93	0.03	-	-	0.84	0.30
Total identified.	42		62		13		21		12		20	

-Maize:*Experimental design:*

Loam soil was treated with Carbofuran uniformly labelled with ¹⁴C in the phenyl ring at a rate of 8.3 kg a.s./ha. The test substance was sprayed in a band on the soil and was incorporated to a depth of about 5 cm before planting maize seed.

Maize samples were taken at 3 growth stages: forage (immature stage, 47 days PHI), silage (99 days, PHI) and stover and grain (kernels without cob and husk, 158 days PHI).

Extraction procedure:

The samples were assayed for total radioactivity by combustion and Liquid scintillation counting.

Each sample was extracted with methanol/water and the extracts acidified to pH 1 and partitioned with methylene chloride/ether. The aqueous fractions from the methylene chloride/ether partitioning of the forage and silage samples were divided in 2 fractions and treated sequentially with B-glucosidase and by acid refluxing followed by partitioning against methylene chloride/ether. The aqueous layer from this extract of the silage and forage samples was acidified by acid refluxing followed by extraction with methylene chloride/ether to collect the organosoluble unconjugated metabolites.

The post extraction solids (PES) from the initial methanol/water extraction were refluxed with 0.25 N HCl. The hydrolysate from the grain was tested to determine the presence of reducing sugars with Benedict's solution and by osazone formation. Both tests indicated reducing sugars.

The residue after acid hydrolysis was treated with a surfactant.

The organosoluble fractions from the forage and silage, i.e. the methylene chloride/ether extracts of the acidified methanol/water extract and of the 0.25 N hydrolysate, were analysed by HPLC, TLC and GC-MS.

The extracts from grain and stover were not further analysed because of the very low level of recovered radioactivity.

Findings:

Fraction/Compounds	Grain		Forage		Stover		Silage	
Total radioactive residues (mg/kg)	0.023		0.81		0.075		0.14	
	% TRR	Mg/kg	% TRR	Mg/kg	% TRR	Mg/kg	% TRR	Mg/kg
Methylene chloride/ether (non conjugates)	5.8	0.001	42	0.34	4.4	0.003	4.6	0.006
Acid-released methylene chloride/ether (aglycones)			32	0.26	–	–	20	0.028
Glucosidase-released (aglycones)	–	–	19	0.15	–	–	23	0.032
Residual acid aqueous			8.1	0.066	22	0.016	31	0.036
Acid-released from PES	48	0.011	3.5	0.028	13	0.010	9.9	0.014
Surfactant-released from PES	–	–	1.6	0.013	4.7	0.004	5.1	0.007
Total released residue	48		87		44		71	
Identification of the metabolites in the organosoluble extracts of maize silage and forage								
Carbofuran			14	0.11			0.18	<0.001
Carbofuran aglycone			2.4	0.019			2.1	0.003
3-keto-carbofuran			1.6	0.013			–	–
3-keto-carbofuran aglycone			0.28	0.003			0.91	0.001
3-OH-carbofuran			13	0.11			1.3	0.002
3-OH-carbofuran aglycone			9.7	0.078			7.9	0.011

7-phenol			0.47	0.004			0.088	<0.001
7-phenol aglycone			7.5	0.060			2.8	<0.001
3-keto-7-phenol			4.8	0.039			1.4	0.002
3-keto-7-phenol aglycone			5.6	0.045			2.4	0.003
3-OH-7-phenol			2.4	0.020			0.88	0.001
3-OH-7-phenol aglycone			3.6	0.029			2.3	0.003
Total			65	0.53			22	0.026

The predominant compounds recovered in maize forage and silage were the carbofuran and 3-OH-carbofuran, free and conjugated. The amount of radioactivity that could not be extracted with solvent or released by acid hydrolysis increased with the PHI, suggesting incorporation of the radioactivity into plants constituents.

Rotational crops:

Experimental design:

In a confined crop rotation study (Phenyl)-14C-Carbofuran was applied directly to a silt loam soil at an application rate of 3.4 kg as/ha. Wheat, soya beans and sugar beet were seeded into the treated soil 4 and 12 months after treatment and grown to maturity. Wheat forage, straw and grain, soya bean silage, stems, pods and beans and sugar beet tops and roots were assayed for the determination of the total radioactive residues.

Extraction procedure:

Each sample was extracted with Methanol/water and separated into non polar and polar fractions for further metabolites identification. Conjugated metabolites were hydrolysed with 0.25 N HCl. Metabolites were identified by TLC, by co-chromatography with reference standards.

Findings:

Crop	Sample	Total radioactive residues (mg/kg)	
		4 months	12 months
Wheat	Forage	-	1.40
	Straw	54.0	0.30
	Grain	0.60	0.04
Soya bean	Silage	16.0	0.50
	Stem	18.0	0.70
	Pod	5.0	0.10
	Beans	1.0	0.08
Sugar beet	Top	0.40	0.05
	Root	0.20	0.05

The phenolic metabolites were the main degradation products recovered in the rotated crops. The carbamates (carbofuran, 3-OH-carbofuran and 3-keto-carbofuran) constituted a small proportion of the total radioactive residues (<10 % of the TRR in any crop sown at 4 and 12 months).

ANNEX B

**Addendum (Jan 2009) to the DAR revised in August
2008**

Benfuracarb

B.8 Environmental fate and behaviour

B.8.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)

B.8.1.1 Route of degradation (Annex IIA 7.1.1.1)

B.8.1.1.1 Aerobic degradation in soil (Annex IIA 7.1.1.1.1)

The assessment of the 2 invalid studies has been transferred from the carbofuran DAR.

Aerobic Soil Metabolism of ¹⁴C carbofuran (Saxena A M *et al*, 1994) (submitted by FMC)

Guidelines :

In accordance with SETAC guidance document

GLP :

yes

Material and Methods :

Test substance : (¹⁴C phenyl ring) carbofuran, 39.2 mCi/mmol, 96.0% radiochemical purity

Soil :

“The rate and degree of aerobic metabolism of ¹⁴C carbofuran and its metabolites, were determined in two soil types; one acidic (pH 5.7) and one alkaline (pH 7.7). The alkaline soil was prepared by adjusting the pH of the collected acidic soil (pH 5.7) to pH 7.7 with lime. Before dosing, limed soil was incubated for approximately 2 months at approximately 25°C until the soil pH and microbial population had reached an equilibrium.”

Table B.8.1.1.1-11: Characteristics of the soil

Origin	Georgia
Textural class (USDA)	Sandy loam
Particle size distribution [%]:	
Sand	73
Silt	16
Clay	11
Organic C [%]	0.70
Microbial biomass at start of incubation CFU/g dry soil]	3.0 x 10 ⁶ acidic cond.; 8.9 x 10 ⁶ alkaline cond.
Microbial biomass at study termination [CFU/g dry soil]	5.5 x 10 ⁷ acidic cond.; 3.3 x 10 ⁷ alkaline cond.
Cation Exchange Capacity [meq/100g]	4.3
PH [100 mM CaCl ₂]	5.7
Moisture at 1/3 bar [g H ₂ O/100g dry soil]	5.4

Experimental design :

The soil samples were fortified with ¹⁴C carbofuran at a nominal concentration of 3 mg a.s./kg soil and incubated at 25°C ± 1°C under aerobic conditions in darkness for 365 days.

PH levels of the acidic soil samples remained constant throughout the study, ranging from 5.2 to 5.8. the pH of alkaline samples showed a wider range (8.0 to 6.6). A viable and stable population of aerobic bacteria was present in the soil samples throughout the length of the study, as shown by the bacteria counts.

Analytical methods :

Soil samples were extracted twice with methanol/water (80/20) and then refluxed with methanol/water (80/20). The radioactivity in traps, soils and soil extracts was determined by LSC. A NaOH based extraction was used to determine the nature of bound residues.

Soils extracts were analyzed by 2D-TLC and HPLC with the following reference substances : carbofuran, 3-OH-7-phenol, 3-OH- carbofuran, 3-keto-7-phenol, 3-keto-carbofuran, 7-phenol

Mass spectrometry was conducted to confirm 3-keto carbofuran in acidic soils because poor separation in the 2D-TLC method.

Findings :

Table B.8.1.1.1-12: Recovery of radioactivity in % AR and distribution of metabolites after application of [¹⁴C]-carbofuran to an acidic sandy loam soil and incubation under aerobic conditions at 25°C

Days	Extractable residue					Volatile traps	Bound residues	Total balance
	carbofuran	3-OH-carbofuran	3-keto-7-phenol	3-keto-carbofuran	7-phenol			
0	97.49	0.06	0.16	0.18	0.04	0.00	0.40	98.32
1	96.10	0.19	0.31	0.31	Nd	0.01	2.91	99.82
3	95.06	0.13	Nd	0.29	Nd	0.03	4.64	100.15
7	92.68	0.32	0.03	0.70	Nd	0.05	5.94	99.71
14	88.89	0.15	0.13	2.10	Nd	0.09	8.35	98.10
30	84.30	0.56	0.02	2.08	0.02	0.16	10.96	98.62
62	82.72	Nd	Nd	2.60	Nd	0.29	13.01	97.45
92	74.98	0.56	Nd	6.36	Nd	0.55	15.00	98.81
122	69.86	Nd	Nd	7.13	Nd	0.94	20.89	97.80
181	58.29	Nd	Nd	12.41	Nd	2.52	24.59	99.05
273	53.85	0.55	Nd	11.41	Nd	3.98	29.28	99.05
365	43.58	0.63	1.91	11.14	0.33	4.96	35.41	97.95

Table B.8.1.1.1-13: Recovery of radioactivity in % AR and distribution of metabolites after application of [¹⁴C]-carbofuran to an alkaline sandy loam soil and incubation under aerobic conditions at 25°C

Days	Extractable residue					Volatile traps	Bound residues	Total balance
	carbofuran	3-OH-carbofuran	3-keto-7-phenol	3-keto-carbofuran	7-phenol			
0	96.63	0.36	0.11	0.12	Nd	0.00	0.52	97.73
1	93.22	0.18	0.33	0.09	0.03	0.01	3.23	97.08
3	91.73	0.10	0.16	0.05	Nd	0.02	7.18	99.23
7	87.73	0.79	0.37	0.07	0.28	0.11	9.98	99.32
14	83.00	0.92	0.77	0.13	0.05	0.25	12.98	98.08
30	77.39	0.33	0.20	0.02	Nd	0.61	18.00	96.54
62	66.53	0.14	0.12	0.17	Nd	1.67	27.48	96.11
92	59.65	Nd	Nd	Nd	0.59	3.18	29.60	93.01
122	25.07	1.32	0.84	0.31	0.32	8.31	55.62	91.78
181	27.14	1.32	0.14	0.22	0.38	10.97	55.95	96.10
273	23.27	0.36	0.24	Nd	1.08	14.11	59.23	98.27
365	20.96	0.56	0.26	0.14	0.36	16.60	57.83	96.71

Conclusions :

Table B.8.1.1.1-14: First order DT₅₀ values for carbofuran at 25°C

Soil	Conditions	DT ₅₀	R ²
Sandy loam soil	Acidic	320.83*	0.9785
	Alkaline	149.35**	0.9213

* the very low water content of the soil can probably explain the limited degradation in this study

** lime has been added to the previous soil in order to modify its pH

Conclusions :

The study is not acceptable. The active substance was slowly degraded in this experiment. Several minor metabolites were formed under alkaline conditions. Under acidic conditions, 3-keto carbofuran was recovered at 11.14-12.41 % AR at day 181-365.

Mineralization accounts for 0.94-8.31 % AR at day 122. The amount of bound residues was equivalent to 20.89-55.62% AR at day 122.

Carbofuran Aerobic Soil Metabolism (Schocken M J, 1989) (submitted by FMC)

Guidelines :

In accordance with SETAC guidance document

GLP :

yes

Material and Methods :

Test substance : (¹⁴C phenyl ring) carbofuran, 39.4 mCi/mmol, 99.9% radiochemical purity

Soil :

“In order to satisfy the ADEQ’s requirements for soil pH (e.g. between 6.5 and 8.5), the soil was amended with lime in a manner consistent with conventional agricultural practices. Following subsequent reanalysis, the soil pH was determined to be 7.1.” (ADEQ = Arizona Department of Environmental Quality)

Table B.8.1.1.1-26: Characteristics of the soil

Origin	Forest City
Textural class (USDA)	Sandy loam
Particle size distribution [%]:	
Sand	68
Silt	13
Clay	19
Organic C [%]	0.64
Cation Exchange Capacity [meq/100g]	6.8
pH	5.8 => 7.1

Experimental design :

Experiment under aerobic conditions : Soil samples fortified with 3 mg/kg ¹⁴C-phenyl labeled carbofuran, were aerobically incubated in the dark at 25°C, 82% FC at 1/3 bar, for 184 days.

Experiment under sterile conditions : The soil samples were autoclaved for 3 consecutive days at 121°C for 60 minutes each. All the manipulations were carried out under aseptic conditions. Soil samples fortified with 3 mg/kg ¹⁴C-phenyl labeled carbofuran, were aerobically incubated in the dark at 25°C, 82 FC at 1/3 bar, for 184 days. The microbial activity was controlled by a separate incubation with ¹⁴C-glucose.

Analytical methods :

Soil samples were extracted twice with methanol/water (80/20). The soils samples were then refluxed with methanol/water (80/20).. The methanol/water extracts were partitioned with dichloromethane into polar and non-polar fractions. The extracted soils, filtrates were analyzed by LSC.

Soils extracts were analyzed by 2D-TLC with the following reference substances : carbofuran, 3-OH- 7-phenol, 3-OH- carbofuran, 3-keto-7-phenol, 3-keto-carbofuran, 7-phenol

Findings :

Table B.8.1.1.1-27: Recovery of radioactivity in % AR and distribution of metabolites after application of 3 mg/kg [¹⁴C – phenyl ring] carbofuran to a sandy loam soil (Forest City) and incubation under aerobic conditions at 25°C

Days	Total of 11 fractions = 100%											Total balance
	CO ₂	Water soluble	origin	3-OH-Carbofuran	3-keto carbofuran	carbofuran	3-OH-7-phenol	3-keto-7-phenol	7-phenol	Others	Bound residue	
	0.0	0.1	0.2	0.0	0.4	95.2	0.3	0.6	2.6	0.1	0.5	99.0
	0.0	0.1	0.1	0.2	0.2	96.1	0.1	0.4	1.0	0.1	1.8	101.0
	0.1	0.3	0.1	0.2	0.1	94.0	0.2	0.4	2.1	0.1	2.5	97.4
	0.1	0.2	0.1	0.1	0.2	93.7	0.3	0.3	0.7	0.1	4.1	99.6
	0.1	0.1	0.1	0.2	0.5	93.8	0.2	0.2	0.2	0.1	4.3	92.0
1	0.1	0.2	0.2	0.3	0.1	92.1	0.5	0.4	0.8	0.2	5.2	98.4
3	0.1	0.3	0.3	0.5	0.2	90.2	Nd	0.5	1.7	0.3	5.9	100.6
5	0.2	0.7	0.3	0.4	0.4	85.4	0.3	0.4	3.4	0.4	8.1	97.6
11	0.7	0.6	2.9	0.8	0.5	80.6	0.0	1.0	2.8	2.3	7.7	89.4
18	1.7	0.5	6.0	0.9	0.6	64.5	0.4	2.0	9.0	4.2	10.3	84.6

Conclusions :

The study is not acceptable since it seems that the carbofuran degradation in this study is occurring through a chemical rather than a microbial process (similar degradation rates under sterile and non-sterile conditions) The first order DT₅₀ under aerobic conditions is 352 days. The mineralization is very limited : 0.7% AR at day 112. The bound residues amount for 7.7% AR at day 112. The metabolite 7-phenol reached a maximum level of 9.0% AR at day 184. Other metabolites were found at low level.

A parallel experiment under anaerobic conditions has been performed. No details on the recovery of radioactivity is available in the study report. The first order DT₅₀ a.s. under sterile conditions is 316 days.

B.8.1.2 Rate of degradation (Annex IIA 7.1.1.2.1; Annex IIIA 9.1.1.1.1)

B.8.1.2.1 Aerobic degradation

The assessment of the study by Taylor and Houseman (1982) has been transferred from the carbofuran DAR.

Added in November 2008

Carbosulfan and carbofuran; Analysis of Nether Poppleton field dissipation investigation (Terry A., 2008)

The notifier considers now that the study presented as acceptable in his original submission is not acceptable anymore:

“There are many deficiencies associated with the available report on the investigation of dissipation of carbosulfan and carbofuran following the application of Marshal 10G (in May 1980) to soil plots at Nether Poppleton (Taylor and Houseman). The study was not carried out according to the rigours of modern study design and does not include any description of experimental methodology. No soil characterisation or meteorological data are reported.

The most likely method used to calculate the DT₅₀ values reported in the EU-DAR was found to be an unreasonable use of the data reported in Taylor and Houseman. (this DT50 was the original notifier’s proposal)

Overall, the study should be regarded as ‘not acceptable for risk assessment purposes’ in the EU-review process.”

Figure 1: Total carbosulfan and carbofuran residues in soil following application of Marshal 10G at Nether Poppleton, UK (1980): Rep 1

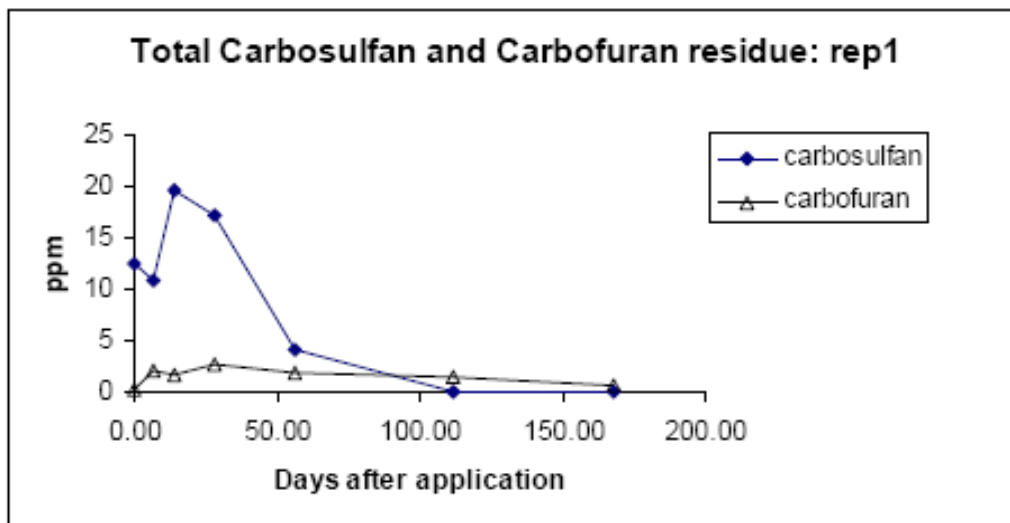
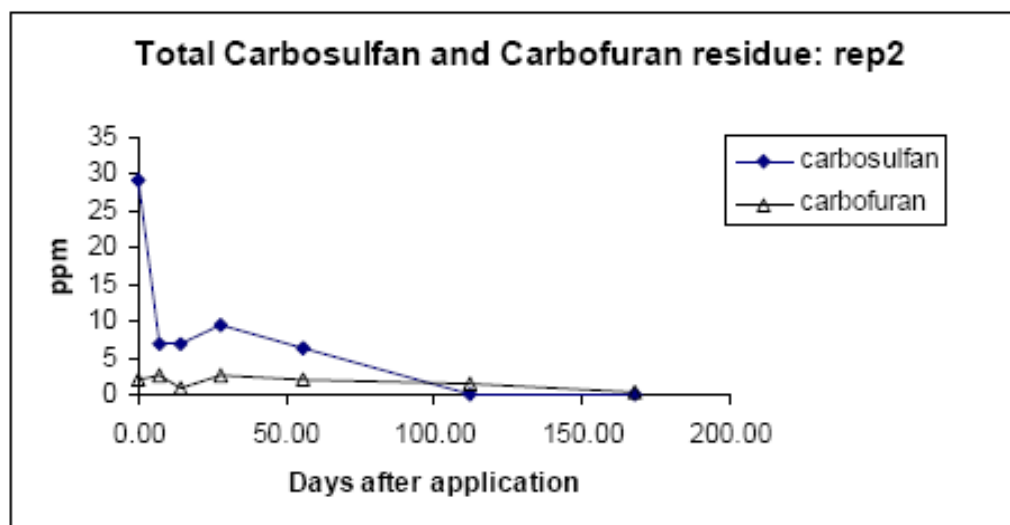


Figure 2: Total carbosulfan and carbofuran residues in soil following application of Marshal 10G at Nether Poppleton, UK (1980): Rep 2



Conclusions of the RMS:

The RMS agrees that the study by Taylor and Houseman, 1982 is of limited quality and probably not sufficient to derive accurate DT50.

It can be clearly seen from the 2 graphs that the carbosulfan residues are erratic and that the calculation of a DT50 from such data, particularly for carbofuran which is generated from carbosulfan would lead to inaccurate values

The RMS considered in the original DAR that all the studies that were performed in the United States were of limited quality (absence of DT50 determination in a large number of studies, protocol and report deficiencies,...) and could not be used in the final assessment.

5 field trials have been performed in European locations with formulations containing carbosulfan; 2 trials were performed with Marshal 25CS by spray application to bare soil. 3 trials were performed with Marshal 5G or 10G by granular application with soil incorporation. (Mol, 2002).

The maximum DT50 carbofuran of **27** days (Coria del Rio, Spain, Marshal 10G) has been proposed as input data for PECsoil calculations. Potential of soil accumulation can be excluded since there is maximum one application each year.

B.8.4.4 Water/sediment study (Annex IIA 7.2.1.3.2)

DT50 carbofuran

OVP	water	sed	total
0	4.91	0	4.91
0.25	20.41	8.95	29.36
1	34.86	14.81	49.67
2	58.26	19.84	78.1
6	44.12	16.68	60.8
14	24.53	11.82	36.35
30	4.84	6.49	11.33
59	0.52	1.35	1.87
103	0	0.62	0.62

In	SUMMARY OUTPUT OVP
0	4.35799
4	4.10759
12	3.593194
28	2.427454
57	0.625938
101	-0.47804

DT50	13.9
r2	0.96
DT90	46.3

<i>Regression Statistics</i>	
Multiple R	0.979339
R Square	0.959105
Adjusted R Square	0.948881
Standard Error	0.44759
Observations	6

ANOVA					
	df	SS	MS	F	Significance F
Regression	1	18.79395	18.79395	93.81162	0.000636
Residual	4	0.801349	0.200337		
Total	5	19.5953			

SW	water	sed	total
0	2.64	0	2.64
0.25	9.19	10.3	19.49
1	17.3	19.02	36.32
2	35.99	21.42	57.41
6	45.6	21.6	67.2
14	38	25.31	63.31
30	16.13	15.87	32
59	1.41	2.55	3.96
103	0.16	0.83	0.99

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%	
0	4.207673	4.113938	0.251582	16.35227	8.19E-05	3.415432	4.812443	3.415432	4.812443
8	4.148043	-0.04975	0.005136	-9.68564	0.000636	-0.06401	-0.03549	-0.06401	-0.03549
24	3.465736								
53	1.376244								
97	-0.01005								

SUMMARY OUTPUT SW	
<i>Regression Statistics</i>	
Multiple R	0.986284
R Square	0.972756
Adjusted R Square	0.963675
Standard Error	0.356988
Observations	5

DT50	14.8
r2	0.97
DT90	49.2

ANOVA

	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	13.65113	13.65113	107.1176	0.001924
Residual	3	0.382322	0.127441		
Total	4	14.03345			

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	4.340982	0.229298	18.93163	0.000322	3.611253	5.070711	3.611253	5.070711
X Variable 1	-0.0468	0.004522	-10.3498	0.001924	-0.06119	-0.03241	-0.06119	-0.03241

DT50 carbofuran-phenol

OVP	water	sed	total
0	0	0	0
0.25	0	1.3	1.3
1	0	1.46	1.46
2	0	3.29	3.29
6	0	8.63	8.63
14	0	13.64	13.64
30	0	6.35	6.35
59	0	2.2	2.2
103	0	0.64	0.64

In	SUMMARY OUTPUT OVP
	DT50 20.5
	r2 0.99
	DT90 68.1
	<u>Regression Statistics</u>
	Multiple R 0.994208
	R Square 0.988449
	Adjusted R Square 0.982674
	Standard Error 0.174901
	<u>Observations</u> 4
0	2.613007
16	1.848455
45	0.788457
89	-0.44629

	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	5.235526	5.235526	171.1504	0.005792
Residual	2	0.06118	0.03059		
Total	3	5.296707			

SW	water	sed	total
0	0	0	0
0.25	0	0.41	0.41
1	0	0.34	0.34
2	0	1.01	1.01
6	0	1.8	1.8
14	0	4.32	4.32

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	2.469205	0.130561	18.91228	0.002784	1.907446	3.030964	1.907446	3.030964
X Variable 1	-0.03382	0.002585	-13.0824	0.005792	-0.04494	-0.0227	-0.04494	-0.0227

30	0	3.66	3.66	16	1.297463
59	0	0	0.01	45	-4.60517
103	0	0.18	0.18		

SUMMARY OUTPUT SW

DT50	4.8
r2	0.89
DT90	16.1

<i>Regression Statistics</i>	
Multiple R	0.944625
R Square	0.892316
Adjusted R Square	0.784632
Standard Error	1.604195
Observations	3

ANOVA

	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	21.32468	21.32468	8.286446	0.212852
Residual	1	2.573441	2.573441		
Total	2	23.89812			

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	2.29586	1.371208	1.674334	0.342754	-15.1269	19.71863	-15.1269	19.71863
X Variable 1	-0.14315	0.049728	-2.87862	0.212852	-0.775	0.488704	-0.775	0.488704

ANNEX B

Addendum January 2009

Benfuracarb

B.8 Environmental fate and behaviour

Two new calculations of PEC_{gw} and PEC_{sw} have been provided by the notifier. These additional PEC are based on the new input data that have been proposed during the PRAPER meetings. As they are based on less favourable endpoints (extreme worst case lab DT₅₀ has been taken into consideration in the calculation of the median DT₅₀ soil of 14 days), it is obvious that the PEC are slightly less favourable.

The PEC_{gw} (PELMO, yearly application) calculations for carbofuran (most relevant residue) indicate that 5 out of 12 scenarios are acceptable. The PEC_{gw} (PELMO, biennial application) calculations indicate that 7 out of 12 scenarios are acceptable. The PEC_{gw} for benfuracarb and the other metabolites are negligible.

The PEC_{sw} (carbofuran, steps 3/4) are similar to the PEC_{sw} that have been calculated in the DAR (August 2009). No carbofuran residue has been detected in the run-off scenarios calculations. The PEC_{sw} calculations are higher for the new drift scenarios calculations. However, the maximum PEC_{sw} (for the scenario D6) are 0.163 and 0.123 µg/L, respectively for the calculations performed in the DAR (August 2008) and the addendum (January 2009)

B.8.6.1 Predicted environmental concentrations in ground water (PEC_{gw}) (Annex IIIA 9.21) (revised in January 2009)

Additional PEC_{gw} calculations following PRAPeR 62 meeting of 13-15 January 2009 concerning benfuracarb Prepared by NOTOX on January 21, 2009 PEC_{gw} benfuracarb and carbofuran

PEC_{gw} were estimated for benfuracarb and carbofuran using FOCUS-PELMO version 3.3.2. Model input was based on the recommendations in “FOCUS groundwater scenarios in the EU review of active substances” Sanco/321/2000 rev.2 and “Generic guidance for FOCUS groundwater scenarios” version 1.1 of April 2002. Annual applications were simulated for a period of 20 years with a six year "warm-up period". Simulations were performed for cabbage on 7 FOCUS locations.

According to GAP, the maximum dose of benfuracarb is 1 kg/ha. Benfuracarb is applied as a granulate at planting of the cabbage at a depth of approximately 2.5 cm. Therefore model inputs were 1 kg/ha with an incorporation depth of 2.5 cm. For certain FOCUS locations, two planting dates of cabbage were possible. For these FOCUS locations, simulations were performed for both planting dates (indicated as crop sequence 1 and 2; Sequence 1 spring (≈ March/April), sequence 2 summer (≈ June/July)). The timing of application was set at emergence + 7 days as the cabbage plants are at the 2 or 4 leaf stage at planting.

Input values for benfuracarb and carbofuran are summarised in Tables 1 and 2 and are in agreement with the outcome of PRAPeR 62.

All other substance parameters in FOCUS-PELMO were set at the default values recommended by the FOCUS document. All FOCUS runs were generated using the FOCUS wizard. Cabbage is not available for the Okehampton and Piacenza locations. Crop sequence 2 is not available for the Jokioinen and Thiva locations. The results of the modelling are shown in Table 3.

Parameter	Value	Source
water solubility	8.4 mg/L (20°C) at pH 7	(LoEP)
vapour pressure	4.2E-6 Pa (25°C)	(LoEP)
geometric mean soil DT ₅₀	0.42 d (20°C, moisture corrected)	PRAPeR 62
mean Koc soil	9.1E+3 L/kg	(LoEP)
1/n	1	PRAPeR 62
Application	1000 g a.i./ha	representative use Oncol 8.6G
Type of application	Soil incorporated (2.5 cm)	representative use Oncol 8.6G
Crop	Cabbage, 2 crop sequences	representative use Oncol 8.6G
Scenarios	Relevant FOCUS scenarios	FOCUS
MW	410.5	-

Table 2. Input values for PEC_{gw} calculations for Carbofuran

Parameter	Value	Source
water solubility	318.5 mg/L (20°C)	(mean value LoEP)
vapour pressure	8E-5 Pa (25°C)	(LoEP)
median soil DT ₅₀	14 d (20°C, moisture corrected)	PRAPeR 62
mean Koc soil	22 L/kg	(LoEP)
mean 1/n	0.96	(LoEP)
Formation fraction	1	PRAPeR 62
MW	221.3	-

Crop	scenario	Application date	80th percentile concentration in groundwater [µg/L] of:	
			Benfuracarb	Carbofuran
Cabbage (seq 1)	Chateaudun	April 27	<0.001	0.126
	Hamburg	April 27	<0.001	0.361
	Jokioinen	May 27	<0.001	0.294
	Kremsmunster	April 27	<0.001	0.122
	Porto	March 07	<0.001	0.007
	Sevilla	March 08	<0.001	<0.001
	Thiva	Aug 22	<0.001	0.101
Cabbage (seq 2)	Chateaudun	August 07	<0.001	0.134
	Hamburg	August 07	<0.001	2.664
	Kremsmunster	August 07	<0.001	0.430
	Porto	August 07	<0.001	0.032
	Sevilla	June 22	<0.001	<0.001

In all scenarios, estimated 80th percentile concentrations in groundwater were <0.001 µg/L for parent benfuracarb, clearly demonstrating that there are a considerable number of regions of the EU where benfuracarb in this formulation can be used without unacceptable risk with respect to groundwater contamination. Estimated 80th percentile concentrations in groundwater of the metabolite carbofuran were <0.001-2.664 µg/L, with concentrations ≤0.1 µg/L in 3 scenarios. The PELMO results demonstrate that there are sufficient regions of the EU where benfuracarb in this formulation can be used without unacceptable risk with respect to groundwater contamination associated with the metabolite carbofuran.

When introducing biennial applications in FOCUS-PELMO, also the Chateaudun scenario will result in PEC_{gw} <0.1µg/L.

PEC_{gw} 3-OH-carbofuran and 3-keto-carbofuran

The DT₅₀, Koc, 1/n and formation fraction (10%) proposed by PRAPeR 62 were implemented in the calculations the notifier provided as clarification (point 4.1 – point of clarification to the applicant) in the week of December 15-19, 2008 (submitted to RMS, EFSA and all MS).

These calculations confirm that PEC_{gw} of these metabolites are <0.001 µg/L for all scenarios.

Appendix: Input and output files for FOCUS-PELMO (PECgw)


```

1
*****
*
* PESTICIDE LEACHING MODEL
* PELMO 3.22, May 2002
* FOCUSPELMO 3.3.2
*
*
*****

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DEVELOPED BY:
U.S. ENVIRONMENTAL PROTECTION AGENCY
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AND
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DEPARTMENT ECOLOGY
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Tel ++ 49-6321-671-422

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PELMO 3.22, May 2002

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*****HYDROLOGY DATAS*****

```

YEAR 1: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 2: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 3: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 4: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 5: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 6: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 7: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 8: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 9: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 10: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 11: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 12: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 13: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 14: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 15: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 16: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 17: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 18: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 19: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 20: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 21: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 22: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 23: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 24: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 25: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc
YEAR 26: Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc

```

HYDROLOGY AND SEDIMENT RELATED PARAMETERS

Pan Evaporation data are used.

```

LATTITUDE OF THE LOCATION: 48.00
PAN COEFFICIENT FOR EVAPORATION 0.9700
FLAG FOR ET (0=EVAP,1=TEMP,2=EVAP/TEMP,3=HAUDE) 0
DEPTH TO WHICH ET IS COMPUTED YEAR-ROUND [CM] 20.00
SNOW MELT COEFFICIENT [CM/DEG-C-DAY] 0.4600
INITIAL CROP NUMBER 26

```

INITIAL CROP CONDITION

1

CALCULATION OF RUNOFF EVENTS BY USING RUNOFF-CURVENUMBERS
INFILTRATION DEPTH BEFORE RUNOFF EVENT STARTS [cm]: 5.00

CROP INFORMATION

CROP NUMBER	MAXIMUM INTERCEPT [CM]	MAXIMUM ROOT DEPTH [CM]	MAXIMUM COVER [%]	MAXIMUM WEIGHT [KG/M**2]	SURFACE CONDITION AFTER HARVEST	AMC	RUNOFF CURVE NUMBER		
							FALLOW	CROP	RES.
26	0.0000	60.00	70.00	0.0000	3	I	80	64	
							91	81	
							96	91	

CROP ROTATION INFORMATION

CROP NUMBER	EMERGENCE DATE	MATURATION DATE	HARVEST DATE
Cabbage	20 APR., 1	31 MAY., 1	15 JULY., 1
Cabbage	31 JULY., 1	5 SEP., 1	15 OCT., 1
Cabbage	20 APR., 2	31 MAY., 2	15 JULY., 2
Cabbage	31 JULY., 2	5 SEP., 2	15 OCT., 2
Cabbage	20 APR., 3	31 MAY., 3	15 JULY., 3
Cabbage	31 JULY., 3	5 SEP., 3	15 OCT., 3
Cabbage	20 APR., 4	31 MAY., 4	15 JULY., 4
Cabbage	31 JULY., 4	5 SEP., 4	15 OCT., 4
Cabbage	20 APR., 5	31 MAY., 5	15 JULY., 5
Cabbage	31 JULY., 5	5 SEP., 5	15 OCT., 5
Cabbage	20 APR., 6	31 MAY., 6	15 JULY., 6
Cabbage	31 JULY., 6	5 SEP., 6	15 OCT., 6
Cabbage	20 APR., 7	31 MAY., 7	15 JULY., 7
Cabbage	31 JULY., 7	5 SEP., 7	15 OCT., 7
Cabbage	20 APR., 8	31 MAY., 8	15 JULY., 8
Cabbage	31 JULY., 8	5 SEP., 8	15 OCT., 8
Cabbage	20 APR., 9	31 MAY., 9	15 JULY., 9
Cabbage	31 JULY., 9	5 SEP., 9	15 OCT., 9
Cabbage	20 APR., 10	31 MAY., 10	15 JULY., 10
Cabbage	31 JULY., 10	5 SEP., 10	15 OCT., 10
Cabbage	20 APR., 11	31 MAY., 11	15 JULY., 11
Cabbage	31 JULY., 11	5 SEP., 11	15 OCT., 11
Cabbage	20 APR., 12	31 MAY., 12	15 JULY., 12
Cabbage	31 JULY., 12	5 SEP., 12	15 OCT., 12
Cabbage	20 APR., 13	31 MAY., 13	15 JULY., 13
Cabbage	31 JULY., 13	5 SEP., 13	15 OCT., 13
Cabbage	20 APR., 14	31 MAY., 14	15 JULY., 14
Cabbage	31 JULY., 14	5 SEP., 14	15 OCT., 14
Cabbage	20 APR., 15	31 MAY., 15	15 JULY., 15
Cabbage	31 JULY., 15	5 SEP., 15	15 OCT., 15
Cabbage	20 APR., 16	31 MAY., 16	15 JULY., 16
Cabbage	31 JULY., 16	5 SEP., 16	15 OCT., 16
Cabbage	20 APR., 17	31 MAY., 17	15 JULY., 17
Cabbage	31 JULY., 17	5 SEP., 17	15 OCT., 17
Cabbage	20 APR., 18	31 MAY., 18	15 JULY., 18
Cabbage	31 JULY., 18	5 SEP., 18	15 OCT., 18
Cabbage	20 APR., 19	31 MAY., 19	15 JULY., 19
Cabbage	31 JULY., 19	5 SEP., 19	15 OCT., 19
Cabbage	20 APR., 20	31 MAY., 20	15 JULY., 20
Cabbage	31 JULY., 20	5 SEP., 20	15 OCT., 20
Cabbage	20 APR., 21	31 MAY., 21	15 JULY., 21
Cabbage	31 JULY., 21	5 SEP., 21	15 OCT., 21
Cabbage	20 APR., 22	31 MAY., 22	15 JULY., 22
Cabbage	31 JULY., 22	5 SEP., 22	15 OCT., 22
Cabbage	20 APR., 23	31 MAY., 23	15 JULY., 23
Cabbage	31 JULY., 23	5 SEP., 23	15 OCT., 23
Cabbage	20 APR., 24	31 MAY., 24	15 JULY., 24
Cabbage	31 JULY., 24	5 SEP., 24	15 OCT., 24
Cabbage	20 APR., 25	31 MAY., 25	15 JULY., 25
Cabbage	31 JULY., 25	5 SEP., 25	15 OCT., 25
Cabbage	20 APR., 26	31 MAY., 26	15 JULY., 26
Cabbage	31 JULY., 26	5 SEP., 26	15 OCT., 26
Cabbage	20 APR., 27	31 MAY., 27	15 JULY., 27
Cabbage	31 JULY., 27	5 SEP., 27	15 OCT., 27

Cabbage	20 APR., 28	31 MAY., 28	15 JULY., 28
Cabbage	31 JULY., 28	5 SEP., 28	15 OCT., 28
Cabbage	20 APR., 29	31 MAY., 29	15 JULY., 29
Cabbage	31 JULY., 29	5 SEP., 29	15 OCT., 29
Cabbage	20 APR., 30	31 MAY., 30	15 JULY., 30
Cabbage	31 JULY., 30	5 SEP., 30	15 OCT., 30
Cabbage	20 APR., 31	31 MAY., 31	15 JULY., 31
Cabbage	31 JULY., 31	5 SEP., 31	15 OCT., 31
Cabbage	20 APR., 32	31 MAY., 32	15 JULY., 32
Cabbage	31 JULY., 32	5 SEP., 32	15 OCT., 32
Cabbage	20 APR., 33	31 MAY., 33	15 JULY., 33
Cabbage	31 JULY., 33	5 SEP., 33	15 OCT., 33
Cabbage	20 APR., 34	31 MAY., 34	15 JULY., 34
Cabbage	31 JULY., 34	5 SEP., 34	15 OCT., 34
Cabbage	20 APR., 35	31 MAY., 35	15 JULY., 35
Cabbage	31 JULY., 35	5 SEP., 35	15 OCT., 35
Cabbage	20 APR., 36	31 MAY., 36	15 JULY., 36
Cabbage	31 JULY., 36	5 SEP., 36	15 OCT., 36
Cabbage	20 APR., 37	31 MAY., 37	15 JULY., 37
Cabbage	31 JULY., 37	5 SEP., 37	15 OCT., 37
Cabbage	20 APR., 38	31 MAY., 38	15 JULY., 38
Cabbage	31 JULY., 38	5 SEP., 38	15 OCT., 38
Cabbage	20 APR., 39	31 MAY., 39	15 JULY., 39
Cabbage	31 JULY., 39	5 SEP., 39	15 OCT., 39
Cabbage	20 APR., 40	31 MAY., 40	15 JULY., 40
Cabbage	31 JULY., 40	5 SEP., 40	15 OCT., 40
Cabbage	20 APR., 41	31 MAY., 41	15 JULY., 41
Cabbage	31 JULY., 41	5 SEP., 41	15 OCT., 41
Cabbage	20 APR., 42	31 MAY., 42	15 JULY., 42
Cabbage	31 JULY., 42	5 SEP., 42	15 OCT., 42
Cabbage	20 APR., 43	31 MAY., 43	15 JULY., 43
Cabbage	31 JULY., 43	5 SEP., 43	15 OCT., 43
Cabbage	20 APR., 44	31 MAY., 44	15 JULY., 44
Cabbage	31 JULY., 44	5 SEP., 44	15 OCT., 44
Cabbage	20 APR., 45	31 MAY., 45	15 JULY., 45
Cabbage	31 JULY., 45	5 SEP., 45	15 OCT., 45
Cabbage	20 APR., 46	31 MAY., 46	15 JULY., 46
Cabbage	31 JULY., 46	5 SEP., 46	15 OCT., 46
Cabbage	20 APR., 47	31 MAY., 47	15 JULY., 47
Cabbage	31 JULY., 47	5 SEP., 47	15 OCT., 47
Cabbage	20 APR., 48	31 MAY., 48	15 JULY., 48
Cabbage	31 JULY., 48	5 SEP., 48	15 OCT., 48
Cabbage	20 APR., 49	31 MAY., 49	15 JULY., 49
Cabbage	31 JULY., 49	5 SEP., 49	15 OCT., 49
Cabbage	20 APR., 50	31 MAY., 50	15 JULY., 50
Cabbage	31 JULY., 50	5 SEP., 50	15 OCT., 50
Cabbage	20 APR., 51	31 MAY., 51	15 JULY., 51
Cabbage	31 JULY., 51	5 SEP., 51	15 OCT., 51
Cabbage	20 APR., 52	31 MAY., 52	15 JULY., 52
Cabbage	31 JULY., 52	5 SEP., 52	15 OCT., 52
Cabbage	20 APR., 53	31 MAY., 53	15 JULY., 53
Cabbage	31 JULY., 53	5 SEP., 53	15 OCT., 53
Cabbage	20 APR., 54	31 MAY., 54	15 JULY., 54
Cabbage	31 JULY., 54	5 SEP., 54	15 OCT., 54
Cabbage	20 APR., 55	31 MAY., 55	15 JULY., 55
Cabbage	31 JULY., 55	5 SEP., 55	15 OCT., 55
Cabbage	20 APR., 56	31 MAY., 56	15 JULY., 56
Cabbage	31 JULY., 56	5 SEP., 56	15 OCT., 56
Cabbage	20 APR., 57	31 MAY., 57	15 JULY., 57
Cabbage	31 JULY., 57	5 SEP., 57	15 OCT., 57
Cabbage	20 APR., 58	31 MAY., 58	15 JULY., 58
Cabbage	31 JULY., 58	5 SEP., 58	15 OCT., 58
Cabbage	20 APR., 59	31 MAY., 59	15 JULY., 59
Cabbage	31 JULY., 59	5 SEP., 59	15 OCT., 59
Cabbage	20 APR., 60	31 MAY., 60	15 JULY., 60
Cabbage	31 JULY., 60	5 SEP., 60	15 OCT., 60
Cabbage	20 APR., 61	31 MAY., 61	15 JULY., 61
Cabbage	31 JULY., 61	5 SEP., 61	15 OCT., 61
Cabbage	20 APR., 62	31 MAY., 62	15 JULY., 62
Cabbage	31 JULY., 62	5 SEP., 62	15 OCT., 62
Cabbage	20 APR., 63	31 MAY., 63	15 JULY., 63
Cabbage	31 JULY., 63	5 SEP., 63	15 OCT., 63
Cabbage	20 APR., 64	31 MAY., 64	15 JULY., 64
Cabbage	31 JULY., 64	5 SEP., 64	15 OCT., 64
Cabbage	20 APR., 65	31 MAY., 65	15 JULY., 65
Cabbage	31 JULY., 65	5 SEP., 65	15 OCT., 65
Cabbage	20 APR., 66	31 MAY., 66	15 JULY., 66
Cabbage	31 JULY., 66	5 SEP., 66	15 OCT., 66

*** PARAMETERS OF ACTIVE SUBSTANCE ***

PESTICIDE APPLICATION INFORMATION

APPLICATION DATE	PESTICIDE APPLIED [KG/HA]	INCORPORATION DEPTH [CM]
27 APR., 1	1.000	0.2500E-01
27 APR., 2	1.000	0.2500E-01
27 APR., 3	1.000	0.2500E-01
27 APR., 4	1.000	0.2500E-01
27 APR., 5	1.000	0.2500E-01
27 APR., 6	1.000	0.2500E-01
27 APR., 7	1.000	0.2500E-01
27 APR., 8	1.000	0.2500E-01
27 APR., 9	1.000	0.2500E-01
27 APR., 10	1.000	0.2500E-01
27 APR., 11	1.000	0.2500E-01
27 APR., 12	1.000	0.2500E-01
27 APR., 13	1.000	0.2500E-01
27 APR., 14	1.000	0.2500E-01
27 APR., 15	1.000	0.2500E-01
27 APR., 16	1.000	0.2500E-01
27 APR., 17	1.000	0.2500E-01
27 APR., 18	1.000	0.2500E-01
27 APR., 19	1.000	0.2500E-01
27 APR., 20	1.000	0.2500E-01
27 APR., 21	1.000	0.2500E-01
27 APR., 22	1.000	0.2500E-01
27 APR., 23	1.000	0.2500E-01
27 APR., 24	1.000	0.2500E-01
27 APR., 25	1.000	0.2500E-01
27 APR., 26	1.000	0.2500E-01

PLANT PESTICIDE PARAMETERS

MODEL UTILIZED (1=SOIL, 2=LINEAR, 3=EXPONENTIAL) 1

VOLATILIZATION PARAMETERS ACTIVE SUBSTANCE

HENRY-CONSTANT [Pa*m3/mole] or [J/mole]	0.2052E-03
CALCULATED USING	
VAPOUR PRESSURE [Pa]	0.4200E-05
MOLECULAR MASS [g/mole]	410.5
WATER SOLUBILITY [mg/l]	8.400
DIFFUSION COEFF. AIR [cm ² /d]	4320.
DEPTH OF SURFACE LAYER FOR VOLATILIZATION [CM]	0.1000
HENRY CONSTANT [-]	0.8425387351E-07

PLANT UPTAKE OF ACTIVE SUBSTANCE

PLANT UPTAKE FACTOR (-) 0.5000

TRANSFORMATION PARAMETERS

TRANSFORM. TO	TRANSFORM. RATE [/DAY]	TEMP. OF STUDY [C]	Q10 VALUE [-]	MOISTURE-DURING-STUDY ABSOLUTE [%]	MOISTURE RELATIVE [%]	MOISTURE EXPONENT [-]
MET. A1	1.650	20.00	2.200	0.0000	100.0	0.7000

SORPTION PARAMETERS

--PARAMETERS TO CALCULATE KD-VALUES WITH KOC--
 KOC [CM**3/G] 9100.
 pKa 20.00
 PH DURING SORPTION STUDY 7.000
 FREUNDLICH-SORPTION EXPONENT 1/n 1.000
 MIN. CONC FOR FREUNDLICH-SORPTION [µG/L] 0.1000E-01
 INCREASE OF SORPTION PER YEAR [%]: 0.0000

DEPTH DEPENDENT SORPTION AND TRANSFORMATION PARAMETERS

HORIZON	KD [CM**3/G]	FR-EXP [-]	TRANSFORMATION RATE TO MET. A1 [/DAY]
1	126.5	1.000	1.650
2	84.63	1.000	0.8252
3	63.70	1.000	0.8252
4	27.30	1.000	0.4951
5	27.30	1.000	0.0000
6	24.57	1.000	0.0000
7	19.11	1.000	0.0000

*** PARAMETERS OF METABOLITE A1 ***

MOLMAS [g/mol] 221.3

PLANT UPTAKE

PLANT UPTAKE FACTOR (-) 0.5000

TRANSFORMATION PARAMETERS

TRANSFORM. TO	TRANSFORM. RATE [/DAY]	TEMP. OF STUDY [C]	Q10 VALUE [-]	MOISTURE-DURING-STUDY ABSOLUTE [%]	MOISTURE RELATIVE [%]	MOISTURE EXPONENT [-]
BR/CO2	0.4951E-01	20.00	2.200	0.0000	100.0	0.7000

SORPTION PARAMETERS

--PARAMETERS TO CALCULATE KD-VALUES WITH KOC--

KOC [CM**3/G] 22.00
pKa 20.00
PH DURING SORPTION STUDY 7.000
FREUNDLICH-SORPTION EXPONENT 1/n 0.9600
MIN. CONC FOR FREUNDLICH-SORPTION [µG/L] 0.1000E-01
INCREASE OF SORPTION PER YEAR [%]: 0.0000

DEPTH DEPENDENT SORPTION AND TRANSFORMATION PARAMETERS

HORIZON	KD [CM**3/G]	FR-EXP [-]	TRANSFORMATION RATE TO BR/CO2 [/DAY]
1	0.3058	0.9600	0.4951E-01
2	0.2046	0.9600	0.2476E-01
3	0.1540	0.9600	0.2476E-01
4	0.6600E-010	0.9600	0.1485E-01
5	0.6600E-010	0.9600	0.0000
6	0.5940E-010	0.9600	0.0000
7	0.4620E-010	0.9600	0.0000

(C) Onco1 S <Benfuracarb>

Ver 2 Chateaudun, cabbage

GENERAL SOIL INFORMATION

CORE DEPTH [CM] 260.0
TOTAL HORIZONS IN CORE 7
TOTAL COMPARTMENTS IN CORE 52
THETA FLAG (0=INPUT,1=PRZM 2=PELM) 0
PARTITION COEFFICIENT FLAG (0=INPUT,1=CALCULATED) 1
BULK DENSITY FLAG (0=INPUT,1=CALCULATED) 0
SOIL HYDRAULICS MODULE (0=HYDR1,1=HYDR2) 0

SOIL HORIZON INFORMATION

HORIZON	THICKNESS [CM]	BULK DENSITY [G/CM**3]	INITIAL SOIL WATER CONTENT [CM/CM]	DRAINAGE PARAMETER [1/DAY]	FIELD CAPACITY WATER CONTENT [CM/CM]	WILTING POINT WATER CONTENT [CM/CM]	DISPERSION COEFF [CM**2/DAY]	ORGANIC CARBON [%]
1	25.0000	1.3000	0.3740	0.1970	0.3740	0.2530	0.0000	1.3900
2	25.0000	1.4100	0.3720	0.1950	0.3720	0.2350	0.0000	0.9300
3	10.0000	1.4100	0.3720	0.2130	0.3720	0.2350	0.0000	0.7000
4	40.0000	1.3700	0.3860	0.2650	0.3860	0.1850	0.0000	0.3000
5	20.0000	1.3700	0.3860	0.2650	0.3860	0.1850	0.0000	0.3000
6	70.0000	1.4100	0.4170	0.2960	0.4170	0.1160	0.0000	0.2700
7	70.0000	1.4900	0.3620	0.2050	0.3620	0.1760	0.0000	0.2100

OUTPUT FILE PARAMETERS

OUTPUT	TIME STEP	LAYER	FREQ
WATR	YEAR		1
PEST	YEAR		1
CONC	YEAR		1

PLOT FILE INFORMATION

NUMBER OF PLOTTING VARIABLES

25

TIMSER NAME	MODE	ARGUMENT	CONSTANT
TETD	TSER	0	0.0000
INFL	TSER	21	0.0000
INFL	TSER	53	0.0000
PRCP	TSER	0	0.0000
RUNP	TSER	0	0.0000
ESLS	TSER	0	0.0000
THET	TSER	1	0.0000
THET	TSER	20	0.0000
THET	TSER	52	0.0000
TEMP	TSER	1	0.0000
TEMP	TSER	20	0.0000
TEMP	TSER	52	0.0000
TPAP	TSER	1	0.1000E+06
TPST	TSER	1	0.0000
TPST	TSER	2	0.0000
TPST	TSER	3	0.0000
TPST	TSER	4	0.0000
TDKF	TSER	52	0.1000E+06
APLX	TSER	20	0.1000E+06
APLX	TSER	52	0.1000E+06
RFLX	TSER	0	0.1000E+06
EFLX	TSER	0	0.1000E+06
TUPP	TSER	0	0.1000E+06
TVOX	TSER	0	0.1000E+06
SNOP	TSER	0	0.0000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Châteaudun, cabbage
(C) Oncol S <Benfuracarb>
Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000

Total	0.0E+00	4411.70	0.000
80 Perc. (10)	0.0E+00	252.500	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	9.9E-06	142.100	0.000
2	0.00064	113.200	0.001
3	0.00568	131.800	0.004
4	0.00986	168.100	0.006
5	0.04451	172.700	0.026
6	0.07894	182.900	0.043

7	0.10290	312.500	0.033
8	0.07333	136.100	0.054
9	0.10140	265.900	0.038
10	0.31800	252.500	0.126
11	0.28090	344.700	0.081
12	0.31130	257.900	0.121
13	0.27630	299.600	0.092
14	0.14000	260.600	0.054
15	0.21840	166.300	0.131
16	0.23670	361.700	0.065
17	0.52100	149.500	0.348
18	0.05529	204.600	0.027
19	0.04727	232.400	0.020
20	0.46030	257.300	0.179
21	0.02530	141.400	0.018
22	0.00338	113.200	0.003
23	0.00592	131.800	0.004
24	0.00986	168.100	0.006
25	0.04451	172.700	0.026
26	0.07894	182.900	0.043

Total	3.31100	4411.70	0.075
80 Perc. (10)	0.31800	252.500	0.126

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000

Total	0.0E+00	4411.70	0.000
80 Perc. (10)	0.0E+00	252.500	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	4.5E-16	113.200	0.000
3	4.1E-11	131.800	0.000
4	2.3E-07	168.100	0.000
5	0.00002	172.700	0.000
6	0.00053	182.900	0.000

7	0.01067	312.500	0.003
8	0.01824	136.100	0.013
9	0.07115	265.900	0.027
10	0.07976	252.500	0.032
11	0.15590	344.700	0.045
12	0.16840	257.900	0.065
13	0.30000	299.600	0.100
14	0.26410	260.600	0.101
15	0.17820	166.300	0.107
16	0.33060	361.700	0.091
17	0.10620	149.500	0.071
18	0.15770	204.600	0.077
19	0.16240	232.400	0.070
20	0.38090	257.300	0.148
21	0.21910	141.400	0.155
22	0.10720	113.200	0.095
23	0.07768	131.800	0.059
24	0.13720	168.100	0.082
25	0.19880	172.700	0.115
26	0.13600	182.900	0.074

Total	3.26020	4411.70	0.074
80 Perc. (15)	0.17820	166.300	0.107

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)

Ver 2 Châteaudun, cabbage

(C) Oncol 5 <Benfuracarb>

Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	312.500	0.000

*** POCUSPELMO 3, 3, 2 *** (PELMO 3.22)
Ver 2 Hamburg, cabbage
(H) Oncol S <Benfuracarb>
Ver 2 Hamburg scenario (53.63 N, 10.00 E) Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	134.600	0.000
2	0.0E+00	125.700	0.000
3	0.0E+00	227.300	0.000
4	0.0E+00	253.700	0.000
5	0.0E+00	387.100	0.000
6	0.0E+00	436.000	0.000

7	0.0E+00	118.300	0.000
8	0.0E+00	147.100	0.000
9	0.0E+00	252.400	0.000
10	0.0E+00	292.000	0.000
11	0.0E+00	220.900	0.000
12	0.0E+00	435.000	0.000
13	0.0E+00	406.800	0.000
14	0.0E+00	183.100	0.000
15	0.0E+00	371.300	0.000
16	0.0E+00	273.300	0.000
17	0.0E+00	177.600	0.000
18	0.0E+00	224.800	0.000
19	0.0E+00	251.800	0.000
20	0.0E+00	300.600	0.000
21	0.0E+00	134.600	0.000
22	0.0E+00	125.700	0.000
23	0.0E+00	227.300	0.000
24	0.0E+00	253.700	0.000
25	0.0E+00	387.100	0.000
26	0.0E+00	436.000	0.000

Total	0.0E+00	5219.40	0.000
80 Perc. (10)	0.0E+00	292.000	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00007	134.600	0.000
2	0.00821	125.700	0.007
3	0.08324	227.300	0.037
4	0.27880	253.700	0.110
5	1.29500	387.100	0.335
6	1.57500	436.000	0.361

7	0.43610	118.300	0.369
8	0.05572	147.100	0.038
9	0.10420	252.400	0.041
10	0.30420	292.000	0.104
11	0.65920	220.900	0.298
12	5.82600	435.000	1.339
13	2.48800	406.800	0.612
14	0.64440	183.100	0.352
15	0.48550	371.300	0.131
16	0.48970	273.300	0.179
17	0.35190	177.600	0.198
18	0.28300	224.800	0.126
19	0.26440	251.800	0.105
20	0.69470	300.600	0.231
21	0.03667	134.600	0.027
22	0.01601	125.700	0.013
23	0.08373	227.300	0.037
24	0.27880	253.700	0.110
25	1.29500	387.100	0.335
26	1.57500	436.000	0.361

Total	16.3722	5219.40	0.314
80 Perc. (26)	1.57500	436.000	0.361

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	134.600	0.000
2	0.0E+00	125.700	0.000
3	0.0E+00	227.300	0.000
4	0.0E+00	253.700	0.000
5	0.0E+00	387.100	0.000
6	0.0E+00	436.000	0.000

7	0.0E+00	118.300	0.000
8	0.0E+00	147.100	0.000
9	0.0E+00	252.400	0.000
10	0.0E+00	292.000	0.000
11	0.0E+00	220.900	0.000
12	0.0E+00	435.000	0.000
13	0.0E+00	406.800	0.000
14	0.0E+00	183.100	0.000
15	0.0E+00	371.300	0.000
16	0.0E+00	273.300	0.000
17	0.0E+00	177.600	0.000
18	0.0E+00	224.800	0.000
19	0.0E+00	251.800	0.000
20	0.0E+00	300.600	0.000
21	0.0E+00	134.600	0.000
22	0.0E+00	125.700	0.000
23	0.0E+00	227.300	0.000
24	0.0E+00	253.700	0.000
25	0.0E+00	387.100	0.000
26	0.0E+00	436.000	0.000

Total	0.0E+00	5219.40	0.000
80 Perc. (10)	0.0E+00	292.000	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	6.4E-10	134.600	0.000
2	0.00017	125.700	0.000
3	0.02819	227.300	0.012
4	0.18320	253.700	0.072
5	0.54550	387.100	0.141
6	2.20500	436.000	0.506

7	0.17040	118.300	0.144
8	0.45130	147.100	0.307
9	0.17940	252.400	0.071
10	0.17550	292.000	0.060
11	0.45320	220.900	0.206
12	2.41200	435.000	0.554
13	6.01000	406.800	1.477
14	0.42710	183.100	0.233
15	0.84650	371.300	0.228
16	0.38990	273.300	0.143
17	0.31210	177.600	0.176
18	0.39630	224.800	0.176
19	0.27650	251.800	0.110
20	0.60030	300.600	0.200
21	0.24630	134.600	0.183
22	0.04440	125.700	0.035
23	0.04674	227.300	0.021
24	0.18350	253.700	0.072
25	0.54590	387.100	0.141
26	2.20500	436.000	0.506

Total	16.3723	5219.40	0.314
80 Perc. (8)	0.45130	147.100	0.307

*** POCUSPELMO 3. 3. 2 *** (PELMO 3.22)

Ver 2 Hamburg, cabbage

(H) Oncol 3 <Benfuracarb>

Ver 2 Hamburg scenario (53.63 N, 10.00 E) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	118.300	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Jokioinen, cabbage
(J) Oncol S <Benfuracarb>
Ver 2 Jokioinen scenario (60.82 N, 23.5 E) Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	20.5700	0.000
2	0.0E+00	62.7900	0.000
3	0.0E+00	308.900	0.000
4	0.0E+00	310.900	0.000
5	0.0E+00	159.600	0.000
6	0.0E+00	143.000	0.000

7	0.0E+00	146.800	0.000
8	0.0E+00	80.1900	0.000
9	0.0E+00	232.600	0.000
10	0.0E+00	333.500	0.000
11	0.0E+00	195.100	0.000
12	0.0E+00	216.000	0.000
13	0.0E+00	358.700	0.000
14	0.0E+00	185.500	0.000
15	0.0E+00	286.400	0.000
16	0.0E+00	234.100	0.000
17	0.0E+00	190.600	0.000
18	0.0E+00	126.900	0.000
19	0.0E+00	23.0300	0.000
20	0.0E+00	36.0200	0.000
21	0.0E+00	25.2500	0.000
22	0.0E+00	62.7900	0.000
23	0.0E+00	308.900	0.000
24	0.0E+00	310.900	0.000
25	0.0E+00	159.600	0.000
26	0.0E+00	143.000	0.000

Total	0.0E+00	3655.88	0.000
80 Perc. (10)	0.0E+00	333.500	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	20.5700	0.000
2	5.4E-06	62.7900	0.000
3	0.05932	308.900	0.019
4	0.72140	310.900	0.232
5	0.24460	159.600	0.153
6	0.13280	143.000	0.093

7	0.08036	146.800	0.055
8	0.04451	80.1900	0.056
9	0.11120	232.600	0.048
10	0.99800	333.500	0.299
11	1.20900	195.100	0.620
12	0.26140	216.000	0.121
13	1.05300	358.700	0.294
14	1.21700	185.500	0.656
15	0.33870	286.400	0.118
16	0.61580	234.100	0.263
17	0.28540	190.600	0.150
18	0.13470	126.900	0.106
19	0.01583	23.0300	0.069
20	0.00609	36.0200	0.017
21	0.00116	25.2500	0.005
22	0.00067	62.7900	0.001
23	0.06084	308.900	0.020
24	0.72150	310.900	0.232
25	0.24460	159.600	0.153
26	0.13280	143.000	0.093

Total	7.53256	3655.88	0.206
80 Perc. (13)	1.05300	358.700	0.294

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	20.5700	0.000
2	0.0E+00	62.7900	0.000
3	0.0E+00	308.900	0.000
4	0.0E+00	310.900	0.000
5	0.0E+00	159.600	0.000
6	0.0E+00	143.000	0.000

7	0.0E+00	146.800	0.000
8	0.0E+00	80.1900	0.000
9	0.0E+00	232.600	0.000
10	0.0E+00	333.500	0.000
11	0.0E+00	195.100	0.000
12	0.0E+00	216.000	0.000
13	0.0E+00	358.700	0.000
14	0.0E+00	185.500	0.000
15	0.0E+00	286.400	0.000
16	0.0E+00	234.100	0.000
17	0.0E+00	190.600	0.000
18	0.0E+00	126.900	0.000
19	0.0E+00	23.0300	0.000
20	0.0E+00	36.0200	0.000
21	0.0E+00	25.2500	0.000
22	0.0E+00	62.7900	0.000
23	0.0E+00	308.900	0.000
24	0.0E+00	310.900	0.000
25	0.0E+00	159.600	0.000
26	0.0E+00	143.000	0.000

Total	0.0E+00	3655.88	0.000
80 Perc. (10)	0.0E+00	333.500	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	20.5700	0.000
2	1.6E-09	62.7900	0.000
3	0.00877	308.900	0.003
4	0.54990	310.900	0.177
5	0.28330	159.600	0.178
6	0.19760	143.000	0.138

7	0.12820	146.800	0.087
8	0.04744	80.1900	0.059
9	0.10850	232.600	0.047
10	0.59990	333.500	0.180
11	1.00500	195.100	0.515
12	0.81570	216.000	0.378
13	0.74290	358.700	0.207
14	0.87940	185.500	0.474
15	0.98330	286.400	0.343
16	0.45620	234.100	0.195
17	0.39060	190.600	0.205
18	0.17520	126.900	0.138
19	0.03011	23.0300	0.131
20	0.04178	36.0200	0.116
21	0.02412	25.2500	0.096
22	0.04107	62.7900	0.065
23	0.03295	308.900	0.011
24	0.55030	310.900	0.177
25	0.28330	159.600	0.178
26	0.19760	143.000	0.138

Total	7.53357	3655.88	0.206
80 Perc. (15)	0.98330	286.400	0.343

*** FOCUSPELMO 3. 3. 2 *** (PELMO 3.22)

Ver 2 Jokioinen, cabbage

(J) Oncol S <Benfuracarb>

Ver 2 Jokioinen scenario (60.82 N, 23.5 E) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	146.800	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Kremsmünster, cabbage
(K) Oncol 5 <Benfuracarb>
Ver 2 Kremsmünster scenario (48.05 N, 14.13 E) Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	176.900	0.000
2	0.0E+00	16.4700	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	315.800	0.000
5	0.0E+00	185.300	0.000
6	0.0E+00	182.600	0.000

7	0.0E+00	303.600	0.000
8	0.0E+00	225.400	0.000
9	0.0E+00	378.400	0.000
10	0.0E+00	345.200	0.000
11	0.0E+00	340.000	0.000
12	0.0E+00	238.800	0.000
13	0.0E+00	359.200	0.000
14	0.0E+00	227.600	0.000
15	0.0E+00	142.200	0.000
16	0.0E+00	204.900	0.000
17	0.0E+00	225.800	0.000
18	0.0E+00	196.700	0.000
19	0.0E+00	250.200	0.000
20	0.0E+00	200.700	0.000
21	0.0E+00	176.200	0.000
22	0.0E+00	16.4700	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	315.800	0.000
25	0.0E+00	185.300	0.000
26	0.0E+00	182.600	0.000

Total	0.0E+00	4515.07	0.000
80 Perc. (10)	0.0E+00	345.200	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00323	176.900	0.002
2	0.00252	16.4700	0.015
3	0.0E+00	0.0E+00	0.000
4	0.02300	315.800	0.007
5	0.04086	185.300	0.022
6	0.09155	182.600	0.050

7	0.04480	303.600	0.015
8	0.18730	225.400	0.083
9	0.34890	378.400	0.092
10	0.72930	345.200	0.211
11	1.53200	340.000	0.451
12	0.13930	238.800	0.058
13	0.32350	359.200	0.090
14	0.29820	227.600	0.131
15	0.07406	142.200	0.052
16	0.02569	204.900	0.013
17	0.23510	225.800	0.104
18	0.23780	196.700	0.121
19	0.15550	250.200	0.062
20	0.24510	200.700	0.122
21	0.02856	176.200	0.016
22	0.00322	16.4700	0.020
23	0.0E+00	0.0E+00	0.000
24	0.02304	315.800	0.007
25	0.04086	185.300	0.022
26	0.09155	182.600	0.050

Total	4.76378	4515.07	0.106
80 Perc. (20)	0.24510	200.700	0.122

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	176.900	0.000
2	0.0E+00	16.4700	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	315.800	0.000
5	0.0E+00	185.300	0.000
6	0.0E+00	182.600	0.000

7	0.0E+00	303.600	0.000
8	0.0E+00	225.400	0.000
9	0.0E+00	378.400	0.000
10	0.0E+00	345.200	0.000
11	0.0E+00	340.000	0.000
12	0.0E+00	238.800	0.000
13	0.0E+00	359.200	0.000
14	0.0E+00	227.600	0.000
15	0.0E+00	142.200	0.000
16	0.0E+00	204.900	0.000
17	0.0E+00	225.800	0.000
18	0.0E+00	196.700	0.000
19	0.0E+00	250.200	0.000
20	0.0E+00	200.700	0.000
21	0.0E+00	176.200	0.000
22	0.0E+00	16.4700	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	315.800	0.000
25	0.0E+00	185.300	0.000
26	0.0E+00	182.600	0.000

Total	0.0E+00	4515.07	0.000
80 Perc. (10)	0.0E+00	345.200	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	8.9E-10	176.900	0.000
2	1.9E-09	16.4700	0.000
3	0.0E+00	0.0E+00	0.000
4	0.00053	315.800	0.000
5	0.00314	185.300	0.002
6	0.00945	182.600	0.005

7	0.06688	303.600	0.022
8	0.07092	225.400	0.031
9	0.16380	378.400	0.043
10	0.30120	345.200	0.087
11	0.58340	340.000	0.172
12	0.83660	238.800	0.350
13	1.00500	359.200	0.280
14	0.15480	227.600	0.068
15	0.12550	142.200	0.088
16	0.28330	204.900	0.138
17	0.18480	225.800	0.082
18	0.07197	196.700	0.037
19	0.18660	250.200	0.075
20	0.21390	200.700	0.107
21	0.15430	176.200	0.088
22	0.01386	16.4700	0.084
23	0.0E+00	0.0E+00	0.000
24	0.27160	315.800	0.086
25	0.05682	185.300	0.031
26	0.01816	182.600	0.010

Total	4.76341	4515.07	0.106
80 Perc. (16)	0.28330	204.900	0.138

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)

Ver 2 Kremmünster, cabbage

(K) Oncol 8 <Benfuracarb>

Ver 2 Kremmünster scenario (48.05 N, 14.13 E) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	303.600	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Porto, cabbage
(O) Oncol S <Benfuracarb>
Ver 2 Porto scenario (41.23 N, 8.68 W) Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	355.200	0.000
2	0.0E+00	383.200	0.000
3	0.0E+00	476.100	0.000
4	0.0E+00	96.4200	0.000
5	0.0E+00	299.800	0.000
6	0.0E+00	353.900	0.000

7	0.0E+00	442.800	0.000
8	0.0E+00	629.000	0.000
9	0.0E+00	705.700	0.000
10	0.0E+00	643.400	0.000
11	0.0E+00	721.500	0.000
12	0.0E+00	341.900	0.000
13	0.0E+00	416.700	0.000
14	0.0E+00	497.200	0.000
15	0.0E+00	406.700	0.000
16	0.0E+00	623.500	0.000
17	0.0E+00	556.100	0.000
18	0.0E+00	542.300	0.000
19	0.0E+00	698.900	0.000
20	0.0E+00	350.500	0.000
21	0.0E+00	338.500	0.000
22	0.0E+00	383.200	0.000
23	0.0E+00	476.100	0.000
24	0.0E+00	96.4200	0.000
25	0.0E+00	299.800	0.000
26	0.0E+00	353.900	0.000

Total	0.0E+00	9524.12	0.000
80 Perc. (10)	0.0E+00	643.400	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	4.1E-06	355.200	0.000
2	0.00016	383.200	0.000
3	0.00107	476.100	0.000
4	0.00002	96.4200	0.000
5	0.00004	299.800	0.000
6	0.00084	353.900	0.000

7	0.00259	442.800	0.001
8	0.00476	629.000	0.001
9	0.06657	705.700	0.009
10	0.02080	643.400	0.003
11	0.05291	721.500	0.007
12	0.03199	341.900	0.009
13	0.00186	416.700	0.000
14	0.00259	497.200	0.001
15	0.00130	406.700	0.000
16	0.02379	623.500	0.004
17	0.02303	556.100	0.004
18	0.00729	542.300	0.001
19	0.00680	698.900	0.001
20	0.02986	350.500	0.009
21	0.00031	338.500	0.000
22	0.00017	383.200	0.000
23	0.00107	476.100	0.000
24	0.00002	96.4200	0.000
25	0.00004	299.800	0.000
26	0.00084	353.900	0.000

Total	0.27859	9524.12	0.003
80 Perc. (11)	0.05291	721.500	0.007

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	355.200	0.000
2	0.0E+00	383.200	0.000
3	0.0E+00	476.100	0.000
4	0.0E+00	96.4200	0.000
5	0.0E+00	299.800	0.000
6	0.0E+00	353.900	0.000

7	0.0E+00	442.800	0.000
8	0.0E+00	629.000	0.000
9	0.0E+00	705.700	0.000
10	0.0E+00	643.400	0.000
11	0.0E+00	721.500	0.000
12	0.0E+00	341.900	0.000
13	0.0E+00	416.700	0.000
14	0.0E+00	497.200	0.000
15	0.0E+00	406.700	0.000
16	0.0E+00	623.500	0.000
17	0.0E+00	556.100	0.000
18	0.0E+00	542.300	0.000
19	0.0E+00	698.900	0.000
20	0.0E+00	350.500	0.000
21	0.0E+00	338.500	0.000
22	0.0E+00	383.200	0.000
23	0.0E+00	476.100	0.000
24	0.0E+00	96.4200	0.000
25	0.0E+00	299.800	0.000
26	0.0E+00	353.900	0.000

Total	0.0E+00	9524.12	0.000
80 Perc. (10)	0.0E+00	643.400	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	6.5E-08	355.200	0.000
2	0.000007	383.200	0.000
3	0.000058	476.100	0.000
4	0.000024	96.4200	0.000
5	0.000033	299.800	0.000
6	0.000040	353.900	0.000

7	0.00158	442.800	0.000
8	0.00223	629.000	0.000
9	0.05846	705.700	0.008
10	0.02651	643.400	0.004
11	0.04633	721.500	0.006
12	0.02434	341.900	0.007
13	0.02115	416.700	0.005
14	0.00309	497.200	0.001
15	0.00135	406.700	0.000
16	0.01841	623.500	0.003
17	0.02194	556.100	0.004
18	0.01183	542.300	0.002
19	0.00517	698.900	0.001
20	0.01433	350.500	0.004
21	0.01841	338.500	0.005
22	0.00187	383.200	0.000
23	0.00062	476.100	0.000
24	0.00024	96.4200	0.000
25	0.00033	299.800	0.000
26	0.00040	353.900	0.000

Total	0.27859	9524.12	0.003
80 Perc. (21)	0.01841	338.500	0.005

*** FOCUSPELMO 3. 3. 2 *** (PELMO 3.22)

Ver 2 Porto, cabbage

(O) Oncol 8 <Benfuracarb>

Ver 2 Porto scenario (41.23 N, 9.68 W) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	442.800	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Sevilla, cabbage
(S) Oncol S <Benfuracarb>
Ver 2 SEVILLA scenario (37.42 N, 5.88 W) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	135.000	0.000
2	0.0E+00	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	0.0E+00	53.5600	0.000
9	0.0E+00	101.100	0.000
10	0.0E+00	50.8900	0.000
11	0.0E+00	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	0.0E+00	6.38200	0.000
15	0.0E+00	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	0.0E+00	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.0E+00	116.400	0.000
22	0.0E+00	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.0E+00	486.742	0.000
80 Perc. (10)	0.0E+00	50.8900	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00002	135.000	0.000
2	0.00002	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	2.9E-07	53.5600	0.000
9	0.00016	101.100	0.000
10	7.9E-06	50.8900	0.000
11	0.00003	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	5.9E-12	6.38200	0.000
15	5.6E-09	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	8.3E-09	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.00004	116.400	0.000
22	0.00005	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.00028	486.742	0.000
80 Perc. (11)	0.00003	95.6500	0.000

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	135.000	0.000
2	0.0E+00	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	0.0E+00	53.5600	0.000
9	0.0E+00	101.100	0.000
10	0.0E+00	50.8900	0.000
11	0.0E+00	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	0.0E+00	6.38200	0.000
15	0.0E+00	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	0.0E+00	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.0E+00	116.400	0.000
22	0.0E+00	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.0E+00	486.742	0.000
80 Perc. (10)	0.0E+00	50.8900	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	4.1E-12	135.000	0.000
2	1.4E-11	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	1.2E-09	53.5600	0.000
9	1.4E-07	101.100	0.000
10	5.7E-07	50.8900	0.000
11	4.8E-06	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	5.9E-07	6.38200	0.000
15	1.7E-06	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	3.9E-06	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.00003	116.400	0.000
22	9.4E-06	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.00006	486.742	0.000
80 Perc. (15)	1.7E-06	15.0000	0.000

*** FOCUSPELMO 3, 3, 2 *** (PELMO 3.22)

Ver 2 Sevilla, cabbage

(S) Oncol S <Benfuracarb>

Ver 2 SEVILLA scenario (37.42 N, 5.88 W) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	0.0E+00	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
 Ver 2 Thiva, cabbage
 (T) Oncol S <Benfuracarb>
 Ver 2 THIVA scenario (38.32 N, 23.32 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	7.44100	0.000
2	0.0E+00	13.9000	0.000
3	0.0E+00	86.2200	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	3.04800	0.000

7	0.0E+00	193.100	0.000
8	0.0E+00	197.300	0.000
9	0.0E+00	26.1600	0.000
10	0.0E+00	204.300	0.000
11	0.0E+00	242.100	0.000
12	0.0E+00	150.700	0.000
13	0.0E+00	225.400	0.000
14	0.0E+00	158.800	0.000
15	0.0E+00	185.800	0.000
16	0.0E+00	102.600	0.000
17	0.0E+00	166.900	0.000
18	0.0E+00	156.300	0.000
19	0.0E+00	141.100	0.000
20	0.0E+00	240.700	0.000
21	0.0E+00	0.0E+00	0.000
22	0.0E+00	13.9000	0.000
23	0.0E+00	86.2200	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	3.04800	0.000

Total	0.0E+00	2494.43	0.000
80 Perc. (10)	0.0E+00	204.300	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	7.44100	0.000
2	1.3E-08	13.9000	0.000
3	0.00044	86.2200	0.001
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	5.3E-10	3.04800	0.000

7	0.00645	193.100	0.003
8	0.23890	197.300	0.121
9	0.00506	26.1600	0.019
10	0.00783	204.300	0.004
11	0.24500	242.100	0.101
12	1.29400	150.700	0.859
13	0.04671	225.400	0.021
14	0.08503	158.800	0.054
15	0.10230	185.800	0.055
16	0.54310	102.600	0.529
17	0.02671	166.900	0.016
18	0.02987	156.300	0.019
19	0.00512	141.100	0.004
20	0.09199	240.700	0.038
21	0.0E+00	0.0E+00	0.000
22	1.2E-06	13.9000	0.000
23	0.00046	86.2200	0.001
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	5.3E-10	3.04800	0.000

Total	2.72852	2494.43	0.109
80 Perc. (11)	0.24500	242.100	0.101

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	0.74410	0.000
2	0.0E+00	13.9000	0.000
3	0.0E+00	86.2200	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	3.04800	0.000

7	0.0E+00	193.100	0.000
8	0.0E+00	197.300	0.000
9	0.0E+00	26.1600	0.000
10	0.0E+00	204.300	0.000
11	0.0E+00	242.100	0.000
12	0.0E+00	150.700	0.000
13	0.0E+00	225.400	0.000
14	0.0E+00	158.800	0.000
15	0.0E+00	185.800	0.000
16	0.0E+00	102.600	0.000
17	0.0E+00	166.900	0.000
18	0.0E+00	156.300	0.000
19	0.0E+00	141.100	0.000
20	0.0E+00	240.700	0.000
21	0.0E+00	0.0E+00	0.000
22	0.0E+00	13.9000	0.000
23	0.0E+00	86.2200	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	3.04800	0.000

Total	0.0E+00	2494.43	0.000
80 Perc. (10)	0.0E+00	204.300	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	0.74410	0.000
2	0.0E+00	13.9000	0.000
3	6.0E-11	86.2200	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	1.4E-11	3.04800	0.000

7	8.8E-06	193.100	0.000
8	0.00037	197.300	0.000
9	0.00027	26.1600	0.001
10	0.05153	204.300	0.025
11	0.16800	242.100	0.069
12	0.03631	150.700	0.024
13	0.30800	225.400	0.137
14	0.75720	158.800	0.477
15	0.45770	185.800	0.246
16	0.07923	102.600	0.077
17	0.07829	166.900	0.047
18	0.21670	156.300	0.139
19	0.28760	141.100	0.204
20	0.16990	240.700	0.071
21	0.0E+00	0.0E+00	0.000
22	0.00312	13.9000	0.022
23	0.01556	86.2200	0.018
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.00653	3.04800	0.017

Total	2.63032	2494.43	0.105
80 Perc. (18)	0.21670	156.300	0.139

*** FOCUSPELMO 3. 3. 2 *** (PELMO 3.22)

Ver 2 Thiva, cabbage

(T) Oncol S <Benfuracarb>

Ver 2 THIVA scenario (38.32 N, 23.32 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	193.100	0.000

*** FOCUSPELMO 3. 3. 2 *** (PELMO 3.2.2)
Ver 2 Châteaudun, cabbage
(C) Oncol S <Benfuracarb>
Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000

Total	0.0E+00	4411.70	0.000
80 Perc. (10)	0.0E+00	252.500	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	7.5E-08	142.100	0.000
2	0.00003	113.200	0.000
3	0.00099	131.800	0.001
4	0.00178	168.100	0.001
5	0.01225	172.700	0.007
6	0.07891	182.900	0.043

7	0.11840	312.500	0.038
8	0.04573	136.100	0.034
9	0.26910	265.900	0.101
10	0.17710	252.500	0.070
11	0.17410	344.700	0.051
12	0.34680	257.900	0.134
13	0.18220	299.600	0.061
14	0.07725	260.600	0.030
15	0.30210	166.300	0.182
16	0.20310	361.700	0.056
17	0.92110	149.500	0.616
18	0.17200	204.600	0.084
19	0.02761	232.400	0.012
20	0.48170	257.300	0.187
21	0.04853	141.400	0.034
22	0.00102	113.200	0.001
23	0.00110	131.800	0.001
24	0.00178	168.100	0.001
25	0.01225	172.700	0.007
26	0.07891	182.900	0.043

Total	3.64188	4411.70	0.083
80 Perc. (12)	0.34680	257.900	0.134 ←

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000

Total	0.0E+00	4411.70	0.000
80. Perc. (10)	0.0E+00	252.500	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	1.8E-18	113.200	0.000
3	6.8E-13	131.800	0.000
4	8.9E-09	168.100	0.000
5	1.9E-06	172.700	0.000
6	0.00007	182.900	0.000

7	0.00210	312.500	0.001
8	0.00596	136.100	0.004
9	0.05379	265.900	0.020
10	0.09113	252.500	0.036
11	0.17980	344.700	0.052
12	0.21460	257.900	0.083
13	0.20240	299.600	0.068
14	0.19070	260.600	0.073
15	0.17350	166.300	0.104
16	0.27160	361.700	0.075
17	0.07734	149.500	0.052
18	0.16860	204.600	0.082
19	0.21370	232.400	0.092
20	0.52470	257.300	0.204
21	0.37570	141.400	0.266
22	0.19680	113.200	0.174
23	0.11920	131.800	0.090
24	0.13390	168.100	0.080
25	0.21030	172.700	0.122
26	0.16770	182.900	0.092

Total	3.57352	4411.70	0.081
80 Perc. (25)	0.21030	172.700	0.122

*** FOCUSPELMO 3. 3. 2 *** (PELMO 3.22)

Ver 2 Châteaudun, cabbage

(C) Oncol 8 <Benfuracarb>

Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	312.500	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Hamburg, cabbage
(H) Oncol S <Benfuracarb>
Ver 2 Hamburg scenario (53.63 N, 10.00 E) Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	134.600	0.000
2	0.0E+00	125.700	0.000
3	0.0E+00	227.300	0.000
4	0.0E+00	253.700	0.000
5	0.0E+00	387.100	0.000
6	0.0E+00	436.000	0.000

7	0.0E+00	118.300	0.000
8	0.0E+00	147.100	0.000
9	0.0E+00	252.400	0.000
10	0.0E+00	292.000	0.000
11	0.0E+00	220.900	0.000
12	0.0E+00	435.000	0.000
13	0.0E+00	406.800	0.000
14	0.0E+00	183.100	0.000
15	0.0E+00	371.300	0.000
16	0.0E+00	273.300	0.000
17	0.0E+00	177.600	0.000
18	0.0E+00	224.800	0.000
19	0.0E+00	251.800	0.000
20	0.0E+00	300.600	0.000
21	0.0E+00	134.600	0.000
22	0.0E+00	125.700	0.000
23	0.0E+00	227.300	0.000
24	0.0E+00	253.700	0.000
25	0.0E+00	387.100	0.000
26	0.0E+00	436.000	0.000

Total	0.0E+00	5219.40	0.000
80 Perc.(10)	0.0E+00	292.000	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00053	134.600	0.000
2	0.07103	125.700	0.057
3	0.99210	227.300	0.436
4	1.92200	253.700	0.758
5	6.04800	387.100	1.562
6	19.5800	436.000	4.491

7	6.24000	118.300	5.275
8	0.59710	147.100	0.406
9	1.14000	252.400	0.452
10	2.48500	292.000	0.851
11	5.88400	220.900	2.664
12	4.62200	435.000	1.063
13	12.2000	406.800	2.999
14	3.87100	183.100	2.114
15	3.80700	371.300	1.025
16	4.36000	273.300	1.595
17	1.91300	177.600	1.077
18	1.94800	224.800	0.867
19	2.44300	251.800	0.970
20	6.68200	300.600	2.223
21	0.45310	134.600	0.337
22	0.18680	125.700	0.149
23	1.00100	227.300	0.440
24	1.92200	253.700	0.758
25	6.04800	387.100	1.562
26	19.5800	436.000	4.491

Total	87.3830	5219.40	1.674
80 Perc.(11)	5.88400	220.900	2.664

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	134.600	0.000
2	0.0E+00	125.700	0.000
3	0.0E+00	227.300	0.000
4	0.0E+00	253.700	0.000
5	0.0E+00	387.100	0.000
6	0.0E+00	436.000	0.000

7	0.0E+00	118.300	0.000
8	0.0E+00	147.100	0.000
9	0.0E+00	252.400	0.000
10	0.0E+00	292.000	0.000
11	0.0E+00	220.900	0.000
12	0.0E+00	435.000	0.000
13	0.0E+00	406.800	0.000
14	0.0E+00	183.100	0.000
15	0.0E+00	371.300	0.000
16	0.0E+00	273.300	0.000
17	0.0E+00	177.600	0.000
18	0.0E+00	224.800	0.000
19	0.0E+00	251.800	0.000
20	0.0E+00	300.600	0.000
21	0.0E+00	134.600	0.000
22	0.0E+00	125.700	0.000
23	0.0E+00	227.300	0.000
24	0.0E+00	253.700	0.000
25	0.0E+00	387.100	0.000
26	0.0E+00	436.000	0.000

Total	0.0E+00	5219.40	0.000
80 Perc. (10)	0.0E+00	292.000	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	4.9E-09	134.600	0.000
2	0.00136	125.700	0.001
3	0.32560	227.300	0.143
4	1.48600	253.700	0.586
5	4.23500	387.100	1.094
6	18.2800	436.000	4.193

7	2.73600	118.300	2.313
8	6.47200	147.100	4.400
9	2.22200	252.400	0.880
10	1.89700	292.000	0.650
11	3.43900	220.900	1.557
12	6.64900	435.000	1.529
13	12.6600	406.800	3.112
14	2.01300	183.100	1.099
15	5.58400	371.300	1.504
16	3.65700	273.300	1.338
17	2.41100	177.600	1.358
18	2.31500	224.800	1.030
19	2.44100	251.800	0.969
20	4.74600	300.600	1.579
21	2.97300	134.600	2.209
22	0.59320	125.700	0.472
23	0.57260	227.300	0.252
24	1.49100	253.700	0.588
25	4.23500	387.100	1.094
26	18.2800	436.000	4.193

Total	87.3868	5219.40	1.674
80 Perc. (7)	2.73600	118.300	2.313

*** FOCUSPELMO 3, 3, 2 *** (PELMO 3.22)

Ver 2 Hamburg, cabbage

(H) Oncol S <Benfuracarb>

Ver 2 Hamburg scenario (53.63 N, 10.00 E) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	118.300	0.000

*** FOCUSPELMO 3. 3. 2 *** (PELMO 3.22)
Ver 2 Kremsmünster, cabbage
(K) Oncol 5 <Benfuracarb>
Ver 2 Kremsmünster scenario (48.05 N, 14.13 E) Year: 01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	176.900	0.000
2	0.0E+00	16.4700	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	315.800	0.000
5	0.0E+00	185.300	0.000
6	0.0E+00	182.600	0.000

7	0.0E+00	303.600	0.000
8	0.0E+00	225.400	0.000
9	0.0E+00	378.400	0.000
10	0.0E+00	345.200	0.000
11	0.0E+00	340.000	0.000
12	0.0E+00	238.800	0.000
13	0.0E+00	359.200	0.000
14	0.0E+00	227.600	0.000
15	0.0E+00	142.200	0.000
16	0.0E+00	204.900	0.000
17	0.0E+00	225.800	0.000
18	0.0E+00	196.700	0.000
19	0.0E+00	250.200	0.000
20	0.0E+00	200.700	0.000
21	0.0E+00	176.200	0.000
22	0.0E+00	16.4700	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	315.800	0.000
25	0.0E+00	185.300	0.000
26	0.0E+00	182.600	0.000

Total	0.0E+00	4515.07	0.000
80 Perc. (10)	0.0E+00	345.200	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00014	176.900	0.000
2	0.00026	16.4700	0.002
3	0.0E+00	0.0E+00	0.000
4	0.17530	315.800	0.056
5	0.45340	185.300	0.245
6	0.33790	182.600	0.185

7	0.26610	303.600	0.088
8	0.67790	225.400	0.301
9	1.62800	378.400	0.430
10	4.63000	345.200	1.341
11	1.65100	340.000	0.486
12	0.81110	238.800	0.340
13	1.13100	359.200	0.315
14	2.51900	227.600	1.107
15	0.45260	142.200	0.318
16	0.12530	204.900	0.061
17	0.79110	225.800	0.350
18	0.40800	196.700	0.207
19	0.28330	250.200	0.113
20	0.13220	200.700	0.066
21	0.05475	176.200	0.031
22	0.00602	16.4700	0.037
23	0.0E+00	0.0E+00	0.000
24	0.17570	315.800	0.056
25	0.45340	185.300	0.245
26	0.33790	182.600	0.185

Total	16.5344	4515.07	0.366
80 Perc. (9)	1.62800	378.400	0.430

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	176.900	0.000
2	0.0E+00	16.4700	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	315.800	0.000
5	0.0E+00	185.300	0.000
6	0.0E+00	182.600	0.000

7	0.0E+00	303.600	0.000
8	0.0E+00	225.400	0.000
9	0.0E+00	378.400	0.000
10	0.0E+00	345.200	0.000
11	0.0E+00	340.000	0.000
12	0.0E+00	238.800	0.000
13	0.0E+00	359.200	0.000
14	0.0E+00	227.600	0.000
15	0.0E+00	142.200	0.000
16	0.0E+00	204.900	0.000
17	0.0E+00	225.800	0.000
18	0.0E+00	196.700	0.000
19	0.0E+00	250.200	0.000
20	0.0E+00	200.700	0.000
21	0.0E+00	176.200	0.000
22	0.0E+00	16.4700	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	315.800	0.000
25	0.0E+00	185.300	0.000
26	0.0E+00	182.600	0.000

Total	0.0E+00	4515.07	0.000
80 Perc.(10)	0.0E+00	345.200	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	5.5E-13	176.900	0.000
2	2.5E-12	16.4700	0.000
3	0.0E+00	0.0E+00	0.000
4	0.00004	315.800	0.000
5	0.00193	185.300	0.001
6	0.06876	182.600	0.038

7	0.53860	303.600	0.177
8	0.35980	225.400	0.160
9	0.64140	378.400	0.170
10	1.36700	345.200	0.396
11	3.36900	340.000	0.991
12	2.11800	238.800	0.887
13	1.71400	359.200	0.477
14	0.60320	227.600	0.265
15	0.52630	142.200	0.370
16	1.75200	204.900	0.855
17	1.36000	225.800	0.602
18	0.40150	196.700	0.204
19	0.62070	250.200	0.248
20	0.49460	200.700	0.246
21	0.26100	176.200	0.148
22	0.01948	16.4700	0.118
23	0.0E+00	0.0E+00	0.000
24	0.24640	315.800	0.078
25	0.05562	185.300	0.030
26	0.08427	182.600	0.046

Total	16.5329	4515.07	0.366
80 Perc.(17)	1.36000	225.800	0.602

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)

Ver 2 Kremmünster, cabbage

(K) Oncol S <Benfuracarb>

Ver 2 Kremmünster scenario (48.05 N, 14.13 E) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	303.600	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Porto, cabbage
(O) Oncol 8 <Benfuracarb>
Ver 2 Porto scenario (41.23 N, 8.68 W) Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	355.200	0.000
2	0.0E+00	383.200	0.000
3	0.0E+00	476.100	0.000
4	0.0E+00	96.4200	0.000
5	0.0E+00	299.800	0.000
6	0.0E+00	353.900	0.000

7	0.0E+00	442.800	0.000
8	0.0E+00	629.000	0.000
9	0.0E+00	705.700	0.000
10	0.0E+00	643.400	0.000
11	0.0E+00	721.500	0.000
12	0.0E+00	341.900	0.000
13	0.0E+00	416.700	0.000
14	0.0E+00	497.200	0.000
15	0.0E+00	406.700	0.000
16	0.0E+00	623.500	0.000
17	0.0E+00	556.100	0.000
18	0.0E+00	542.300	0.000
19	0.0E+00	698.900	0.000
20	0.0E+00	350.500	0.000
21	0.0E+00	338.500	0.000
22	0.0E+00	383.200	0.000
23	0.0E+00	476.100	0.000
24	0.0E+00	96.4200	0.000
25	0.0E+00	299.800	0.000
26	0.0E+00	353.900	0.000

Total	0.0E+00	9524.12	0.000
80 Perc. (10)	0.0E+00	643.400	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00011	355.200	0.000
2	0.00868	383.200	0.002
3	0.06763	476.100	0.014
4	0.00123	96.4200	0.001
5	0.00036	299.800	0.000
6	0.01691	353.900	0.005

7	0.03146	442.800	0.007
8	0.20280	629.000	0.032
9	3.72900	705.700	0.528
10	0.14990	643.400	0.023
11	0.11700	721.500	0.016
12	0.04712	341.900	0.014
13	0.00871	416.700	0.002
14	0.01749	497.200	0.004
15	0.10720	406.700	0.026
16	0.02814	623.500	0.005
17	0.38610	556.100	0.069
18	0.03621	542.300	0.007
19	0.08819	698.900	0.013
20	0.63510	350.500	0.181
21	0.00878	338.500	0.003
22	0.00894	383.200	0.002
23	0.06764	476.100	0.014
24	0.00123	96.4200	0.001
25	0.00036	299.800	0.000
26	0.01691	353.900	0.005

Total	5.68828	9524.12	0.060
80 Perc. (8)	0.20280	629.000	0.032

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	355.200	0.000
2	0.0E+00	383.200	0.000
3	0.0E+00	476.100	0.000
4	0.0E+00	96.4200	0.000
5	0.0E+00	299.800	0.000
6	0.0E+00	353.900	0.000

7	0.0E+00	442.800	0.000
8	0.0E+00	629.000	0.000
9	0.0E+00	705.700	0.000
10	0.0E+00	643.400	0.000
11	0.0E+00	721.500	0.000
12	0.0E+00	341.900	0.000
13	0.0E+00	416.700	0.000
14	0.0E+00	497.200	0.000
15	0.0E+00	406.700	0.000
16	0.0E+00	623.500	0.000
17	0.0E+00	556.100	0.000
18	0.0E+00	542.300	0.000
19	0.0E+00	698.900	0.000
20	0.0E+00	350.500	0.000
21	0.0E+00	338.500	0.000
22	0.0E+00	383.200	0.000
23	0.0E+00	476.100	0.000
24	0.0E+00	96.4200	0.000
25	0.0E+00	299.800	0.000
26	0.0E+00	353.900	0.000

Total	0.0E+00	9524.12	0.000
80 Perc. (10)	0.0E+00	643.400	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	1.4E-06	355.200	0.000
2	0.00357	383.200	0.001
3	0.03737	476.100	0.008
4	0.01545	96.4200	0.016
5	0.01953	299.800	0.007
6	0.00766	353.900	0.002

7	0.02516	442.800	0.006
8	0.03903	629.000	0.006
9	3.40900	705.700	0.483
10	0.60370	643.400	0.094
11	0.13100	721.500	0.018
12	0.04718	341.900	0.014
13	0.03814	416.700	0.009
14	0.01090	497.200	0.002
15	0.06116	406.700	0.015
16	0.07693	623.500	0.012
17	0.25680	556.100	0.046
18	0.16110	542.300	0.030
19	0.05249	698.900	0.008
20	0.26060	350.500	0.074
21	0.39720	338.500	0.117
22	0.03713	383.200	0.010
23	0.03809	476.100	0.008
24	0.01545	96.4200	0.016
25	0.01954	299.800	0.007
26	0.00766	353.900	0.002

Total	5.68826	9524.12	0.060
80 Perc. (20)	0.26060	350.500	0.074

*** FOCUSPELMO 3, 3, 2 *** (PELMO 3.22)

Ver 2 Porto, cabbage

(O) Oncol S <Benfuracarb>

Ver 2 Porto scenario (41.23 N, 8.68 W) Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	442.800	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Sevilla, cabbage
(S) Oncol 5 <Benfuracarb>
Ver 2 SEVILLA scenario (37.42 N, 5.88 W) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	135.000	0.000
2	0.0E+00	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	0.0E+00	53.5600	0.000
9	0.0E+00	101.100	0.000
10	0.0E+00	50.8900	0.000
11	0.0E+00	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	0.0E+00	6.38200	0.000
15	0.0E+00	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	0.0E+00	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.0E+00	116.400	0.000
22	0.0E+00	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.0E+00	486.742	0.000
80 Perc. (10)	0.0E+00	50.8900	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00025	135.000	0.000
2	0.00032	20.0400	0.002
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	1.5E-07	53.5600	0.000
9	0.00010	101.100	0.000
10	6.4E-06	50.8900	0.000
11	0.00003	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	5.6E-12	6.38200	0.000
15	2.3E-08	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	4.7E-08	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.00024	116.400	0.000
22	0.00032	20.0400	0.002
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.00068	486.742	0.000
80 Perc. (11)	0.00003	95.6500	0.000

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	135.000	0.000
2	0.0E+00	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	0.0E+00	53.5600	0.000
9	0.0E+00	101.100	0.000
10	0.0E+00	50.8900	0.000
11	0.0E+00	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	0.0E+00	6.38200	0.000
15	0.0E+00	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	0.0E+00	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.0E+00	116.400	0.000
22	0.0E+00	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.0E+00	486.742	0.000
80 Perc. (10)	0.0E+00	50.8900	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	4.9E-11	135.000	0.000
2	1.7E-10	20.0400	0.000
3	0.0E+00	0.0E+00	0.000
4	0.0E+00	0.0E+00	0.000
5	0.0E+00	0.0E+00	0.000
6	0.0E+00	0.0E+00	0.000

7	0.0E+00	0.0E+00	0.000
8	1.6E-08	53.5600	0.000
9	1.9E-06	101.100	0.000
10	7.6E-06	50.8900	0.000
11	0.00006	95.6500	0.000
12	0.0E+00	0.0E+00	0.000
13	0.0E+00	0.0E+00	0.000
14	6.6E-06	6.38200	0.000
15	0.00002	15.0000	0.000
16	0.0E+00	0.0E+00	0.000
17	0.00004	27.7200	0.000
18	0.0E+00	0.0E+00	0.000
19	0.0E+00	0.0E+00	0.000
20	0.0E+00	0.0E+00	0.000
21	0.00020	116.400	0.000
22	0.00004	20.0400	0.000
23	0.0E+00	0.0E+00	0.000
24	0.0E+00	0.0E+00	0.000
25	0.0E+00	0.0E+00	0.000
26	0.0E+00	0.0E+00	0.000

Total	0.00037	486.742	0.000
80 Perc. (15)	0.00002	15.0000	0.000

*** FOCUSPELMO 3, 3, 2 *** (PELMO 3.22)

Ver 2 Sevilla, cabbage

(S) Oncol S <Benfuracarb>

Ver 2 SEVILLA scenario (37.42 N, 5.88 W) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	0.0E+00	0.000

*** POCUSPELMO 3.3.2 *** (PELMO 3.22)
 Ver 2 Châteaudun, cabbage
 (C) Oncol S <Benfuracarb>
 Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000
27	0.0E+00	140.800	0.000
28	0.0E+00	259.800	0.000
29	0.0E+00	252.500	0.000
30	0.0E+00	344.700	0.000
31	0.0E+00	260.400	0.000
32	0.0E+00	302.700	0.000
33	0.0E+00	260.600	0.000
34	0.0E+00	166.300	0.000
35	0.0E+00	358.500	0.000
36	0.0E+00	145.200	0.000
37	0.0E+00	204.600	0.000
38	0.0E+00	232.400	0.000
39	0.0E+00	252.500	0.000
40	0.0E+00	134.900	0.000
41	0.0E+00	113.200	0.000
42	0.0E+00	131.800	0.000
43	0.0E+00	170.200	0.000
44	0.0E+00	167.100	0.000
45	0.0E+00	182.900	0.000
46	0.0E+00	312.500	0.000

Total	0.0E+00	8805.30	0.000
80 Perc. (14)	0.0E+00	260.600	0.000

Metab.AI in the percolate at 1 m soil depth

Year	Metab.AI Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	9.9E-06	142.100	0.000
2	0.00062	113.200	0.001
3	0.00126	131.800	0.001
4	0.00268	168.100	0.002
5	0.00330	172.700	0.002
6	0.06235	182.900	0.034

7	0.07388	312.500	0.024
8	0.07123	136.100	0.052
9	0.02381	265.900	0.009
10	0.30800	252.500	0.122
11	0.05721	344.700	0.017
12	0.28590	257.900	0.111
13	0.03050	299.600	0.010

14	0.08315	260.600	0.032
15	0.00894	166.300	0.005
16	0.02633	361.700	0.007
17	0.00398	149.500	0.003
18	0.01941	204.600	0.009
19	0.02937	232.400	0.013
20	0.44950	257.300	0.175
21	0.01350	141.400	0.010
22	0.00072	113.200	0.001
23	0.00126	131.800	0.001
24	0.00268	168.100	0.002
25	0.00330	172.700	0.002
26	0.06235	182.900	0.034
27	0.00495	140.800	0.004
28	0.07736	259.800	0.030
29	0.00986	252.500	0.004
30	0.22250	344.700	0.065
31	0.02549	260.400	0.010
32	0.26860	302.700	0.089
33	0.05544	260.600	0.021
34	0.20940	166.300	0.126
35	0.18590	358.500	0.052
36	0.46830	145.200	0.323
37	0.03364	204.600	0.016
38	0.01714	232.400	0.007
39	0.01023	252.500	0.004
40	0.00796	134.900	0.006
41	0.00212	113.200	0.002
42	0.00459	131.800	0.003
43	0.00719	170.200	0.004
44	0.03865	167.100	0.023
45	0.01590	182.900	0.009
46	0.02833	312.500	0.009

Total	3.24868	8805.30	0.037
80 Perc. (8)	0.07123	136.100	0.052

Pesticide in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000
27	0.0E+00	140.800	0.000
28	0.0E+00	259.800	0.000
29	0.0E+00	252.500	0.000
30	0.0E+00	344.700	0.000
31	0.0E+00	260.400	0.000
32	0.0E+00	302.700	0.000
33	0.0E+00	260.600	0.000
34	0.0E+00	166.300	0.000
35	0.0E+00	358.500	0.000
36	0.0E+00	145.200	0.000
37	0.0E+00	204.600	0.000

38	0.0E+00	232.400	0.000
39	0.0E+00	252.500	0.000
40	0.0E+00	134.900	0.000
41	0.0E+00	113.200	0.000
42	0.0E+00	131.800	0.000
43	0.0E+00	170.200	0.000
44	0.0E+00	167.100	0.000
45	0.0E+00	182.900	0.000
46	0.0E+00	312.500	0.000

Total	0.0E+00	8805.30	0.000
80 Perc. (14)	0.0E+00	260.600	0.000

Metab.A1 in the percolate at the bottom of the simulated soil core

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	4.5E-16	113.200	0.000
3	4.1E-11	131.800	0.000
4	2.2E-07	168.100	0.000
5	0.00002	172.700	0.000
6	0.00025	182.900	0.000

7	0.00243	312.500	0.001
8	0.00423	136.100	0.003
9	0.03470	265.900	0.013
10	0.05528	252.500	0.022
11	0.11370	344.700	0.033
12	0.12030	257.900	0.047
13	0.21150	299.600	0.071
14	0.13580	260.600	0.052
15	0.11900	166.300	0.072
16	0.13510	361.700	0.037
17	0.03480	149.500	0.023
18	0.03324	204.600	0.016
19	0.01953	232.400	0.008
20	0.01738	257.300	0.007
21	0.00932	141.400	0.007
22	0.01043	113.200	0.009
23	0.02704	131.800	0.021
24	0.11330	168.100	0.067
25	0.18740	172.700	0.109
26	0.12700	182.900	0.069
27	0.03343	140.800	0.024
28	0.01406	259.800	0.005
29	0.02578	252.500	0.010
30	0.06520	344.700	0.019
31	0.05046	260.400	0.019
32	0.08916	302.700	0.029
33	0.12640	260.600	0.049
34	0.06066	166.300	0.036
35	0.21060	358.500	0.059
36	0.07146	145.200	0.049
37	0.12460	204.600	0.061
38	0.13870	232.400	0.060
39	0.31750	252.500	0.126
40	0.18760	134.900	0.139
41	0.09592	113.200	0.085
42	0.05153	131.800	0.039
43	0.02448	170.200	0.014
44	0.01099	167.100	0.007
45	0.00796	182.900	0.004
46	0.01346	312.500	0.004

Total	3.23143	8805.30	0.037
80 Perc. (24)	0.11330	168.100	0.067

*** FOCUSPELMO 3, 3. 2 *** (PELMO 3.22)

Ver 2 Châteaudun, cabbage

(C) Oncol 8 <Benfuracarb>

Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	448.600	0.000

*** FOCUSPELMO 3.3.2 *** (PELMO 3.22)
Ver 2 Châteaudun, cabbage
(C) Oncol S <Benfuracarb>
Ver 2 Châteaudun scenario (48.05 N, 1.38 E) vegetables etc IRR Year:01

Pesticide in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000
27	0.0E+00	140.800	0.000
28	0.0E+00	259.800	0.000
29	0.0E+00	252.500	0.000
30	0.0E+00	344.700	0.000
31	0.0E+00	260.400	0.000
32	0.0E+00	302.700	0.000
33	0.0E+00	260.600	0.000
34	0.0E+00	166.300	0.000
35	0.0E+00	358.500	0.000
36	0.0E+00	145.200	0.000
37	0.0E+00	204.600	0.000
38	0.0E+00	232.400	0.000
39	0.0E+00	252.500	0.000
40	0.0E+00	134.900	0.000
41	0.0E+00	113.200	0.000
42	0.0E+00	131.800	0.000
43	0.0E+00	170.200	0.000
44	0.0E+00	167.100	0.000
45	0.0E+00	182.900	0.000
46	0.0E+00	312.500	0.000

Total	0.0E+00	8805.30	0.000
50 Perc. (14)	0.0E+00	260.600	0.000

Metab.A1 in the percolate at 1 m soil depth

Year	Metab.A1 Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	7.5E-08	142.100	0.000
2	0.00003	113.200	0.000
3	0.00028	131.800	0.000
4	0.00046	168.100	0.000
5	0.00119	172.700	0.001
6	0.06091	182.900	0.033

7	0.05607	312.500	0.018
8	0.03734	136.100	0.027
9	0.04779	265.900	0.018
10	0.09069	252.500	0.036
11	0.08629	344.700	0.025
12	0.29740	257.900	0.115
13	0.09765	299.600	0.033

14	0.04617	260.600	0.018
15	0.01922	166.300	0.012
16	0.04126	361.700	0.011
17	0.01726	149.500	0.012
18	0.00144	204.600	0.001
19	0.00500	232.400	0.002
20	0.44260	257.300	0.172
21	0.04797	141.400	0.034
22	0.00066	113.200	0.001
23	0.00029	131.800	0.000
24	0.00046	168.100	0.000
25	0.00119	172.700	0.001
26	0.06091	182.900	0.033
27	0.01297	140.800	0.009
28	0.20600	259.800	0.079
29	0.08482	252.500	0.034
30	0.08646	344.700	0.025
31	0.04761	260.400	0.018
32	0.09414	302.700	0.031
33	0.03123	260.600	0.012
34	0.28160	166.300	0.169
35	0.16200	358.500	0.045
36	0.90600	145.200	0.624
37	0.17110	204.600	0.084
38	0.02234	232.400	0.010
39	0.03632	252.500	0.014
40	0.00054	134.900	0.000
41	0.00031	113.200	0.000
42	0.00080	131.800	0.001
43	0.00135	170.200	0.001
44	0.01038	167.100	0.006
45	0.01706	182.900	0.009
46	0.06097	312.500	0.020

Total	3.63167	8805.30	0.041
80 Perc. (10)	0.09069	252.500	0.036

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Pesticide in the percolate at the bottom of the simulated soil core:

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0E+00	142.100	0.000
2	0.0E+00	113.200	0.000
3	0.0E+00	131.800	0.000
4	0.0E+00	168.100	0.000
5	0.0E+00	172.700	0.000
6	0.0E+00	182.900	0.000

7	0.0E+00	312.500	0.000
8	0.0E+00	136.100	0.000
9	0.0E+00	265.900	0.000
10	0.0E+00	252.500	0.000
11	0.0E+00	344.700	0.000
12	0.0E+00	257.900	0.000
13	0.0E+00	299.600	0.000
14	0.0E+00	260.600	0.000
15	0.0E+00	166.300	0.000
16	0.0E+00	361.700	0.000
17	0.0E+00	149.500	0.000
18	0.0E+00	204.600	0.000
19	0.0E+00	232.400	0.000
20	0.0E+00	257.300	0.000
21	0.0E+00	141.400	0.000
22	0.0E+00	113.200	0.000
23	0.0E+00	131.800	0.000
24	0.0E+00	168.100	0.000
25	0.0E+00	172.700	0.000
26	0.0E+00	182.900	0.000
27	0.0E+00	140.800	0.000
28	0.0E+00	259.800	0.000
29	0.0E+00	252.500	0.000
30	0.0E+00	344.700	0.000
31	0.0E+00	260.400	0.000
32	0.0E+00	302.700	0.000
33	0.0E+00	260.600	0.000
34	0.0E+00	166.300	0.000
35	0.0E+00	358.500	0.000
36	0.0E+00	145.200	0.000
37	0.0E+00	204.600	0.000

B.8.6.2 Predicted environmental concentrations in surface water (PEC_{sw}) (Annex IIIA 9.2.3) (revised in January 2009)**PEC_{sw} and PEC_{sed} calculations following based on PRAPeR 62 input parameters**

Prepared by NOTOX on January 22, 2008

BENFURACARB

Predicted environmental concentrations in surface water (PEC_{sw}) of Benfuracarb were calculated according to STEP 1/2 procedures outlined in Sanco/4802/2001 rev.2 final (May 2003) “FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC”. The relevant input parameters were taken from Table 4. The results are given in Tables 1 (STEP 1), 2 (STEP 2 - SE) and 3 (STEP 2 - NE). The STEP 1 calculations use a default run-off + drainage of 10%. In STEP 2 the default for run-off and drainage is 4% (SE) and 2% (NE) for spring or autumn planting. Detailed STEP1/2 calculation results are given in Appendix I.

Time (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	25.3807	-	2.31E+03	-
1	8.4465	16.9136	768.6343	1.54E+03
2	2.8109	11.0179	255.7964	1.E+03
4	0.3113	6.0769	28.3298	553.0002
7	0.0115	3.5115	1.0442	319.5429
14	0.0000	1.7565	0.0005	159.8392
21	0.0000	1.1710	0.0000	106.5595
28	0.0000	0.8782	0.0000	79.9196
42	0.0000	0.5855	0.0000	53.2798
50	0.0000	0.4918	0.0000	44.7550
100	0.0000	0.2459	0.0000	22.3775

Time after max. peak(d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.0013	0.0161	-	1.4633
1	0.0004	0.0054	0.0107	0.4870
2	0.0001	0.0018	0.0071	0.1621
4	0.0000	0.0002	0.0040	0.0179
7	0.0000	0.0000	0.0023	0.0007
14	0.0000	0.0000	0.0011	0.0000
21	0.0000	0.0000	0.0008	0.0000
28	0.0000	0.0000	0.0006	0.0000
42	0.0000	0.0000	0.0004	0.0000
50	0.0000	0.0000	0.0003	0.0000
100	0.0000	0.0000	0.0002	0.0000

Time after max. peak(d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.0080	-	0.7316	-
1	0.0027	0.0054	0.2435	0.4876
2	0.0009	0.0036	0.0810	0.3249
4	0.0001	0.0020	0.0090	0.1804
7	0.0000	0.0011	0.0003	0.1043
14	0.0000	0.0006	0.0000	0.0522
21	0.0000	0.0004	0.0000	0.0348
28	0.0000	0.0003	0.0000	0.0261
42	0.0000	0.0002	0.0000	0.0174
50	0.0000	0.0002	0.0000	0.0146
100	0.0000	0.0001	0.0000	0.0073

STEP 3 calculations were performed for the drainage scenarios according to procedures outlined in Sanco/4802/2001 rev.2 final (May 2003) “FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC” and the recommendations as outlined in EFSA Journal (2004) 145, 1-31 using the SWASH software tool, version 2.1. The appropriate (worst case) standard scenarios were used for the calculations for applications on cabbage. For soil, the geometric mean soil DT_{50,lab} and mean K_{om} were used in agreement with the guidance. For water and sediment, no individual DT₅₀ values are available, therefore the available DT₅₀ value for the whole water/sediment system was used for the water phase and a default of 1000d was used for the sediment layer in agreement with the guidance. The FOCUS wizard was used to generate all relevant crop-scenario combinations for cabbage. The application window width was 30 days starting from 14 days before emergence to 14 days after emergence (i.e. spring and/or summer application). All other input parameters were set at the default FOCUS values. Benfuracarb inputs in surface water via drainage were calculated using MACRO software version 4.4.2 and PEC_{SW} values were obtained using TOXSWA software version 2.2.1. The used input values and their source are summarised in Table 4.

In the MACRO submodel, soil incorporation was selected as the method of application, in agreement with the procedures outlined in EFSA Journal ((2004) 145,1-31). STEP 3 calculations for the R (run-off) scenarios use as default a homogeneous distribution of the active ingredient in the top 0-4 cm soil layer. This default assumption, however, is not applicable to the application of ONCOL 8.6G at the planting of cabbage/cauliflower. According to GAP, cabbage/cauliflower is planted as young seedlings. The granules are placed in the furrow at the time of planting. The depth of the rooting system of the cabbage/cauliflower seedlings is at least 2.5 cm. Hence, the ONCOL 8.6G granules are placed at a depth of at least 2.5 cm. In order to reflect this method of application in the PRZM submodel, it was specified that the active ingredient was placed at exactly 2.5 cm and not homogeneously distributed in the top 0-4 cm soil layer. (This was done by setting CAM=8 and DEPI=2.5 according to the procedures outlined in EFSA Journal (2004) 145,1-31).

Parameter	Value	Source
water solubility	8.4 mg/L (20°C) at pH 7	(LoEP)
vapour pressure	4.2E-6 Pa (25°C)	(LoEP)
geometric mean soil DT ₅₀	0.42 d (20°C, pF 2.0 normalised)	PRAPeR 62
Mean K _{oc} soil	9.1E+3 L/kg	(LoEP)
1/n	1.0	PRAPeR 62
DT ₅₀ water/sediment whole system	6-15 hours (estimation). Calculations performed with DT ₅₀ of 15 hours (0.625 d).	(LoEP)
Application	1000 g a.i./ha	representative use Oncol 8.6G
Type of application	Granular application (PRZM, CAM=8, DEPI=2.5) Soil incorporated (MACRO) (according to guidance published in the EFSA journal (2004) 145, 1-31)	representative use Oncol 8.6G
Crop	Vegetables, leafy (cabbage)	representative use Oncol 8.6G
Scenarios	Relevant FOCUS scenarios: D3,	FOCUS

	D4, D6, R1, R2, R3, R4 (for the D3 scenario and all R scenarios, two application dates are possible)	
Run-off	No run-off (according to guidance published in the EFSA journal (2004) 145, 1-31)	FOCUS
Drainage	MACRO model (FOCUS)	FOCUS
PEC _{sw}	TOXSWA (FOCUS)	FOCUS

The results of the FOCUS STEP3/4 calculations are presented in Appendix II. PEC_{sw} and PEC_{sed} for benfuracarb were <0.001 µg/L for all D- and R-scenarios.

In summary, PEC_{sw} and PEC_{sed} values (STEP 3) for the D-scenarios are all 0.000 µg/L. PEC_{sw} and PEC_{sed} for the R-scenarios are all 0.000 µg/L as run-off can be excluded for this application. The maximum and 28 day TWA PEC_{sw} and PEC_{sed} concentrations to be used for the initial aquatic risk assessment for Benfuracarb are summarised in Table 5.

Scenario	System	Relevant for		Application date	Water		Sediment	
		NE	SE		Max PEC _{sw} (µg/L)	TWA 28 days (µg/L)	Max PEC _{sed} (µg/kg)	TWA 28 days (µg/kg)
D3 (STEP3)	ditch	X		April 10	0.000	0.000	0.000	0.000
	ditch	X		July 25	0.000	0.000	0.000	0.000
D4 (STEP3)	pond	X		May 16	0.000	0.000	0.000	0.000
	stream	X		May 16	0.000	0.000	0.000	0.000
D6 (STEP3)	ditch		X	Aug 04	0.000	0.000	0.000	0.000
R1 (STEP4)	pond	X		April 26	0.000	0.000	0.000	0.000
	pond	X		July 28	0.000	0.000	0.000	0.000
	stream	X		April 26	0.000	0.000	0.000	0.000
	stream	X		July 28	0.000	0.000	0.000	0.000
R2 (STEP4)	stream		X	March 06	0.000	0.000	0.000	0.000
	stream		X	Aug 05	0.000	0.000	0.000	0.000
R3 (STEP4)	stream		X	Feb 19	0.000	0.000	0.000	0.000
	stream		X	June 02	0.000	0.000	0.000	0.000
R4 (STEP4)	stream		X	March 01	0.000	0.000	0.000	0.000
	stream		X	June 01	0.000	0.000	0.000	0.000
STEP1	na	na	na	na	25.381	0.8782	2310	79.9196
STEP2	na		X	March-May Aug-Sep	0.0161	0.0000	1.4633	0.0522
STEP2	na	X		March-May Aug-Sep	0.0080	0.0000	0.7316	0.0261

na = not applicable

¹ The run-off scenarios are referred to as STEP 4 calculations because the defaults for CAM and DEPI were adjusted (see description above)

CARBOFURAN

Predicted environmental concentrations in surface water (PEC_{sw}) of Carbofuran were calculated according to STEP 3 and STEP 4 procedures outlined in Sanco/4802/2001 rev.2 final (May 2003) “FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC” and the recommendations as outlined in EFSA Journal (2004) 145, 1-31 using the SWASH software tool, version 2.1. FOCUS STEP 1/2 calculations were not performed as STEP 3 and STEP 4 calculations will be used in the risk assessment.

The appropriate (worst case) standard scenarios were used for the calculations for applications on cabbage. For soil, the geometric mean soil DT_{50,lab} and mean K_{om} was used in agreement with the guidance. For water and sediment, no individual DT₅₀ values are available. Therefore the geometric mean of the available DT₅₀ values for the whole water/sediment system was used for the water phase and the default of 1000d was used for the sediment layer in agreement with the guidance. The FOCUS wizard was used to generate all relevant crop-scenario combinations for cabbage. The application window width was 30 days starting from 14 days before emergence to 14 days after emergence (i.e. spring and/or summer application). All other input parameters were set at the default FOCUS values. Carbofuran inputs in surface water via drainage were calculated using MACRO software version 4.4.2, inputs via runoff using PRZM3 software, version 1.1.1 and PEC_{sw} values were obtained using TOXSWA software version 2.2.1.

STEP 3 calculations for the R (run-off) scenarios use as default a homogeneous distribution of the active ingredient in the top 0-4 cm soil layer. This default assumption, however, is not applicable to the application of ONCOL 8.6G at the planting of cabbage/cauliflower. According to GAP, cabbage/cauliflower is planted as young seedlings. The granules are placed in the furrow at the time of planting. The depth of the rooting system of the cabbage/cauliflower seedlings is at least 2.5 cm. Hence, the ONCOL 8.6G granules are placed at a depth of at least 2.5 cm. In order to reflect this method of application in the PRZM submodel, it was specified that the active ingredient was placed at exactly 2.5 cm and not homogeneously distributed in the top 0-4 cm soil layer. (This was done by setting CAM=8 and DEPI=2.5 according to the procedures outlined in EFSA Journal (2004) 145,1-31). As a result, run-off was greatly reduced and no exposure of surface water to carbofuran was calculated by the model: PEC_{SW} and PEC_{SED} were 0.000 µg/L for all R-scenarios. In the MACRO submodel, soil incorporation was selected as the method of application, in agreement with the procedures outlined in EFSA Journal ((2004) 145,1-31).

The used input values and their source are summarised in the Table 6.

Table 6. Selected input values for FOCUS STEP 3/STEP 4 calculations for Carbofuran

Parameter	Value	Source
water solubility	318.5 mg/L (20°C)	mean value LoEP
vapour pressure	8E-5 Pa (25°C)	LoEP
geometric mean soil DT ₅₀	14 d (normalised to pF2 and 20°C)	PRAPeR 62
mean Koc soil	22 L/kg	LoEP
1/n	0.96	LoEP
DT ₅₀ water/sediment whole system	BFC study: 13.9 d, 14.8 d CF study: 7.8 d, 11.6 d, 44.6 d geometric mean: 15.3 d	Calculated from BFC study ¹ (LoEP)
Application	As if 100% application of CF with MW correction: 540 g/ha	PRAPeR 62 (ff =1)
Type of application	Granular application (PRZM, CAM=8, DEPI=2.5) Soil incorporated (MACRO) (according to guidance published in the EFSA journal (2004) 145, 1-31)	representative use Oncol 8.6G
Crop	Vegetables, leafy (cabbage)	representative use Oncol 8.6G
Scenarios	Relevant FOCUS scenarios: D3, D4, D6, R1, R2, R3, R4 (for the D3 scenario and all R scenarios, two application dates are possible)	FOCUS
Run-off	PRZM model (FOCUS)	FOCUS
Drainage	MACRO model (FOCUS)	FOCUS
PEC _{sw}	TOXSWA (FOCUS)	FOCUS

¹ Calculated from the data presented in the DAR of benfuracarb (1st order log-linear regression using the data points from the maximum occurrence of carbofuran until the end of the study (r² 0.96-0.97)).

BFC= benfuracarb
CF = carbofuran

The maximum STEP 3 PEC_{SW} and PEC_{SED} concentrations for all R- and D-scenarios are presented in Appendix III. The PEC_{SW} and PEC_{SED} for all R-scenarios were <0.001 µg/L. PEC_{sw} for the D-scenarios ranged from 0.011 to 0.163 µg/L.

The maximum and 28 day TWA PEC_{SW} and PEC_{SED} concentrations to be used for the initial aquatic risk assessment for Benfuracarb are summarised in Table 7.

Table 7. Summary of maximum and 28 days TWA PEC_{sw} and PEC_{sed} concentrations for Carbofuran (FOCUS STEP3/STEP4)

Scenario	System	Relevant for		Application date	Water		Sediment	
		NE	SE		Max PEC _{sw} (µg/L)	TWA 28 days (µg/L)	Max PEC _{sed} (µg/kg)	TWA 28 days (µg/kg)
D3 (STEP3)	Ditch	X		April 10	0.0110	0.0110	0.0191	0.0191
	Ditch	X		July 25	0.159	0.158	0.241	0.241
D4 (STEP3)	Pond	X		May 16	0.0522	0.0468	0.0650	0.0644
	Stream	X		May 16	0.163	0.0791	0.0918	0.0756
D6 (STEP3)	Ditch		X	Aug 04	0.163	0.0283	0.0246	0.0205
R1 (STEP4) ¹	Pond	X		April 26	0.000	0.000	0.000	0.000
	pond	X		July 28	0.000	0.000	0.000	0.000
	stream	X		April 26	0.000	0.000	0.000	0.000
	stream	X		July 28	0.000	0.000	0.000	0.000
R2 (STEP4)	stream		X	March 06	0.000	0.000	0.000	0.000
	stream		X	Aug 05	0.000	0.000	0.000	0.000
R3 (STEP4)	stream		X	Feb 19	0.000	0.000	0.000	0.000
	stream		X	June 02	0.000	0.000	0.000	0.000
R4 (STEP4)	stream		X	March 01	0.000	0.000	0.000	0.000
	stream		X	June 01	0.000	0.000	0.000	0.000

¹ The run-off scenarios are referred to as STEP 4 calculations because the defaults for CAM and DEPI were adjusted (see description above)

CARBOFURAN-PHENOL

Carbofuran-phenol was not detected in soil. Therefore, entry of carbofuran-phenol into surface water through run-off and drainage is not relevant. Because benfuracarb does not enter surface water (see PEC_{sw} benfuracarb above) in significant amounts, carbofuran-phenol will predominantly occur in surface water and sediment through degradation of carbofuran to carbofuran-phenol. Therefore it is appropriate to calculate carbofuran-phenol concentrations based on simulated carbofuran concentrations in surface water bodies. Transformation of carbofuran to carbofuran-phenol, which mainly consists of a hydrolytic process, may take place in surface water bodies. Because of the high K_{oc} of carbofuran-phenol, carbofuran-phenol formed in the water is expected to be rapidly transferred to the sediment. This is also indicated by the fact that in water/sediment studies, carbofuran-phenol was only observed in the sediment.

In order to obtain an estimate of maximum concentrations of carbofuran-phenol in surface water and sediment, following application of granular benfuracarb in the furrow, the maximum PEC_{sw} and PEC_{sed} for carbofuran were multiplied using a MW correction factor ($164/221.3 = 0.74$) and the maximum % occurrence of carbofuran-phenol in water and sediment. In a water sediment study performed with benfuracarb, no carbofuran-phenol was detected in the water layer (hence PEC_{sw} for carbofuran-phenol will be 0 µg/L) and a maximum of 14% of applied radioactivity was detected in the sediment layer. Calculations were performed using the PEC_{sed} and PEC_{sw} results for carbofuran, which were calculated based on a carbofuran soil DT₅₀ of 14 days. The results are given in Table 8.

Table 8 Summary of maximum PEC_{SW} and PEC_{SED} concentrations for carbofuran-phenol (FOCUS STEP3/STEP4)

Scenario	System	Relevant for		Application date	Carbofuran-phenol	
		NE	SE		Max PEC _{sw} (µg/L) ²	Max PEC _{sed} (µg/kg)
D3 (STEP3)	ditch	X		April 10	0.000	0.0020
	ditch	X		July 25	0.000	0.0250
D4 (STEP3)	pond	X		May 16	0.000	0.0067
	stream	X		May 16	0.000	0.0095
D6 (STEP3)	ditch		X	Aug 04	0.000	0.0026
R1 (STEP4) ¹	pond	X		April 26	0.000	0.000
	pond	X		July 28	0.000	0.000
	stream	X		April 26	0.000	0.000
	stream	X		July 28	0.000	0.000
R2 (STEP4)	stream		X	March 06	0.000	0.000
	stream		X	Aug 05	0.000	0.000
R3 (STEP4)	stream		X	Feb 19	0.000	0.000
	stream		X	June 02	0.000	0.000
R4 (STEP4)	stream		X	March 01	0.000	0.000
	stream		X	June 01	0.000	0.000

¹ The run-off scenarios are referred to as STEP 4 calculations because the defaults for CAM and DEPI were adjusted (see description above)

² PEC_{sw} values for carbofuran-phenol are all 0.000 µg/L as no carbofuran-phenol was detected in the water layer of water/sediment studies

Appendix I: FOCUS STEP 1-2 calculations for benfuracarb

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 1

developed by Michael Klein

Program version: Version 1.1
Date of this simulation: 21/01/2009,
13:15:46

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: BFC

Active substance: benfuracarb
Application rate (g/ha) of a.i.: 1000.00
Application/crop type: no drift (incorp or
seed trtmt)
Number of applications per season: 1.00
Water solubility (mg/L): 8.40
KOC (L/kg): 9100.00
DT50 water/sediment (d): 0.63

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m): 1.00
Spraydrift (% of application): 0.0000
Runoff + drainage(% of application): 10.00
Ratio of field to water body: 10.00

Water depth (cm): 30.00
Sediment depth (cm): 5.00
Effective sediment depth for sorption (cm): 1.00
Sediment OC (%): 5.00
Sed. bulk density (kg/L): 0.80

RESULTS OF THE CALCULATION

Equivalent application rate for drift (g/ha): 1000.00
Equivalent application rate for runoff/drainage(g/ha): 1000.00
Loading to water body via drift (mg/m²): 0.0000
Loading to water body via runoff/drainage(mg/m²): 100.0000
fraction of substance entering water body in water phase: 0.0761
fraction of substance entering water body in sediment phase: 0.9239

Table: Calculated Concentrations in the water body

	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA
0	25.3807		2.31E+03	

1	8.4465	16.9136	768.6343	1.54E+03
2	2.8109	11.0179	255.7964	1.E+03
4	0.3113	6.0769	28.3298	553.0002
7	0.0115	3.5115	1.0442	319.5429
14	0.0000	1.7565	0.0005	159.8392
21	0.0000	1.1710	0.0000	106.5595
28	0.0000	0.8782	0.0000	79.9196
42	0.0000	0.5855	0.0000	53.2798
50	0.0000	0.4918	0.0000	44.7550
100	0.0000	0.2459	0.0000	22.3775

Maximum PEC_{sw} values in water and sediment are calculated from single application.
Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 2

developed by Michael Klein

Program version: Version 1.1
Date of this simulation: 21/01/2009, 13:17:46

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: BFC

Active substance: benfuracarb
Application rate (g/ha) of a.i.: 1000.00
Crop Interzeption: no interception (0 %)
Application/crop type: no drift (incorp or seed trtmt)
Number of applications per season: 1
Region and season of application: South Europe, Mar. - May
Water solubility (mg/L): 8.40
KOC (L/kg): 9100.00
DT50 water(d): 0.63
DT50 sediment (d): 0.63
DT50 soil (d): 0.43

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m): 1.00
Spraydrift (% of application): 0.0000
Runoff + drainage(% of application): 4.00
Ratio of field to water body: 10.00
Water depth (cm): 30.00
Sediment depth (cm): 5.00

Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	1000.00
Equivalent application rate for runoff/drainage(g/ha):	1000.00
Loading to water body per drift event(mg/m ²):	0.0000
Loading to water body via runoff/drainage(mg/m ²):	0.0634
fraction of substance entering water body in water phase:	0.0761
fraction of substance entering water body in sediment phase:	0.9239
Total Loading to water body via drift (mg/m ²):	0.0000 (0.0000%)
Total Loading to water body via water phase(mg/m ²):	0.0048 (7.6142%)
Total Loading to water body via sediment phase (mg/m ²):	0.0585 (92.3858%)
Maximum PECSW (µg/L):	0.0161
Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	1.4633
Maximum PECsed occurring on day:	4

Table: Calculated Concentrations in the water body

Time after max. peak(d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.0161	---	1.4633	---
1	0.0054	0.0107	0.4870	0.9751
2	0.0018	0.0071	0.1621	0.6498
4	0.0002	0.0040	0.0179	0.3609
7	0.0000	0.0023	0.0007	0.2087
14	0.0000	0.0011	0.0000	0.1044
21	0.0000	0.0008	0.0000	0.0696
28	0.0000	0.0006	0.0000	0.0522
42	0.0000	0.0004	0.0000	0.0348
50	0.0000	0.0003	0.0000	0.0292
100	0.0000	0.0002	0.0000	0.0146

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 2

developed by Michael Klein

Program version: Version 1.1
Date of this simulation: 21/01/2009, 13:16:30

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: BFC

Active substance:	benfuracarb
Application rate (g/ha) of a.i.:	1000.00
Crop Interzeption:	no interception (0 %)
Application/crop type:	no drift (incorp or seed trtmt)
Number of applications per season:	1
Region and season of application:	North Europe, Mar. - May
Water solubility (mg/L):	8.40
KOC (L/kg):	9100.00
DT50 water(d):	0.63
DT50 sediment (d):	0.63
DT50 soil (d):	0.43

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	0.0000
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	1000.00
Equivalent application rate for runoff/drainage(g/ha):	1000.00
Loading to water body per drift event(mg/m ²):	0.0000
Loading to water body via runoff/drainage(mg/m ²):	0.0317
fraction of substance entering water body in water phase:	0.0761
fraction of substance entering water body in sediment phase:	0.9239
Total Loading to water body via drift (mg/m ²):	0.0000 (0.0000%)
Total Loading to water body via water phase(mg/m ²):	0.0024 (7.6142%)
Total Loading to water body via sediment phase (mg/m ²):	0.0293 (92.3858%)

Maximum PECSW ($\mu\text{g/L}$):	0.0080
Maximum PECSW occurring on day:	4
Maximum PECsed ($\mu\text{g/kg}$ dry sediment):	0.7316
Maximum PECsed occurring on day:	4

Table: Calculated Concentrations in the water body

Time after max. peak(d)	PEC _{sw} ($\mu\text{g/L}$)		PEC _{sed} ($\mu\text{g/kg}$ dry sediment)	
	Actual	TWA	Actual	TWA
0	0.0080	---	0.7316	---
1	0.0027	0.0054	0.2435	0.4876
2	0.0009	0.0036	0.0810	0.3249
4	0.0001	0.0020	0.0090	0.1804
7	0.0000	0.0011	0.0003	0.1043
14	0.0000	0.0006	0.0000	0.0522
21	0.0000	0.0004	0.0000	0.0348
28	0.0000	0.0003	0.0000	0.0261
42	0.0000	0.0002	0.0000	0.0174
50	0.0000	0.0002	0.0000	0.0146
100	0.0000	0.0001	0.0000	0.0073

Appendix II FOCUS STEP3/4 calculations for benfuracarb


```
*-----*
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  #####  #####  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  #####  #####  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:43:31
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00421d_pa
* TOXSWA input file      : 00421d_pa.twx
* TOXSWA warnings/errors file : 00421d_pa.err
* TOXSWA summary file   : 00421d_pa.sum
*
* Project           : benfuracarb7
* Substance         : BEC7
* Crop             : Vegetables, leafy
* Location          : D3 (Meteo station: Vredep)
* Type of water body : focus_ditch
* Simulation period  : 01-Jan-1992 to 01-May-1993
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      10-Apr-1992 09:00      1000.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\MACRO\vegetables_leafy\macro00421_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 0.10 mm.h-1      02-Jan-1992 23:00
* Substance        : 0.00 mg.m-2.h-1    01-Jan-1992 00:00
* Substance concentration : 0.00 µg.L-1      01-Jan-1992 00:00
*
* Properties of substance           : BEC7
* Molar mass (g.mol-1)             : 410.5
* Saturated vapour pressure (Pa)    : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)         : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)            : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)         : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)           : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)           : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*-----*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Jan-1992 00:00
* PEC 1 day 0.000000 02-Jan-1992 00:00
* PEC 2 days 0.000000 03-Jan-1992 00:00
* PEC 4 days 0.000000 05-Jan-1992 00:00
* PEC 7 days 0.000000 08-Jan-1992 00:00
* PEC 14 days 0.000000 15-Jan-1992 00:00
* PEC 21 days 0.000000 22-Jan-1992 00:00
```

```

* PEC 28 days      0.000000      29-Jan-1992 00:00
* PEC 42 days      0.000000      12-Feb-1992 00:00
* PEC 50 days      0.000000      20-Feb-1992 00:00
* PEC 100 days     0.000000      10-Apr-1992 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jan-1992 00:00
* PEC 1 day        0.000000      02-Jan-1992 00:00
* PEC 2 days       0.000000      03-Jan-1992 00:00
* PEC 4 days       0.000000      05-Jan-1992 00:00
* PEC 7 days       0.000000      08-Jan-1992 00:00
* PEC 14 days      0.000000      15-Jan-1992 00:00
* PEC 21 days      0.000000      22-Jan-1992 00:00
* PEC 28 days      0.000000      29-Jan-1992 00:00
* PEC 42 days      0.000000      12-Feb-1992 00:00
* PEC 50 days      0.000000      20-Feb-1992 00:00
* PEC 100 days     0.000000      10-Apr-1992 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```
*****
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
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* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* Compiled with:VisualFortran v6.6.0.
* #####
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
* #####
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* #####
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:43:47
* Working Directory: C:\SwashProjects\benfuracarb7\towswa
* Run ID           : 00422d_pa
* TOXSWA input file      : 00422d_pa.twx
* TOXSWA warnings/errors file : 00422d_pa.err
* TOXSWA summary file   : 00422d_pa.sum
*
* Project           : benfuracarb7
* Substance         : BFC7
* Crop              : Vegetables, leafy
* Location          : D3 (Meteo station: Vredep
* Type of water body : focus_ditch
* Simulation period  : 01-Jan-1992 to 01-May-1993
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1      25-Jul-1992 09:00      1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\MACRO\vegetables_leafy\macro00422d_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 0.10 mm.h-1      03-Jan-1992 10:00
* Substance       : 0.00 mg.m-2.h-1    01-Jan-1992 00:00
* Substance concentration : 0.00 µg.L-1      01-Jan-1992 00:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)       : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)      : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)   : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*
* Actual concentrations in water layer in µg.L-1
* #####
* Global maximum 0.000000 01-Jan-1992 00:00
* PEC 1 day      0.000000 02-Jan-1992 00:00
* PEC 2 days     0.000000 03-Jan-1992 00:00
* PEC 4 days     0.000000 05-Jan-1992 00:00
* PEC 7 days     0.000000 06-Jan-1992 00:00
* PEC 14 days    0.000000 15-Jan-1992 00:00
* PEC 21 days    0.000000 22-Jan-1992 00:00
```

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* PEC 28 days      0.000000      29-Jan-1992 00:00
* PEC 42 days      0.000000      12-Feb-1992 00:00
* PEC 50 days      0.000000      20-Feb-1992 00:00
* PEC 100 days     0.000000      10-Apr-1992 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jan-1992 00:00
* PEC 1 day        0.000000      02-Jan-1992 00:00
* PEC 2 days       0.000000      03-Jan-1992 00:00
* PEC 4 days       0.000000      05-Jan-1992 00:00
* PEC 7 days       0.000000      08-Jan-1992 00:00
* PEC 14 days      0.000000      15-Jan-1992 00:00
* PEC 21 days      0.000000      22-Jan-1992 00:00
* PEC 28 days      0.000000      29-Jan-1992 00:00
* PEC 42 days      0.000000      12-Feb-1992 00:00
* PEC 50 days      0.000000      20-Feb-1992 00:00
* PEC 100 days     0.000000      10-Apr-1992 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations:
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

*-----*
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
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* #####  #####  ##  ##  #####  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* Compiled with: Visual Fortran v6.6.0. Copyright Alterra
*-----*
* T O X I C  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----*
* Alterra, Wageningen UR http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:44:04
* Working Directory: C:\SwashProjects\benfuracarb7\towswa
* Run ID : 00423p_pa
* TOXSWA input file : 00423p_pa.twx
* TOXSWA warnings/errors file : 00423p_pa.err
* TOXSWA summary file : 00423p_pa.sum
*
* Project : benfuracarb7
* Substance : BFC7
* Crop : Vegetables, leafy
* Location : D4 (Meteo station: Skousb
* Type of water body : focus_pond
* Simulation period : 01-Jan-1985 to 01-May-1986
*
* Applications
* Appl.No Date/Hour Mass (g ai.ha-1) Areaic mean deposition (%)
* 1 16-May-1985 09:00 1000.0 0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\MACRO\vegetables leafy\macro00423_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water : 0.30 mm.h-1 04-Dec-1985 15:00
* Substance : 0.00 mg.m-2.h-1 01-Jan-1985 00:00
* Substance concentration : 0.00 µg.L-1 01-Jan-1985 00:00
*
* Properties of substance : BFC7
* Molar mass (g.mol-1) : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1) : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d) : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d) : 0.63 measured at (°C) : 20.0
* Koc susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-) : 1.00
* Koc sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-) : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*-----*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Jan-1985 00:00
* PEC 1 day 0.000000 02-Jan-1985 00:00
* PEC 2 days 0.000000 03-Jan-1985 00:00
* PEC 4 days 0.000000 05-Jan-1985 00:00
* PEC 7 days 0.000000 08-Jan-1985 00:00
* PEC 14 days 0.000000 15-Jan-1985 00:00
* PEC 21 days 0.000000 22-Jan-1985 00:00

```

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* PEC 28 days      0.000000      29-Jan-1985 00:00
* PEC 42 days      0.000000      12-Feb-1985 00:00
* PEC 50 days      0.000000      20-Feb-1985 00:00
* PEC 100 days     0.000000      11-Apr-1985 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jan-1985 00:00
* PEC 1 day        0.000000      02-Jan-1985 00:00
* PEC 2 days       0.000000      03-Jan-1985 00:00
* PEC 4 days       0.000000      05-Jan-1985 00:00
* PEC 7 days       0.000000      08-Jan-1985 00:00
* PEC 14 days      0.000000      15-Jan-1985 00:00
* PEC 21 days      0.000000      22-Jan-1985 00:00
* PEC 28 days      0.000000      29-Jan-1985 00:00
* PEC 42 days      0.000000      12-Feb-1985 00:00
* PEC 50 days      0.000000      20-Feb-1985 00:00
* PEC 100 days     0.000000      11-Apr-1985 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```
***** FOCUS_TOXSWA v2.2.1
*      TOXSWA v2.1.2-F2
*      10-Nov-2005
*      Copyright: Alterra
* Compiled with: Visual Fortran v6.6.0.

-----
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
-----
* Alterra, Wageningen UR      http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
-----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:44:15
* Working Directory: C:\SwashProjects\benfuracarb7\towswa
* Run ID           : 00423s_pa
* TOXSWA input file      : 00423s_pa.tkw
* TOXSWA warnings/errors file : 00423s_pa.err
* TOXSWA summary file   : 00423s_pa.sum
*
* Project           : benfuracarb7
* Substance         : BFC7
* Crop              : Vegetables, leafy
* Location          : D4 (Meteo station: Skousb)
* Type of water body : focus_stream
* Simulation period  : 01-Jan-1985 to 01-May-1986
*
* Applications
* Appl.No Date/Hour      Mass (g al.ha-1)  Areic mean deposition (%)
* 1      16-May-1985 09:00      1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\MACRO\vegetables leafy\macro00423_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 0.30 mm.h-1      04-Dec-1985 15:00
* Substance       : 0.00 mg.m-2.h-1   01-Jan-1985 00:00
* Substance concentration : 0.00 µg.l-1      01-Jan-1985 00:00
*
* Properties of substance      : BFC7
* Molar masa (g.mol-1)       : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)      : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)   : 0.63 measured at (°C) : 20.0
* Kow susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Koc sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
-----
* Global maximum 0.000000 01-Jan-1985 00:00
* PEC 1 day 0.000000 02-Jan-1985 00:00
* PEC 2 days 0.000000 03-Jan-1985 00:00
* PEC 4 days 0.000000 05-Jan-1985 00:00
* PEC 7 days 0.000000 08-Jan-1985 00:00
* PEC 14 days 0.000000 15-Jan-1985 00:00
* PEC 21 days 0.000000 22-Jan-1985 00:00
```

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* PEC 28 days      0.000000      29-Jan-1985 00:00
* PEC 42 days      0.000000      12-Feb-1985 00:00
* PEC 50 days      0.000000      20-Feb-1985 00:00
* PEC 100 days     0.000000      11-Apr-1985 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.l-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jan-1985 00:00
* PEC 1 day        0.000000      02-Jan-1985 00:00
* PEC 2 days       0.000000      03-Jan-1985 00:00
* PEC 4 days       0.000000      05-Jan-1985 00:00
* PEC 7 days       0.000000      08-Jan-1985 00:00
* PEC 14 days      0.000000      15-Jan-1985 00:00
* PEC 21 days      0.000000      22-Jan-1985 00:00
* PEC 28 days      0.000000      29-Jan-1985 00:00
* PEC 42 days      0.000000      12-Feb-1985 00:00
* PEC 50 days      0.000000      20-Feb-1985 00:00
* PEC 100 days     0.000000      11-Apr-1985 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```



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*-----*
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
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* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* #####  ####  ##  ##  #####  ##  ##  #####  Copyright Alterra
* Compiled with: Visual Fortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                                http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:45:59
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00424d_pa
* TOXSWA input file      : 00424d_pa.twx
* TOXSWA warnings/errors file : 00424d_pa.err
* TOXSWA summary file   : 00424d_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : D6 (Meteo station: Thiva)
* Type of water body   : focus_ditch
* Simulation period    : 01-Jan-1986 to 01-May-1987
*
* Applications
* Appl.No  Date/Hour      Mass (g al.ha-1)  Areaic mean deposition (%)
* 1        04-Aug-1986 09:00       1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\MACRO\vegetables_leafy\macro00424_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 1.76 mm.h-1      19-Jan-1987 06:00
* Substance       : 0.00 mg.m-2.h-1   16-Aug-1986 19:00
* Substance concentration : 0.00 µg.L-1   16-Aug-1986 19:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)        : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)    : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)       : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)    : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)      : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)      : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Jan-1986 00:00
* PEC 1 day      0.000000 02-Jan-1986 00:00
* PEC 2 days     0.000000 03-Jan-1986 00:00
* PEC 4 days     0.000000 05-Jan-1986 00:00
* PEC 7 days     0.000000 08-Jan-1986 00:00
* PEC 14 days    0.000000 15-Jan-1986 00:00
* PEC 21 days    0.000000 22-Jan-1986 00:00
```

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* PEC 28 days      0.000000      29-Jan-1986 00:00
* PEC 42 days      0.000000      12-Feb-1986 00:00
* PEC 50 days      0.000000      20-Feb-1986 00:00
* PEC 100 days     0.000000      11-Apr-1986 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jan-1986 00:00
* PEC 1 day        0.000000      02-Jan-1986 00:00
* PEC 2 days       0.000000      03-Jan-1986 00:00
* PEC 4 days       0.000000      05-Jan-1986 00:00
* PEC 7 days       0.000000      08-Jan-1986 00:00
* PEC 14 days      0.000000      15-Jan-1986 00:00
* PEC 21 days      0.000000      22-Jan-1986 00:00
* PEC 28 days      0.000000      29-Jan-1986 00:00
* PEC 42 days      0.000000      12-Feb-1986 00:00
* PEC 50 days      0.000000      20-Feb-1986 00:00
* PEC 100 days     0.000000      11-Apr-1986 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

*-----*
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
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* ##  #####  ##  ##  #####  ##  ##  #####  ##  ##  #####  ##  ##  #####  ##  ##  #####
* #####  ##  ##  #####  ##  ##  #####  ##  ##  #####  ##  ##  #####  ##  ##  #####
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:49:12
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00425p_pa
* TOXSWA input file      : 00425p_pa.twx
* TOXSWA warnings/errors file : 00425p_pa.err
* TOXSWA summary file   : 00425p_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : R1 (Meteo station: Weiher)
* Type of water body   : focus_pond
* Simulation period    : 01-Mar-1984 to 01-Mar-1985
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1      26-Apr-1984 09:00      1000.0          0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PRZM\vegetables_leafy\00425-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.41 mm.h-1      22-Jan-1985 01:00
* Substance in water      : 0.00 mg.m-2.h-1      01-Mar-1984 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Mar-1984 00:00
* Substance concentration : 0.00 ug.L-1      01-Mar-1984 00:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)       : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)      : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)   : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*
* Actual concentrations in water layer in ug.L-1
*-----*
* Global maximum 0.000000 01-Mar-1984 00:00
* PEC 1 day 0.000000 02-Mar-1984 00:00
* PEC 2 days 0.000000 03-Mar-1984 00:00
* PEC 4 days 0.000000 05-Mar-1984 00:00
* PEC 7 days 0.000000 08-Mar-1984 00:00
* PEC 14 days 0.000000 15-Mar-1984 00:00

```

```

* PEC 21 days      0.000000      22-Mar-1984 00:00
* PEC 28 days      0.000000      29-Mar-1984 00:00
* PEC 42 days      0.000000      12-Apr-1984 00:00
* PEC 50 days      0.000000      20-Apr-1984 00:00
* PEC 100 days     0.000000      09-Jun-1984 00:00
-----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Mar-1984 00:00
* PEC 1 day        0.000000      02-Mar-1984 00:00
* PEC 2 days       0.000000      03-Mar-1984 00:00
* PEC 4 days       0.000000      05-Mar-1984 00:00
* PEC 7 days       0.000000      08-Mar-1984 00:00
* PEC 14 days      0.000000      15-Mar-1984 00:00
* PEC 21 days      0.000000      22-Mar-1984 00:00
* PEC 28 days      0.000000      29-Mar-1984 00:00
* PEC 42 days      0.000000      12-Apr-1984 00:00
* PEC 50 days      0.000000      20-Apr-1984 00:00
* PEC 100 days     0.000000      09-Jun-1984 00:00
-----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
* End of TOXSWA report

```

```
*-----*
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  ##  #####  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  #####  #####  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I c   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:49:21
* Working Directory: C:\SwashProjects\benfuracarb7\toxawa
* Run ID           : 00425a_pa
* TOXSWA input file      : 00425a_pa.twx
* TOXSWA warnings/errors file : 00425a_pa.err
* TOXSWA summary file   : 00425a_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : R1 (Meteo station: Weiher)
* Type of water body   : focus_stream
* Simulation period    : 01-Mar-1984 to 01-Mar-1985
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      26-Apr-1984 09:00      1000.0            0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PRIM\vegetables_leafy\00425-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water              : 1.41 mm.h-1      22-Jan-1985 01:00
* Substance in water   : 0.00 mg.m-2.h-1      01-Mar-1984 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Mar-1984 00:00
* Substance concentration : 0.00 µg.L-1      01-Mar-1984 00:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)        : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)    : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)       : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)    : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)      : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)      : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Mar-1984 00:00
* PEC 1 day 0.000000 02-Mar-1984 00:00
* PEC 2 days 0.000000 03-Mar-1984 00:00
* PEC 4 days 0.000000 05-Mar-1984 00:00
* PEC 7 days 0.000000 08-Mar-1984 00:00
* PEC 14 days 0.000000 15-Mar-1984 00:00
```

```

* PEC 21 days      0.000000      22-Mar-1984 00:00
* PEC 28 days      0.000000      29-Mar-1984 00:00
* PEC 42 days      0.000000      12-Apr-1984 00:00
* PEC 50 days      0.000000      20-Apr-1984 00:00
* PEC 100 days     0.000000      09-Jun-1984 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.l-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000      01-Mar-1984 00:00
* PEC 1 day       0.000000      02-Mar-1984 00:00
* PEC 2 days     0.000000      03-Mar-1984 00:00
* PEC 4 days     0.000000      05-Mar-1984 00:00
* PEC 7 days     0.000000      08-Mar-1984 00:00
* PEC 14 days    0.000000      15-Mar-1984 00:00
* PEC 21 days    0.000000      22-Mar-1984 00:00
* PEC 28 days    0.000000      29-Mar-1984 00:00
* PEC 42 days    0.000000      12-Apr-1984 00:00
* PEC 50 days    0.000000      20-Apr-1984 00:00
* PEC 100 days   0.000000      09-Jun-1984 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

*-----*
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* Compiled with:VisualFortran v6.6.0. Copyright Alterra
*-----*
* T O X i c  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----*
* Alterra, Wageningen UR http://www.alterra.wor.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:50:09
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID : 00426p_pa
* TOXSWA input file : 00426p_pa.twx
* TOXSWA warnings/errors file : 00426p_pa.err
* TOXSWA summary file : 00426p_pa.sum
*
* Project : benfuracarb7
* Substance : BFC7
* Crop : Vegetables, leafy
* Location : R1 (Meteo station: Weiher
* Type of water body : focus_pond
* Simulation period : 01-Jun-1978 to 01-Jun-1979
*
* Applications
* Appl.No Date/Hour Mass (g a.l.ha-1) Areaic mean deposition (%)
* 1 28-Jul-1978 09:00 1000.0 0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PR2M\vegetables_leafy\00426-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water : 1.39 mm.h-1 09-Dec-1978 01:00
* Substance in water : 0.00 mg.m-2.h-1 01-Jun-1978 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1 01-Jun-1978 00:00
* Substance concentration : 0.00 ug.L-1 01-Jun-1978 00:00
*
* Properties of substance : BFC7
* Molar mass (g.mol-1) : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1) : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d) : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d) : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-) : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-) : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in ug.L-1
*-----*
* Global maximum 0.000000 01-Jun-1978 00:00
* PEC 1 day 0.000000 02-Jun-1978 00:00
* PEC 2 days 0.000000 03-Jun-1978 00:00
* PEC 4 days 0.000000 05-Jun-1978 00:00
* PEC 7 days 0.000000 08-Jun-1978 00:00
* PEC 14 days 0.000000 15-Jun-1978 00:00

```

```

* PEC 21 days      0.000000      22-Jun-1978 00:00
* PEC 28 days      0.000000      29-Jun-1978 00:00
* PEC 42 days      0.000000      13-Jul-1978 00:00
* PEC 50 days      0.000000      21-Jul-1978 00:00
* PEC 100 days     0.000000      09-Sep-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000      01-Jun-1978 00:00
* PEC 1 day       0.000000      02-Jun-1978 00:00
* PEC 2 days      0.000000      03-Jun-1978 00:00
* PEC 4 days      0.000000      05-Jun-1978 00:00
* PEC 7 days      0.000000      08-Jun-1978 00:00
* PEC 14 days     0.000000      15-Jun-1978 00:00
* PEC 21 days     0.000000      22-Jun-1978 00:00
* PEC 28 days     0.000000      29-Jun-1978 00:00
* PEC 42 days     0.000000      13-Jul-1978 00:00
* PEC 50 days     0.000000      21-Jul-1978 00:00
* PEC 100 days    0.000000      09-Sep-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations:
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```



```

* -----
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  #####  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  #####  ##  ##  #####  ##  ##  ##  ##  #####  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X I c  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:50:18
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00426s_pa
* TOXSWA input file       : 00426s_pa.twx
* TOXSWA warnings/errors file : 00426s_pa.err
* TOXSWA summary file    : 00426s_pa.sum
*
* Project           : benfuracarb7
* Substance         : BFC7
* Crop              : Vegetables, leafy
* Location          : R1 (Meteo station: Weiher)
* Type of water body : focus_stream
* Simulation period  : 01-Jun-1978 to 01-Jun-1979
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1       28-Jul-1978 09:00      1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PR2M\vegetables_leafy\00426-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.39 mm.h-1      09-Dec-1978 01:00
* Substance in water : 0.00 mg.m-2.h-1      01-Jun-1978 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1978 00:00
* Substance concentration : 0.00 µg.L-1      01-Jun-1978 00:00
*
* Properties of substance : BFC7
* Molar mass (g.mol-1) : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1) : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d) : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d) : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-) : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-) : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum 0.000000 01-Jun-1978 00:00
* PEC 1 day 0.000000 02-Jun-1978 00:00
* PEC 2 days 0.000000 03-Jun-1978 00:00
* PEC 4 days 0.000000 05-Jun-1978 00:00
* PEC 7 days 0.000000 08-Jun-1978 00:00
* PEC 14 days 0.000000 15-Jun-1978 00:00

```

```

* PEC 21 days      0.000000      22-Jun-1978 00:00
* PEC 28 days      0.000000      29-Jun-1978 00:00
* PEC 42 days      0.000000      13-Jul-1978 00:00
* PEC 50 days      0.000000      21-Jul-1978 00:00
* PEC 100 days     0.000000      09-Sep-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000      01-Jun-1978 00:00
* PEC 1 day       0.000000      02-Jun-1978 00:00
* PEC 2 days     0.000000      03-Jun-1978 00:00
* PEC 4 days     0.000000      05-Jun-1978 00:00
* PEC 7 days     0.000000      08-Jun-1978 00:00
* PEC 14 days    0.000000      15-Jun-1978 00:00
* PEC 21 days    0.000000      22-Jun-1978 00:00
* PEC 28 days    0.000000      29-Jun-1978 00:00
* PEC 42 days    0.000000      13-Jul-1978 00:00
* PEC 50 days    0.000000      21-Jul-1978 00:00
* PEC 100 days   0.000000      09-Sep-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations:
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

* -----
* #####      ## ##      ##### ## ##      #####      FOCUS_TOXSWA v2.2.1
* ## ## ## ## ## ##      ## ##      ## ## ##      TOXSWA v2.1.2-F2
* ## ## ## ## ## ##      ##### ## ## ## ## ##      10-Nov-2005
* ## ## ## ## ## ##      ## ## ## ## ## ##      #####
* ## ##### ## ## ##### ## ## ## ##      Copyright Alterra
* Compiled with:VisualFortran v6.6.0
* -----
* T O X I c   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:51:05
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00427s_pa
* TOXSWA input file      : 00427s_pa.txw
* TOXSWA warnings/errors file : 00427s_pa.err
* TOXSWA summary file   : 00427s_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : R2 (Meteo station: Porto)
* Type of water body   : focus_stream
* Simulation period    : 01-Oct-1977 to 01-Oct-1978
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      06-Mar-1978 09:00      1000.0            0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PR2M\vegetables_leafy\00427-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.22 mm.h-1      16-Feb-1978 01:00
* Substance in water : 0.00 mg.m-2,h-1      01-Oct-1977 00:00
* Substance in eroded mass : 0.00 mg.m-2,h-1      01-Oct-1977 00:00
* Substance concentration : 0.00 µg.L-1      01-Oct-1977 00:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)       : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)      : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)   : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum 0.000000 01-Oct-1977 00:00
* PEC 1 day 0.000000 02-Oct-1977 00:00
* PEC 2 days 0.000000 03-Oct-1977 00:00
* PEC 4 days 0.000000 05-Oct-1977 00:00
* PEC 7 days 0.000000 08-Oct-1977 00:00
* PEC 14 days 0.000000 15-Oct-1977 00:00

```

```

* PEC 21 days      0.000000      22-Oct-1977 00:00
* PEC 28 days      0.000000      29-Oct-1977 00:00
* PEC 42 days      0.000000      12-Nov-1977 00:00
* PEC 50 days      0.000000      20-Nov-1977 00:00
* PEC 100 days     0.000000      09-Jan-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.l-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000      01-Oct-1977 00:00
* PEC 1 day       0.000000      02-Oct-1977 00:00
* PEC 2 days     0.000000      03-Oct-1977 00:00
* PEC 4 days     0.000000      05-Oct-1977 00:00
* PEC 7 days     0.000000      08-Oct-1977 00:00
* PEC 14 days    0.000000      15-Oct-1977 00:00
* PEC 21 days    0.000000      22-Oct-1977 00:00
* PEC 28 days    0.000000      29-Oct-1977 00:00
* PEC 42 days    0.000000      12-Nov-1977 00:00
* PEC 50 days    0.000000      20-Nov-1977 00:00
* PEC 100 days   0.000000      09-Jan-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

* -----
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  #####  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  #####  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X i c   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:52:23
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00428s_pa
* TOXSWA input file      : 00428s_pa.twx
* TOXSWA warnings/errors file : 00428s_pa.err
* TOXSWA summary file   : 00428s_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : R2 (Meteo station: Porto)
* Type of water body   : focus_stream
* Simulation period    : 01-Jun-1989 to 01-Jun-1990
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1      05-Aug-1989 09:00      1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PRZM\vegetables_leafy\00428-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.27 mm.h-1      25-Dec-1989 01:00
* Substance in water : 0.00 mg.m-2.h-1      01-Jun-1989 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1989 00:00
* Substance concentration : 0.00 µg.L-1      01-Jun-1989 00:00
*
* Properties of substance           : BFC7
* Molar mass (g.mol-1)             : 410.5
* Saturated vapour pressure (Pa)    : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)         : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)            : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)         : 0.63 measured at (°C) : 20.0
* Kom ausp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)           : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)           : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum 0.000000 01-Jun-1989 00:00
* PEC 1 day      0.000000 02-Jun-1989 00:00
* PEC 2 days     0.000000 03-Jun-1989 00:00
* PEC 4 days     0.000000 05-Jun-1989 00:00
* PEC 7 days     0.000000 08-Jun-1989 00:00
* PEC 14 days    0.000000 15-Jun-1989 00:00

```

```

* PEC 21 days      0.000000      22-Jun-1989 00:00
* PEC 28 days      0.000000      29-Jun-1989 00:00
* PEC 42 days      0.000000      13-Jul-1989 00:00
* PEC 50 days      0.000000      21-Jul-1989 00:00
* PEC 100 days     0.000000      09-Sep-1989 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000      01-Jun-1989 00:00
* PEC 1 day       0.000000      02-Jun-1989 00:00
* PEC 2 days      0.000000      03-Jun-1989 00:00
* PEC 4 days      0.000000      05-Jun-1989 00:00
* PEC 7 days      0.000000      08-Jun-1989 00:00
* PEC 14 days     0.000000      15-Jun-1989 00:00
* PEC 21 days     0.000000      22-Jun-1989 00:00
* PEC 28 days     0.000000      29-Jun-1989 00:00
* PEC 42 days     0.000000      13-Jul-1989 00:00
* PEC 50 days     0.000000      21-Jul-1989 00:00
* PEC 100 days    0.000000      09-Sep-1989 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

*-----*
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  #####  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* #####  #####  #####  #####  #####  #####  #####  #####  #####  #####  #####  #####  #####  #####
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:53:41
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00429s_pa
* TOXSWA input file       : 00429s_pa.twx
* TOXSWA warnings/errors file : 00429s_pa.err
* TOXSWA summary file    : 00429s_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : R3 (Meteo-station: Bologn
* Type of water body   : focus_stream
* Simulation period    : 01-Oct-1980 to 01-Oct-1981
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1      19-Feb-1981 09:00      1000.0          0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PR2M\vegetables_leafy\00429-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.17 mm.h-1      27-Nov-1980 01:00
* Substance in water : 0.00 mg.m-2.h-1      01-Oct-1980 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Oct-1980 00:00
* Substance concentration : 0.00 ug.L-1      01-Oct-1980 00:00
*
* Properties of substance           : BFC7
* Molar mass (g.mol-1)             : 410.5
* Saturated vapour pressure (Pa)    : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)         : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)            : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)         : 0.63 measured at (°C) : 20.0
* Kom ausp.solid (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)           : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)           : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in ug.L-1
*-----*
* Global maximum 0.000000 01-Oct-1980 00:00
* PEC 1 day      0.000000 02-Oct-1980 00:00
* PEC 2 days     0.000000 03-Oct-1980 00:00
* PEC 4 days     0.000000 05-Oct-1980 00:00
* PEC 7 days     0.000000 08-Oct-1980 00:00
* PEC 14 days    0.000000 15-Oct-1980 00:00

```

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* PEC 21 days      0.000000      22-Oct-1980 00:00
* PEC 28 days      0.000000      29-Oct-1980 00:00
* PEC 42 days      0.000000      12-Nov-1980 00:00
* PEC 50 days      0.000000      20-Nov-1980 00:00
* PEC 100 days     0.000000      09-Jan-1981 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Oct-1980 00:00
* PEC 1 day        0.000000      02-Oct-1980 00:00
* PEC 2 days      0.000000      03-Oct-1980 00:00
* PEC 4 days      0.000000      05-Oct-1980 00:00
* PEC 7 days      0.000000      08-Oct-1980 00:00
* PEC 14 days     0.000000      15-Oct-1980 00:00
* PEC 21 days     0.000000      22-Oct-1980 00:00
* PEC 28 days     0.000000      29-Oct-1980 00:00
* PEC 42 days     0.000000      12-Nov-1980 00:00
* PEC 50 days     0.000000      20-Nov-1980 00:00
* PEC 100 days    0.000000      09-Jan-1981 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```



```

* -----
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* #####  ##  ##  ##  ##  ##  ##  ##  ##  #####  TOXSWA v2.1.2-F2
* ##  ##  ##  ##  ##  #####  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  ##  ##  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  #####  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X I C  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:54:28
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00430s_pa
* TOXSWA input file      : 00430s_pa.twx
* TOXSWA warnings/errors file : 00430s_pa.err
* TOXSWA summary file   : 00430s_pa.sum
*
* Project              : benfuracarb7
* Substance            : BFC7
* Crop                 : Vegetables, leafy
* Location             : R3 (Meteo station: Bologn
* Type of water body   : focus_stream
* Simulation period    : 01-Jun-1975 to 01-Jun-1976
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (t)
* 1      02-Jun-1975 09:00      1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PKZM\vegetables_leafy\00430-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.21 mm.h-1      11-Oct-1975 01:00
* Substance in water      : 0.00 mg.m-2.h-1      01-Jun-1975 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1975 00:00
* Substance concentration : 0.00 µg.L-1      01-Jun-1975 00:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)       : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)      : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)   : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)    : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)    : 1.00
* Kmp (Coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum 0.000000 01-Jun-1975 00:00
* PEC 1 day 0.000000 02-Jun-1975 00:00
* PEC 2 days 0.000000 03-Jun-1975 00:00
* PEC 4 days 0.000000 05-Jun-1975 00:00
* PEC 7 days 0.000000 08-Jun-1975 00:00
* PEC 14 days 0.000000 15-Jun-1975 00:00

```

```

* PEC 21 days      0.000000      22-Jun-1975 00:00
* PEC 28 days      0.000000      29-Jun-1975 00:00
* PEC 42 days      0.000000      13-Jul-1975 00:00
* PEC 50 days      0.000000      21-Jul-1975 00:00
* PEC 100 days     0.000000      09-Sep-1975 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000      01-Jun-1975 00:00
* PEC 1 day       0.000000      02-Jun-1975 00:00
* PEC 2 days     0.000000      03-Jun-1975 00:00
* PEC 4 days     0.000000      05-Jun-1975 00:00
* PEC 7 days     0.000000      08-Jun-1975 00:00
* PEC 14 days    0.000000      15-Jun-1975 00:00
* PEC 21 days    0.000000      22-Jun-1975 00:00
* PEC 28 days    0.000000      29-Jun-1975 00:00
* PEC 42 days    0.000000      13-Jul-1975 00:00
* PEC 50 days    0.000000      21-Jul-1975 00:00
* PEC 100 days   0.000000      09-Sep-1975 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report

```

```

*-----*
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
*-----*
* TOXIC SUBSTANCES IN SURFACE WATERS
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:55:15
* Working Directory: C:\SwashProjects\benfuracarb7\towswa
* Run ID           : 00431s_pa
* TOXSWA input file       : 00431s_pa.twx
* TOXSWA warnings/errors file : 00431s_pa.err
* TOXSWA summary file    : 00431s_pa.sum
*
* Project           : benfuracarb7
* Substance         : BFC7
* Crop              : Vegetables, leafy
* Location          : R4 (Meteo station: Roujan)
* Type of water body : focus_stream
* Simulation period  : 01-Oct-1979 to 01-Oct-1980
*
* Applications
* Appl.No Date/Hour      Mass (g al.ha-1)  Areaic mean deposition (%)
* 1       01-Mar-1980 09:00      1000.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PRZM\vegetables_leafy\00431-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 2.01 mm.h-1      04-Oct-1979 01:00
* Substance in water : 0.00 mg.m-2.h-1      01-Oct-1979 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Oct-1979 00:00
* Substance concentration : 0.00 µg.L-1      01-Oct-1979 00:00
*
* Properties of substance           : BFC7
* Molar mass (g.mol-1)             : 410.5
* Saturated vapour pressure (Pa)    : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)        : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)           : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)        : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)          : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)          : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Oct-1979 00:00
* PEC 1 day 0.000000 02-Oct-1979 00:00
* PEC 2 days 0.000000 03-Oct-1979 00:00
* PEC 4 days 0.000000 05-Oct-1979 00:00
* PEC 7 days 0.000000 08-Oct-1979 00:00
* PEC 14 days 0.000000 15-Oct-1979 00:00

```

```
* PEC 21 days      0.000000      22-Oct-1979 00:00
* PEC 28 days      0.000000      29-Oct-1979 00:00
* PEC 42 days      0.000000      12-Nov-1979 00:00
* PEC 50 days      0.000000      20-Nov-1979 00:00
* PEC 100 days     0.000000      09-Jan-1980 00:00
```

```
-----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.l-1
```

```
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
```

```
* Actual concentrations in sediment in µg.kg-1 DW
```

```
-----
* Global maximum 0.000000      01-Oct-1979 00:00
* PEC 1 day       0.000000      02-Oct-1979 00:00
* PEC 2 days     0.000000      03-Oct-1979 00:00
* PEC 4 days     0.000000      05-Oct-1979 00:00
* PEC 7 days     0.000000      08-Oct-1979 00:00
* PEC 14 days    0.000000      15-Oct-1979 00:00
* PEC 21 days    0.000000      22-Oct-1979 00:00
* PEC 28 days    0.000000      29-Oct-1979 00:00
* PEC 42 days    0.000000      12-Nov-1979 00:00
* PEC 50 days    0.000000      20-Nov-1979 00:00
* PEC 100 days   0.000000      09-Jan-1980 00:00
-----
```

```
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
```

```
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
```

```
* End of TOXSWA report.
```

```

*-----*
* #####  ####  ##  ##  ####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  10-Nov-2005
*  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  #####
*  ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
*-----*
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-13:56:11
* Working Directory: C:\SwashProjects\benfuracarb7\toxswa
* Run ID           : 00432s_pa
* TOXSWA input file      : 00432s_pa.twx
* TOXSWA warnings/errors file : 00432s_pa.err
* TOXSWA summary file   : 00432s_pa.sum
*
* Project                : benfuracarb7
* Substance              : BFC7
* Crop                  : Vegetables, leafy
* Location               : R4 (Meteo station: Roujan)
* Type of water body    : focus_stream
* Simulation period     : 01-Jun-1985 to 01-Jun-1986
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)   Areaic mean deposition (%)
* 1      01-Jun-1985 09:00      1000.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb7\PRZM\vegetables_leafy\00432-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water                : 1.86 mm.h-1      15-Feb-1986 01:00
* Substance in water   : 0.00 mg.m-2.h-1    01-Jun-1985 00:00
* Substance in eroded mass : 0.00 mg.m-2.h-1    01-Jun-1985 00:00
* Substance concentration : 0.00 µg.L-1      01-Jun-1985 00:00
*
* Properties of substance      : BFC7
* Molar mass (g.mol-1)       : 410.5
* Saturated vapour pressure (Pa) : 0.420E-05 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.840E+01 measured at (°C) : 20.0
* Half-life in water (d)      : 1000.00 measured at (°C) : 20.0
* Half-life in sediment (d)   : 0.63 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 5278.42
* Freundlich exponent (-)     : 1.00
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Jun-1985 00:00
* PEC 1 day 0.000000 02-Jun-1985 00:00
* PEC 2 days 0.000000 03-Jun-1985 00:00
* PEC 4 days 0.000000 05-Jun-1985 00:00
* PEC 7 days 0.000000 08-Jun-1985 00:00
* PEC 14 days 0.000000 15-Jun-1985 00:00

```

```

* PEC 21 days      0.000000      22-Jun-1985 00:00
* PEC 28 days      0.000000      29-Jun-1985 00:00
* PEC 42 days      0.000000      13-Jul-1985 00:00
* PEC 50 days      0.000000      21-Jul-1985 00:00
* PEC 100 days     0.000000      09-Sep-1985 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jun-1985 00:00
* PEC 1 day        0.000000      02-Jun-1985 00:00
* PEC 2 days       0.000000      03-Jun-1985 00:00
* PEC 4 days       0.000000      05-Jun-1985 00:00
* PEC 7 days       0.000000      08-Jun-1985 00:00
* PEC 14 days      0.000000      15-Jun-1985 00:00
* PEC 21 days      0.000000      22-Jun-1985 00:00
* PEC 28 days      0.000000      29-Jun-1985 00:00
* PEC 42 days      0.000000      13-Jul-1985 00:00
* PEC 50 days      0.000000      21-Jul-1985 00:00
* PEC 100 days     0.000000      09-Sep-1985 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSsed1
* simulated period too short for calculation of TWAECSsed2
* simulated period too short for calculation of TWAECSsed4
* simulated period too short for calculation of TWAECSsed7
* simulated period too short for calculation of TWAECSsed14
* simulated period too short for calculation of TWAECSsed21
* simulated period too short for calculation of TWAECSsed28
* simulated period too short for calculation of TWAECSsed42
* simulated period too short for calculation of TWAECSsed50
* simulated period too short for calculation of TWAECSsed100
-----
*
* End of TOXSWA report

```

Appendix III FOCUS STEP3/4 calculations for carbofuran

```
*-----*
* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-PZ
* ##  ##  ##  ###  #####  ##  ###  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-08:54:04
* Working Directory: C:\SwashProjects\benfuracarb6\toxswa
* Run ID           : 00417d_pa
* TOXSWA input file      : 00417d_pa.twx
* TOXSWA warnings/errors file : 00417d_pa.err
* TOXSWA summary file   : 00417d_pa.sum
*
* Project              : benfuracarb6
* Substance            : CF5
* Crop                 : Vegetables, leafy
* Location             : D3 (Meteo station; Vredep
* Type of water body   : focus_ditch
* Simulation period    : 01-Jan-1992 to 01-May-1993
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      10-Apr-1992 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb6\MACRO\vegetables_leafy\macro00417_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 0.10 mm.h-1      02-Jan-1992 23:00
* Substance       : 0.00 mg.m-2.h-1   02-Jan-1992 23:00
* Substance concentration : 0.03 µg.L-1      23-Nov-1992 01:00
*
* Properties of substance      : CF5
* Molar mass (g.mol-1)        :      221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)    : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)       :      15.30 measured at (°C) : 20.0
* Half-life in sediment (d)    :      1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) :      12.76
* Freundlich exponent (-)      :      0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) :      12.76
* Freundlich exponent (-)      :      0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) :      0.00
*
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum      0.0110      23-Nov-1992 09:00
* PEC 1 day           0.0110      24-Nov-1992 09:00
* PEC 2 days          0.0110      25-Nov-1992 09:00
* PEC 4 days          0.0110      27-Nov-1992 09:00
* PEC 7 days          0.0110      30-Nov-1992 09:00
* PEC 14 days         0.0110      07-Dec-1992 09:00
* PEC 21 days         0.0110      14-Dec-1992 09:00
```



```
* PEC 28 days      0.0110      21-Dec-1992 09:00
* PEC 42 days      0.0110      04-Jan-1993 09:00
* PEC 50 days      0.0109      12-Jan-1993 09:00
* PEC 100 days     0.0104      03-Mar-1993 09:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day      0.0110      23-Nov-1992 21:00
* TWAEC 2 days     0.0110      24-Nov-1992 11:00
* TWAEC 4 days     0.0110      25-Nov-1992 17:00
* TWAEC 7 days     0.0110      28-Nov-1992 08:00
* TWAEC 14 days    0.0110      04-Dec-1992 13:00
* TWAEC 21 days    0.0110      12-Dec-1992 03:00
* TWAEC 28 days    0.0110      19-Dec-1992 05:00
* TWAEC 42 days    0.0110      01-Jan-1993 18:00
* TWAEC 50 days    0.0110      09-Jan-1993 11:00
* TWAEC 100 days   0.0109      08-Feb-1993 11:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum   0.0191      31-Mar-1993 11:00
* PEC 1 day        0.0191      01-Apr-1993 11:00
* PEC 2 days       0.0191      02-Apr-1993 11:00
* PEC 4 days       0.0190      04-Apr-1993 11:00
* PEC 7 days       0.0190      07-Apr-1993 11:00
* PEC 14 days      0.0190      14-Apr-1993 11:00
* PEC 21 days      0.0190      21-Apr-1993 11:00
* PEC 28 days      0.0190      28-Apr-1993 11:00
* simulated period too short for calculation of PECsed42
* simulated period too short for calculation of PECsed50
* simulated period too short for calculation of PECsed100
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day      0.0191      01-Apr-1993 01:00
* TWAEC 2 days     0.0191      01-Apr-1993 02:00
* TWAEC 4 days     0.0191      01-Apr-1993 05:00
* TWAEC 7 days     0.0191      01-Apr-1993 10:00
* TWAEC 14 days    0.0191      02-Apr-1993 04:00
* TWAEC 21 days    0.0191      03-Apr-1993 15:00
* TWAEC 28 days    0.0191      08-Apr-1993 17:00
* TWAEC 42 days    0.0190      22-Apr-1993 21:00
* TWAEC 50 days    0.0190      27-Apr-1993 16:00
* TWAEC 100 days   0.0189      01-May-1993 00:00
-----
*
* End of TCXSWA report
```

```

* #####  ####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* #####  ####  ##  ##  #####  ##  ##  #####  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
*-----
* T O X i c  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----
* Alterra, Wageningen UR      http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-08:54:56
* Working Directory: C:\SwashProjects\benfuracarb6\toxswa
* Run ID      : 00418d_pa
* TOXSWA input file      : 00418d_pa.twx
* TOXSWA warnings/errors file : 00418d_pa.err
* TOXSWA summary file    : 00418d_pa.sum
*
* Project      : benfuracarb6
* Substance    : CF5
* Crop        : Vegetables, leafy
* Location     : D3 (Meteo station: Vredep
* Type of water body : focus_ditch
* Simulation period : 01-Jan-1992 to 01-May-1993
*
* Applications
* Appl.No Date/Hour      Mass (g al.ha-1)   Areaic mean deposition (%)
* 1      25-Jul-1992 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb6\MACRO\vegetables leafy\macro00418_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water      : 0.10 mm.h-1      03-Jan-1992 10:00
* Substance   : 0.00 mg.m-2.h-1      07-Jan-1992 21:00
* Substance concentration : 0.49 µg.L-1      22-May-1992 08:00
*
* Properties of substance      : CF5
* Molar mass (g.mol-1)      : 221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)    : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)      : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)   : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)     : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)     : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*-----
* Actual concentrations in water layer in µg.L-1
*-----
* Global maximum      0.159      13-Jun-1992 09:00
* PEC 1 day           0.159      14-Jun-1992 09:00
* PEC 2 days          0.158      15-Jun-1992 09:00
* PEC 4 days          0.158      17-Jun-1992 09:00
* PEC 7 days          0.158      20-Jun-1992 09:00
* PEC 14 days         0.157      27-Jun-1992 09:00
* PEC 21 days         0.156      04-Jul-1992 09:00

```

```
* PEC 28 days      0.155      11-Jul-1992 09:00
* PEC 42 days      0.153      25-Jul-1992 09:00
* PEC 50 days      0.151      02-Aug-1992 09:00
* PEC 100 days     0.131      21-Sep-1992 09:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day      0.159      13-Jun-1992 19:00
* TWAEC 2 days     0.159      14-Jun-1992 12:00
* TWAEC 4 days     0.159      15-Jun-1992 11:00
* TWAEC 7 days     0.158      17-Jun-1992 13:00
* TWAEC 14 days    0.158      23-Jun-1992 03:00
* TWAEC 21 days    0.158      17-Jun-1992 20:00
* TWAEC 28 days    0.158      20-Jun-1992 18:00
* TWAEC 42 days    0.158      26-Jun-1992 13:00
* TWAEC 50 days    0.158      29-Jun-1992 19:00
* TWAEC 100 days   0.156      23-Jul-1992 04:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum   0.241      14-Mar-1993 12:00
* PEC 1 day        0.241      15-Mar-1993 12:00
* PEC 2 days       0.241      16-Mar-1993 12:00
* PEC 4 days       0.241      18-Mar-1993 12:00
* PEC 7 days       0.241      21-Mar-1993 12:00
* PEC 14 days      0.241      26-Mar-1993 12:00
* PEC 21 days      0.240      04-Apr-1993 12:00
* PEC 28 days      0.240      11-Apr-1993 12:00
* PEC 42 days      0.239      25-Apr-1993 12:00
* simulated period too short for calculation of PECsed50
* simulated period too short for calculation of PECsed100
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day      0.241      14-Mar-1993 19:00
* TWAEC 2 days     0.241      15-Mar-1993 10:00
* TWAEC 4 days     0.241      16-Mar-1993 17:00
* TWAEC 7 days     0.241      18-Mar-1993 20:00
* TWAEC 14 days    0.241      24-Mar-1993 06:00
* TWAEC 21 days    0.241      29-Mar-1993 20:00
* TWAEC 28 days    0.241      02-Apr-1993 02:00
* TWAEC 42 days    0.241      08-Apr-1993 14:00
* TWAEC 50 days    0.241      13-Apr-1993 09:00
* TWAEC 100 days   0.240      01-May-1993 00:00
-----
*
* End of TOXSWA report
```

```

* #####      ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
-----
* T O X i c   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
-----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
-----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-08:55:45
* Working Directory: C:\SwashProjects\benfuracarb6\towswa
* Run ID           : 00419p_pa
* TOXSWA input file      : 00419p_pa.twx
* TOXSWA warnings/errors file : 00419p_pa.err
* TOXSWA summary file    : 00419p_pa.sum
*
* Project              : benfuracarb6
* Substance            : CF5
* Crop                 : Vegetables, leafy
* Location             : D4 (Meteo station:-Skousb
* Type of water body   : focus_pond
* Simulation period     : 01-Jan-1985 to 01-May-1986
*
* Applications
* Appl.No Date/Hour      Mass (g ai,ha-1)  Areaic mean deposition (%)
* 1      16-May-1985 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb6\MACRO\vegetables_leafy\macro00419_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water      : 0.30 mm,h-1      04-Dec-1985 15:00
* Substance   : 0.00 mg,m-2,h-1  21-Aug-1985 07:00
* Substance concentration : 0.83 µg,L-1  21-Aug-1985 12:00
*
* Properties of substance      : CF5
* Molar mass (g.mol-1)        : 221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg,L-1)    : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)       : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)    : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg,L-1
-----
* Global maximum      0.0522      25-Aug-1985 22:00
* PEC 1 day           0.0520      26-Aug-1985 22:00
* PEC 2 days          0.0513      27-Aug-1985 22:00
* PEC 4 days          0.0492      29-Aug-1985 22:00
* PEC 7 days          0.0453      01-Sep-1985 22:00
* PEC 14 days         0.0380      08-Sep-1985 22:00
* PEC 21 days         0.0315      15-Sep-1985 22:00

```

```
* PEC 28 days      0.0262      22-Sep-1985 22:00
* PEC 42 days      0.0190      06-Oct-1985 22:00
* PEC 50 days      0.0174      14-Oct-1985 22:00
* PEC 100 days     0.0110      03-Dec-1985 22:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day      0.0522      26-Aug-1985 11:00
* TWAEC 2 days     0.0521      27-Aug-1985 01:00
* TWAEC 4 days     0.0518      28-Aug-1985 05:00
* TWAEC 7 days     0.0511      30-Aug-1985 04:00
* TWAEC 14 days    0.0488      05-Jan-1986 18:00
* TWAEC 21 days    0.0480      10-Jan-1986 17:00
* TWAEC 28 days    0.0468      16-Jan-1986 00:00
* TWAEC 42 days    0.0458      31-Jan-1986 22:00
* TWAEC 50 days    0.0455      07-Feb-1986 09:00
* TWAEC 100 days   0.0396      19-Mar-1986 05:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum   0.0650      11-Feb-1986 02:00
* PEC 1 day        0.0650      12-Feb-1986 02:00
* PEC 2 days       0.0650      13-Feb-1986 02:00
* PEC 4 days       0.0649      15-Feb-1986 02:00
* PEC 7 days       0.0646      18-Feb-1986 02:00
* PEC 14 days      0.0637      25-Feb-1986 02:00
* PEC 21 days      0.0623      04-Mar-1986 02:00
* PEC 28 days      0.0606      11-Mar-1986 02:00
* PEC 42 days      0.0569      25-Mar-1986 02:00
* PEC 50 days      0.0546      02-Apr-1986 02:00
* simulated period too short for calculation of PECsed100
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day      0.0650      11-Feb-1986 14:00
* TWAEC 2 days     0.0650      12-Feb-1986 03:00
* TWAEC 4 days     0.0650      13-Feb-1986 04:00
* TWAEC 7 days     0.0650      14-Feb-1986 18:00
* TWAEC 14 days    0.0649      18-Feb-1986 15:00
* TWAEC 21 days    0.0647      22-Feb-1986 16:00
* TWAEC 28 days    0.0644      26-Feb-1986 22:00
* TWAEC 42 days    0.0638      07-Mar-1986 20:00
* TWAEC 50 days    0.0633      12-Mar-1986 16:00
* TWAEC 100 days   0.0602      08-Apr-1986 11:00
-----
*
* End of TOXSWA report
```

```

* -----
* #####   #####   ##   ##   #####   ##   ##   #####   FOCUS TOXSWA v2.2.1
* ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   TOXSWA v2.1.2-F2
* ##   ##   ##   ##   #####   ##   ##   ##   ##   ##   10-Nov-2005
* ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   #####
* ##   #####   ##   ##   #####   ##   ##   ##   ##   ##   Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-08:56:01
* Working Directory: C:\SwashProjects\benfuracarb6\toxswa
* Run ID            : 00419s_pa
* TOXSWA input file  : 00419s_pa.twx
* TOXSWA warnings/errors file : 00419s_pa.err
* TOXSWA summary file   : 00419s_pa.sum
*
* Project           : benfuracarb6
* Substance         : CFS
* Crop              : Vegetables, leafy
* Location          : D4 (Meteo station: Skousb
* Type of water body : focus_stream
* Simulation period  : 01-Jan-1985 to 01-May-1985
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      16-May-1985 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb6\MACRO\vegetables_leafy\macro00419_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 0.30 mm.h-1    04-Dec-1985 15:00
* Substance       : 0.00 mg.m-2.h-1  21-Aug-1985 07:00
* Substance concentration : 0.83 µg.L-1    21-Aug-1985 12:00
*
* Properties of substance           : CFS
* Molar mass (g.mol-1)              : 221.3
* Saturated vapour pressure (Pa)    : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)         : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)             : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)         : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)           : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)           : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum      0.163      21-Aug-1985 12:00
* PEC 1 day           0.154      22-Aug-1985 12:00
* PEC 2 days          0.133      23-Aug-1985 12:00
* PEC 4 days          0.103      25-Aug-1985 12:00
* PEC 7 days          0.0643     28-Aug-1985 12:00
* PEC 14 days         0.0247     04-Sep-1985 12:00
* PEC 21 days         0.0177     11-Sep-1985 12:00

```

```
* PEC 28 days      0.0153      18-Sep-1985 12:00
* PEC 42 days      0.0148      02-Oct-1985 12:00
* PEC 50 days      0.0198      10-Oct-1985 12:00
* PEC 100 days     0.0146      29-Nov-1985 12:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day      0.161       22-Aug-1985 01:00
* TWAEC 2 days     0.158       22-Aug-1985 17:00
* TWAEC 4 days     0.146       24-Aug-1985 07:00
* TWAEC 7 days     0.136       24-Aug-1985 09:00
* TWAEC 14 days    0.110       29-Aug-1985 15:00
* TWAEC 21 days    0.0849      04-Sep-1985 21:00
* TWAEC 28 days    0.0791      29-Aug-1985 04:00
* TWAEC 42 days    0.0626      08-Sep-1985 22:00
* TWAEC 50 days    0.0556      11-Sep-1985 06:00
* TWAEC 100 days   0.0386      05-Sep-1985 00:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum   0.0918      24-Aug-1985 12:00
* PEC 1 day        0.0913      25-Aug-1985 12:00
* PEC 2 days       0.0899      26-Aug-1985 12:00
* PEC 4 days       0.0862      28-Aug-1985 12:00
* PEC 7 days       0.0787      31-Aug-1985 12:00
* PEC 14 days      0.0669      07-Sep-1985 12:00
* PEC 21 days      0.0597      14-Sep-1985 12:00
* PEC 28 days      0.0547      21-Sep-1985 12:00
* PEC 42 days      0.0482      05-Oct-1985 12:00
* PEC 50 days      0.0478      13-Oct-1985 12:00
* PEC 100 days     0.0388      02-Dec-1985 12:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day      0.0917      24-Aug-1985 23:00
* TWAEC 2 days     0.0916      25-Aug-1985 10:00
* TWAEC 4 days     0.0911      26-Aug-1985 14:00
* TWAEC 7 days     0.0898      28-Aug-1985 16:00
* TWAEC 14 days    0.0846      02-Sep-1985 22:00
* TWAEC 21 days    0.0798      08-Sep-1985 00:00
* TWAEC 28 days    0.0756      14-Sep-1985 04:00
* TWAEC 42 days    0.0688      27-Sep-1985 03:00
* TWAEC 50 days    0.0658      04-Oct-1985 15:00
* TWAEC 100 days   0.0564      09-Nov-1985 11:00
-----
*
* End of TOXSWA report
```

```

* -----
* #####      ##  ##  #####  ##  ##  #####      FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  #####  ##  ##  #####  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Bcx 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-08:59:31
* Working Directory: C:\SwashProjects\benfuracarb6\ttoxswa
* Run ID           : 00420d_pa
* TOXSWA input file      : 00420d_pa.twx
* TOXSWA warnings/errors file : 00420d_pa.err
* TOXSWA summary file   : 00420d_pa.sum
*
* Project           : benfuracarb6
* Substance         : CFS
* Crop              : Vegetables, leafy
* Location          : D6 (Meteo station: Thiva)
* Type of water body : focus_ditch
* Simulation period  : 01-Jan-1986 to 01-May-1987
*
* Applications
* Appl.No  Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1       04-Aug-1986 09:00      540.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb6\MACRO\vegetables_leafy\macro00420_p.m2t
* Maximum hourly fluxes and concentrations in drained water
* Water           : 1.76 mm.h-1      19-Jan-1987 06:00
* Substance       : 0.00 mg.m-2.h-1   16-Aug-1986 18:00
* Substance concentration : 0.51 µg.L-1      16-Aug-1986 18:00
*
* Properties of substance      : CFS
* Molar mass (g.mol-1)       : 221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)      : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)   : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)    : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)    : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum      0.163      16-Aug-1986 21:00
* PEC 1 day           0.0993     17-Aug-1986 21:00
* PEC 2 days          0.0570     18-Aug-1986 21:00
* PEC 4 days          0.0244     20-Aug-1986 21:00
* PEC 7 days          0.0430     23-Aug-1986 21:00
* PEC 14 days         0.0250     30-Aug-1986 21:00
* PEC 21 days         0.0161     06-Sep-1986 21:00

```



```
* PEC 28 days      0.0138      13-Sep-1986 21:00
* PEC 42 days      0.0127      27-Sep-1986 21:00
* PEC 50 days      0.0121      05-Oct-1986 21:00
* PEC 100 days     0.00823     24-Nov-1986 21:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day      0.141       17-Aug-1986 16:00
* TWAEC 2 days    0.114       18-Aug-1986 14:00
* TWAEC 4 days    0.0786      20-Aug-1986 12:00
* TWAEC 7 days    0.0548      23-Aug-1986 13:00
* TWAEC 14 days   0.0402      30-Aug-1986 12:00
* TWAEC 21 days   0.0327      06-Sep-1986 11:00
* TWAEC 28 days   0.0283      13-Sep-1986 11:00
* TWAEC 42 days   0.0234      27-Sep-1986 10:00
* TWAEC 50 days   0.0216      05-Oct-1986 10:00
* TWAEC 100 days  0.0168      24-Nov-1986 10:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.0246      18-Aug-1986 04:59
* PEC 1 day       0.0233      19-Aug-1986 05:00
* PEC 2 days     0.0214      20-Aug-1986 05:00
* PEC 4 days     0.0185      22-Aug-1986 05:00
* PEC 7 days     0.0217      25-Aug-1986 05:00
* PEC 14 days    0.0209      01-Sep-1986 05:00
* PEC 21 days    0.0198      08-Sep-1986 05:00
* PEC 28 days    0.0195      15-Sep-1986 05:00
* PEC 42 days    0.0193      29-Sep-1986 05:00
* PEC 50 days    0.0192      07-Oct-1986 05:00
* PEC 100 days   0.0184      26-Nov-1986 05:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day     0.0244      18-Aug-1986 19:00
* TWAEC 2 days    0.0239      19-Aug-1986 11:00
* TWAEC 4 days    0.0226      21-Aug-1986 03:00
* TWAEC 7 days    0.0212      24-Aug-1986 07:00
* TWAEC 14 days   0.0210      31-Aug-1986 06:00
* TWAEC 21 days   0.0207      07-Sep-1986 03:00
* TWAEC 28 days   0.0205      14-Sep-1986 02:00
* TWAEC 42 days   0.0201      28-Sep-1986 02:00
* TWAEC 50 days   0.0200      06-Oct-1986 02:00
* TWAEC 100 days  0.0197      25-Nov-1986 01:00
-----
*
* End of TOXSWA report
```

```
*-----*
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:06:58
* Working Directory: C:\SwashProjects\benfuracarb8\toxswa
* Run ID           : 00437p_pa
* TOXSWA input file      : 00437p_pa.twx
* TOXSWA warnings/errors file : 00437p_pa.err
* TOXSWA summary file   : 00437p_pa.sum
*
* Project              : benfuracarb8
* Substance            : CF5
* Crop                 : Vegetables, leafy
* Location             : RI (Meteo station: Weiher)
* Type of water body   : focus_pond
* Simulation period    : 01-Mar-1984 to 01-Mar-1985
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      26-Apr-1984 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PR2M\vegetables_leafy\00437-Cl.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water      : 1.41 mm.h-1      22-Jan-1985 01:00
* Substance in water      : 0.00 mg.m-2.h-1      07-May-1984 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Mar-1984 00:00
* Substance concentration : 0.00 µg.L-1      07-May-1984 01:00
*
* Properties of substance      : CF5
* Molar mass (g.mol-1)        : 221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)    : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)       : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)    : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000      07-May-1984 09:59
* PEC 1 day      0.000000      08-May-1984 10:00
* PEC 2 days     0.000000      09-May-1984 10:00
* PEC 4 days     0.000000      11-May-1984 10:00
* PEC 7 days     0.000000      14-May-1984 10:00
* PEC 14 days    0.000000      21-May-1984 10:00
```

```
* PEC 21 days 0.000000 28-May-1984 10:00
* PEC 28 days 0.000000 04-Jun-1984 10:00
* PEC 42 days 0.000000 18-Jun-1984 10:00
* PEC 50 days 0.000000 26-Jun-1984 10:00
* PEC 100 days 0.000000 15-Aug-1984 10:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* TWAEC 1 day 0.000000 08-May-1984 09:00
* TWAEC 2 days 0.000000 09-May-1984 09:00
* TWAEC 4 days 0.000000 11-May-1984 08:00
* TWAEC 7 days 0.000000 14-May-1984 08:00
* TWAEC 14 days 0.000000 21-May-1984 06:00
* TWAEC 21 days 0.000000 28-May-1984 05:00
* TWAEC 28 days 0.000000 04-Jun-1984 04:00
* TWAEC 42 days 0.000000 18-Jun-1984 03:00
* TWAEC 50 days 0.000000 26-Jun-1984 02:00
* TWAEC 100 days 0.000000 15-Aug-1984 00:00
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000 22-May-1984 12:59
* PEC 1 day 0.000000 23-May-1984 13:00
* PEC 2 days 0.000000 24-May-1984 13:00
* PEC 4 days 0.000000 26-May-1984 13:00
* PEC 7 days 0.000000 29-May-1984 13:00
* PEC 14 days 0.000000 05-Jun-1984 13:00
* PEC 21 days 0.000000 12-Jun-1984 13:00
* PEC 28 days 0.000000 19-Jun-1984 13:00
* PEC 42 days 0.000000 03-Jul-1984 13:00
* PEC 50 days 0.000000 11-Jul-1984 13:00
* PEC 100 days 0.000000 30-Aug-1984 13:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day 0.000000 23-May-1984 01:00
* TWAEC 2 days 0.000000 23-May-1984 14:00
* TWAEC 4 days 0.000000 24-May-1984 18:00
* TWAEC 7 days 0.000000 26-May-1984 10:00
* TWAEC 14 days 0.000000 30-May-1984 08:00
* TWAEC 21 days 0.000000 03-Jun-1984 22:00
* TWAEC 28 days 0.000000 08-Jun-1984 09:00
* TWAEC 42 days 0.000000 19-Jun-1984 22:00
* TWAEC 50 days 0.000000 27-Jun-1984 04:00
* TWAEC 100 days 0.000000 15-Aug-1984 05:00
-----
*
* End of TOXSWA report
```

```

* -----
* #####      ##  ##  #####  ##  ##  #####      FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* #####      ##  ##  #####  ##  ##  #####      Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X i c   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:07:10
* Working Directory: C:\SwashProjects\benfuracarb8\ttoxswa
* Run ID           : 00437s_pa
* TOXSWA input file      : 00437s_pa.twx
* TOXSWA warnings/errors file : 00437s_pa.err
* TOXSWA summary file   : 00437s_pa.sum
*
* Project              : benfuracarb8
* Substance            : CP5
* Crop                 : Vegetables, leafy
* Location             : RI (Meteo station: Weiher)
* Type of water body   : focus_stream
* Simulation period     : 01-Mar-1984 to 01-Mar-1985
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1      26-Apr-1984 09:00      540.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PRZM\vegetables_leafy\00437-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.41 mm.h-1      22-Jan-1985 01:00
* Substance in water : 0.00 mg.m-2.h-1      07-May-1984 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Mar-1984 00:00
* Substance concentration : 0.00 µg.L-1      07-May-1984 01:00
*
* Properties of substance           : CP5
* Molar mass (g.mol-1)             : 221.3
* Saturated vapour pressure (Pa)    : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)        : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)           : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)        : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in µg.L-1
* -----
* Global maximum 0.000000 07-May-1984 09:00
* PEC 1 day      0.000000 08-May-1984 09:00
* PEC 2 days     0.000000 09-May-1984 09:00
* PEC 4 days     0.000000 11-May-1984 09:00
* PEC 7 days     0.000000 14-May-1984 09:00
* PEC 14 days    0.000000 21-May-1984 09:00

```

```
* PEC 21 days 0.000000 28-May-1984 09:00
* PEC 28 days 0.000000 04-Jun-1984 09:00
* PEC 42 days 0.000000 18-Jun-1984 09:00
* PEC 50 days 0.000000 26-Jun-1984 09:00
* PEC 100 days 0.000000 15-Aug-1984 09:00
```

```
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
```

```
* TWAEC 1 day 0.000000 08-May-1984 00:00
* TWAEC 2 days 0.000000 09-May-1984 00:00
* TWAEC 4 days 0.000000 11-May-1984 00:00
* TWAEC 7 days 0.000000 14-May-1984 00:00
* TWAEC 14 days 0.000000 21-May-1984 00:00
* TWAEC 21 days 0.000000 21-May-1984 08:00
* TWAEC 28 days 0.000000 21-May-1984 08:00
* TWAEC 42 days 0.000000 21-May-1984 08:00
* TWAEC 50 days 0.000000 21-May-1984 08:00
* TWAEC 100 days 0.000000 21-May-1984 08:00
```

```
*
* Actual concentrations in sediment in µg.kg-1 DW
```

```
* Global maximum 0.000000 07-May-1984 12:00
* PEC 1 day 0.000000 08-May-1984 12:00
* PEC 2 days 0.000000 09-May-1984 12:00
* PEC 4 days 0.000000 11-May-1984 12:00
* PEC 7 days 0.000000 14-May-1984 12:00
* PEC 14 days 0.000000 21-May-1984 12:00
* PEC 21 days 0.000000 28-May-1984 12:00
* PEC 28 days 0.000000 04-Jun-1984 12:00
* PEC 42 days 0.000000 18-Jun-1984 12:00
* PEC 50 days 0.000000 26-Jun-1984 12:00
* PEC 100 days 0.000000 15-Aug-1984 12:00
```

```
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
```

```
* TWAEC 1 day 0.000000 08-May-1984 06:00
* TWAEC 2 days 0.000000 09-May-1984 05:00
* TWAEC 4 days 0.000000 11-May-1984 04:00
* TWAEC 7 days 0.000000 14-May-1984 04:00
* TWAEC 14 days 0.000000 21-May-1984 03:00
* TWAEC 21 days 0.000000 28-May-1984 03:00
* TWAEC 28 days 0.000000 04-Jun-1984 03:00
* TWAEC 42 days 0.000000 18-Jun-1984 03:00
* TWAEC 50 days 0.000000 26-Jun-1984 03:00
* TWAEC 100 days 0.000000 15-Aug-1984 02:00
```

```
* End of TOXSWA report
```

```
*-----*
* #####      ##  ##  #####  ##  ##  #####      FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* #####      ##  ##  #####  ##  ##  #####      Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W A T e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:08:43
* Working Directory: C:\SwashProjects\benfuracarb8\toxawa
* Run ID           : 00438p_pa
* TOXSWA input file      : 00438p_pa.twx
* TOXSWA warnings/errors file : 00438p_pa.err
* TOXSWA summary file   : 00438p_pa.sum
*
* Project           : benfuracarb8
* Substance         : CF5
* Crop              : Vegetables, leafy
* Location          : RI (Meteo station: Weiher)
* Type of water body : focus_pond
* Simulation period  : 01-Jun-1978 to 01-Jun-1979
*
* Applications
* Appl.No Date/Hour      Mass (g ai,ha-1)  Areaic mean deposition (#)
* 1      28-Jul-1978 09:00      540.0            0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PR2M\vegetables_leafy\00438-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.39 mm.h-1      09-Dec-1978 01:00
* Substance in water : 0.00 mg.m-2.h-1      17-Sep-1978 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1978 00:00
* Substance concentration : 0.00 µg.L-1      17-Sep-1978 01:00
*
* Properties of substance           : CF5
* Molar mass (g.mol-1)              : 221.3
* Saturated vapour pressure (Pa)     : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)         : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)            : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)         : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)           : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)           : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Jun-1978 00:00
* PEC 1 day      0.000000 02-Jun-1978 00:00
* PEC 2 days     0.000000 03-Jun-1978 00:00
* PEC 4 days     0.000000 05-Jun-1978 00:00
* PEC 7 days     0.000000 08-Jun-1978 00:00
* PEC 14 days    0.000000 15-Jun-1978 00:00
```

```

* PEC 21 days      0.000000      22-Jun-1978 00:00
* PEC 28 days      0.000000      29-Jun-1978 00:00
* PEC 42 days      0.000000      13-Jul-1978 00:00
* PEC 50 days      0.000000      21-Jul-1978 00:00
* PEC 100 days     0.000000      09-Sep-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Jun-1978 00:00
* PEC 1 day        0.000000      02-Jun-1978 00:00
* PEC 2 days       0.000000      03-Jun-1978 00:00
* PEC 4 days       0.000000      05-Jun-1978 00:00
* PEC 7 days       0.000000      08-Jun-1978 00:00
* PEC 14 days      0.000000      15-Jun-1978 00:00
* PEC 21 days      0.000000      22-Jun-1978 00:00
* PEC 28 days      0.000000      29-Jun-1978 00:00
* PEC 42 days      0.000000      13-Jul-1978 00:00
* PEC 50 days      0.000000      21-Jul-1978 00:00
* PEC 100 days     0.000000      09-Sep-1978 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSed1
* simulated period too short for calculation of TWAECSed2
* simulated period too short for calculation of TWAECSed4
* simulated period too short for calculation of TWAECSed7
* simulated period too short for calculation of TWAECSed14
* simulated period too short for calculation of TWAECSed21
* simulated period too short for calculation of TWAECSed28
* simulated period too short for calculation of TWAECSed42
* simulated period too short for calculation of TWAECSed50
* simulated period too short for calculation of TWAECSed100
-----
*
* End of TOXSWA report.

```

```

* -----
* #####      ##  ##  #####  ##      ##  #####      FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##      TOXSWA v2.1.2-F2
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##      10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  #####  ##  ##  #####  ##  ##  ##  ##      Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X I C  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
* -----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:08:55
* Working Directory: C:\SwashProjects\benfuracarb8\toxswa
* Run ID           : 00438s_pa
* TOXSWA input file : 00438s_pa.twx
* TOXSWA warnings/errors file : 00438s_pa.err
* TOXSWA summary file : 00438s_pa.sum
*
* Project           : benfuracarb8
* Substance         : CF5
* Crop              : Vegetables, leafy
* Location          : R1 (Meteo station: Weiher)
* Type of water body : focus_stream
* Simulation period : 01-Jun-1978 to 01-Jun-1979
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1       28-Jul-1978 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PR2M\vegetables_leafy\00438-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.39 mm.h-1      09-Dec-1978 01:00
* Substance in water : 0.00 mg.m-2.h-1      17-Sep-1978 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1978 00:00
* Substance concentration : 0.00 ug.L-1      17-Sep-1978 01:00
*
* Properties of substance           : CF5
* Molar mass (g.mol-1)             : 221.3
* Saturated vapour pressure (Pa)    : 0.600E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)        : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)           : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)        : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in ug.L-1
* -----
* Global maximum 0.000000      17-Sep-1978 02:00
* PEC 1 day      0.000000      18-Sep-1978 02:00
* PEC 2 days     0.000000      19-Sep-1978 02:00
* PEC 4 days     0.000000      21-Sep-1978 02:00
* PEC 7 days     0.000000      24-Sep-1978 02:00
* PEC 14 days    0.000000      01-Oct-1978 02:00

```



```
* PEC 21 days      0.000000      08-Oct-1978 02:00
* PEC 28 days      0.000000      15-Oct-1978 02:00
* PEC 42 days      0.000000      29-Oct-1978 02:00
* PEC 50 days      0.000000      06-Nov-1978 02:00
* PEC 100 days     0.000000      26-Dec-1978 02:00
```

```
* -----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
```

```
* -----
* TWAEC 1 day      0.000000      18-Sep-1978 00:00
* TWAEC 2 days     0.000000      18-Sep-1978 02:00
* TWAEC 4 days     0.000000      18-Sep-1978 02:00
* TWAEC 7 days     0.000000      18-Sep-1978 02:00
* TWAEC 14 days    0.000000      18-Sep-1978 02:00
* TWAEC 21 days    0.000000      18-Sep-1978 02:00
* TWAEC 28 days    0.000000      18-Sep-1978 02:00
* TWAEC 42 days    0.000000      18-Sep-1978 02:00
* TWAEC 50 days    0.000000      18-Sep-1978 02:00
* TWAEC 100 days   0.000000      18-Sep-1978 02:00
```

```
* -----
* Actual concentrations in sediment in µg.kg-1 DW
```

```
* Global maximum  0.000000      17-Sep-1978 15:59
* PEC 1 day        0.000000      18-Sep-1978 16:00
* PEC 2 days       0.000000      19-Sep-1978 16:00
* PEC 4 days       0.000000      21-Sep-1978 16:00
* PEC 7 days       0.000000      24-Sep-1978 16:00
* PEC 14 days      0.000000      01-Oct-1978 16:00
* PEC 21 days      0.000000      08-Oct-1978 16:00
* PEC 28 days      0.000000      15-Oct-1978 16:00
* PEC 42 days      0.000000      29-Oct-1978 16:00
* PEC 50 days      0.000000      06-Nov-1978 16:00
* PEC 100 days     0.000000      26-Dec-1978 16:00
```

```
* -----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
```

```
* -----
* TWAEC 1 day      0.000000      18-Sep-1978 05:00
* TWAEC 2 days     0.000000      19-Sep-1978 01:00
* TWAEC 4 days     0.000000      21-Sep-1978 00:00
* TWAEC 7 days     0.000000      21-Sep-1978 01:00
* TWAEC 14 days    0.000000      21-Sep-1978 01:00
* TWAEC 21 days    0.000000      21-Sep-1978 01:00
* TWAEC 28 days    0.000000      21-Sep-1978 01:00
* TWAEC 42 days    0.000000      21-Sep-1978 01:00
* TWAEC 50 days    0.000000      21-Sep-1978 01:00
* TWAEC 100 days   0.000000      21-Sep-1978 01:00
```

```
* -----
* End of TOXSWA report
```

```

* #####      ##  ##  #####  ##  ##  #####      FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* Compiled with:VisualFortran v6.6.0.
*
*-----*
* T O X i c   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:10:08
* Working Directory: C:\SwashProjects\benfuracarb8\tomswa
* Run ID           : 00439s_pa
* TOXSWA input file      : 00439s_pa.tkw
* TOXSWA warnings/errors file : 00439s_pa.err
* TOXSWA summary file    : 00439s_pa.sum
*
* Project           : benfuracarb8
* Substance         : CFS
* Crop             : Vegetables, leafy
* Location          : R2 (Meteo station: Porto)
* Type of water body : focus_stream
* Simulation period  : 01-Oct-1977 to 01-Oct-1978
*
* Applications
* Appl.No Date/Hour      Mass (g a.l.ha-1)  Areaic mean deposition (%)
* 1      06-Mar-1978 09:00      540.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PR2M\vegetables_leafy\00439-Cl.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.22 mm.h-1      16-Feb-1978 01:00
* Substance in water : 0.00 mg.m-2.h-1      16-Mar-1978 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Oct-1977 00:00
* Substance concentration : 0.00 µg.L-1      16-Mar-1978 01:00
*
* Properties of substance           : CFS
* Molar mass (g.mol-1)             : 221.3
* Saturated vapour pressure (Pa)    : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)        : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)           : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)        : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*-----*
* Actual concentrations in water layer in µg.l-1
*-----*
* Global maximum 0.000000      16-Mar-1978 01:59
* PEC 1 day      0.000000      17-Mar-1978 02:00
* PEC 2 days     0.000000      18-Mar-1978 02:00
* PEC 4 days     0.000000      20-Mar-1978 02:00
* PEC 7 days     0.000000      23-Mar-1978 02:00
* PEC 14 days    0.000000      30-Mar-1978 02:00

```

```
* PEC 21 days      0.000000      06-Apr-1978 02:00
* PEC 28 days      0.000000      13-Apr-1978 02:00
* PEC 42 days      0.000000      27-Apr-1978 02:00
* PEC 50 days      0.000000      05-May-1978 02:00
* PEC 100 days     0.000000      24-Jun-1978 02:00
```

```
-----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
```

```
-----
* TWAEC 1 day      0.000000      16-Mar-1978 13:00
* TWAEC 2 days     0.000000      16-Mar-1978 13:00
* TWAEC 4 days     0.000000      16-Mar-1978 13:00
* TWAEC 7 days     0.000000      16-Mar-1978 13:00
* TWAEC 14 days    0.000000      16-Mar-1978 13:00
* TWAEC 21 days    0.000000      16-Mar-1978 13:00
* TWAEC 28 days    0.000000      16-Mar-1978 13:00
* TWAEC 42 days    0.000000      16-Mar-1978 13:00
* TWAEC 50 days    0.000000      16-Mar-1978 13:00
* TWAEC 100 days   0.000000      16-Mar-1978 13:00
```

```
-----
* Actual concentrations in sediment in µg.kg-1 DW
```

```
-----
* Global maximum 0.000000      16-Mar-1978 10:00
* PEC 1 day       0.000000      17-Mar-1978 10:00
* PEC 2 days     0.000000      18-Mar-1978 10:00
* PEC 4 days     0.000000      20-Mar-1978 10:00
* PEC 7 days     0.000000      23-Mar-1978 10:00
* PEC 14 days    0.000000      30-Mar-1978 10:00
* PEC 21 days    0.000000      06-Apr-1978 10:00
* PEC 28 days    0.000000      13-Apr-1978 10:00
* PEC 42 days    0.000000      27-Apr-1978 10:00
* PEC 50 days    0.000000      05-May-1978 10:00
* PEC 100 days   0.000000      24-Jun-1978 10:00
```

```
-----
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
```

```
-----
* TWAEC 1 day      0.000000      17-Mar-1978 01:00
* TWAEC 2 days     0.000000      17-Mar-1978 21:00
* TWAEC 4 days     0.000000      17-Mar-1978 21:00
* TWAEC 7 days     0.000000      17-Mar-1978 21:00
* TWAEC 14 days    0.000000      17-Mar-1978 21:00
* TWAEC 21 days    0.000000      17-Mar-1978 21:00
* TWAEC 28 days    0.000000      17-Mar-1978 21:00
* TWAEC 42 days    0.000000      17-Mar-1978 21:00
* TWAEC 50 days    0.000000      17-Mar-1978 21:00
* TWAEC 100 days   0.000000      17-Mar-1978 21:00
```

```
-----
* End of TOXSWA report
```

```

* #####      ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
-----
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
-----
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
-----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:12:06
* Working Directory: C:\SwashProjects\benfuracarb8\ttoxawa
* Run ID           : 00440s_pa
* TOXSWA input file      : 00440s_pa.twx
* TOXSWA warnings/errors file : 00440s_pa.err
* TOXSWA summary file    : 00440s_pa.sum
*
* Project              : benfuracarb8
* Substance            : CF5
* Crop                 : Vegetables, leafy
* Location             : R2 (Meteo station: Porto)
* Type of water body   : focus_stream
* Simulation period     : 01-Jun-1989 to 01-Jun-1990
*
* Applications
* Appl.No Date/Hour      Mass (g a1.ha-1)  Area1 mean deposition (%)
* 1      05-Aug-1989 09:00      540.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PRZM\vegetables leafy\00440-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.27 mm.h-1      25-Dec-1989 01:00
* Substance in water : 0.00 mg.m-2.h-1      22-Oct-1989 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1989 00:00
* Substance concentration : 0.00 µg.L-1      22-Oct-1989 01:00
*
* Properties of substance      : CF5
* Molar mass (g.mol-1)        : 221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)    : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)       : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)    : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
-----
* Global maximum 0.000000 22-Oct-1989 01:59
* PEC 1 day 0.000000 23-Oct-1989 02:00
* PEC 2 days 0.000000 24-Oct-1989 02:00
* PEC 4 days 0.000000 26-Oct-1989 02:00
* PEC 7 days 0.000000 29-Oct-1989 02:00
* PEC 14 days 0.000000 05-Nov-1989 02:00

```

```
* PEC 21 days      0.000000      12-Nov-1989 02:00
* PEC 28 days      0.000000      19-Nov-1989 02:00
* PEC 42 days      0.000000      03-Dec-1989 02:00
* PEC 50 days      0.000000      11-Dec-1989 02:00
* PEC 100 days     0.000000      30-Jan-1990 02:00
```

```
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
```

```
-----
* TWAEC 1 day      0.000000      23-Oct-1989 00:00
* TWAEC 2 days     0.000000      24-Oct-1989 00:00
* TWAEC 4 days     0.000000      26-Oct-1989 00:00
* TWAEC 7 days     0.000000      29-Oct-1989 00:00
* TWAEC 14 days    0.000000      05-Nov-1989 00:00
* TWAEC 21 days    0.000000      12-Nov-1989 00:00
* TWAEC 28 days    0.000000      19-Nov-1989 00:00
* TWAEC 42 days    0.000000      03-Dec-1989 00:00
* TWAEC 50 days    0.000000      11-Dec-1989 00:00
* TWAEC 100 days   0.000000      24-Dec-1989 22:00
```

```
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
```

```
-----
* Global maximum  0.000000      22-Oct-1989 13:59
* PEC 1 day        0.000000      23-Oct-1989 14:00
* PEC 2 days       0.000000      24-Oct-1989 14:00
* PEC 4 days       0.000000      26-Oct-1989 14:00
* PEC 7 days       0.000000      29-Oct-1989 14:00
* PEC 14 days      0.000000      05-Nov-1989 14:00
* PEC 21 days      0.000000      12-Nov-1989 14:00
* PEC 28 days      0.000000      19-Nov-1989 14:00
* PEC 42 days      0.000000      03-Dec-1989 14:00
* PEC 50 days      0.000000      11-Dec-1989 14:00
* PEC 100 days     0.000000      30-Jan-1990 14:00
```

```
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
```

```
-----
* TWAEC 1 day      0.000000      23-Oct-1989 05:00
* TWAEC 2 days     0.000000      24-Oct-1989 03:00
* TWAEC 4 days     0.000000      26-Oct-1989 02:00
* TWAEC 7 days     0.000000      29-Oct-1989 02:00
* TWAEC 14 days    0.000000      05-Nov-1989 01:00
* TWAEC 21 days    0.000000      12-Nov-1989 01:00
* TWAEC 28 days    0.000000      19-Nov-1989 01:00
* TWAEC 42 days    0.000000      03-Dec-1989 01:00
* TWAEC 50 days    0.000000      11-Dec-1989 01:00
* TWAEC 100 days   0.000000      30-Jan-1990 01:00
```

```
-----
* End of TOXSWA report
```

```

*-----*
* #####    ##   ##   #####  ##   ##   #####   FOCUS_TOXSWA v2.2.1
*   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##
*   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##
*   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##
*   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##
*   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##   ##
*-----*
* Compiled with: Visual Fortran v6.6.0.
*-----*
* T O X I C   S u b s t a n c e s   i n   S u r f a c e   W a t e r s
*-----*
* Alterra, Wageningen UR                   http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*-----*
* Run comments: FOCUS run
*-----*
* TOXSWA simulation: 21-Jan-2009-14:14:28
* Working Directory: C:\SwashProjects\benfuracarb8\toxswa
* Run ID           : 00441s_pa
* TOXSWA input file      : 00441s_pa.twx
* TOXSWA warnings/errors file : 00441s_pa.err
* TOXSWA summary file   : 00441s_pa.sum
*-----*
* Project           : benfuracarb8
* Substance         : CF5
* Crop              : Vegetables, leafy
* Location          : R3 (Meteo station: Bologna)
* Type of water body : focus_stream
* Simulation period  : 01-Oct-1980 to 01-Oct-1981
*-----*
* Applications
* Appl.No Date/Hour     Mass (g ai.ha-1) Area's mean deposition (%)
*-----*
* 1      19-Feb-1981 09:00       540.0          0.0000E+00
*-----*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PR2M\vegetables_leafy\00441-C1.p2t
*-----*
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.17 mm.h-1      27-Nov-1980 01:00
* Substance in water : 0.00 mg.m-2.h-1      15-Apr-1981 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Oct-1980 00:00
* Substance concentration : 0.00 µg.L-1      15-Apr-1981 01:00
*-----*
* Properties of substance           : CF5
* Molar mass (g.mol-1)              : 221.3
* Saturated vapour pressure (Pa)    : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)         : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)            : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)         : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)           : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)           : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*-----*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 01-Oct-1980 00:00
* PEC 1 day 0.000000 02-Oct-1980 00:00
* PEC 2 days 0.000000 03-Oct-1980 00:00
* PEC 4 days 0.000000 05-Oct-1980 00:00
* PEC 7 days 0.000000 08-Oct-1980 00:00
* PEC 14 days 0.000000 15-Oct-1980 00:00

```

```

* PEC 21 days      0.000000      22-Oct-1980 00:00
* PEC 28 days      0.000000      29-Oct-1980 00:00
* PEC 42 days      0.000000      12-Nov-1980 00:00
* PEC 50 days      0.000000      20-Nov-1980 00:00
* PEC 100 days     0.000000      09-Jan-1981 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in water layer in µg.L-1
-----
* simulated period too short for calculation of TWAECSw1
* simulated period too short for calculation of TWAECSw2
* simulated period too short for calculation of TWAECSw4
* simulated period too short for calculation of TWAECSw7
* simulated period too short for calculation of TWAECSw14
* simulated period too short for calculation of TWAECSw21
* simulated period too short for calculation of TWAECSw28
* simulated period too short for calculation of TWAECSw42
* simulated period too short for calculation of TWAECSw50
* simulated period too short for calculation of TWAECSw100
-----
*
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      01-Oct-1980 00:00
* PEC 1 day        0.000000      02-Oct-1980 00:00
* PEC 2 days      0.000000      03-Oct-1980 00:00
* PEC 4 days      0.000000      05-Oct-1980 00:00
* PEC 7 days      0.000000      08-Oct-1980 00:00
* PEC 14 days     0.000000      15-Oct-1980 00:00
* PEC 21 days     0.000000      22-Oct-1980 00:00
* PEC 28 days     0.000000      29-Oct-1980 00:00
* PEC 42 days     0.000000      12-Nov-1980 00:00
* PEC 50 days     0.000000      20-Nov-1980 00:00
* PEC 100 days    0.000000      09-Jan-1981 00:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECS) in sediment in µg.kg-1 DW
-----
* simulated period too short for calculation of TWAECSsed1
* simulated period too short for calculation of TWAECSsed2
* simulated period too short for calculation of TWAECSsed4
* simulated period too short for calculation of TWAECSsed7
* simulated period too short for calculation of TWAECSsed14
* simulated period too short for calculation of TWAECSsed21
* simulated period too short for calculation of TWAECSsed28
* simulated period too short for calculation of TWAECSsed42
* simulated period too short for calculation of TWAECSsed50
* simulated period too short for calculation of TWAECSsed100
-----
*
* End of TOXSWA report

```

```

* -----
* #####      ## ## ## ## ## ## ## ## ## ##      FOCUS_TOXSWA v2.2.1
* ## ## ## ## ## ## ## ## ## ##      TOXSWA v2.1.2-F2
* ## ## ## ## ## ## ## ## ## ##      10-Nov-2005
* ## ## ## ## ## ## ## ## ## ##
* ## ##### ## ## ## ## ## ## ## ##      Copyright Alterra
* Compiled with:VisualFortran v6.6.0.
* -----
* T O X i c   S u b s t a n c e s   i n   S u r f a c e   W A t e r s
* -----
* Alterra, Wageningen UR      http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
* -----
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:15:41
* Working Directory: C:\SwashProjects\benfuracarb8\towswa
* Run ID      : 00442s_pa
* TOXSWA input file      : 00442s_pa.twx
* TOXSWA warnings/errors file : 00442s_pa.err
* TOXSWA summary file    : 00442s_pa.sum
*
* Project      : benfuracarb8
* Substance    : CF5
* Crop         : Vegetables, leafy
* Location     : R3 (Meteo station: Bologn
* Type of water body : focus_stream
* Simulation period : 01-Jun-1975 to 01-Jun-1976
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)   Areaic mean deposition (%)
* 1      02-Jun-1975 09:00      540.0             0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PRZN\vegetables_leafy\00442-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water      : 1.21 mm.h-1      11-Oct-1975 01:00
* Substance in water      : 0.00 mg.m-2.h-1      09-Jun-1975 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1975 00:00
* Substance concentration : 0.00 ug.L-1      09-Jun-1975 01:00
*
* Properties of substance      : CF5
* Molar mass (g.mol-1)      : 221.3
* Saturated vapour pressure (Pa) : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)   : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)      : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)   : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)      : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* -----
* Actual concentrations in water layer in ug.L-1
* -----
* Global maximum 0.000000      09-Jun-1975 01:59
* PEC 1 day      0.000000      10-Jun-1975 02:00
* PEC 2 days     0.000000      11-Jun-1975 02:00
* PEC 4 days     0.000000      13-Jun-1975 02:00
* PEC 7 days     0.000000      16-Jun-1975 02:00
* PEC 14 days    0.000000      23-Jun-1975 02:00

```



```
* PEC 21 days 0.000000 30-Jun-1975 02:00
* PEC 28 days 0.000000 07-Jul-1975 02:00
* PEC 42 days 0.000000 21-Jul-1975 02:00
* PEC 50 days 0.000000 29-Jul-1975 02:00
* PEC 100 days 0.000000 17-Sep-1975 02:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day 0.000000 10-Jun-1975 00:00
* TWAEC 2 days 0.000000 11-Jun-1975 00:00
* TWAEC 4 days 0.000000 13-Jun-1975 00:00
* TWAEC 7 days 0.000000 16-Jun-1975 00:00
* TWAEC 14 days 0.000000 23-Jun-1975 00:00
* TWAEC 21 days 0.000000 30-Jun-1975 00:00
* TWAEC 28 days 0.000000 07-Jul-1975 00:00
* TWAEC 42 days 0.000000 10-Jul-1975 23:00
* TWAEC 50 days 0.000000 10-Jul-1975 23:00
* TWAEC 100 days 0.000000 10-Jul-1975 23:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum 0.000000 09-Jun-1975 19:59
* PEC 1 day 0.000000 10-Jun-1975 20:00
* PEC 2 days 0.000000 11-Jun-1975 20:00
* PEC 4 days 0.000000 13-Jun-1975 20:00
* PEC 7 days 0.000000 16-Jun-1975 20:00
* PEC 14 days 0.000000 23-Jun-1975 20:00
* PEC 21 days 0.000000 30-Jun-1975 20:00
* PEC 28 days 0.000000 07-Jul-1975 20:00
* PEC 42 days 0.000000 21-Jul-1975 20:00
* PEC 50 days 0.000000 29-Jul-1975 20:00
* PEC 100 days 0.000000 17-Sep-1975 20:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day 0.000000 10-Jun-1975 09:00
* TWAEC 2 days 0.000000 11-Jun-1975 05:00
* TWAEC 4 days 0.000000 13-Jun-1975 03:00
* TWAEC 7 days 0.000000 16-Jun-1975 02:00
* TWAEC 14 days 0.000000 23-Jun-1975 01:00
* TWAEC 21 days 0.000000 30-Jun-1975 01:00
* TWAEC 28 days 0.000000 07-Jul-1975 01:00
* TWAEC 42 days 0.000000 21-Jul-1975 01:00
* TWAEC 50 days 0.000000 29-Jul-1975 01:00
* TWAEC 100 days 0.000000 17-Sep-1975 00:00
-----
*
* End of TOXSWA report
```

```

*-----*
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS_TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  #####  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* ##  #####  ##  ##  #####  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  ##
* Compiled with:VisualFortran v6.6.0.
*-----*
* T O X i c  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:17:14
* Working Directory: C:\SwashProjects\benfuracarb8\toxswa
* Run ID           : 00443s_pa
* TOXSWA input file       : 00443s_pa.twx
* TOXSWA warnings/errors file : 00443s_pa.err
* TOXSWA summary file    : 00443s_pa.sum
*
* Project                : benfuracarb8
* Substance               : CFS
* Crop                   : Vegetables, leafy
* Location                : R4 (Meteo station: Roujan)
* Type of water body     : focus_stream
* Simulation period      : 01-Oct-1979 to 01-Oct-1980
*
* Applications
* Appl.No Date/Hour      Mass (g ai.ha-1)  Areaic mean deposition (%)
* 1      01-Mar-1980 09:00      540.0              0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PR2M\vegetables_leafy\00443-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 2.01 mm.h-1      04-Oct-1979 01:00
* Substance in water : 0.00 mg.m-2.h-1      12-Mar-1980 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Oct-1979 00:00
* Substance concentration : 0.00 µg.L-1      12-Mar-1980 01:00
*
* Properties of substance           : CFS
* Molar mass (g.mol-1)             : 221.3
* Saturated vapour pressure (Pa)    : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)        : 0.318E+03 measured at (°C) : 20.0
* Half-life in water (d)           : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)        : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
*-----*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 12-Mar-1980 01:59
* PEC 1 day 0.000000 13-Mar-1980 02:00
* PEC 2 days 0.000000 14-Mar-1980 02:00
* PEC 4 days 0.000000 16-Mar-1980 02:00
* PEC 7 days 0.000000 19-Mar-1980 02:00
* PEC 14 days 0.000000 26-Mar-1980 02:00

```

```
* PEC 21 days      0.000000      02-Apr-1980 02:00
* PEC 28 days      0.000000      09-Apr-1980 02:00
* PEC 42 days      0.000000      23-Apr-1980 02:00
* PEC 50 days      0.000000      01-May-1980 02:00
* PEC 100 days     0.000000      20-Jun-1980 02:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in water layer in µg.L-1
-----
* TWAEC 1 day      0.000000      13-Mar-1980 09:00
* TWAEC 2 days     0.000000      13-Mar-1980 09:00
* TWAEC 4 days     0.000000      13-Mar-1980 09:00
* TWAEC 7 days     0.000000      13-Mar-1980 09:00
* TWAEC 14 days    0.000000      19-Mar-1980 18:00
* TWAEC 21 days    0.000000      19-Mar-1980 18:00
* TWAEC 28 days    0.000000      19-Mar-1980 18:00
* TWAEC 42 days    0.000000      19-Mar-1980 18:00
* TWAEC 50 days    0.000000      19-Mar-1980 18:00
* TWAEC 100 days   0.000000      19-Mar-1980 18:00
-----
*
* Actual concentrations in sediment in µg.kg-1 DW
-----
* Global maximum  0.000000      12-Mar-1980 16:00
* PEC 1 day        0.000000      13-Mar-1980 16:00
* PEC 2 days       0.000000      14-Mar-1980 16:00
* PEC 4 days       0.000000      16-Mar-1980 16:00
* PEC 7 days       0.000000      19-Mar-1980 16:00
* PEC 14 days      0.000000      26-Mar-1980 16:00
* PEC 21 days      0.000000      02-Apr-1980 16:00
* PEC 28 days      0.000000      09-Apr-1980 16:00
* PEC 42 days      0.000000      23-Apr-1980 16:00
* PEC 50 days      0.000000      01-May-1980 16:00
* PEC 100 days     0.000000      20-Jun-1980 16:00
-----
*
* Maximum Time Weighted Averaged Exposure Concentrations
* (TWAECs) in sediment in µg.kg-1 DW
-----
* TWAEC 1 day      0.000000      13-Mar-1980 06:00
* TWAEC 2 days     0.000000      14-Mar-1980 03:00
* TWAEC 4 days     0.000000      16-Mar-1980 02:00
* TWAEC 7 days     0.000000      19-Mar-1980 01:00
* TWAEC 14 days    0.000000      26-Mar-1980 01:00
* TWAEC 21 days    0.000000      02-Apr-1980 00:00
* TWAEC 28 days    0.000000      09-Apr-1980 00:00
* TWAEC 42 days    0.000000      09-Apr-1980 22:00
* TWAEC 50 days    0.000000      09-Apr-1980 22:00
* TWAEC 100 days   0.000000      09-Apr-1980 22:00
-----
*
* End of TOXSWA report
```

```

*-----*
* #####  #####  ##  ##  #####  ##  ##  #####  FOCUS TOXSWA v2.2.1
* ##  ##  ##  ##  ##  ##  ##  ##  ##  ##  TOXSWA v2.1.2-F2
* ##  ##  ##  ##  #####  ##  ##  ##  ##  ##  10-Nov-2005
* ##  ##  ##  ##  ##  ##  ##  #####  #####
* ##  #####  ##  ##  #####  ##  ##  ##  ##  Copyright: Alterra
* Compiled with: Visual Fortran v6.6.0.
*-----*
* T O X I c  S u b s t a n c e s  i n  S u r f a c e  W a t e r s
*-----*
* Alterra, Wageningen UR                               http://www.alterra.wur.nl
* PO Box 47
* 6700 AA Wageningen
* The Netherlands
*-----*
* Output generated for FOCUS
*
* Run comments: FOCUS run
*
* TOXSWA simulation: 21-Jan-2009-14:18:42
* Working Directory: C:\SwashProjects\benfuracarb8\toxswa
* Run ID           : 00444s_pa
* TOXSWA input file       : 00444s_pa.twx
* TOXSWA warnings/errors file : 00444s_pa.err
* TOXSWA summary file    : 00444s_pa.sum
*
* Project           : benfuracarb8
* Substance         : CFS
* Crop             : Vegetables, leafy
* Location          : R4 (Meteo station: Roujan)
* Type of water body : focus_stream
* Simulation period  : 01-Jun-1985 to 01-Jun-1986
*
* Applications
* Appl.No Date/Hour      Mass (q ai.ha-1)  Areic mean deposition (%)
* 1      01-Jun-1985 09:00      540.0           0.0000E+00
*
* File with drainage or runoff data:
* C:\SwashProjects\benfuracarb8\PREM\vegetables_leafy\00444-C1.p2t
* Maximum hourly fluxes and concentrations in runoff
* Water           : 1.86 mm.h-1      15-Feb-1986 01:00
* Substance in water : 0.00 mg.m-2.h-1      07-Jun-1985 01:00
* Substance in eroded mass : 0.00 mg.m-2.h-1      01-Jun-1985 00:00
* Substance concentration : 0.00 µg.L-1      07-Jun-1985 01:00
*
* Properties of substance           : CFS
* Molar mass (g.mol-1)             : 221.3
* Saturated vapour pressure (Pa)    : 0.800E-04 measured at (°C) : 25.0
* Water solubility (mg.L-1)        : 0.319E+03 measured at (°C) : 20.0
* Half-life in water (d)            : 15.30 measured at (°C) : 20.0
* Half-life in sediment (d)        : 1000.00 measured at (°C) : 20.0
* Kom susp.solids (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kom sediment (coef. for sorption on organic matter) (L.kg-1) : 12.76
* Freundlich exponent (-)          : 0.96
* Kmp (coef. for sorption on macrophytes-dry weight) (L.kg-1) : 0.00
*
* Actual concentrations in water layer in µg.L-1
*-----*
* Global maximum 0.000000 07-Jun-1985 02:00
* PEC 1 day      0.000000 08-Jun-1985 02:00
* PEC 2 days     0.000000 09-Jun-1985 02:00
* PEC 4 days     0.000000 11-Jun-1985 02:00
* PEC 7 days     0.000000 14-Jun-1985 02:00
* PEC 14 days    0.000000 21-Jun-1985 02:00

```

EFSA addendum for benfuracarb

to Volume 3 section B.8 Environmental fate and behaviour

January 2009

Contents:

1): Kinetic fit of benfuracarb

2): Kinetic fit of carbofuran

3): PEC_{gw} of benfuracarb and carbofuran simulated by FOCUS PEARL

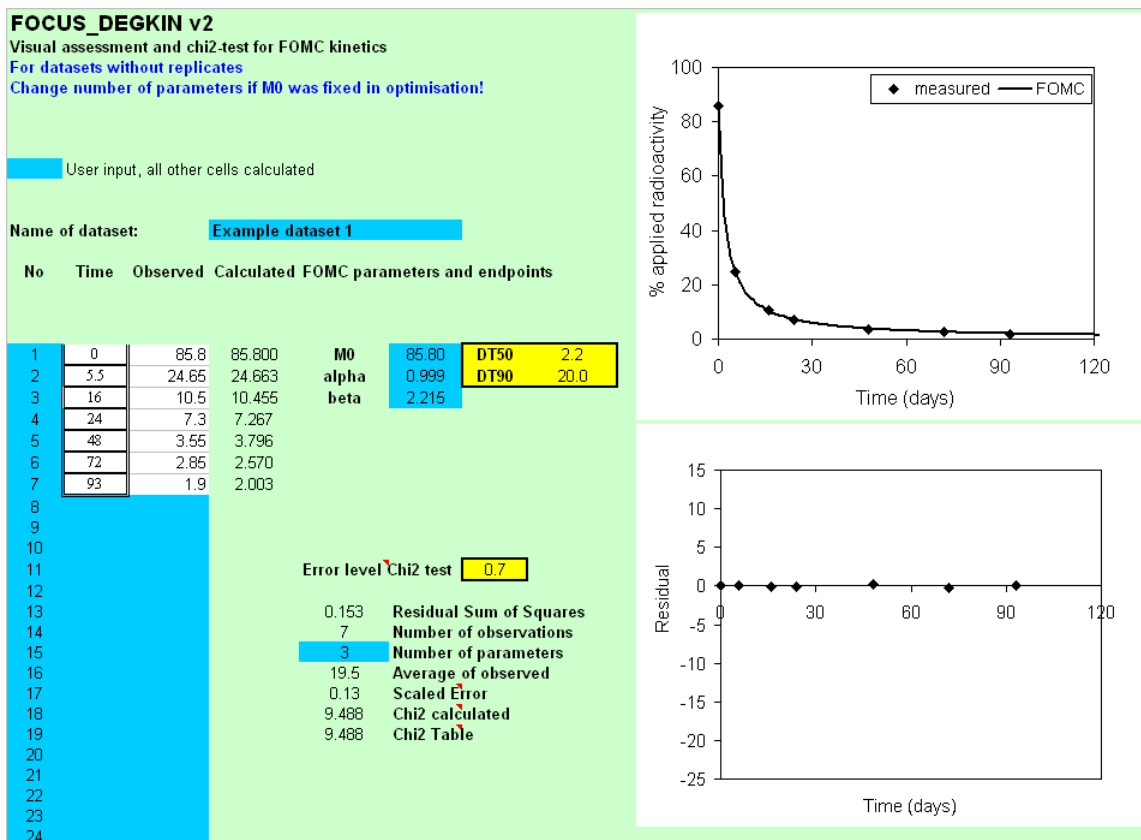
4): Examples from the output files of PEC_{gw} calculations of 3-keto-carbofuran and 3-hydroxy-carbofuran simulated by FOCUS PEARL

1): Kinetic fit of benfuracarb

Update to Section B.8.1.1.1 Aerobic degradation in soil of the additional report for the parent benfuracarb and supporting information to 'Derivation of DT50', to sections B.8.6.1 Predicted environmental concentration in groundwater and B.8.6.2 Predicted environmental concentration in surface water of the addendum 2 dated January 2009 prepared by the RMS.

(note these graphs were available at the meeting of experts PRAPeR 62 of January 2009).

Kinetic fit based on benfuracarb residues reported in Table B.8.1.1.1-23 of the additional report (from study by Noorloos, B. van; Brands, C.)

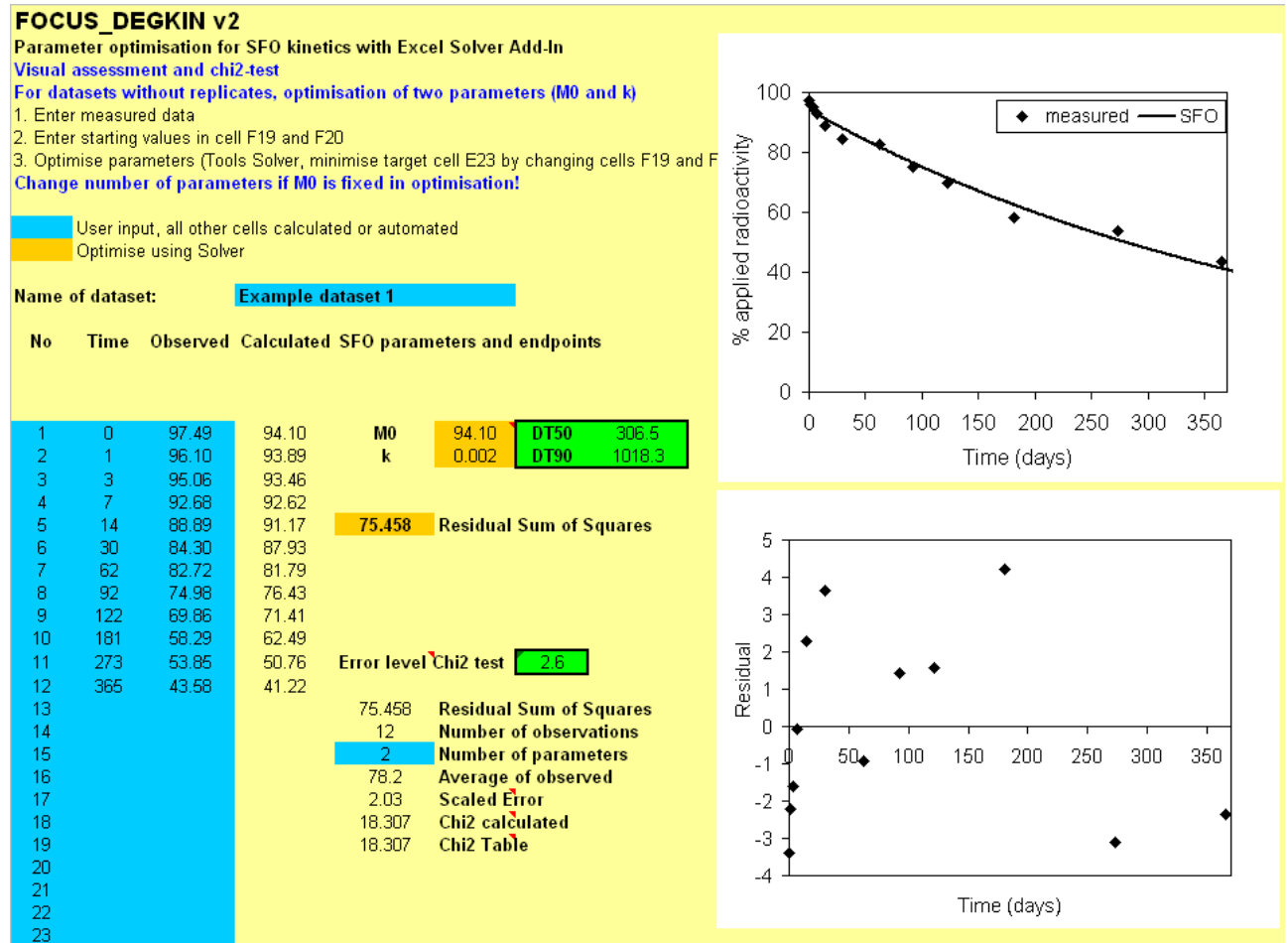


2): Kinetic fit of carbofuran

Update to Section B.8.1.1.1 Aerobic degradation in soil of the additional report, ‘Derivation of DT50’ for the metabolite carbofuran and supporting information to sections B.8.6.1 Predicted environmental concentration in groundwater and B.8.6.2 Predicted environmental concentration in surface water of the addendum 2 dated January 2009 prepared by the RMS.
(note these graphs were available at the meeting of experts PRAPeR 62 of January 2009).

Kinetic fits based on carbofuran residues from studies by Saxena *et al.*, 1994 and Schocken, 1989

Acidic sandy loam soil (Saxena *et al.*, 1994)



FOCUS_DEGKIN v2

Parameter optimisation for SFO kinetics with Excel Solver Add-In

Visual assessment and chi2-test

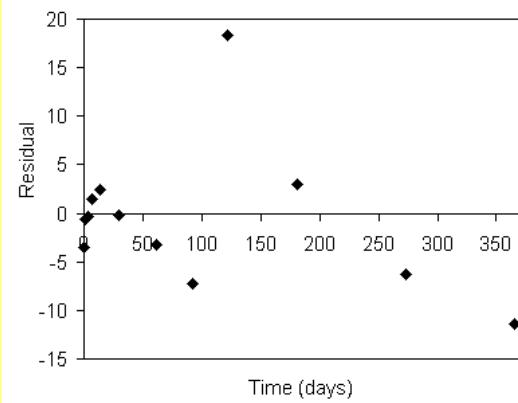
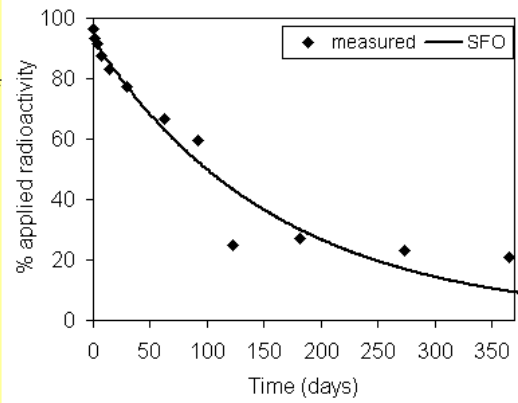
For datasets without replicates, optimisation of two parameters (M0 and k)

1. Enter measured data
 2. Enter starting values in cell F19 and F20
 3. Optimise parameters (Tools Solver, minimise target cell E23 by changing cells F19 and F20)
- Change number of parameters if M0 is fixed in optimisation!**

- User input, all other cells calculated or automated
- Optimise using Solver

Name of dataset: Example dataset 1

No	Time	Observed	Calculated	SFO parameters and endpoints		
1	0	96.63	93.17	M0	93.17	DT50 110.9
2	1	93.22	92.59	k	0.006	DT90 368.5
3	3	91.73	91.44			
4	7	87.73	89.19			
5	14	83.00	85.37	601.333	Residual Sum of Squares	
6	30	77.39	77.25			
7	62	66.53	63.25			
8	92	59.65	52.43			
9	122	25.07	43.47			
10	181	27.14	30.07			
11	273	23.27	16.92	Error level Chi2 test		9.1
12	365	20.96	9.52			
13				601.333	Residual Sum of Squares	
14				12	Number of observations	
15				2	Number of parameters	
16				62.7	Average of observed	
17				5.73	Scaled Error	
18				18.307	Chi2 calculated	
19				18.307	Chi2 Table	
20						
21						
22						



Forest sandy loam soil (Schocken, 1989)

FOCUS_DEGKIN v2
 Parameter optimisation for SFO kinetics with Excel Solver Add-In
 Visual assessment and chi2-test
 For datasets without replicates, optimisation of two parameters (M0 and k)

1. Enter measured data
2. Enter starting values in cell F19 and F20
3. Optimise parameters (Tools Solver, minimise target cell E23 by changing cells F19 and F20)

Change number of parameters if M0 is fixed in optimisation!

User input, all other cells calculated or automated
 Optimise using Solver

Name of dataset: **Example dataset 1**

No	Time	Observed	Calculated	SFO parameters and endpoints		
1	0	95.20	95.31	M0	95.31	DT50 362.1
2	1	96.10	95.13	k	0.002	DT90 1202.9
3	2	94.00	94.95			
4	4	93.70	94.58			
5	8	93.80	93.86			
6	16	92.10	92.44			
7	30	90.20	89.99			
8	57	85.40	85.46			
9	112	80.60	76.92			
10	184	64.50	67.02			

22.677 Residual Sum of Squares

Error level Chi2 test 1.4

22.677	Residual Sum of Squares
10	Number of observations
2	Number of parameters
88.6	Average of observed
1.21	Scaled Error
15.507	Chi2 calculated
15.507	Chi2 Table

The top graph shows the percentage of applied radioactivity over time. The y-axis ranges from 60 to 100, and the x-axis ranges from 0 to 200 days. Measured data points are shown as diamonds, and the SFO model fit is a solid line. The data points generally follow a downward trend, starting at 100% at day 0 and reaching approximately 65% at day 184.

The bottom graph is a residual plot showing the difference between observed and calculated values. The y-axis ranges from -4 to 3, and the x-axis ranges from 0 to 180 days. The residuals are scattered around zero, with a notable positive outlier at approximately 184 days.

3): PECgw of benfuracarb and carbofuran simulated by FOCUS PEARL

Supporting information to Section B.8.6.1 Predicted environmental concentration in groundwater of the addendum 2, dated January 2009 (prepared by the RMS). The addendum of the RMS includes only FOCUS PELMO calculations. The FOCUS PEARL calculations below were made by EFSA using the same input parameters used in FOCUS PELMO calculations in the addendum by RMS and what was agreed by the meeting PRAPeR 62

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 11
 * Input file generated on : 27-01-2009
 *

* Report_type : FOCUS
 * Location : CHATEAUDUN
 * Meteo station : CHAT-M
 * Soil type : CHAT-S_Soil
 * Crop calendar : CHAT-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : CHAT-IRR-F
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 27-Apr; dosage = 1.0000 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	472.190	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	309.991	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	356.436	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	345.681	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	509.847	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	365.827	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	396.178	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	451.529	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	327.488	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	538.177	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	258.376	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	354.154	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	346.100	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	398.988	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	266.630	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	214.137	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	251.936	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	321.942	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	278.828	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	323.619	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	472.190	0.0045495	0.963
2	01-Jan-1908	31-Dec-1908	309.991	0.0018989	0.613
3	01-Jan-1909	31-Dec-1909	356.436	0.0013565	0.381

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4	01-Jan-1910	31-Dec-1910	345.681	0.0019411	0.562
5	01-Jan-1911	31-Dec-1911	509.847	0.0028192	0.553
6	01-Jan-1912	31-Dec-1912	365.827	0.0019028	0.520
7	01-Jan-1913	31-Dec-1913	396.178	0.0023009	0.581
8	01-Jan-1914	31-Dec-1914	451.529	0.0029156	0.646
9	01-Jan-1915	31-Dec-1915	327.488	0.0008230	0.251
10	01-Jan-1916	31-Dec-1916	538.177	0.0059893	1.113
11	01-Jan-1917	31-Dec-1917	258.376	0.0012768	0.494
12	01-Jan-1918	31-Dec-1918	354.154	0.0019531	0.551
13	01-Jan-1919	31-Dec-1919	346.100	0.0019324	0.558
14	01-Jan-1920	31-Dec-1920	398.988	0.0022707	0.569
15	01-Jan-1921	31-Dec-1921	266.630	0.0011473	0.430
16	01-Jan-1922	31-Dec-1922	214.137	0.0004777	0.223
17	01-Jan-1923	31-Dec-1923	251.936	0.0006783	0.269
18	01-Jan-1924	31-Dec-1924	321.942	0.0021584	0.670
19	01-Jan-1925	31-Dec-1925	278.828	0.0014483	0.519
20	01-Jan-1926	31-Dec-1926	323.619	0.0014473	0.447

* The average concentration of MetB4 closest to the 80th percentile is 0.646 ug/L

* This value occurs in period from 01-Jan-1914 to 31-Dec-1914

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 32
 * Input file generated on : 27-01-2009
 *

* Report_type : FOCUS
 * Location : CHATEAUDUN
 * Meteo station : CHAT-M
 * Soil type : CHAT-S_Soil
 * Crop calendar : CHAT-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage2seq
 * Irrigation scheme : CHAT-IRR-F
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 07-Aug; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	472.190	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	309.991	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	356.436	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	345.681	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	509.847	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	365.827	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	396.178	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	451.529	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	327.488	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	538.177	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	258.376	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	354.154	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	346.100	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	398.988	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	266.630	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	214.137	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	251.936	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	321.942	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	278.828	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	323.619	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1925 to 31-Dec-1925

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	472.190	0.0011054	0.234
2	01-Jan-1908	31-Dec-1908	309.991	0.0017155	0.553
3	01-Jan-1909	31-Dec-1909	356.436	0.0014627	0.410

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4	01-Jan-1910	31-Dec-1910	345.681	0.0012671	0.367
5	01-Jan-1911	31-Dec-1911	509.847	0.0013659	0.268
6	01-Jan-1912	31-Dec-1912	365.827	0.0020999	0.574
7	01-Jan-1913	31-Dec-1913	396.178	0.0010250	0.259
8	01-Jan-1914	31-Dec-1914	451.529	0.0013256	0.294
9	01-Jan-1915	31-Dec-1915	327.488	0.0027551	0.841
10	01-Jan-1916	31-Dec-1916	538.177	0.0021073	0.392
11	01-Jan-1917	31-Dec-1917	258.376	0.0045849	1.775
12	01-Jan-1918	31-Dec-1918	354.154	0.0004174	0.118
13	01-Jan-1919	31-Dec-1919	346.100	0.0006266	0.181
14	01-Jan-1920	31-Dec-1920	398.988	0.0023813	0.597
15	01-Jan-1921	31-Dec-1921	266.630	0.0001430	0.054
16	01-Jan-1922	31-Dec-1922	214.137	0.0000365	0.017
17	01-Jan-1923	31-Dec-1923	251.936	0.0001280	0.051
18	01-Jan-1924	31-Dec-1924	321.942	0.0001390	0.043
19	01-Jan-1925	31-Dec-1925	278.828	0.0006046	0.217
20	01-Jan-1926	31-Dec-1926	323.619	0.0015010	0.464

* The average concentration of MetB4 closest to the 80th percentile is 0.574 ug/L
 * This value occurs in period from 01-Jan-1912 to 31-Dec-1912

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 12
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : HAMBURG
 * Meteo station : HAMB-M
 * Soil type : HAMB-S_Soil
 * Crop calendar : HAMB-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 27-Apr; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	102.299	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	263.827	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	335.969	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	269.744	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	510.319	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	548.038	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	295.095	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	370.436	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	377.829	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	249.568	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	262.710	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	327.532	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	376.736	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	204.000	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	141.595	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	300.421	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	262.989	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	431.948	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	536.147	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1913 to 31-Dec-1913

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0003866	0.198
2	01-Jan-1908	31-Dec-1908	102.299	0.0001263	0.123
3	01-Jan-1909	31-Dec-1909	263.827	0.0006490	0.246

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4	01-Jan-1910	31-Dec-1910	335.969	0.0024615	0.733
5	01-Jan-1911	31-Dec-1911	269.744	0.0016845	0.624
6	01-Jan-1912	31-Dec-1912	510.319	0.0144728	2.836
7	01-Jan-1913	31-Dec-1913	548.038	0.0042608	0.777
8	01-Jan-1914	31-Dec-1914	295.095	0.0018692	0.633
9	01-Jan-1915	31-Dec-1915	370.436	0.0011126	0.300
10	01-Jan-1916	31-Dec-1916	377.829	0.0022297	0.590
11	01-Jan-1917	31-Dec-1917	249.568	0.0018239	0.731
12	01-Jan-1918	31-Dec-1918	262.710	0.0012740	0.485
13	01-Jan-1919	31-Dec-1919	327.532	0.0024133	0.737
14	01-Jan-1920	31-Dec-1920	376.736	0.0019347	0.514
15	01-Jan-1921	31-Dec-1921	204.000	0.0006069	0.297
16	01-Jan-1922	31-Dec-1922	141.595	0.0003051	0.215
17	01-Jan-1923	31-Dec-1923	300.421	0.0014176	0.472
18	01-Jan-1924	31-Dec-1924	262.989	0.0007679	0.292
19	01-Jan-1925	31-Dec-1925	431.948	0.0042112	0.975
20	01-Jan-1926	31-Dec-1926	536.147	0.0021819	0.407

* The average concentration of MetB4 closest to the 80th percentile is 0.737 ug/L

* This value occurs in period from 01-Jan-1919 to 31-Dec-1919

* End of PEARL REPORT: FOCUS

Pearl 2 Focus Report

* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 33
 * Input file generated on : 27-01-2009
 *

* Report_type : FOCUS
 * Location : HAMBURG
 * Meteo station : HAMB-M
 * Soil type : HAMB-S_Soil
 * Crop calendar : HAMB-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage2seq
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 07-Aug; dosage = 1.0000 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	102.299	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	263.827	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	335.969	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	269.744	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	510.319	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	548.038	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	295.095	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	370.436	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	377.829	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	249.568	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	262.710	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	327.532	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	376.736	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	204.000	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	141.595	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	300.421	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	262.989	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	431.948	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	536.147	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1925 to 31-Dec-1925

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0104893	5.369
2	01-Jan-1908	31-Dec-1908	102.299	0.0000961	0.094
3	01-Jan-1909	31-Dec-1909	263.827	0.0038438	1.457

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4	01-Jan-1910	31-Dec-1910	335.969	0.0086603	2.578
5	01-Jan-1911	31-Dec-1911	269.744	0.0116598	4.323
6	01-Jan-1912	31-Dec-1912	510.319	0.0112825	2.211
7	01-Jan-1913	31-Dec-1913	548.038	0.0171387	3.127
8	01-Jan-1914	31-Dec-1914	295.095	0.0092104	3.121
9	01-Jan-1915	31-Dec-1915	370.436	0.0075228	2.031
10	01-Jan-1916	31-Dec-1916	377.829	0.0092498	2.448
11	01-Jan-1917	31-Dec-1917	249.568	0.0053424	2.141
12	01-Jan-1918	31-Dec-1918	262.710	0.0062446	2.377
13	01-Jan-1919	31-Dec-1919	327.532	0.0100881	3.080
14	01-Jan-1920	31-Dec-1920	376.736	0.0109511	2.907
15	01-Jan-1921	31-Dec-1921	204.000	0.0024334	1.193
16	01-Jan-1922	31-Dec-1922	141.595	0.0017537	1.239
17	01-Jan-1923	31-Dec-1923	300.421	0.0065173	2.169
18	01-Jan-1924	31-Dec-1924	262.989	0.0052330	1.990
19	01-Jan-1925	31-Dec-1925	431.948	0.0121778	2.819
20	01-Jan-1926	31-Dec-1926	536.147	0.0322847	6.022

* The average concentration of MetB4 closest to the 80th percentile is 3.127 ug/L

* This value occurs in period from 01-Jan-1913 to 31-Dec-1913

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 13
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : JOKIOINEN
 * Meteo station : JOKI-M
 * Soil type : JOKI-S_Soil
 * Crop calendar : JOKI-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 27-May; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	180.789	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	140.601	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	267.411	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	449.172	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	254.313	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	245.125	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	502.985	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	254.339	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	347.631	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	435.086	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	288.136	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	175.101	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	42.566	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	47.070	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	32.826	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	56.715	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	433.184	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	544.875	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	262.933	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	173.521	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1925 to 31-Dec-1925

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	180.789	0.0002706	0.150
2	01-Jan-1908	31-Dec-1908	140.601	0.0002946	0.210
3	01-Jan-1909	31-Dec-1909	267.411	0.0007091	0.265

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4	01-Jan-1910	31-Dec-1910	449.172	0.0039633	0.882
5	01-Jan-1911	31-Dec-1911	254.313	0.0028505	1.121
6	01-Jan-1912	31-Dec-1912	245.125	0.0006666	0.272
7	01-Jan-1913	31-Dec-1913	502.985	0.0030822	0.613
8	01-Jan-1914	31-Dec-1914	254.339	0.0026829	1.055
9	01-Jan-1915	31-Dec-1915	347.631	0.0009699	0.279
10	01-Jan-1916	31-Dec-1916	435.086	0.0032219	0.741
11	01-Jan-1917	31-Dec-1917	288.136	0.0008739	0.303
12	01-Jan-1918	31-Dec-1918	175.101	0.0009540	0.545
13	01-Jan-1919	31-Dec-1919	42.566	0.0001091	0.256
14	01-Jan-1920	31-Dec-1920	47.070	0.0000489	0.104
15	01-Jan-1921	31-Dec-1921	32.826	0.0000098	0.030
16	01-Jan-1922	31-Dec-1922	56.715	0.0000106	0.019
17	01-Jan-1923	31-Dec-1923	433.184	0.0014414	0.333
18	01-Jan-1924	31-Dec-1924	544.875	0.0029277	0.537
19	01-Jan-1925	31-Dec-1925	262.933	0.0015543	0.591
20	01-Jan-1926	31-Dec-1926	173.521	0.0004946	0.285

* The average concentration of MetB4 closest to the 80th percentile is 0.741 ug/L

* This value occurs in period from 01-Jan-1916 to 31-Dec-1916

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Pearldb
 * Run ID : 14
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : KREMSMUNSTER
 * Meteo station : KREM-M
 * Soil type : KREM-S_Soil
 * Crop calendar : KREM-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 27-Apr; dosage = 1.0000 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00
 *

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	367.145	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	577.155	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	617.313	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	548.525	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	402.436	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	536.945	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	405.128	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	309.916	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	363.080	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	399.700	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	348.560	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	462.435	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	317.879	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	373.910	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	19.718	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	-44.071	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	476.080	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	303.262	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	344.234	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96
 *

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0009336	0.193
2	01-Jan-1908	31-Dec-1908	367.145	0.0010074	0.274
3	01-Jan-1909	31-Dec-1909	577.155	0.0028324	0.491

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4	01-Jan-1910	31-Dec-1910	617.313	0.0069252	1.122
5	01-Jan-1911	31-Dec-1911	548.525	0.0043734	0.797
6	01-Jan-1912	31-Dec-1912	402.436	0.0010818	0.269
7	01-Jan-1913	31-Dec-1913	536.945	0.0033083	0.616
8	01-Jan-1914	31-Dec-1914	405.128	0.0014786	0.365
9	01-Jan-1915	31-Dec-1915	309.916	0.0008803	0.284
10	01-Jan-1916	31-Dec-1916	363.080	0.0010469	0.288
11	01-Jan-1917	31-Dec-1917	399.700	0.0025372	0.635
12	01-Jan-1918	31-Dec-1918	348.560	0.0023236	0.667
13	01-Jan-1919	31-Dec-1919	462.435	0.0038780	0.839
14	01-Jan-1920	31-Dec-1920	317.879	0.0019800	0.623
15	01-Jan-1921	31-Dec-1921	373.910	0.0007894	0.211
16	01-Jan-1922	31-Dec-1922	19.718	0.0001275	0.647
17	01-Jan-1923	31-Dec-1923	-44.071	-0.0002022	0.000
18	01-Jan-1924	31-Dec-1924	476.080	0.0006235	0.131
19	01-Jan-1925	31-Dec-1925	303.262	0.0005042	0.166
20	01-Jan-1926	31-Dec-1926	344.234	0.0007433	0.216

* The average concentration of MetB4 closest to the 80th percentile is 0.667 ug/L
 * This value occurs in period from 01-Jan-1918 to 31-Dec-1918

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2_2\Database\Pearldb
 * Run ID : 14
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : KREMSMUNSTER
 * Meteo station : KREM-M
 * Soil type : KREM-S_Soil
 * Crop calendar : KREM-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 27-Apr; dosage = 1.0000 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	367.145	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	577.155	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	617.313	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	548.525	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	402.436	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	536.945	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	405.128	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	309.916	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	363.080	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	399.700	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	348.560	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	462.435	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	317.879	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	373.910	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	19.718	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	-44.071	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	476.080	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	303.262	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	344.234	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0009336	0.193
2	01-Jan-1908	31-Dec-1908	367.145	0.0010074	0.274
3	01-Jan-1909	31-Dec-1909	577.155	0.0028324	0.491

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4	01-Jan-1910	31-Dec-1910	617.313	0.0069252	1.122
5	01-Jan-1911	31-Dec-1911	548.525	0.0043734	0.797
6	01-Jan-1912	31-Dec-1912	402.436	0.0010818	0.269
7	01-Jan-1913	31-Dec-1913	536.945	0.0033083	0.616
8	01-Jan-1914	31-Dec-1914	405.128	0.0014786	0.365
9	01-Jan-1915	31-Dec-1915	309.916	0.0008803	0.284
10	01-Jan-1916	31-Dec-1916	363.080	0.0010469	0.288
11	01-Jan-1917	31-Dec-1917	399.700	0.0025372	0.635
12	01-Jan-1918	31-Dec-1918	348.560	0.0023236	0.667
13	01-Jan-1919	31-Dec-1919	462.435	0.0038780	0.839
14	01-Jan-1920	31-Dec-1920	317.879	0.0019800	0.623
15	01-Jan-1921	31-Dec-1921	373.910	0.0007894	0.211
16	01-Jan-1922	31-Dec-1922	19.718	0.0001275	0.647
17	01-Jan-1923	31-Dec-1923	-44.071	-0.0002022	0.000
18	01-Jan-1924	31-Dec-1924	476.080	0.0006235	0.131
19	01-Jan-1925	31-Dec-1925	303.262	0.0005042	0.166
20	01-Jan-1926	31-Dec-1926	344.234	0.0007433	0.216

* The average concentration of MetB4 closest to the 80th percentile is 0.667 ug/L

* This value occurs in period from 01-Jan-1918 to 31-Dec-1918

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Pearldb
 * Run ID : 35
 * Input file generated on : 27-01-2009
 *-----

* Report type : FOCUS
 * Location : KREMSMUNSTER
 * Meteo station : KREM-M
 * Soil type : KREM-S_Soil
 * Crop calendar : KREM-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage2seq
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 07-Aug; dosage = 1.0000 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00
 *-----

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	367.145	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	577.155	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	617.313	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	548.525	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	402.436	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	536.945	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	405.128	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	309.916	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	363.080	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	399.700	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	348.560	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	462.435	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	317.879	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	373.910	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	19.718	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	-44.071	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	476.080	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	303.262	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	344.234	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96
 *-----

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0019513	0.404
2	01-Jan-1908	31-Dec-1908	367.145	0.0056205	1.531
3	01-Jan-1909	31-Dec-1909	577.155	0.0063670	1.103

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4	01-Jan-1910	31-Dec-1910	617.313	0.0122561	1.985
5	01-Jan-1911	31-Dec-1911	548.525	0.0077066	1.405
6	01-Jan-1912	31-Dec-1912	402.436	0.0045814	1.138
7	01-Jan-1913	31-Dec-1913	536.945	0.0066061	1.230
8	01-Jan-1914	31-Dec-1914	405.128	0.0082698	2.041
9	01-Jan-1915	31-Dec-1915	309.916	0.0022366	0.722
10	01-Jan-1916	31-Dec-1916	363.080	0.0008253	0.227
11	01-Jan-1917	31-Dec-1917	399.700	0.0066056	1.653
12	01-Jan-1918	31-Dec-1918	348.560	0.0021407	0.614
13	01-Jan-1919	31-Dec-1919	462.435	0.0024709	0.534
14	01-Jan-1920	31-Dec-1920	317.879	0.0009493	0.299
15	01-Jan-1921	31-Dec-1921	373.910	0.0013273	0.355
16	01-Jan-1922	31-Dec-1922	19.718	0.0000130	0.066
17	01-Jan-1923	31-Dec-1923	-44.071	-0.0001161	0.000
18	01-Jan-1924	31-Dec-1924	476.080	0.0028371	0.596
19	01-Jan-1925	31-Dec-1925	303.262	0.0025645	0.846
20	01-Jan-1926	31-Dec-1926	344.234	0.0025295	0.735

* The average concentration of MetB4 closest to the 80th percentile is 1.531 ug/L

* This value occurs in period from 01-Jan-1908 to 31-Dec-1908

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Pearldb
 * Run ID : 15
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : PORTO
 * Meteo station : PORT-M
 * Soil type : PORT-S_Soil
 * Crop calendar : PORT-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 07-Mar; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	525.594	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	693.514	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	844.089	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	770.495	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	813.912	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	466.784	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	521.624	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	639.052	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	591.724	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	813.995	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	723.224	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	749.470	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	908.344	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	525.291	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	419.049	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	470.303	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	598.652	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	150.185	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	339.191	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	403.963	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	525.594	0.0000104	0.002
2	01-Jan-1908	31-Dec-1908	693.514	0.0000235	0.003
3	01-Jan-1909	31-Dec-1909	844.089	0.0000871	0.010

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4	01-Jan-1910	31-Dec-1910	770.495	0.0000538	0.007
5	01-Jan-1911	31-Dec-1911	813.912	0.0001185	0.015
6	01-Jan-1912	31-Dec-1912	466.784	0.0001275	0.027
7	01-Jan-1913	31-Dec-1913	521.624	0.0000087	0.002
8	01-Jan-1914	31-Dec-1914	639.052	0.0000407	0.006
9	01-Jan-1915	31-Dec-1915	591.724	0.0000385	0.007
10	01-Jan-1916	31-Dec-1916	813.995	0.0001812	0.022
11	01-Jan-1917	31-Dec-1917	723.224	0.0000674	0.009
12	01-Jan-1918	31-Dec-1918	749.470	0.0000340	0.005
13	01-Jan-1919	31-Dec-1919	908.344	0.0000568	0.006
14	01-Jan-1920	31-Dec-1920	525.291	0.0000657	0.013
15	01-Jan-1921	31-Dec-1921	419.049	0.0000001	0.000
16	01-Jan-1922	31-Dec-1922	470.303	0.0000029	0.001
17	01-Jan-1923	31-Dec-1923	598.652	0.0000083	0.001
18	01-Jan-1924	31-Dec-1924	150.185	0.0000002	0.000
19	01-Jan-1925	31-Dec-1925	339.191	0.0000009	0.000
20	01-Jan-1926	31-Dec-1926	403.963	0.0000076	0.002

* The average concentration of MetB4 closest to the 80th percentile is 0.013 ug/L

* This value occurs in period from 01-Jan-1920 to 31-Dec-1920

* End of PEARL REPORT: FOCUS

Pearl 2 Focus Report

* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 36
 * Input file generated on : 27-01-2009
 *

* Report_type : FOCUS
 * Location : PORTO
 * Meteo station : PORT-M
 * Soil type : PORT-S_Soil
 * Crop calendar : PORT-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage2seq
 * Irrigation scheme : No
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 07-Aug; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00
 *

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	525.594	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	693.514	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	844.089	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	770.495	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	813.912	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	466.784	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	521.624	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	639.052	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	591.724	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	813.995	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	723.224	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	749.470	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	908.344	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	525.291	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	419.049	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	470.303	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	598.652	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	150.185	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	339.191	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	403.963	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1925 to 31-Dec-1925

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96
 *

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	525.594	0.0002538	0.048
2	01-Jan-1908	31-Dec-1908	693.514	0.0022048	0.318
3	01-Jan-1909	31-Dec-1909	844.089	0.0074728	0.885

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4	01-Jan-1910	31-Dec-1910	770.495	0.0006669	0.087
5	01-Jan-1911	31-Dec-1911	813.912	0.0010279	0.126
6	01-Jan-1912	31-Dec-1912	466.784	0.0008750	0.187
7	01-Jan-1913	31-Dec-1913	521.624	0.0000648	0.012
8	01-Jan-1914	31-Dec-1914	639.052	0.0004729	0.074
9	01-Jan-1915	31-Dec-1915	591.724	0.0011837	0.200
10	01-Jan-1916	31-Dec-1916	813.995	0.0003095	0.038
11	01-Jan-1917	31-Dec-1917	723.224	0.0019380	0.268
12	01-Jan-1918	31-Dec-1918	749.470	0.0007279	0.097
13	01-Jan-1919	31-Dec-1919	908.344	0.0021219	0.234
14	01-Jan-1920	31-Dec-1920	525.291	0.0045429	0.865
15	01-Jan-1921	31-Dec-1921	419.049	0.0000065	0.002
16	01-Jan-1922	31-Dec-1922	470.303	0.0006449	0.137
17	01-Jan-1923	31-Dec-1923	598.652	0.0010286	0.172
18	01-Jan-1924	31-Dec-1924	150.185	0.0000082	0.005
19	01-Jan-1925	31-Dec-1925	339.191	0.0000059	0.002
20	01-Jan-1926	31-Dec-1926	403.963	0.0003129	0.077

* The average concentration of MetB4 closest to the 80th percentile is 0.268 ug/L

* This value occurs in period from 01-Jan-1917 to 31-Dec-1917

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 16
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : SEVILLA
 * Meteo station : SEVI-M
 * Soil type : SEVI-S_Soil
 * Crop calendar : SEVI-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : SEVI-IRR-F
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 08-Mar; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	179.981	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	398.657	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	465.421	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	229.952	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	477.343	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	154.686	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	52.807	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	233.987	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	313.475	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	273.126	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	250.055	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	207.233	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	410.404	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	61.377	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	429.433	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	219.512	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	167.636	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	117.173	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	35.691	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	64.287	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	179.981	0.0000337	0.019
2	01-Jan-1908	31-Dec-1908	398.657	0.0004467	0.112
3	01-Jan-1909	31-Dec-1909	465.421	0.0004350	0.093

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4	01-Jan-1910	31-Dec-1910	229.952	0.0001213	0.053
5	01-Jan-1911	31-Dec-1911	477.343	0.0003776	0.079
6	01-Jan-1912	31-Dec-1912	154.686	0.0001608	0.104
7	01-Jan-1913	31-Dec-1913	52.807	0.0000609	0.115
8	01-Jan-1914	31-Dec-1914	233.987	0.0001526	0.065
9	01-Jan-1915	31-Dec-1915	313.475	0.0002596	0.083
10	01-Jan-1916	31-Dec-1916	273.126	0.0002268	0.083
11	01-Jan-1917	31-Dec-1917	250.055	0.0001647	0.066
12	01-Jan-1918	31-Dec-1918	207.233	0.0001097	0.053
13	01-Jan-1919	31-Dec-1919	410.404	0.0003634	0.089
14	01-Jan-1920	31-Dec-1920	61.377	-0.0000049	0.000
15	01-Jan-1921	31-Dec-1921	429.433	0.0002596	0.060
16	01-Jan-1922	31-Dec-1922	219.512	0.0000394	0.018
17	01-Jan-1923	31-Dec-1923	167.636	0.0000796	0.048
18	01-Jan-1924	31-Dec-1924	117.173	0.0000507	0.043
19	01-Jan-1925	31-Dec-1925	35.691	0.0000073	0.020
20	01-Jan-1926	31-Dec-1926	64.287	0.0000269	0.042

* The average concentration of MetB4 closest to the 80th percentile is 0.093 ug/L

* This value occurs in period from 01-Jan-1909 to 31-Dec-1909

* End of PEARL REPORT: FOCUS

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* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 37
 * Input file generated on : 27-01-2009
 *

* Report_type : FOCUS
 * Location : SEVILLA
 * Meteo station : SEVI-M
 * Soil type : SEVI-S_Soil
 * Crop calendar : SEVI-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage2sseveq
 * Irrigation scheme : SEVI-IRR-F
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 22-Jun; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	179.981	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	398.657	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	465.421	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	229.952	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	477.343	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	154.686	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	52.807	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	233.987	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	313.475	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	273.126	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	250.055	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	207.233	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	410.404	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	61.377	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	429.433	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	219.512	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	167.636	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	117.173	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	35.691	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	64.287	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1926 to 31-Dec-1926

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	179.981	0.0000017	0.001
2	01-Jan-1908	31-Dec-1908	398.657	0.0000160	0.004
3	01-Jan-1909	31-Dec-1909	465.421	0.0000987	0.021

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4	01-Jan-1910	31-Dec-1910	229.952	0.0000788	0.034
5	01-Jan-1911	31-Dec-1911	477.343	0.0000403	0.008
6	01-Jan-1912	31-Dec-1912	154.686	0.0000044	0.003
7	01-Jan-1913	31-Dec-1913	52.807	-0.0000001	0.000
8	01-Jan-1914	31-Dec-1914	233.987	0.0000060	0.003
9	01-Jan-1915	31-Dec-1915	313.475	0.0000779	0.025
10	01-Jan-1916	31-Dec-1916	273.126	0.0000677	0.025
11	01-Jan-1917	31-Dec-1917	250.055	0.0000598	0.024
12	01-Jan-1918	31-Dec-1918	207.233	0.0000102	0.005
13	01-Jan-1919	31-Dec-1919	410.404	0.0000628	0.015
14	01-Jan-1920	31-Dec-1920	61.377	0.0000077	0.013
15	01-Jan-1921	31-Dec-1921	429.433	0.0000666	0.016
16	01-Jan-1922	31-Dec-1922	219.512	0.0000424	0.019
17	01-Jan-1923	31-Dec-1923	167.636	0.0000033	0.002
18	01-Jan-1924	31-Dec-1924	117.173	0.0000024	0.002
19	01-Jan-1925	31-Dec-1925	35.691	-0.0000019	0.000
20	01-Jan-1926	31-Dec-1926	64.287	-0.0000012	0.000

* The average concentration of MetB4 closest to the 80th percentile is 0.024 ug/L

* This value occurs in period from 01-Jan-1917 to 31-Dec-1917

* End of PEARL REPORT: FOCUS

Pearl 2 Focus Report

* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM/Alterra
 * FOCUS PEARL version : 2.2.2
 * PEARL model version : 1.5.8-F2
 * SWAP model version : swap209d
 * PEARL created on : 16-Jun-2003
 *
 * Working directory : C:\Program Files\FOCUSPEARL_2_2\Database\Fearldb
 * Run ID : 17
 * Input file generated on : 25-01-2009
 *

* Report_type : FOCUS
 * Location : THIVA
 * Meteo station : THIV-M
 * Soil type : THIV-S_Soil
 * Crop calendar : THIV-CABBAGE
 * Substance : Benf2
 * Application scheme : BenfCabbage
 * Irrigation scheme : THIV-IRR-F
 * Deposition scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 22-Aug; dosage = 1.0000 kg,ha-1; depth = 0.03 m

* FOCUS summary for compound Benf2
 * Molar mass (g.mol-1) : 410.5
 * Saturated vapour pressure (Pa) : 0.4E-05; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 8. ; measured at (C) 20.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 5278.4
 * Freundlich exponent (-) : 1.00

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	535.967	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	546.295	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	332.836	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	544.209	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	551.606	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	460.452	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	529.504	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	482.680	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	571.725	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	410.082	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	562.919	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	445.787	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	451.703	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	603.216	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	243.491	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	259.709	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	381.851	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	249.380	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	157.243	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	298.891	0.0000000	0.000

* The average concentration of Benf2 closest to the 80th percentile is 0.000 ug/L
 * This value occurs in period from 01-Jan-1924 to 31-Dec-1924

* FOCUS summary for compound MetB4
 * Molar mass (g.mol-1) : 221.3
 * Saturated vapour pressure (Pa) : 0.8E-04; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.3E+03; measured at (C) 20.0
 * Half-life (d) : 14.0; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 12.8
 * Freundlich exponent (-) : 0.96

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	535.967	0.0001909	0.036
2	01-Jan-1908	31-Dec-1908	546.295	0.0011908	0.218
3	01-Jan-1909	31-Dec-1909	332.836	0.0004406	0.132

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4	01-Jan-1910	31-Dec-1910	544.209	0.0004175	0.077
5	01-Jan-1911	31-Dec-1911	551.606	0.0012609	0.229
6	01-Jan-1912	31-Dec-1912	460.452	0.0026193	0.569
7	01-Jan-1913	31-Dec-1913	529.504	0.0002898	0.055
8	01-Jan-1914	31-Dec-1914	482.680	0.0007463	0.155
9	01-Jan-1915	31-Dec-1915	571.725	0.0016609	0.291
10	01-Jan-1916	31-Dec-1916	410.082	0.0022322	0.544
11	01-Jan-1917	31-Dec-1917	562.919	0.0002837	0.050
12	01-Jan-1918	31-Dec-1918	445.787	0.0005959	0.134
13	01-Jan-1919	31-Dec-1919	451.703	0.0003535	0.078
14	01-Jan-1920	31-Dec-1920	603.216	0.0007415	0.123
15	01-Jan-1921	31-Dec-1921	243.491	0.0002460	0.101
16	01-Jan-1922	31-Dec-1922	259.709	0.0000030	0.001
17	01-Jan-1923	31-Dec-1923	381.851	0.0003140	0.082
18	01-Jan-1924	31-Dec-1924	249.380	0.0000298	0.012
19	01-Jan-1925	31-Dec-1925	157.243	-0.0000009	0.000
20	01-Jan-1926	31-Dec-1926	298.891	0.0000454	0.015

* The average concentration of MetB4 closest to the 80th percentile is 0.229 ug/L
 * This value occurs in period from 01-Jan-1911 to 31-Dec-1911

* End of PEARL REPORT: FOCUS

4): Examples from the output files of PECgw calculations of 3-keto-carbofuran and 3-hydroxy-carbofuran simulated by FOCUS PEARL

Supporting information to Section B.8.6.1 Predicted environmental concentration in groundwater of the addendum 2, dated January 2009 (prepared by the RMS). The addendum of the RMS did not contained any updated PECgw calculations for the minor metabolites 3-keto-carbofuran and 3-hydroxy-carbofuran. Appropriate calculations were, however, submitted by the applicant. Some example of these FOCUS PEARL calculations are inserted below. The input parameters used were what was agreed by the meeting PRAPeR 62

```

* PEARL REPORT: Header
* Results from the PEARL model (c) RIVM, MNP and Alterra
* FOCUS PEARL version      : 3.3.3
* PEARL model version     : 1.7.7-F3
* SWAP model version      : swap209e
* PEARL created on       : 21-Apr-2006
*
* Working directory      : C:\Program Files\FOCUSPEARL_3_3_3\Database\Pearldb
* Run ID                 : 388
* Input file generated on : 20-10-2008
* -----
*
* Report type           : FOCUS
* Location              : HAMBURG
* Meteo station         : HAMB-M
* Soil type             : HAMB-S Soil
* Crop calendar        : HAMB-CABBAGE
* Substance             : 3KCF1
* Application scheme    : 3KCF1
* Deposition scheme     : No
* Irrigation scheme    : No
*
* End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
* Start date           : 01-Jan-1901
* End date             : 31-Dec-1926
* Target depth        : 1.00 m
* Annual incorporation at 27-Apr; dosage = 0.0570 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound 3KCF1
* Molar mass (g.mol-1) : 235.2
* Saturated vapour pressure (Pa) : 0.3E-02; measured at (C) 25.0
* Solubility in water (mg.L-1) : 0.4E+04; measured at (C) 25.0
* Half-life (d) : 3.0; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 191.7
* KF (overall sorption coefficient of FOCUS layer) (L.kg-1) : 2.57
* Freundlich exponent (-) : 1.00
* -----
*
* Period      From      To      Water percolated      Substance leached      Average substance
* number      From      To      below target depth (mm)  below target depth (kg/ha)  concentration in water
*                                     at target depth (ug/L)
* -----
1      01-Jan-1907 31-Dec-1907      195.360      0.0000000      0.000
2      01-Jan-1908 31-Dec-1908      102.298      0.0000000      0.000
3      01-Jan-1909 31-Dec-1909      263.828      0.0000000      0.000
4      01-Jan-1910 31-Dec-1910      335.968      0.0000000      0.000
5      01-Jan-1911 31-Dec-1911      269.744      0.0000000      0.000
6      01-Jan-1912 31-Dec-1912      510.319      0.0000000      0.000
7      01-Jan-1913 31-Dec-1913      548.038      0.0000000      0.000
8      01-Jan-1914 31-Dec-1914      295.095      0.0000000      0.000
9      01-Jan-1915 31-Dec-1915      370.436      0.0000000      0.000
10     01-Jan-1916 31-Dec-1916      377.829      0.0000000      0.000
11     01-Jan-1917 31-Dec-1917      249.568      0.0000000      0.000
12     01-Jan-1918 31-Dec-1918      262.710      0.0000000      0.000
13     01-Jan-1919 31-Dec-1919      327.532      0.0000000      0.000
14     01-Jan-1920 31-Dec-1920      376.736      0.0000000      0.000
15     01-Jan-1921 31-Dec-1921      204.000      0.0000000      0.000
16     01-Jan-1922 31-Dec-1922      141.595      0.0000000      0.000
17     01-Jan-1923 31-Dec-1923      300.421      0.0000000      0.000
18     01-Jan-1924 31-Dec-1924      262.989      0.0000000      0.000
19     01-Jan-1925 31-Dec-1925      431.948      0.0000000      0.000
20     01-Jan-1926 31-Dec-1926      536.147      0.0000000      0.000

* The average concentration of 3KCF1 closest to the 80th percentile is 0.0000 ug/L
* This value occurs in period from 01-Jan-1914 to 31-Dec-1914

* End of PEARL REPORT: FOCUS

```

```

* PEARL REPORT: Header
* Results from the PEARL model (c) RIVM, MNP and Alterra
* FOCUS PEARL version      : 3.3.3
* PEARL model version     : 1.7.7-F3
* SWAP model version      : swap209e
* PEARL created on       : 21-Apr-2006
*
* Working directory      : C:\Program Files\FOCUSPEARL_3_3_3\Database\Pearl1db
* Run ID                 : 395
* Input file generated on : 20-10-2008
* -----

```

```

* Report_type      : FOCUS
* Location         : HAMBURG
* Meteo station    : HAMB-M
* Soil type       : HAMB-S Soil
* Crop calendar    : HAMB-CABBAGE
* Substance       : 3KCF1
* Application scheme : 3KCF2
* Deposition scheme : No
* Irrigation scheme : No
*
* End of PEARL REPORT: Header

```

```

* PEARL REPORT: FOCUS
* Start date      : 01-Jan-1901
* End date        : 31-Dec-1926
* Target depth    : 1.00 m
* Annual incorporation at 07-Aug; dosage = 0.0570 kg.ha-1; depth = 0.03 m

```

```

* FOCUS summary for compound 3KCF1
* Molar mass (g.mol-1)      : 235.2
* Saturated vapour pressure (Pa) : 0.3E-02; measured at (C) 25.0
* Solubility in water (mg.L-1) : 0.4E+04; measured at (C) 25.0
* Half-life (d)             : 3.0; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 191.7
* KF (overall sorption coefficient of FOCUS layer) (L.kg-1) : 2.57
* Freundlich exponent (-)    : 1.00
* -----

```

* Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	102.298	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	263.828	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	335.968	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	269.744	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	510.319	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	548.038	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	295.095	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	370.436	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	377.829	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	249.568	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	262.710	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	327.532	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	376.736	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	204.000	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	141.595	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	300.421	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	262.989	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	431.948	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	536.147	0.0000000	0.000

```

* The average concentration of 3KCF1 closest to the 80th percentile is 0.0000 ug/L
* This value occurs in period from 01-Jan-1911 to 31-Dec-1911
*
* End of PEARL REPORT: FOCUS

```

```

* PEARL REPORT: Header
* Results from the PEARL model (c) RIVM, MNP and Alterra
* FOCUS PEARL version      : 3.3.3
* PEARL model version     : 1.7.7-F3
* SWAP model version      : swap209e
* PEARL created on        : 21-Apr-2006
*
* Working directory       : C:\Program Files\FOCUSPEARL_3_3_3\Database\Pearldb
* Run ID                  : 396
* Input file generated on : 20-10-2008
* -----

```

```

* Report type      : FOCUS
* Location         : KREMSMUNSTER
* Meteo station    : KREM-M
* Soil type       : KREM-S_Soil
* Crop calendar    : KREM-CABBAGE
* Substance       : 3KCF1
* Application scheme : 3KCF2
* Deposition scheme : No
* Irrigation scheme : No
*
* End of PEARL REPORT: Header

```

```

* PEARL REPORT: FOCUS
* Start date      : 01-Jan-1901
* End date        : 31-Dec-1926
* Target depth    : 1.00 m
* Annual incorporation at 07-Aug; dosage = 0.0570 kg.ha-1; depth = 0.03 m

```

```

* FOCUS summary for compound 3KCF1
* Molar mass (g.mol-1)      : 235.2
* Saturated vapour pressure (Pa) : 0.3E-02; measured at (C) 25.0
* Solubility in water (mg.L-1) : 0.4E+04; measured at (C) 25.0
* Half-life (d)            : 3.0; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 191.7
* KF (overall sorption coefficient of FOCUS layer) (L.kg-1) : 2.93
* Freundlich exponent (-)   : 1.00
* -----

```

Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	367.100	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	577.155	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	617.313	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	548.525	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	402.436	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	536.945	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	405.080	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	309.917	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	363.080	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	399.700	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	348.560	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	462.435	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	317.879	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	373.910	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	19.732	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	-44.045	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	476.204	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	303.262	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	344.232	0.0000000	0.000

```

* The average concentration of 3KCF1 closest to the 80th percentile is 0.0000 ug/L
* This value occurs in period from 01-Jan-1917 to 31-Dec-1917

```

```

* End of PEARL REPORT: FOCUS

```

```

* PEARL REPORT: Header
* Results from the PEARL model (c) RIVM, MNP and Alterra
* FOCUS PEARL version : 3.3.3
* PEARL model version : 1.7.7-F3
* SWAP model version : swap209e
* PEARL created on : 21-Apr-2006
*
* Working directory : C:\Program Files\FOCUSPEARL_3_3_3\Database\Pearldb
* Run ID : 400
* Input file generated on : 20-10-2008

```

```

-----
* Report type : FOCUS
* Location : HAMBURG
* Meteo station : HAMB-M
* Soil type : HAMB-S_Soil
* Crop calendar : HAMB-CABBAGE
* Substance : 30HCl
* Application scheme : 30HCF1
* Deposition scheme : No
* Irrigation scheme : No
*
* End of PEARL REPORT: Header

```

```

* PEARL REPORT: FOCUS
* Start date : 01-Jan-1901
* End date : 31-Dec-1926
* Target depth : 1.00 m
* Annual incorporation at 27-Apr; dosage = 0.0580 kg.ha-1; depth = 0.03 m

```

```

* FOCUS summary for compound 30HCl
* Molar mass (g.mol-1) : 237.3
* Saturated vapour pressure (Pa) : 0.3E-02; measured at (C) 25.0
* Solubility in water (mg.L-1) : 0.6E+04; measured at (C) 25.0
* Half-life (d) : 0.4; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 31.9
* KF (overall sorption coefficient of FOCUS layer) (L.kg-1) : 0.428
* Freundlich exponent (-) : 1.00

```

```

-----
* Period From To Water percolated Substance leached Average substance
* number below target depth (mm) below target depth (kg/ha) concentration in water
* at target depth (ug/L)
-----

```

* number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	102.298	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	263.828	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	335.968	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	269.744	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	510.319	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	548.038	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	295.095	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	370.436	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	377.829	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	249.568	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	262.710	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	327.532	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	376.736	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	204.000	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	141.595	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	300.421	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	262.989	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	431.948	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	536.147	0.0000000	0.000

```

* The average concentration of 30HCl closest to the 80th percentile is 0.0000 ug/L
* This value occurs in period from 01-Jan-1914 to 31-Dec-1914
*
* End of PEARL REPORT: FOCUS

```

```

* PEARL REPORT: Header
* Results from the PEARL model (c) RIVM, MNP and Alterra
* FOCUS PEARL version      : 3.3.3
* PEARL model version     : 1.7.7-F3
* SWAP model version      : swap209e
* PEARL created on       : 21-Apr-2006
*
* Working directory       : C:\Program Files\FOCUSPEARL_3_3_3\Database\Pearldb
* Run ID                  : 407
* Input file generated on : 20-10-2008

```

```

-----
* Report_type      : FOCUS
* Location         : HAMBURG
* Meteo station    : HAMB-M
* Soil type        : HAMB-S Soil
* Crop calendar    : HAMB-CABBAGE
* Substance        : 30HC1
* Application scheme : 30HCF2
* Deposition scheme : No
* Irrigation scheme : No
*
* End of PEARL REPORT: Header

```

```

* PEARL REPORT: FOCUS
* Start date      : 01-Jan-1901
* End date        : 31-Dec-1926
* Target depth    : 1.00 m
* Annual incorporation at 07-Aug; dosage = 0.0580 kg.ha-1; depth = 0.03 m

```

```

* FOCUS summary for compound 30HC1
* Molar mass (g.mol-1)      : 237.3
* Saturated vapour pressure (Pa) : 0.3E-02; measured at (C) 25.0
* Solubility in water (mg.L-1) : 0.6E+04; measured at (C) 25.0
* Half-life (d)            : 0.4; measured at (C) 20.0
* Kom (coef. for sorption on organic matter) (L.kg-1) : 31.9
* KF (overall sorption coefficient of FOCUS layer) (L.kg-1) : 0.428
* Freundlich exponent (-)   : 1.00

```

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-----
* Period          From          To          Water percolated          Substance leached          Average substance
* number          below target depth (mm) below target depth (kg/ha) concentration in water
*                                                         at target depth (ug/L)
*

```

Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	195.360	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	102.298	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	263.828	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	335.968	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	269.744	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	510.319	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	548.038	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	295.095	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	370.436	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	377.829	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	249.568	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	262.710	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	327.532	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	376.736	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	204.000	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	141.595	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	300.421	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	262.989	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	431.948	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	536.147	0.0000000	0.000

```

* The average concentration of 30HC1 closest to the 80th percentile is 0.0000 ug/L
* This value occurs in period from 01-Jan-1912 to 31-Dec-1912
* End of PEARL REPORT: FOCUS

```

* PEARL REPORT: Header
 * Results from the PEARL model (c) RIVM, MNP and Alterra
 * FOCUS PEARL version : 3.3.3
 * PEARL model version : 1.7.7-F3
 * SWAP model version : swap209e
 * PEARL created on : 21-Apr-2006
 *
 * Working directory : C:\Program Files\FOCUSPEARL_3_3_3\Database\Pearldb
 * Run ID : 408
 * Input file generated on : 20-10-2008

 * Report type : FOCUS
 * Location : KREMSMUNSTER
 * Meteo station : KREM-M
 * Soil type : KREM-S_Soil
 * Crop calendar : KREM-CABBAGE
 * Substance : 3OHC1
 * Application scheme : 3OHC2
 * Deposition scheme : No
 * Irrigation scheme : No
 *
 * End of PEARL REPORT: Header

* PEARL REPORT: FOCUS
 * Start date : 01-Jan-1901
 * End date : 31-Dec-1926
 * Target depth : 1.00 m
 * Annual incorporation at 07-Aug; dosage = 0.0580 kg.ha-1; depth = 0.03 m

* FOCUS summary for compound 3OHC1
 * Molar mass (g.mol-1) : 237.3
 * Saturated vapour pressure (Pa) : 0.3E-02; measured at (C) 25.0
 * Solubility in water (mg.L-1) : 0.6E+04; measured at (C) 25.0
 * Half-life (d) : 0.4; measured at (C) 20.0
 * Kom (coef. for sorption on organic matter) (L.kg-1) : 31.9
 * KF (overall sorption coefficient of FOCUS layer) (L.kg-1) : 0.488
 * Freundlich exponent (-) : 1.00

Period number	From	To	Water percolated below target depth (mm)	Substance leached below target depth (kg/ha)	Average substance concentration in water at target depth (ug/L)
1	01-Jan-1907	31-Dec-1907	482.861	0.0000000	0.000
2	01-Jan-1908	31-Dec-1908	367.100	0.0000000	0.000
3	01-Jan-1909	31-Dec-1909	577.155	0.0000000	0.000
4	01-Jan-1910	31-Dec-1910	617.313	0.0000000	0.000
5	01-Jan-1911	31-Dec-1911	548.525	0.0000000	0.000
6	01-Jan-1912	31-Dec-1912	402.436	0.0000000	0.000
7	01-Jan-1913	31-Dec-1913	536.945	0.0000000	0.000
8	01-Jan-1914	31-Dec-1914	405.080	0.0000000	0.000
9	01-Jan-1915	31-Dec-1915	309.917	0.0000000	0.000
10	01-Jan-1916	31-Dec-1916	363.080	0.0000000	0.000
11	01-Jan-1917	31-Dec-1917	399.700	0.0000000	0.000
12	01-Jan-1918	31-Dec-1918	348.560	0.0000000	0.000
13	01-Jan-1919	31-Dec-1919	462.435	0.0000000	0.000
14	01-Jan-1920	31-Dec-1920	317.879	0.0000000	0.000
15	01-Jan-1921	31-Dec-1921	373.910	0.0000000	0.000
16	01-Jan-1922	31-Dec-1922	19.732	0.0000000	0.000
17	01-Jan-1923	31-Dec-1923	-44.045	0.0000000	0.000
18	01-Jan-1924	31-Dec-1924	476.204	0.0000000	0.000
19	01-Jan-1925	31-Dec-1925	303.262	0.0000000	0.000
20	01-Jan-1926	31-Dec-1926	344.232	0.0000000	0.000

* The average concentration of 3OHC1 closest to the 80th percentile is 0.0000 ug/L
 * This value occurs in period from 01-Jan-1916 to 31-Dec-1916
 * End of PEARL REPORT: FOCUS

ANNEX B

**Addendum January 2009
(updated after PRAPeR expert meeting 63,
13 January 2009)**

Benfuracarb

B.9 Ecotoxicology

B.9.1 Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.11 Summary of effects on birds - exposure and risk assessment for birds (Annex IIIA 10.1)Open Point 5.6 :

Table B.9.1.11-1 : Summary of effects of benfuracarb on birds (Otsuka studies)

Test species	Test system	Endpoints	References
<i>Coturnix coturnix japonica</i>	acute oral toxicity	LD _{50,male} = 48.3 mg a.s./kg b.w. LD _{50,female} = 39.9 mg a.s./kg b.w.	Tadashi Jyonouchi, 1982
<i>Anas platyrhynchos</i>		LD50 = 19.8 mg a.s./kg b.w.	Robert Fink, Joann B. Beavers, 1982
<i>Colinus virginianus</i>	5-day dietary toxicity	LC50 = 179 mg a.s./kg b.w./day	Robert Fink, Joann B. Beavers, 1982
<i>Anas platyrhynchos</i>		LC50 = 15 mg a.s./kg b.w./day	Robert Fink, Joann B. Beavers, 1982
<i>Colinus virginianus</i>	22 weeks reproduction study	NOEC = 8.93 mg a.s./kg b.w./day	Teunissen M.S., 2001

Risk assessment for birds for the uptake of granules :

The notifier submitted a statement on acceptance of granules by birds (de Roode, D.F., 2007).

The risk assessment for birds is conducted following the recommendations from the EPPO scheme on terrestrial vertebrates (2003).

The first step in the risk assessment scheme is the assessment according to the **one-granule criterion**. In this initial assessment of potential high risk, the amount of active substance in one granule is compared to the LD₅₀ (exposure toxicity ratio, ETR). If the resulting ETR is > 1, the application should be classified as a potential high-risk application for birds.

Subsequently, in all cases the second step in the scheme is a risk assessment for **granular formulations** conducted for the specific exposure scenarios of intentional and accidental ingestion of granules.

1 – One granule criterion (initial assessment of potential high risk) :

This part of the EPPO subscheme can be considered as a precautionary warning system for potential high-risk applications for birds and mammals. It enables the user to calculate whether an indicator species of either bird or mammal has a 50 % chance of dying following the consumption of only one treated seed or one granule. The following assumptions are made in the calculation of the risk associated with the consumption of one seed or granule :

- an average concentration (amount) of the compound on/in one seed/granule is used
- the fifth percentile of the toxicity distribution (LD₅₀^{5th percentile}) and,
- a body weight of 25 g (the smallest birds and mammals in Europe have a body weight of several grams).

In the risk assessment the following values were used regarding the Oncol 8.6G granules :

weight of 1 granule :	0.064 mg
amount of active substance/granule :	0.0055 mg a.s./granule
diameter of the granule :	0.25 – 0.71 mm

The exposure level as a result of the consumption of one granule is calculated as :

$$\text{OGD (one granule dose)} = \text{short-cut value} \times G_{\text{loading}}$$

For small birds with a body weight of 25 g consuming small granules (< 3.5 mm), a short-cut value of 40 (number of granules consumed per kg body weight) is used.

$$\text{OGD} = 40 \text{ granules/kg b.w.} \times 0.0055 \text{ mg a.s./granule} = 0.22 \text{ mg a.s./kg b.w.}$$

If LD₅₀ values are available for five or fewer species, the method of Luttik and Aldenberg (1997) is used to estimate the fifth percentile from the available data, by applying the extrapolation factors especially derived for small samples to the geometric mean of the species tested :

$$5^{\text{th}} \text{ percentile of SSD} = \frac{10^{(\text{mean log toxicity value})}}{\text{extrapolation factor}}$$

The extrapolation factor depends on the number of species for which a toxicity endpoint is available. In agreement with Luttik and Aldenberg (1997), the more conservative method (one-sided left confidence limits : 95 %) should be used. Acute toxicity tests are available for 2 species (LD₅₀ = 19.8 mg a.s./kg b.w. for *Anas platyrhynchos* and LD_{50, female} = 39.9 mg a.s./kg b.w. for *Coturnix coturnix japonica*), resulting in an extrapolation factor of 19.6 (see Table 15 of EPPO scheme).

$$\text{Mean log toxicity value} = \frac{(\log 19.8) + (\log 39.9)}{2} = 1.45$$

$$\text{SSD}^{5^{\text{th}} \text{ percentile}} = \frac{10^{1.45}}{19.6} = 1.44 \text{ mg a.s./kg b.w.}$$

The one granule dose should then be compared to the fifth percentile of the toxicity distribution (LD₅₀^{5th percentile}) to calculate the exposure toxicity ratio (ETR).

$$\text{ETR} = \frac{\text{OGD}}{\text{LD}_{50}^{5^{\text{th}} \text{ percentile}}} = \frac{0.22}{1.44} = 0.15$$

The ETR_{1 granule} < 1, and hence, there is no indication that the application under consideration is of high-risk to birds.

2 – Risk assessment for granular formulations :

According to the risk assessment scheme, if it is uncertain whether ingestion is predominantly accidental or intentional, both routes should be examined. For intentional ingestion, it should be then decided if granules are mistaken for food or grit. Since benfuracarb granules are not based on an organic carrier having a nutritional value, mistaking granules for food is not considered relevant. In this case therefore, exposure as a result of accidental ingestion needs to be considered. In addition, intake as grit should also be assessed. Below, the accidental ingestion of granules is considered, followed by an assessment of the intake of grit.

Accidental ingestion of Oncol 8.6G granules (as part of soil ingestion) :

For the accidental ingestion of granules, the reasonable worst-case daily dry soil dose for a 25 g bird (representative bird weight) is calculated using the following equation (step 30 of EPPO scheme).

$$\text{DDSD}_{\text{rwc}} = \text{short-cut value} \times \text{application rate}$$

The application rate is expressed in kg a.s./ha and DDSD_{rwc} is expressed in mg a.s./kg b.w./day. The short-cut values are available in Table 8 of the EPPO scheme.

short-cut value (short-term exposure) = 0.473

short-cut value (medium-term exposure) = 0.095

short-cut value (long-term exposure) = 0.095 x f_{TWA}

For the long-term exposure, the f_{TWA} is the time weighted average factor for residue decline, derived from the DT_{50} in soil (DT_{50} in soil = 0.44 days, mean value without correction for soil moisture) as $f_{\text{TWA}} = (1 - e^{-kt})/kt$, where $k = \ln 2/\text{DT}_{50}$, and t is the averaging time (taken to be the time of standard long-term risk assessment : 21 days), thus $f_{\text{TWA}} = 0.030$.

The PRAPeR meeting decided to set $f_{\text{TWA}} = 1$ as default, since there were no data to extrapolate from the DT_{50} of benfuracarb in the granules to the DT_{50} of benfuracarb in soil.

Table B.9.1.11-2 : Calculated reasonable worst-case daily dry soil doses (DDSD_{rwc}) for small birds (25 g body weight) resulting from accidental ingestion of granules

Scenario	Short-cut value	f_{TWA}	Application rate (kg a.s./ha)	DDSD_{RWC} (mg a.s./kg b.w./day)
Short-term	0.473	-	1	0.473
Medium-term	0.095	-	1	0.095
Long-term	0.095	1	1	0.095

For the accidental intake of granules, the 5th percentile of the LD_{50} , LC_{50} and NOEC values should be calculated for short-term, medium-term and long-term exposure, respectively. Since toxicity tests are only available for 1 or 2 species, the method of Luttk and Aldenberg (1997) is used to estimate the 5th percentile from the available data, by applying the extrapolation factors especially derived for small samples to the geometric mean of the species tested. For short-term, medium-term and long-term toxicity, the LD_{50} values from the acute toxicity studies with birds, the LC_{50} values for birds and the NOEC value from the reproduction study with birds are used, respectively.

The 5th percentile toxicity value is calculated as :

$$5^{\text{th}} \text{ percentile of SSD} = \frac{10^{(\text{mean log toxicity value})}}{\text{extrapolation factor}}$$

The extrapolation factor depends on the number of species for which a toxicity endpoint is available. In agreement with Luttk and Aldenberg (1997), the more conservative method (one-sided left confidence limits : 95 %) should be used.

Table B.9.1.11-3 : Toxicity endpoints, extrapolation factors and resulting 5th percentile toxicity values to be used for the risk assessment due to accidental ingestion of granules

Scenario	Toxicity endpoint (mg a.s./kg b.w./day)	Extrapolation factor	5 th percentile toxicity value (mg a.s./kg b.w./day)
Short-term	$\text{LD}_{50} = 19.8$ and 39.9	19.6	1.43
Medium-term	$\text{LC}_{50} = 15$ and 179	19.6	2.64
Long-term	NOEC = 8.93	32.9	0.27

The resulting exposure toxicity ratio (ETR) values, calculated as $\text{DDSD}_{\text{rwc}} / 5^{\text{th}} \text{ percentile toxicity value}$, are shown in the table below. According to EPPO, when $\text{ETR} \leq 1$, the risk is low. Since all ETR values are < 1 , the risk for small birds as a result of accidental ingestion of granules is low.

Table B.9.1.11-4 : Calculated exposure toxicity ratios for accidental ingestion of granules for small birds (25 g body weight)

Scenario	DDSD _{RWC} (mg a.s./kg b.w./day)	5 th percentile toxicity value (mg a.s./kg b.w./day)	ETR _{RWC}
Short-term	0.473	1.43	0.330
Medium-term	0.095	2.64	0.036
Long-term	0.095	0.27	0.350

Intentional ingestion of Oncol 8.6G granules (as part of grit ingestion) :

For the intentional ingestion of granules, the reasonable worst-case daily granule dose (expressed in mg/kg b.w./day) is calculated for a representative bird. Based on the size of the granules (0.25 – 0.71 mm), the risk assessment is based on a small bird.

For short-term and medium-term exposure, the daily granule dose is calculated as :

$$\text{Daily Granule Dose (DGD}_{RWC}) = \text{DGI}_{RWC} * [G_{\text{surface}} / (\text{SP}_{\text{surface}} + G_{\text{surface}})] * G_{\text{loading}} \text{ (mg kg}^{-1} \text{ body weight day}^{-1})$$

For the long-term exposure, the daily granule dose is calculated as :

$$\text{Daily Granule Dose (DGD}_{RWC}) = \text{DGI}_{RWC} * [G_{\text{surface}} / (\text{SP}_{\text{surface}} + G_{\text{surface}})] * G_{\text{loading}} * \text{TWA}_{\text{factor for a.s.}} \text{ (mg kg}^{-1} \text{ body weight day}^{-1})$$

Where :

DGI_{RWC} = Daily grit intake of birds

G_{surface} = Number of granules at soil surface

SP_{surface} = Number of soil particles at soil surface in the same size classes as granules

G_{loading} = The amount of the active substance in one granule.

Information Required for Calculation of Daily Granule Dose (DGD) Data Source

Daily grit intake of birds (DGI) See Table B.9.1.11-5. Default values for small and large birds taken from EPPO (2003) and Luttik (2003).

Number of granules at soil surface (G_{surface}) Calculated from the actual dose of 1 kg a.s./ha, equivalent to 18182 granules/m²

Number of soil particles at soil surface in the same size classes as granules (SP_{surface}) See Table B.9.1.11-5. Default values taken from EPPO (2003) and Luttik and DeSnoo (2004).

The amount of the active substance in one granule (G_{loading}) Standard value for Oncol 8.6G (0.0055 mg a.s./granule).

Table B.9.1.11-5 : Input Values for Use in the Estimation of Reasonable Worst-case (RWC) and Most Likely Case (MLC) values for short-, medium- and long-term exposure scenarios for birds ingesting granules intentionally when seeking grit. (Reproduced from Table 9, EPPO, 2003)

RWC/MLC	Size of birds	No of grit particles per	No of soil particles	PT	f _{TWA} for no of granules	f _{TWA} for the active
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		day*	(SP _{surface}) ^a			substance
Acute – Short-term Exposure						
Realistic worst-case (RWC)	Large	2453	71	1	No	No
	Small	651	15200	1	No	No
Most likely case (MLC)	Large	1306	71	0.5	No	No
	Small	386	15200	0.5	No	No
Dietary Medium-term Exposure						
Realistic worst-case (RWC)	Large	2453	71	1	No	No
	Small	651	15200	1	No	No
Most likely case (MLC)	Large	1306	71	0.5	Yes	Yes
	Small	386	15200	0.5	Yes	Yes
Reproduction – Long term exposure						
Realistic worst-case (RWC)	Large	2453	71	1	Yes	Yes
	Small	651	15200	1	Yes	Yes
Most likely case (MLC)	Large	1306	71	0.5	Yes	Yes
	Small	386	15200	0.5	Yes	Yes

*On the basis of Fischer and Best (1995), a 4.2 conversion factor is used to take account of the turnover rate of grit.

^a SP_{surface} is based on three samples from three Dutch soils, two sands and one clay

f_{TWA}: Time weighted average factor

A TWA_{factor} can be used if data are available for the active substance in granules. No data are available on the degradation rate of benfuracarb in granules. However, for the aspect of accidental ingestion of granules (see above), the f_{TWA} was derived from the DT₅₀ in soil (0.44 day, mean value without correction for moisture and a 21-day averaging time). This f_{TWA} (0.030) is taken to be the TWA_{factor} in the current assessment.

The PRAPeR meeting decided to set f_{TWA} = 1 as default, since there were no data to extrapolate from the DT₅₀ of benfuracarb in the granules to the DT₅₀ of benfuracarb in soil.

The daily granule doses should then be compared to the appropriate toxicity values. These toxicity values are the same as used for the accidental ingestion of granules. If ETR values are ≤ 1, the granular formulation is classified as low risk for short-term, medium-term and/or long-term exposure. If ETR values are > 1, the risk assessment needs to be refined. The table below summarises the DGI, G_{surface}, TWA_{factor}, DGD, 5th percentile toxicity and resulting ETR values for the short-, medium- and long-term exposure.

Table B.9.1.11-6 : Calculated exposure toxicity ratios for intentional ingestion of granules for small birds as part of grit ingestion, RWC scenario

Scenario	DGI _{RWC} (granules/kg b.w./day)	G _{surface} (granules/m ²)	TWA _{factor}	DGD _{RWC} (mg a.s./kg b.w./day)	5 th percentile toxicity value (mg a.s./kg b.w.)	ETR _{RWC}
Short-term	651	18182	-	1.95	1.43	1.36
Medium-term	651	18182	-	1.95	2.64	0.74
Long-term	651	18182	1	1.95	0.27	7.18

The ETR value for short-term and long-term ingestion of granules is above 1, and the risk assessment needs to be refined. According to the assessment scheme, the DGI should now be based on the most likely case (MLC) instead of on the reasonable worst case (RWC). In effect, this implies the use of a lower DGI (386 granules/kg bw/day) and PT = 0.5.

The refined risk assessment for short-term and long-term exposure based on the MLC scenario is shown in the table below.

Table B.9.1.11-7 : Calculated exposure toxicity ratios for intentional ingestion of granules for small birds as part of grit ingestion, MLC scenario

Scenario	DGI _{MLC} (granules/kg b.w./day)	G _{surface} (granules/m ²)	TWA _{factor}	DGD _{MLC} (mg a.s./kg b.w./day)	5 th percentile toxicity value (mg a.s./kg b.w.)	ETR _{MLC}
Short-term	386	18182	-	0.58	1.43	0.40
Long-term	386	18182	1	0.58	0.27	2.13

The refined ETR value is <1 for short-term exposure, indicating low risk due to intentional ingestion as part of grit ingestion.

Furthermore, considering the mode of application (furrow application), only a small fraction of the granules will remain on the soil surface following application. This information is not incorporated in the risk assessment scheme of EPPO, yielding an unrealistically high estimation of the DGI. Taking the low fraction of granules present on the soil surface, the ETR values for short-term, medium-term and long-term exposure will be even lower than calculated in the above assessment. The risk due to intentional ingestion as part of grit ingestion is considered to be low.

Conclusion :

Based on the risk assessment performed according to the EPPO assessment scheme, the risk to birds as a result of uptake of granules is low.

Open point 5.7 :

The risk for birds drinking water contaminated by benfuracarb is not relevant. Due to the rapid conversion of benfuracarb to carbofuran (DT_{50} in water = 0.25 – 0.625 days), the risk assessment will be done for carbofuran.

The risk for birds drinking water possibly contaminated with carbofuran is assessed by the puddle scenario.

$$PEC_{\text{puddle}} = \frac{AR/10}{1000(w + K_{oc} \times s)}$$

With :

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m²

w = 0.02 (pore water term: volume)

s = 0.0015 (soil term: volume, density, organic carbon content)

The application rate for benfuracarb is 1 kg a.s./ha. This is equivalent to 540 g carbofuran/ha (as if 100 % formation out of parent with MW correction). This information can be found in the section on fate and behaviour.

The K_{foc} value for carbofuran is 22 mL/g.

$$PEC_{\text{puddle}} = \frac{540/10}{1000(0.02 + 22 \times 0.0015)} = 1.02 \text{ mg carbofuran/L}$$

A small granivorous bird (passerines) has a drinking water rate DRW equivalent to 0.46 L/kg b.w./day.

The estimated theoretical exposure to carbofuran via drinking water is calculated as :

$$ETE = 0.46 \text{ L/kg b.w./day} \times PEC_{\text{puddle}} = 0.47 \text{ mg carbofuran/kg b.w./day}$$

The acute risk is calculated as :

$$TER = LD_{50} / ETE = 0.76 / 0.47 = 1.62$$

The acute TER is below the trigger value of 10.

Open point 5.18 :

The notifier proposed the following refinement of the risk assessment considering PT values.

“Long-term risk assessment (Tier III)

Southern Europe (crested lark)

For further refinement of the risk assessment, PT data may be used. Currently, no data are available for determination of a PT value for crested lark but data for the skylark (a related species) may be used. The home range of a skylark is 1-8 ha, depending on habitat structure, which may cover several fields containing brassica crops. On this basis, the PT for skylarks feeding in carbofuran treated cabbage fields may be set at 0.3. Using this data, the margin of safety for Southern Europe would be even higher than that calculated in the Tier II risk assessment. Therefore, the long-term risk for birds due to consumption of contaminated cabbage seedlings and earthworms is considered acceptable for Southern Europe.

Northern Europe (woodpigeon)

For further refinement of the risk assessment, PT data may be used. It is unlikely that birds would obtain their complete intake of brassica crops for four weeks from the same cabbage plot, treated with Oncol 8.6G. In France, only 10 % of all cabbage grown is treated with Oncol 8.6G (communication by DuPont, distributor of Oncol 8.6G in France). A PT value (PT = Proportion of diet in Treated area) value of 0.1 however might underestimate the risk since this would assume that birds will cover a very large area during foraging. The maximum PT that would result in a TER value > 5 can however be calculated to be 0.75 (TER would be 5.4 using a PT of 0.70). This PT value is not considered unrealistic, considering the home range of a wood pigeon, which is 250-300 ha. This home range could cover several fields with brassica crops. The PT for woodpigeons feeding in carbofuran treated cabbage fields may therefore conservatively be set at 0.5, yielding a long-term TER of 7.5. Therefore, the long-term risk for birds due to consumption of contaminated cabbage seedlings and earthworms is considered acceptable for Northern Europe.”

B.9.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3)

Open point 5.10 :

Table B.9.3-1 : Summary of effects of benfuracarb on mammals

<i>Test species</i>	<i>Test system</i>	<i>Endpoints</i>	<i>References</i>
Rat	acute oral	LD₅₀ = 205 mg a.s./kg b.w.	Masaaike Shirai, 1996a
Rat	2-generation study	NOAEL = 1.2 mg a.s./kg b.w./day	Schroeder, 1984

Risk assessment for mammals for the uptake of granules :

The notifier submitted a statement on the long-term risk assessment for mammals from uptake of granules (de Roode, D.F., 2007).

The risk assessment for mammals is conducted following the recommendations from the EPPO scheme on terrestrial vertebrates (2003).

Accidental ingestion of Oncol 8.6G granules (as part of soil ingestion) :

For the accidental ingestion of granules, the reasonable worst-case daily dry soil dose for a 25 g mammal (representative mammal weight) is calculated using the following equation (step 30 of EPPO scheme).

$$DDSD_{rwc} = \text{short-cut value} \times \text{application rate} \times f_{TWA}$$

The application rate is expressed in kg a.s./ha and $DDSD_{rwc}$ is expressed in mg a.s./kg b.w./day. The short-cut values are available in Table 8 of the EPPO scheme.

$$\text{short-cut value (long-term exposure)} = 0.023$$

For the long-term exposure, the f_{TWA} is the time weighted average factor for residue decline, derived from the DT_{50} in soil (DT_{50} in soil = 0.44 days, mean value without correction for soil moisture) as $f_{TWA} = (1 - e^{-kt})/kt$, where $k = \ln 2/DT_{50}$, and t is the averaging time (taken to be the time of standard long-term risk assessment : 21 days), thus $f_{TWA} = 0.030$.

The PRAPeR meeting decided to set $f_{TWA} = 1$ as default, since there were no data to extrapolate from the DT_{50} of benfuracarb in the granules to the DT_{50} of benfuracarb in soil.

Table B.9.3-2 : Calculated reasonable worst-case daily dry soil doses ($DDSD_{rwc}$) for small mammals (25 g body weight) resulting from accidental ingestion of granules

Scenario	Short-cut value	f_{TWA}	Application rate (kg a.s./ha)	$DDSD_{RWC}$ (mg a.s./kg b.w./day)
Long-term	0.023	1	1	0.023

For the accidental intake of granules, the 5th percentile of the NOED values should be calculated for long-term exposure. Since a toxicity test is only available for 1 species, the method of Luttk and Aldenberg (1997) is used to estimate the fifth percentile from the available data, by applying the extrapolation factors especially derived for small samples to the geometric mean of the species tested.

The 5th percentile toxicity value is calculated as :

$$5^{\text{th}} \text{ percentile of SSD} = \frac{10^{(\text{mean log toxicity value})}}{\text{extrapolation factor}}$$

The extrapolation factor depends on the number of species for which a toxicity endpoint is available. In agreement with Luttk and Aldenberg (1997), the more conservative method (one-sided left confidence limits : 95 %) should be used.

Table B.9.3-3 : Toxicity endpoint, extrapolation factor and resulting 5th percentile toxicity value to be used for the risk assessment due to accidental ingestion of granules

Scenario	Toxicity endpoint (mg a.s./kg b.w./day)	Extrapolation factor	5 th percentile toxicity value (mg a.s./kg b.w./day)
Long-term	NOAEL = 1.2	14.9	0.081

The resulting exposure toxicity ratio (ETR) values, calculated as $DDSD_{RWC} / 5^{\text{th}}$ percentile toxicity value, are shown in the table below. According to EPPO, when $ETR \leq 1$, the risk is low. Since the ETR value is < 1 , the risk for small mammals as a result of accidental ingestion of granules is low.

Table B.9.3-4 : Calculated exposure toxicity ratio for accidental ingestion of granules for small mammals (25 g body weight)

Scenario	$DDSD_{RWC}$ (mg a.s./kg b.w./day)	5 th percentile toxicity value (mg a.s./kg b.w./day)	ETR_{RWC}
Long-term	0.023	0.081	0.286

Conclusion :

The long-term risk to mammals from the ingestion of granules contaminated with benfuracarb is low ($ETR_{RWC} < 1$).

Open point 5.7 :

The risk for mammals drinking water contaminated by benfuracarb is not relevant. Due to the rapid conversion of benfuracarb to carbofuran (DT_{50} in water = 0.25 – 0.625 days), the risk assessment will be done for carbofuran.

The risk for mammals drinking water possibly contaminated with carbofuran is assessed by the puddle scenario.

$$PEC_{\text{puddle}} = \frac{AR/10}{1000(w + K_{oc} \times s)}$$

With :

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m²

w = 0.02 (pore water term: volume)

s = 0.0015 (soil term: volume, density, organic carbon content)

The application rate for benfuracarb is 1 kg a.s./ha. This is equivalent to 540 g carbofuran/ha (as if 100 % formation out of parent with MW correction). This information can be found in the section on fate and behaviour.

The K_{foc} value for carbofuran is 22 mL/g.

$$PEC_{\text{puddle}} = \frac{540/10}{1000(0.02 + 22 \times 0.0015)} = 1.02 \text{ mg carbofuran/L}$$

A small granivorous mammal (non-desert species) has a drinking water rate DRW equivalent to 0.24 L/kg b.w./day. The estimated theoretical exposure to carbofuran via drinking water is calculated as :

$$ETE = 0.24 \text{ L/kg b.w./day} \times PEC_{\text{puddle}} = 0.24 \text{ mg carbofuran/kg b.w./day}$$

The acute risk is calculated as :

$$TER = LD_{50} / ETE = 5.3 / 0.24 = 22$$

The acute TER value is above the trigger value of 10, indicating that the risk is low.

Open point 5.12 :

Sufficient explanation on the derivation of the endpoint NOAEL (carbofuran) was given in the DAR (revision August 2008) on pages 9-89 and 9-90.

B.9.12 References relied on

None

ANNEX B

Original version July 2004, revised in August 2008, revised in
January 2009

Benfuracarb

B.9 Ecotoxicology

B.9.1 Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.1 Acute oral toxicity (Annex IIA 8.1.1)

Acute oral toxicity of Benfuracarb in Japanese quail (*Coturnix coturnix japonica*). (Tadashi Jyonouchi, 1982).

Guidelines :

The methods used were in-house methods.

GLP :

No

Material and Methods :

Test Substance : benfuracarb, chemical purity : 93.03 %, batch n° : not reported

Test species : Japanese quail (*Coturnix coturnix japonica*)

Sex, weight, age : 10 males per treatment group, 77 – 87 g, 6 weeks old,

10 females per treatment group, 84 – 100 g, 6 weeks old

Applied concentrations : untreated control, 15, 29.4, 41.2, 57.6, 80.7, 113 mg a.s./kg body weight

Type of application : oral by gavage using corn oil

Time of exposure : one single application, monitoring during 14 days

Findings :

Mortality : There were no mortalities in the control group. At test concentration of 41.2 mg a.s./kg b.w. in the male group 50 % had died. At test concentration of 80.7 mg a.s./kg b.w. all of the male birds had died. At test concentration of 29.4 mg a.s./kg b.w. 20 % of the female birds had died. At test concentration of 80.7 mg a.s./kg b.w. all of the female birds had died.

Body weight : No significant differences in body weight changes were observed compared to the control.

Clinical signs : In the 29.4 mg a.s./kg b.w. group symptoms such as opened mouth, drooping wings, ataxic gait, muscle twitch and clonic convulsion were observed 10 to 20 minutes after administration. These symptoms in the surviving birds disappeared 4 hours after administration. In the 41.2 and 57.6 mg a.s./kg b.w. groups in addition to the above symptoms, salivation, epiphora, miosis, quadriplegia, tremor and anorexia were observed 10 to 15 minutes after administration. These symptoms in the surviving birds disappeared 2 days after administration. In the 80.7 mg a.s./kg b.w. the above symptoms were observed 10 minutes after administration.

Feed consumption : No data on feed consumption.

Conclusions :

The study is acceptable.

Endpoints :

LD₅₀ (*Coturnix coturnix japonica*, male) = 48.3 mg a.s./kg b.w.

LD₅₀ (*Coturnix coturnix japonica*, female) = 39.9 mg a.s./kg b.w.

NOEL (*Coturnix coturnix japonica*) = 15 mg a.s./kg b.w.

Acute oral toxicity of Benfuracarb to the mallard duck (*Anas platyrhynchos*). (Robert Fink, Joann B. Beavers, 1982).

Guidelines :

The methods used were in-house methods.

GLP :

No

Material and Methods :

Test Substance : benfuracarb, chemical purity : 94.8 %, batch n°: 2A79

Test species : mallard duck (*Anas platyrhynchos*)

Sex, weight, age : 5 males and 5 females per treatment group, 1074 – 1186 g, 10 months old

Applied concentrations : untreated control, 14.7, 21.5, 31.6, 46.4, 68.1 mg a.s./kg body weight
Type of application : oral by gavage using corn oil

Time of exposure : one single application, monitoring during 14 days

Findings :

Mortality : There were no mortalities in the control group. At test concentration of 21.5 mg a.s./kg b.w. there was 60 % mortality. 100 % mortality was recorded in treatment groups of 31.6 and 46.4 mg a.s./kg b.w. At test concentration of 68.1 mg a.s./kg b.w. 90 % mortality was observed.

Body weight : No significant differences in body weight changes were observed compared to the control.

Clinical signs : At the 14.7 mg a.s./kg b.w. dosage level lethargy and wing droop were apparent within one hour after dosing, and loss of coordination, lower limb weakness, lacrimation and prolapse of the penis were observed during day 1. All surviving birds appeared normal by day 2, and remained so until the termination of the study.

Feed consumption : No substance-related change.

Conclusions :

The study is acceptable.

Endpoints :

LD₅₀ (*Anas platyrhynchos*) = 19.8 mg a.s./kg b.w.

NOEL (*Anas platyrhynchos*) < 14.7 mg a.s./kg b.w.

B.9.1.2 Avian dietary toxicity (5 day) (Annex IIA 8.1.2)

Eight-day dietary toxicity of Benfuracarb to bobwhite quail (*Colinus virginianus*). (Robert Fink, Joann B. Beavers, 1982).

Guidelines :

The methods used were in-house methods.

GLP :

Yes (certified laboratory)

Material and Methods :

Test Substance: benfuracarb, chemical purity : 94.8 %, batch n°: 2A79

Test species : bobwhite quail (*Colinus virginianus*)

Sex, weight, age : 10 birds per treatment (50 birds for control), not sexed, 24 – 32 g, 14 days old

Applied concentrations : untreated control; 56.2, 100, 178, 316, 562 mg a.s./kg feed; laboratory standard: 15.9, 25.1, 39.8, 63.1, 100 mg dieldrin/kg feed

Type of application : dietary application

Time of exposure : short-term feeding test (5 days exposure period + 3 days observation period)

Findings :

Mortality : There was one mortality in the control group which is attributed to cannibalism. There was one mortality at test concentration of 100 mg a.s./kg feed, though this mortality is also attributed to cannibalism. There was a 10 % mortality at the 316 mg a.s./kg feed concentration level and a 50 % mortality rate at the 562 mg a.s./kg feed concentration level. The LC₅₀ of dieldrin was 33 mg/kg feed.

Body weight : There was a concentration related reduction in body weight gain of surviving birds at the 316 and 562 mg a.s./kg feed concentration levels.

Clinical signs : Lethargy and reduced reaction to external stimuli (sound and movement) are the only symptoms of toxicity observed at the 562 mg a.s./kg feed concentration level.

Feed consumption : The feed consumption of all treatments was slightly increased compared to the control.

Conclusions :

The study is acceptable.

Endpoints :

LC₅₀ (*Colinus virginianus*, 5 d) = 558 mg a.s./kg feed or 179 mg a.s./kg b.w./day based on a mean food consumption of 12.2 g/bird/day and a mean body weight of 38.1 g/bird

NOEC (*Colinus virginianus*, 5 d) = 178 mg a.s./kg feed or 57 mg a.s./kg b.w./day based on a food consumption of 12.2 g/bird/day and a body weight of 38.1 g/bird

Eight-day dietary toxicity of Benfuracarb to mallard duck (*Anas platyrhynchos*). (Robert Fink, Joann B. Beavers, 1982).

Guidelines :

The methods used were in-house methods.

GLP :

Yes (certified laboratory)

Material and Methods :

Test Substance: benfuracarb, chemical purity : 94.8 %, batch n°: 2A79

Test species : mallard duck (*Anas platyrhynchos*)

Sex, weight, age : 10 birds per treatment (50 birds for control), not sexed, 183-276 g, 14 days old

Applied concentrations : untreated control; 56.2, 100, 178, 316, 562, 1000 mg a.s./kg feed; laboratory standard: 72, 100, 139, 193, 269 mg dieldrin/kg feed

Type of application : dietary application

Time of exposure : short-term feeding test (5 days exposure period + 3 days observation period)

Findings :

Mortality : There were no mortalities in the control group. There was a 20 % mortality rate at both the test concentrations of 100 and 178 mg a.s./kg feed. At test concentration of 316 mg a.s./kg feed there was 90 % mortality. 100 % mortality was observed at both test concentrations of 562 and 1000 mg a.s./kg feed. The LC₅₀ of dieldrin was 106 mg/kg feed.

Body weight : There was a reduction in body weight gain of all surviving birds.

Clinical signs : Symptoms of toxicity noted at the concentration levels from 56.2 mg a.s./kg feed onwards included regurgitation, lethargy progressing to depression, reduced reaction to external stimuli (sound and movement), wing droop, loss of coordination, lower limb weakness and prostrate posture. In addition, at the higher concentration levels minor muscle fasciculations, loss of righting reflex, gulping and gasping were also observed.

Feed consumption : There was a marked concentration related reduction in feed consumption at all concentration levels tested.

Conclusions :

The study is acceptable.

Endpoints :

LC₅₀ (*Anas platyrhynchos*, 5 d) = 195 mg a.s./kg feed or 15 mg a.s./kg b.w./day based on a mean food consumption of 18 g/bird/day and a mean body weight of 233.8 g/bird

NOEC (*Anas platyrhynchos*, 5 d) = 56.2 mg a.s./kg feed or 4.3 mg a.s./kg b.w./day based on a mean food consumption of 18 g/bird/day and a mean body weight of 233.8 g/bird

B.9.1.3 Subchronic and reproductive toxicity (Annex IIA 8.1.3)

Reproduction Study in bobwhite quail (*Colinus virginianus*) with Benfuracarb (by dietary admixture). (Teunissen M.S., 2001).

Guidelines :

USEPA Series 71-4

USEPA OPPTS 850.2300

USEPA 40 CFR 158.490

OECD 206

GLP :

Yes

Material and Methods :*Test substance* : benfuracarb, chemical purity : 93.4 %, batch n°: 0D96*Test species* : bobwhite quail (*Colinus virginianus*)*Sex, weight, age* : 16 replicates per treatment, each replicate consists of one male and one female bird, males: 155-233 g, females: 161-219 g, 25 weeks at start of treatment*Applied concentrations* : untreated control, 30, 115, 450 mg a.s./kg in the feed*Type of application* : dietary application, the stability of the a.s. was determined (between 81 and 96 % (method I) and between 94 and 106 % (method II) of the nominal concentration)*Time of exposure :*

11.5 weeks : pre-egg production period

10.5 weeks : egg production period

Findings :

Table B.9.1.3-1 : Major effects of Benfuracarb observed during the reproduction study of bobwhite quail

Endpoints	Doses (mg a.s./kg feed)							
	0		30		115		450	
Adults								
Mortality	1/32		0/32		0/32		0/32	
Body weight after 22 weeks (g/bird)	M:215	F:241	M:214	F:239	M:211	F:229	M:215	F:227
Mean food consumption (g/bird/day)	16		16		16		16	

Endpoints	Doses (mg a.s./kg feed)			
	0	30	115	450
<i>Reproduction parameters</i>				
No. of eggs laid	652	738	706	450*
No. of eggs laid/female bird	43.5	46.1	44.1	28.1*
Cracked eggs of eggs laid (%)	0.3	0.3	0.3	0.2
Broken eggs of eggs laid (%)	0	0.4	1.3	1.8*
Mean egg weight (g)	9.9	9.8*	9.7*	9.4*
Mean egg shell thickness (mm)	0.22	0.22	0.23	0.22
No. of eggs set initially	603	684	649	409
Fertile eggs of eggs set (%)	90.5	98.0	97.8	98.5
Early embryonic mortalities of fertile eggs (%)	4.8	4.8	2.7	3.2
Viable 11-day old embryos of eggs set (%)	86.1	93.3	95.2	95.4
Late embryonic mortalities of fertile eggs (%)	1.3	0.4	0.3	1.2
Viable 18-day old embryos of eggs set (%)	84.9	92.8*	94.9*	94.1*
Viable 18-day old embryos of fertile eggs (%)	93.8	94.8	97.0	95.5
No. of chicks “death-in-shell”	67	70	110	86
No. of normal hatchlings	443	564	504	299
No. of normal hatchlings/female bird	29.5	35.3	31.5	18.7*
Normal hatchlings of eggs set (%)	73.5	82.5	77.7	73.1
Normal hatchlings of fertile eggs (%)	81.1	84.2	79.4	74.2
Normal hatchlings of live 11-day old embryos (%)	85.4	88.4	81.6	76.7*
Normal hatchlings of live 18-day old embryos (%)	86.5	88.8	81.8	77.7*
No. of 14-day surviving chicks	402	520	451	251
No. of 14-day surviving chicks/female bird	26.8	32.5	28.2	15.7*
14-day old surviving chicks of normal hatchlings (%)	90.7	92.2	89.5	83.9*
Mean body weight of chicks at hatching (g)	6.9	6.9	6.8*	6.5*
Mean body weight of chicks 14 days	24.2	23.6*	23.0*	22.0*

	Doses (mg a.s./kg feed)			
after hatching (g)				

* statistically significant ($p \leq 0.05$) when compared to the control group

One male of the control group died spontaneously in week 17.

No adverse parental effects were noted after exposure of breeding pairs of bobwhite quail to Benfuracarb. Due to excessive aggression, a few pairs from each group were separated by dividing the cage in two parts for a longer period of time. These birds were together for a half-an-hour a day, if possible. Since no effect on the fertility of the affected animals was observed, the separation was considered not to have any effect on the study integrity.

Parameters showing biologically significant differences between treatments and control are:

- No. of eggs laid
- No. of eggs laid/female bird
- Broken eggs of eggs laid (%)
- Mean egg weight
- Viable 18-day old embryos of eggs set (%)
- No. of normal hatchlings/female bird
- Normal hatchlings of live 11-day old embryos (%)
- Normal hatchlings of live 18-day old embryos (%)
- No. of 14-day surviving chicks/female bird
- 14-day old surviving chicks of normal hatchlings (%)
- Mean body weight of chicks at hatching (g)
- Mean body weight of chicks 14 days after hatching (g)

Revised in August 2008

Benfuracarb : Statement on comparison on keypoints on hatchling body weights with historical data with regard to reproductive NOEC for birds. (de Roode D.F., 2007).

A comparison of the key endpoints on hatchling body weights with historical control data has been performed.

“In the original dossier, a reproduction study with bobwhite quail was submitted (Teunissen, M., 2001, NOTOX B.V., project 295054). In this study, birds were exposed to doses of 30, 115 and 450 mg/kg diet. The report of the study also contained historical data (page 10 of the original report).

Effects on hatchling body weight were most relevant for determination of the NOEC (i.e. no relevant effects were observed on any other parameter at 30 and 115 mg/kg diet).

Body weight of 1-day old chicks, body weight of 14-day old survivors and growth rate of 14-day old survivors were statistically significantly reduced at 30, 115 and 450 mg/kg diet. However, at 30 and 115 mg/kg diet, these effects were only minimal and body weights and growth rate were within the range of the historical control data (see Table below). Accordingly, these effects are not considered to be ecologically relevant. At 450 mg/kg diet, body weight and growth rate of 14-day old survivors were also within the range of the historical control data, but body weight of 1-day old chicks was not (see Table below). Therefore, the effect on body weight of 1-day old chicks at 450 mg/kg diet is considered to be ecologically relevant, even though it was not a sustained effect. Consequently, the NOEC is maintained at 115 mg/kg diet.

Table B.9.1.3-2 : Mean body weights of 1- and 14-day old chicks and growth rate of 14-day old chicks. Historical control data are included; endpoints printed in bold are outside the range of the historical control data.

	Dose (mg/kg diet)				Historical control data ⁽¹⁾ (range)
	0	30	115	450	
Body weight of 1-day old chicks (g)	6.9	6.9	6.8*	6.5*	6.8-7.4
Body weight of 14-day old chicks (g)	24.2	23.6*	23.0*	22.0*	19.9-25.4
Growth rate of 14-day old survivors (g/day)	1.2	1.2*	1.2*	1.1*	0.9-1.3

* Significantly different from control at 5% level

⁽¹⁾ Historical data were derived from ten studies performed between 1996 and 2001

Based on an ecologically relevant effect on body weight of 1-day old chicks (+ significant effects previously reported on the number of eggs laid per female bird and the number of 14-day surviving chicks per female bird) at 450 mg/kg diet, and the lack of ecologically relevant effects on body weight of 1-day old chicks and body weight and growth rate of 14-day old survivors at 30 and 115 mg/kg diet, the NOEC is considered to be 115 mg/kg diet.

Conclusions :

The study is acceptable.

NOEC (*Colinus virginianus*, 22 weeks) = 115 mg a.s./kg feed or 8.93 mg a.s./kg b.w./day based on a food consumption of 16 g/bird/day and a body weight of 206 g

At 450 mg a.s./kg diet significant effects were observed for the number of eggs laid per female bird and the number of 14-day surviving chicks per female bird. Therefore the NOEC was established at 115 mg a.s./kg diet. The effects on mean egg weight, the percentage of viable 18-day old embryos of eggs set and the mean body weight of chicks 14 days after hatching at 30 and 115 mg a.s./kg feed were considered as not biologically relevant.

B.9.1.4 Acute oral toxicity of the preparations (Annex IIIA 10.1.1)

Not required. (See B.9.1.6).

B.9.1.5 Supervised cage or field trials (Annex IIIA 10.1.2)

Not required. (See B.9.1.6).

B.9.1.6 Acceptance of bait, granules or treated seeds by birds (palatability test) (Annex IIIA 10.1.3)

Added in August 2008

Avoidance of Japanese quail from seed scattered on granules containing Oncol 8.6G. (Teunissen M.S., 2004).

Material and Methods:

Test Substance: Oncol 8.6G, formulation containing 9.08 % benfuracarb, batch n°: 28DC1E

Test species: Japanese quail, *Coturnix coturnix japonica*

Sex, weight, age: 18 females birds (one control group and one treatment group, consisting of 2 replicates (2A and 2B), 213-253 g, 25 weeks old at start

Experimental design:

avoidance test (1 day exposure period + 3 days observation period)

Granules containing Oncol 8.6G at an amount of 1.2 g/m² were scattered on the ground of a defined area of a temperature cabin. 5 Grams of seed (wheat)/bird was scattered on the granules layer. Prior to dosing food was withheld for 15-20 hours. The birds were exposed to the test conditions for 24 hours, followed by a non-exposure period of 3 days. A control group was housed in a cabin without granules, with 5 grams of seed/bird scattered on the cabin floor.

Observations:

Clinical observations were made on day of dosing continuously during the first 1 - 2 hours after dosing, and subsequently every hour until the end of the working day, and at the end of the 24 hours exposure period. During the post-treatment period, clinical observations were monitored at least daily. Body weights were measured on day 1 (day of exposure) and on day 5.

Consumption of the seeds and granules was determined after separation at the end of the 24 hours exposure period by weighing. At the end of every post-treatment day, consumption of seeds and powder diets was also determined.

Macroscopic *post mortem* examination was performed at termination (day 5). Gross necropsy including general inspection of the gastro-intestinal tract (special attention to the presence of granules), liver, kidney, heart and spleen.

Findings:

Mortality: No mortality was recorded.

Body weight: Body weight loss was noted between days 1 and 5 of the study in a majority of birds of the control and treatments groups. This was probably caused by the fasting period before testing and reduced food intake during the test. This effect is considered not treatment-related.

Food consumption:

During the treatment day, seed consumption of treatment group 2B and control group birds was comparable. Seed consumption of treatment group 2A was clearly lowered in comparison with the control group.

Test substance weight was approximately 0.3 g lower than the initial weight of 1.2 g at start of the exposure in groups 2A and 2B, which suggest uptake of Oncol 8.6G by the birds.

During the post-treatment period (3 days), the overall food consumption was slightly increasing. Seeds and standard diet consumption was comparable in the control and treatments groups except for group 2B on days 2 and 3.

Clinical signs:

One treated animal showed clinical observations which might be caused by the test substance. However, no clinical observations were noted in the remaining animals. Further, at the macroscopic examinations, no test substance related abnormalities were found in any of the birds and no granules were found in the intestines of the birds during necropsy.

Conclusions :

The study is acceptable.

It is concluded that under the conditions of this test no avoiding behaviour of Japanese quail from seed scattered on granules containing Oncol 8.6G during 24-hours was noted.

B.9.1.7 Effects of secondary poisoning (Annex IIIA 10.1.4)

Study to evaluate the palatability to blackbirds (*Turdus merula*) of earthworms exposed to Oncol 10G, when denied or allowed dietary choice. (Partington Keith, 1997).

Guidelines :

The basic test methods in this study were designed to satisfy Data Requirements imposed by the UK Pesticide Safety Directorate following their review of benfuracarb; the protocol was submitted to them for comment prior to the start of the study and no adverse comment was received.

GLP :

Yes

Material and methods :

Test substance : Oncol 10G, granules, 10.34 % benfuracarb, batch n°: 0087/FEB/95

Test species : blackbird, *Turdus merula*

Number of organisms : 6 birds (3 males and 3 females) per treatment, captured from the wild, housed in individual test aviaries

Method of application :

The artificial soil (a mixture of sand and potting compost) was treated with Oncol 10 G. A single treatment level of 264 mg Oncol 10G/kg soil (dry weight) was used. Earthworms (*Lumbricus terrestris*) were added to treated soil for 48 hours.

Treatment groups :

Groups of birds were presented with different dietary choices:

Table B.9.1.7-1 : Treatment groups

Treatment	Number of birds
No-choice feeding on exposed worms	6
Choice between exposed and untreated worms	6
Control, untreated worms only	6

The birds were acclimatized for 19 – 21 weeks and allowed to accustom to earthworm diet. According to their treatment group, birds were offered the appropriate type of earthworms for 2 days. The birds of the choice test were offered 2 trays, one containing treated earthworms and the other untreated earthworms. The daily supply of test food was presented as two samples with a changeover in the middle of the test period. Water was provided *ad libitum* and changed daily. Immediately after the test phase, birds were returned to normal maintenance diet for a 7 day observation period. Mortality and changes in bodyweight were observed.

Findings :

Table B.9.1.7-2 : Summary of the results of analysis of benfuracarb and carbofuran in earthworm test samples

Feeding session	Sample type	Detected residue level (mg/kg)	
		benfuracarb	carbofuran
Test day 1, morning	untreated	< 0.05	< 0.05
	treated	0.32	1.62
Test day 1, afternoon	untreated	< 0.05	< 0.05
	treated	0.28	1.48
Test day 2, morning	untreated	< 0.05	< 0.05
	treated	1.3	2.8
Test day 2, afternoon	untreated	< 0.05	< 0.05
	treated	0.56	1.96

The procedural recoveries in the earthworm test samples were in the range of 70 – 91 % for benfuracarb and 82 – 102 % for carbofuran.

Table B.9.1.7-3 : Consumption of earthworms during the test phase (unadjusted for controls)

Test group	Mean consumption (g) (range)					
	Test day 1			Test day 2		
	treated	untreated	total	treated	untreated	total
No choice	71.19 (65.29-78.15)	-	71.19 (65.29-78.15)	71.34 (55.99-80.44)	-	71.34 (55.99-80.44)
Choice	19.48 (6.32-29.85)	57.25 (41.54-66.30)	76.72 (60.27-86.09)	18.85 (9.35-32.22)	55.01 (28.84-79.02)	73.87 (55.57-88.37)
Control	-	63.90 (49.44-76.12)	63.90 (49.44-76.12)	-	71.58 (57.38-83.34)	71.58 (57.38-83.34)

In the choice test group, there was evidence of avoidance with consumption of treated earthworms lower than that of untreated earthworms. Treated earthworms made up approximately 25 % of total daily consumption on both test days for birds in this group. The difference in consumption of treated and untreated earthworms was significant on both test day 1 and test day 2.

All blackbirds lost some weight during the main test phase, including the controls offered untreated worms only. However the level of loss was similar at approximately 10 % overall in the no-choice group, 12 % in the choice group and 10 % in the control group.

There were no mortalities or serious symptoms of poisoning observed during the pre-treatment phase, test phase or the observation phase.

Conclusions :

Considering a body weight of the blackbird of 100 g, a daily food consumption of 70 g earthworms per day and a mean residue content of 0.62 mg benfuracarb/kg food, the exposure to blackbirds is equivalent to 0.43 mg benfuracarb/kg b.w./day. With a mean residue content of 1.97 mg carbofuran/kg food, the exposure to blackbirds is equivalent to 1.40 mg carbofuran/kg b.w./day.

No mortalities or serious symptoms of poisoning were observed.

B.9.1.8 Residue content in food items

Field studies to determine residues of benfuracarb, carbofuran and 3-OH-carbofuran in cabbage and cauliflower seedlings treated with Oncol 8.6G were submitted. The residues of the 3 compounds were also measured in earthworms captured in these studies.

Magnitude of the residue of benfuracarb in brassica seedlings after one application of microgranule insecticide Oncol 8.6G at transplanting and residue determination on earthworms. France 2005. Biotek Agriculture study BPL 05/014/CL. [already submitted under IIIA 10.1 and included in the addendum to the DAR of May 2006] IIA 6.3/13. (Huaultmé J.-M.C., 2005).

Magnitude of residues in cabbage following one localized application with Oncol 8.6G (Benfuracarb) at planting TrialCamp, Spain, report no TRC05-19. [already submitted under IIIA 10.1 and included in the addendum to the DAR of May 2006] IIA 6.3/14. (Gimeno C., 2006b).

Magnitude of residues in cauliflower following one pre-transplant application in furrows with Oncol 8.6G (Benfuracarb) TrialCamp, Spain, report no: TRC05-20. [already submitted under IIIA 10.1 and included in the addendum to the DAR of May 2006], IIA 6.3/16. (Gimeno C., 2006a).

Magnitude of residues in cauliflower following one pre-transplant broadcast application with Oncol 8.6G (Benfuracarb) TrialCamp, Spain, report no: TRC05-21, IIA 6.3/18. (Gimeno C., 2006c).

Magnitude of residue of benfuracarb in cauliflower seedlings and raw agricultural commodities after one application of microgranule insecticide Oncol 8.6G at transplanting, Northern France, 2006. BIOTEK Agriculture, France, report No.: BPL 06/063/CL, IIA 6.3/20. (Huaultmé J., 2007).

Magnitude of residues in cauliflower following one pre-transplant application in furrows with Oncol 8.6G (benfuracarb). TrialCamp, Spain, report No.: TRC06-11, IIA 6.3/21. (Gimeno C., 2007).

Study to determine the magnitude of benfuracarb residues in the raw agricultural commodity head/flowering brassica resulting from a single directed application of ONCOL 8.6G in the row, in Northern Europe 2007. Agrisearch project AF/12035/OT., IIA 6.3/23. (Scrimshaw O., 2007a).

Study to determine the magnitude of benfuracarb residues in the raw agricultural commodity head/flowering brassica resulting from a single directed application of ONCOL 8.6G in the row, in Southern Europe 2007. Agrisearch project AF/12036/OT., IIA 6.3/24. (Scrimshaw O., 2007b).

Guidelines :

EC Commission Directive 1607/VI/97EC: Guidelines for the generation of data concerning residues as provided in Annex II part A, section 8 of the Directive 91/414/EEC concerning the placing of plant protection products on the market

Doc 7029/VI/95 rev 5: Appendix B General recommendations for the design, preparation and realization of residue trials.

Guidance document on risk assessment for birds and mammals under directive 91/414/EEC SANCO/41459/2000), 25 September 2002

GLP :

Yes

Material and methods :

Test substance : Oncol 8.6G, granules, formulation containing 8.6 % benfuracarb

Experimental design :

The purpose of those studies is to determine the magnitude of residue of benfuracarb, carbofuran and 3-OH-carbofuran in brassica seedlings sampled at day 0 (granule incorporation, transplantation) up to day 42. The samples of whole plants without root (representative feed items of birds and mammals) were taken at each sampling time. The sampling regime allows monitoring the evolution of the concentrations in the feed items. Residue levels in earthworms were also determined.

Sufficient cabbage seedlings were taken at each sampling date in order to get samples of at least 50-100 g leaves for the first sampling date (up to 1-2 kg for the last sampling dates) and at least 15 g earthworms samples (up to 30 g for some samples).

Two modes of application of the formulation were tested:

In-furrow application: the granule formulation was applied uniformly along the furrows, at the rate of 12 kg formulation/ha (1 kg a.s./ha).

In the plant-hole application: the granule formulation was applied in the plant-hole, at the rate of 12 kg formulation/ha (1 kg a.s./ha). Considering the high residue level observed in this type of application, the notifier does not support the use of granule with plant-hole application.

Analytical methods :

The methods for the determination of residues of benfuracarb and its metabolites carbofuran and 3-hydroxy-carbofuran in brassica crops and earthworms are evaluated in chapter B.5 of the DAR.

Derivation of the “total residues for risk assessment”, based on the measured field data :

Risk to birds/mammals following the consumption of seedlings and earthworms after application of Oncol 8.6G at planting/sowing of brassica. (NOTOX, June 2007).

In July 2007, the RMS responded to a position paper prepared by NOTOX to discuss the quantification of residues for risk assessment. It was decided that the total carbofuran residue in seedlings should be considered as carbofuran equivalents, including 3-OH-carbofuran (free + conjugated) and bound carbofuran, corrected by a conversion factor.

Metabolism in seedlings :

Metabolism, distribution and expression of benfuracarb residues in cabbage seedlings. NOTOX report 445905. (Van Noorloos B., 2006).

The results of the metabolism study in seedlings are summarised below (Table B.9.1.8-1) :

Table B.9.1.8-1 : Distribution and identification of radioactivity in cabbage seedlings following application of Oncol 8.6G at planting of cabbage

Days after planting	free carbofuran (% TRR)	free 3-OH-carbofuran (% TRR)	polar fraction (% TRR)	unextractables (% TRR)
7	65.1	21.8	0	0.5
14	35.7	29.3	25.6	0.5
21	19.1	23.4	34.9	0.6
28	14.7	15.0	51.9	1.5

The polar fraction of 28 days, which contains the conjugates, was subjected to acid hydrolysis. The hydrolysate was partitioned into an organic phase and aqueous phase and both phases were subjected to TLC. The results of the identification after acid hydrolysis are presented in the table below (Table B.9.1.8-2).

Table B.9.1.8-2 : Identification/characterisation of radioactivity in the polar fraction (28 days) of cabbage seedlings following application of Oncol 8.6G at planting of cabbage

Days after planting	total polar fraction (% TRR)	released carbofuran (% TRR)	conjugated 3-OH-carbofuran (% TRR)	unknown (% TRR)
28	51.9	24.7	6.1	18.3

When combining the results of Table B.9.1.8-1 and Table B.9.1.8-2, the following residue situation is obtained after 28 days (Table B.9.1.8-3).

Table B.9.1.8-3 : Distribution and identification of radioactivity in cabbage seedlings following application of Oncol 8.6G at planting of cabbage

Days after planting	free carbofuran (% TRR)	bound carbofuran (% TRR)	free 3-OH-carbofuran (% TRR)	conjugated 3-OH-carbofuran (% TRR)	polar fraction (% TRR)	unextractables (% TRR)
28	14.7	24.7	15.0	6.1	18.3	1.5

The following qualitative observations can be made from these results :

1. Carbofuran levels decrease with time from 65.1 % at day 7 to 14 % TRR at day 28
2. Benfuracarb was not observed in the seedlings
3. Free 3-OH-carbofuran residue levels were fairly constant with time, and lower than or equal to carbofuran residues.
4. At seven days, no conjugated metabolite fractions were present
5. From day 14 onwards conjugated metabolite fractions were present, which increased from 25.6 % TRR to 51.9 % TRR (day 28)
6. Conjugated forms consisted of carbofuran and 3-OH-carbofuran
7. Without further knowledge on toxicity, the residue of concern for birds/mammals should be "carbofuran + free 3-OH-carbofuran + polar fraction" (the polar fraction is included because it contains bound carbofuran and 3-OH-carbofuran conjugates)

Field studies indicate that the highest residues are found between day 4 and 14. These maximum levels represent the worst-case situation for risk to birds/mammals.

Based on the day 14 residue situation in seedlings, which is considered representative for the risk assessment to birds/mammals as it also represents the situation when residue levels are highest, the following conversion factors could be used:

1. Total residues for risk assessment = carbofuran residues x **2.5** [$2.5 = (35.7+29.3+25.6)/35.7$]
2. Total residues for risk assessment = [carbofuran + free 3-OH-carbofuran residues expressed as carbofuran equivalents] x **1.4** [$1.4 = (35.7+29.3+25.6)/(35.7+29.3)$]

By using the conversion factor the measured residues are converted to total residues relevant for the risk assessment of birds/mammals. A risk assessment can therefore be performed based on: (1) carbofuran residues only or (2) carbofuran + free 3-OH-residues. [Note: The concept of conversion factors is often used in dietary risk assessment for consumers].

Comment of the RMS :

The RMS agrees with the proposed conversion factors.

By using the conversion factor, the **measured residues in cabbage seedlings** are converted to total residues relevant for the risk assessment of birds/mammals. A risk assessment can therefore be performed based on:

- (1) field trials where measurements were made only for carbofuran residues, or
- (2) field trials where measurements were made for carbofuran + free 3-OH-carbofuran residues.

1 - Total residues for RA (in cabbage seedlings) = carbofuran residues x **2.5**

2 - Total residues for RA (in cabbage seedlings) = [carbofuran + free 3-OH-carbofuran residues expressed as carbofuran equivalents] x **1.4**

In this calculation, residues of 3-OH-carbofuran are expressed as carbofuran equivalents by correction for the difference in molecular weights (221.3/237.3).

Where a residue was <LOQ, the value of the LOQ was used in the calculation (1.5 µg/kg for carbofuran; 3.0 µg/kg for 3-OH-carbofuran).

Metabolism in earthworms :

The notifier has assumed that carbofuran and 3-OH-carbofuran were only present as free **residues in earthworms** matrices. Hence the total of residues for risk assessment is calculated as :

3 - Total residues for RA (in earthworms) = [carbofuran + free 3-OH-carbofuran residues expressed as carbofuran equivalents]

In this calculation, residues of 3-OH-carbofuran are expressed as carbofuran equivalents by correction for the difference in molecular weights (221.3/237.3). The RMS has accepted this assumption, which has no impact on the outcome of the risk assessment.

Derivation of the residue levels used in the TER calculations :

The residue levels for the various risk assessments were calculated following the recommendations of the Guidance Document on Risk Assessment for Birds and Mammals, with some adaptations. In the case of a granule containing a systemic a.s. (carbofuran is formed), the maximum residue appears only after a few days.

- For the acute assessment : the 90th percentile (or equivalent) of maximum residues
- For the short-term assessment : the arithmetic means of the maximum residues
- For the long-term assessment : the mean time-weighted-average residues (averaging has been done by considering the observed area under-curve)

Findings:

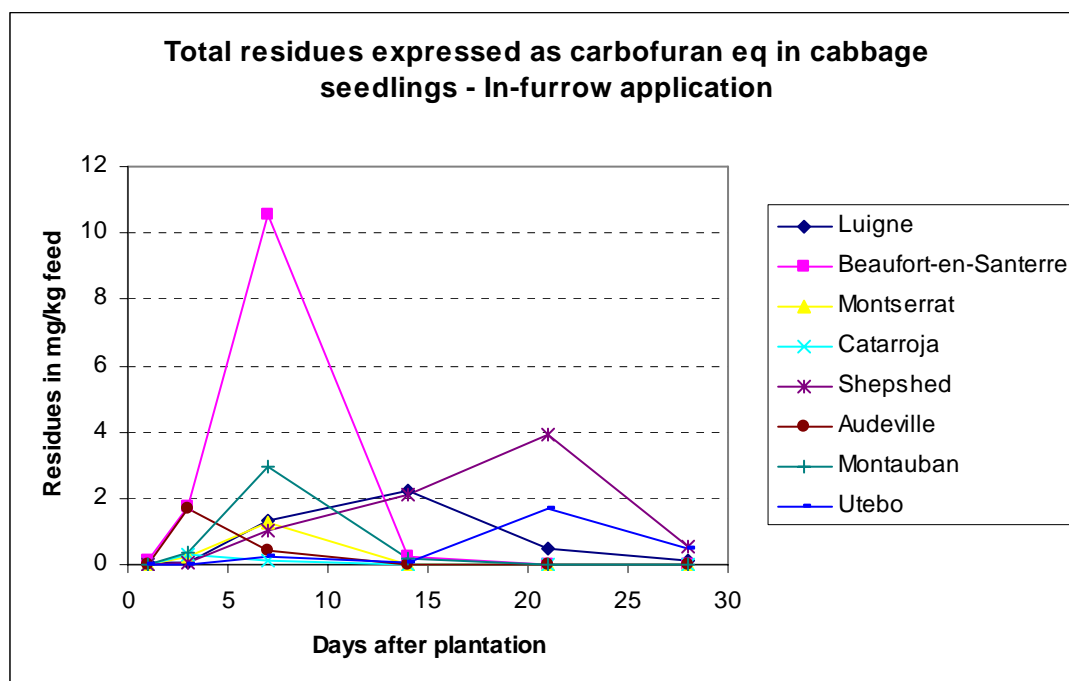
The information on the test design, mode of application, individual results, ... are presented in the summary tables B.9.1.8-7 (localized in furrow); B.9.1.8-8 (localized in plant-hole); B.9.1.8-9 (broadcast application).

Two field trials were performed to compare residue levels in brassica seedlings following application according to method 1 (plant-hole application) and 2 (in-furrow application) both at 12 kg product/ha according to the GAP. The results of the trials performed in Monserrat (Spain) in 2005 are given in Tables B.9.1.8-4 and B.9.1.8-5. These results clearly indicate that the maximum residue levels of carbofuran following application method 2 (in-furrow) are much lower (by a factor of at least 41) than residue levels of carbofuran following application method 1 (in the plant-hole). Residue levels of benfuracarb were <LOQ (0.005 mg/kg). In the case of plant-hole application, the whole amount of formulation (1 kg a.s./ha) is available at the roots of the cabbages while in the case of in-furrow application, the formulation is scattered along the furrow. A large proportion of the total amount of benfuracarb (1 kg a.s./ha) is not available at cabbage root level. (Assuming that there is a 50 cm distance between seedlings in the rows and that 2.5 cm of the furrow-length is accessible to the roots of each seedling, only 5 % of the total application rate is available for uptake by the seedlings).

Considering the high residue level in cabbage seedlings observed with plant-hole application, the notifier does not support this type of use of benfuracarb granules.

I. Residue levels in seedlings (in-furrow application) relevant for the TER calculations :Table B.9.1.8-4 : Total (carbofuran + 3-OH-carbofuran) residues for risk assessment (expressed as carbofuran equivalents – formula n°2 except Spain 2005) in each trial (mg/kg) – cabbage seedlings – **in-furrow application**

Day after treatment	France-N 2006 Luigne	France-N 2006 Beaufort-en-Santerre	Spain 2005 Monserrat	Spain 2006 Catarroja	UK 2007 Shepshed	France-N 2007 Audeville	France-S 2007 Montauban	Spain 2007 Utebo
0	∞	∞	∞	∞	0.007	0.006	0.006	0.006
1	0.048	0.103	∞	0.028	∞	∞	∞	∞
3	0.065	1.729	0.260	0.327	0.083	1.710	0.356	0.006
7	1.345	10.566	1.238	0.102	1.007	0.444	2.966	0.267
14	2.251	0.270	0.023	0.020	2.117	0.010	0.205	0.069
21	0.472	0.020	0.004	0.020	3.920	0.006	0.006	1.670
28	0.107	0.022	0.004	0.020	0.518	0.006	0.006	0.466
42					0.006	0.028		
TWA from days 3 to 21 (mg carbofuran equivalents/kg cabbage seedlings)	1.39	3.53	0.42	0.08	1.90	0.33	1.03	0.43



Acute exposure risk assessment : The 90th percentile residue level in cabbage seedlings is equivalent to **3.92 mg carbofuran equivalents/kg cabbage seedlings** (7th max value out of 8 or 87,5th percentile).

Short-term risk assessment : The arithmetic mean of the maximum residue levels has been considered : **3.08 mg carbofuran equivalents/kg cabbage seedlings** (mean of 8 max residue values).

Long-term risk assessment : The mean of the TWA concentrations calculated for each individual field is equivalent to **1.14 mg carbofuran equivalents/kg cabbage seedlings**. The TWA is calculated between days 3 and 21 (period with maximum concentration carbofuran present) and considering the area under the curve.

TWA residue = $[(\text{mean residue of day 3 and 7}) * 4 \text{ days}] + [(\text{mean residue of day 7 and 14}) * 7 \text{ days}] + [(\text{mean residue of day 14 and 21}) * 7 \text{ days}] / (21 - 3 \text{ days})$

Based on the lack of a clear distinction between residue levels in Northern and Southern Europe, the mean of TWA concentrations measured in the 8 field trials is representative of the long-term exposure level of birds populations foraging on cabbage fields when the residues in seedlings are the highest.

The notifier commented that the results of the report of Huauhmé (2007) (France-N 2006, Beaufort-en-Santerre) should not be included in the risk assessment, since results from this trial are not reliable.

The reasons for not selecting the results from this trial are following :

- the field growing period was too long
- the crop was planted too late in the season
- no duplicate samples (at day 7, 14, 21 and 28) were taken because of too little plant material and outlier samples could therefore not be re-analysed
- no control samples (at day 14, 21, 28) were taken and therefore no reference analyses are possible for the residues found
- according to the Dixons test, the selected value of 10.566 mg carbofuran equivalents/kg cabbage seedlings at day 7 after application should be considered as an outlier.

The RMS cannot agree with the notifier and considers the study results of the report of Huaultmé (2007) (France-N 2006, Beaufort-en-Santerre) valid. According to Porteneuve C. (Chou-fleur, Protection Phytosanitaire, situation actuelle et perspectives, Rencontre technique, Carquefou, 4 décembre 2007, Quel avenir pour la protection phytosanitaire des légumes) cabbage can be planted up to August-September. The planting date of the crop in this trial was 4th of August and thus during the planting season. The RMS is also of the opinion that the value of 10.566 mg carbofuran equivalents/kg cabbage seedlings is valid. Moreover, in calculating the 90th percentile residue level for the acute risk assessment, the potential outliers are ruled out.

2. Residue levels in seedlings (in plant-hole application) relevant for the TER calculations :

Table B.9.1.8-5 : Total carbofuran residues for risk assessment (expressed as sum of carbofuran and conjugated carbofuran – formula n°1) in each trial (mg/kg) – cabbage seedlings – **in-plant hole application**

	France-S 2005 Meynes	France-N 2005 Rosières -en -Santerre	Spain 2005 Monserat
0			
1	0.085	2.033	
3	0.595	8.900	22.200
7	21.975	44.500	50.250
14	60.000	5.075	8.400
21		0.530	0.228
28	1.845		0.047
29		0.059	
35			0.004
TWA from days 3 to 21 (mg a.s. equivalent/kg cabbage seedlings)	30.60	16.66	21.13

Acute exposure risk assessment : Since, only 3 trials are available, the highest residue level in cabbage of **60.00 mg carbofuran equivalents/kg cabbage seedlings** can be considered as the relevant acute exposure level (worst-case).

Short-term risk assessment : The arithmetic mean of the maximum residue levels has been considered : **51.58 mg carbofuran equivalents/kg cabbage seedlings**.

Long-term risk assessment : The mean of the TWA concentrations calculated for each individual field is equivalent to **22.80 mg carbofuran equivalents/kg cabbage seedlings**. The TWA is calculated between days 3 and 21 (period with maximum concentration carbofuran present) and considering the area under the curve.

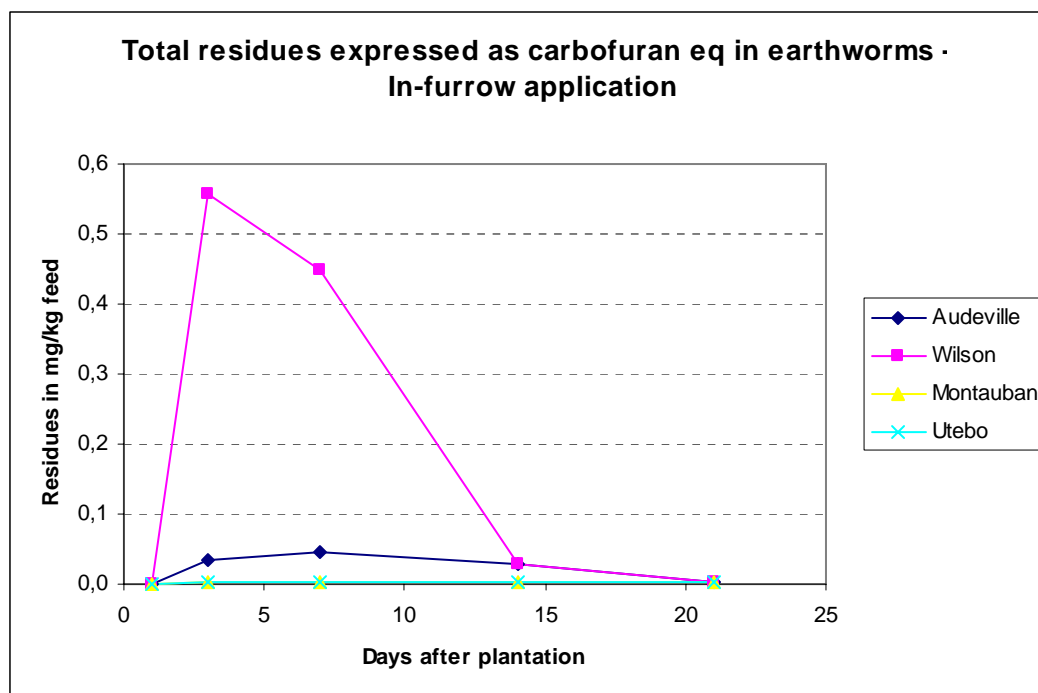
TWA residue = $[(\text{mean residue of day 3 and 7}) * 4 \text{ days}] + [(\text{mean residue of day 7 and 14}) * 7 \text{ days}] + [(\text{mean residue of day 14 and 21}) * 7 \text{ days}] / (21 - 3 \text{ days})$

Based on the lack of a clear distinction between residue levels in Northern and Southern Europe, the mean of TWA concentrations measured in the 3 fields is representative of the long-term exposure level of birds populations foraging on cabbage fields when the residues in seedlings are the highest.

3. Residue levels in earthworms (in-furrow application) relevant for the TER calculations :

Table B.9.1.8-6 : Total (carbofuran + 3-OH-carbofuran) residues for risk assessment (expressed as carbofuran equivalents) in each trial (mg/kg) – earthworms – **in-furrow application**

	France-N 2007 Audeville	UK 2007 Wilson	France-S 2007 Montauban	Spain 2007 Utebo
1				
3	0.035	0.558	0.004	0.004
7	0.045	0.450	0.004	0.004
14	0.029	0.028	0.004	0.004
21	0.004	0.006	0.004	0.004
TWA from days 3 to 14 (mg a.s. equivalent/kg earthworms)	0.038	0.335	0.004	0.004



Acute exposure risk assessment : Since, only 4 trials are available, the highest residue level in earthworms of **0.56 mg carbofuran equivalents/kg earthworms** can be considered as the relevant acute exposure level (worst-case).

Short-term risk assessment : The arithmetic mean of the maximum residue levels has been considered : **0.15 mg carbofuran equivalents/kg earthworms**.

Long-term risk assessment : The mean of the TWA concentrations calculated for each individual field is equivalent to **0.095 mg carbofuran equivalents/kg earthworms**. The TWA is calculated between days 3 and 14 (period with maximum concentration carbofuran present) and considering the area under the curve.

TWA residue = $[(\text{mean residue of day 3 and 7}) * 4 \text{ days}] + [(\text{mean residue of day 7 and 14}) * 7 \text{ days}] / (14 - 3 \text{ days})$

Based on the lack of a clear distinction between residue levels in Northern and Southern Europe, the mean of TWA concentrations measured in the 4 fields is representative of the long-term exposure level of birds populations foraging on cabbage fields when the residues in earthworms are the highest.

Conclusions of the RMS :

The residue levels for the various risk assessments were calculated according to the Guidance Document on Risk Assessment for Birds and Mammals under directive 91/414/EEC, and are appropriate to refine the risk assessment for birds and mammals.

Table B.9.1.8-7 : Residues in cabbage seedlings and earthworms after Oncol 8.6G application localised in-furrow (According to the notifier the following data are relevant for the in-furrow use, except the second trial where the planting has not been done according to the GAP)

Active substance (common name): Benfuracarb
 Commercial Product (name): ONCOL 8.6G
 Formulation (e.g. WP): GR
 Content of active substance (g/kg or g/L): 86 g/kg
 Crop/crop group: brassica
 Producer of commercial product:-
 Responsible body for reporting (name, address):
 Indoor/Glasshouse/Outdoor: Outdoor
 - trials in France (1996): HLS, PO Box 2, Huntingdon, UK Other active substance in the formulation (common name and content): none
 - trials in UK (2001): Oxford Analytical Ltd., Bicester, UK Residues reported as: benfuracarb, carbofuran, 3-OH-carbofuran (mg/kg)
 - trials in UK, France, Spain, Germany, Italy (2005-2007):
 Biotek, Trialcamp, Agrisearch

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH-CF		
BPL 06/063/CL-1 (analyse: 473928) trial no.: BPL 06/063/CL-1. F- 49320 LUIGNE (France Northern area) (IIA 6.3/20)	Cauliflower / Aviso	1/10-July-06 (Planting) 3/06-Oct-06	Micro-granulator (Localised application in furrow, 17857 seedlings/ha)	Not applicable	Not applicable	0.991 (11.13 kg product/ ha)	10-July-06	BBCH 13	Seedlings	nd	0.0203	0.0153	1 3 7 14 21 28	crop spacing on the row (0.70 m), between the rows (0.80 m)
										nd	0.0292	0.0183		
										nd	0.669	0.313		
										nd	1.070	0.577		
										nd	0.2030	0.144		
										nd	0.0325	0.0469		

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH-CF		
BPL 06/063/CL (analyse: 473928) trial no.: BPL 06/063/CL-2. F- 80170 BEAUFORT EN SANTERRE (France Northern area) (IIA 6.3/20)	Cauliflower	1/ 04-Aug-06 (Planting) 3/ 12-Dec-06	Micro-granulator (Localised application in furrow, 17857 seedlings/ha)	Not applicable	Not applicable	0.933 (10.49 kg product/ ha)	04-Aug-06	BBCH 13	Seedlings	nd nd nd nd nd nd	0.0641 0.839 6.26 0.0839 <0.005* 0.0065	<0.01* 0.425 1.38 0.117 <0.01* <0.01*	1 3 7 14 21 28	- LOQ 3-OH-CF was set at 0.01 mg/kg. (see remark under paragraph 4.4) According to the notifier, the 2 nd planting has been done outside normal planting period for that area due to crop failure. Retarded growth and results not representative for GAP. In France (Bretagne, Nord- Pas de Calais) the plantations are spread between end of January- Begin September - Crop spacing on the row (0.70 m), between the rows (0.80 m)
TRC05-20; trial no.: TRC05-20RI SP - 46192 MONSERRAT (Valencia) (IIA 6.3/16)	Cabbage / Arizona	1/ 03-Aug-05 (Planting)	Grain scatterer (granules uniformly scattered in furrow, then covered with disk harrow, finally plantation as usual;, 41667 seedlings/ha, 49.25 g ONCOL 8.6G/ 70 meters row) immediately after planting the field was flooded following good agricultural practice	Not applicable	Not applicable	1.032	03-Aug-05	BBCH 13	Seedlings	<0.5 <0.5 <0.5 <0.005 <0.005 <0.005	0.104 0.495 0.009 <0.0015 <0.0015 <0.0015	Not analysed	3 7 14 21 28 35	- Carfofuran conc. X 2.5 = figure used in the RA, because 3-OH-CF has not been analyzed - Crop spacing on the row (0.4 m), between the rows (0.6 m)

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH-CF		
Trial no.: TRC-06-11 Catarroja (Valencia), Spain (IIA 6.3/21)	Cauliflower/ Arizona	1. 11-07-06	Grain scatterer (granules uniformly scattered in furrow, then covered with disk harrow, finally plantation as usual., 47619 seedlings/ha, 49.25 g ONCOL 8.6G/ 70 meters row disk harrow + immediately after planting the field was flooded following good agricultural practice	Not applicable	Not applicable	1.032	11-07-06	BBCH 13	Seedlings	nd	0.0105	<0.01	1 3 7 14 21 28	Crop spacing on the row (0.35 m), between the rows (0.6 m)
										nd	0.136	0.105		
										nd	0.0180	0.0585		
										nd	<0.005	<0.01		
										nd	<0.005	<0.01		
										nd	<0.005	<0.01		
Trial no.: AF/12035/OT-1, Shepshed, Leicester, England (IIA 6.3/23)	Broccoli/ Marathon	1. 06-06-2007 2.- 3.-	Micro-granulator (Localised application in furrow, 62000 seedlings/ha)	Not applicable	Not applicable	1.000	06-06-2007	BBCH 12	Seedlings	< 0.05*	0.00238	< 0.003*	0 3 7 14 21 28 42	
										< 0.05*	0.047	0.0129		
										nd	0.540	0.192		
										nd	0.972	0.579		
										nd	1.713	1.165		
										nd	0.193	0.190		
Trial no.: AF/12035/OT-2, Audeville, France (North) (IIA 6.3/23)	Head cabbage, var. Eton	1. 19-06-2007 2.- 3.-	Micro-granulator (Localised application in furrow, 26667 seedlings/ha)	Not applicable	Not applicable	1.000	19-06-2007	BBCH 13-14	Seedlings	< 0.05	< 0.0015	< 0.003*	0 3 7 14 21 28 42	# This results seems an outlier, however it was included in the RA birds/mammals as worst- case.
										< 0.05	0.912	0.332		
										nd	0.124	0.207		
										nd	< 0.0015	0.00588		
										nd	< 0.0015	< 0.003		
										nd	< 0.0015	< 0.003		
									Earth- worms	< 0.05*	< 0.0323	< 0.003*		
										< 0.05*	0.0425	< 0.003*		
										< 0.05*	< 0.0264	< 0.003*		
										< 0.05*	< 0.0015*	< 0.003*		

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH-CF		
Trial no.: AF/12035/OT-9, Wilson, Derbyshire, England (IIA 6.3/23)	Cauliflower/ Flamenco F1	1.22-06-2007 2.- 3.-	Micro-granulator (Localised application in furrow, 57000 seedlings/ha)	Not applicable	Not applicable	1.000	22-06-2007	BBCH 14	Earth- worms	<0.05* <0.05* <0.05* <0.05*	0.504 0.417 0.0255 0.00284	0.0576 0.0349 <0.003* <0.003*	3 7 14 21	
Trial no.: AF/12036/OT-1, Montauban (82) France (South) (IIA 6.3/24)	Cauliflower/ Nautilus	1. 03-07-2007 2.- 3.-	Micro-granulator (Localised application in furrow, 12500 seedlings/ha)	Not applicable	Not applicable	1.000	03-07-2007	BBCH 12	Seed- lings Earth- worms	<0.05* <0.05* <0.05* <0.05* <0.05* <0.05* in progress	<0.0015* 0.176 1.286 0.0317 <0.0015* <0.0015* in progress	<0.003* 0.0843 0.893 0.123 <0.003* <0.003* in progress	0 3 7 14 21 28 42 3 7 14 21	
Trial no.: AF/12036/OT-2, Utebo Spain (IIA 6.3/24)	Broccoli/ Partenon	1. 21-09-2007 2.- 3.-	Micro-granulator (Localised application in furrow, 27700 seedlings/ha)	Not applicable	Not applicable	1.000	21-09-2007	BBCH 13	Seed- lings Earth- worms	<0.05* <0.05* <0.05* <0.05* <0.05* <0.05* in progress	<0.0015* <0.0015* 0.168 0.0169 0.640 0.146 in progress	<0.003* <0.003* 0.0242 0.035 0.593 0.200 in progress	0 3 7 14 21 28 42 3 7 14 21	Immature crop sample. The crop had not yet reached maturity. However, in order to prevent from further delays and to be able to assess the residue situation at harvest, a premature sample was taken. A mature sample will be taken when available.

nd = not determined
* = denotes LOQ

Table B.9.1.8-8 : Residues in cabbage seedlings and earthworms after Oncol 8.6G application localised in plant-hole (According to the notifier these are supplementary data – the residue trials are not applicable for the relevant use (in-furrow application) and therefore not used for risk assessment birds/mammals)

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH- CF		
				BPL 05/014/CL; trial no.: BPL 05/014/CL – 1. F- 30840 MEYNES (Southern area) (IIA 6.3/13)	Cauliflower / White passion	1/ 29-Mar-05 (Planting)				Micro- granulator (localised application in plant-hole, 15000 seedlings/ha)	Not applicable	Not applicable		
BPL 05/014/CL; trial no.: BPL 05/014/CL – 2. F- 80170 ROSIERES EN SANTERRE (Northern area) (IIA 6.3/13)	Cauliflower / Aviso	1/ 25-May- 05 (Planting)	Micro- granulator (localised application in plant-hole, 15000 seedlings/ha)	Not applicable	Not applicable	1.161	25-May-05	BBCH 14	Seedlings	0.0069 <0.005* <0.005* <0.005* <0.005* <0.005*	0.813 3.56 17.80 2.03 0.212 0.0237	Not analyse d	1 3 7 14 21 29	- Results for BFC indicative because of low procedural recoveries (44-45%) - Trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) - Crop spacing on the row (0.95 m), between the rows (0.7 m)

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH- CF		
BPL 05/014/CL; trial no. : BPL 05/014/CL – 3. F- 30620 BERNIS (Southern area) (IIA 6.3/13)	Cauliflower / Aviso	1/ 30-May-05 (Planting)	Micro-granulator (localised application in plant-hole, 15000 seedlings/ha)	Not applicable	Not applicable	1.099	30-May-05	BBCH 14	Earth-worms	<0.02* <0.02* <0.02* <0.02* no sampling in the areas 10 cm around the cabbage	<0.005* <0.005* <0.005* <0.005*	nd nd nd nd	1 7 14 28	- Trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) - Crop spacing on the row (0.95 m), between the rows (0.7 m)
BPL 05/014/CL; trial no. : BPL 05/014/CL – 4. F- 80170 ROSIERES EN SANTERRE (Northern area) (IIA 6.3/13)	Cauliflower / Aviso	1/ 09-Jun-05 (Planting)	Micro-granulator (localised application in plant-hole, 15000 seedlings/ha)	Not applicable	Not applicable	1.077	09-Jun-05	BBCH 14	Earth-worms	<0.02* <0.02* <0.02* <0.02*	<0.005* <0.005* <0.005* <0.005*	Not analysed	1 7 14 27	- Trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) - Crop spacing on the row (0.95 m), between the rows (0.7 m)
TRC05-19; trial no.: TRC05-19R1 SP - 46192 MONSERRAT (Valencia) (IIA 6.3/14)	Cabbage / Arizona	1/ 03-Aug-05 (Planting)	Direct to the transplanting hole (localised application in plant-hole, 0.28 g ONCOL 8.6G in each transplanting hole, 41167 seedlings/ha immediately after planting the field was flooded following good agricultural practice	Not applicable	Not applicable	1.032	03-Aug-05	BBCH 13	Seed-lings	<0.5* <0.5* <0.5* <0.005* <0.005* <0.005*	8.88 20.1 3.36 0.091 0.0189 <0.0015*	Not analysed	3 7 14 21 28 35	- LOQ BFC set at 0.5 for certain samples because of poor recoveries at 0.005. - Trial not relevant for intended use (localised in the plant hole application instead of homogeneous distribution in furrow) - Crop spacing on the row (0.4 m), between the rows (0.6 m)

Table B.9.1.8-9 : Residues in cabbage seedlings and earthworms after Oncol 8.6G broadcast application (According to the notifier these are supplementary data – the residue trials are not applicable for the relevant use (in-furrow application) and therefore not used for risk assessment birds/mammals)

1 Report No. Location (region)	2 Commodity/ Variety	3 Date of 1. Sowing or Planting 2. Flowering 3. Harvest	4 Method of treatment	5 Application rate Per treatment			6 Dates of treatment and plantation	7 Growth stage at plantation	8 Portion analyzed	9 Residues (mg/kg)			10 Collection time (Days After Treatment)	11 Remarks:
				kg as/hL	Water (L/ha)	kg as/ha				BFC	CF	3-OH-CF		
				TRC05-21; trial no.: TRC05-21 Spain CATARROJA (Valencia) (IIA 6.3/18)	Cabbage / Arizona	1/ 03-Aug- 05 (Planting)				Broadcast application immediately after planting the field was flooded following good agricultural practice	Not applicable	Not applicable		

B.9.1.9 Habitation and feeding behaviour of birds in treated areas (focal species, PD and PT factors)

1. Determination of the focal species :

Bird species in cabbage fields in Northern and Southern Europe: field data for the determination of focal species. (Muenderle M., Dietzen C., 2007).

Focal bird species in cabbage fields in Europe with regard to granular application of Oncol 8.6G. (Dietzen C., 2007).

Aim :

As an aid to refined risk assessment for plant (crop) protection products, the aim of the current study is to propose a range of candidate bird species for inclusion in a list of focal species present in cabbage fields in Northern and Southern Europe.

Objectives :

The primary objective of the current study was to determine the qualitative and quantitative composition of the bird community present in cabbage fields in Northern and Southern Europe. Frequency of occurrence (FO)¹⁾ and dominance²⁾ were used as parameters to describe variation within the resident bird community and the observed species were subsequently assigned to foraging guild, diet guild and size class.

Study area :

A total of 58 fields in Bretagne (Northern France), Provence (Southern France), Puglia (Italy) and Murcia (Spain) was selected to represent typical conditions for the cultivation of cabbage in Northern and Southern Europe.

Method and parameters :

In order to provide an overview of bird communities present in the cabbage fields, a line transect survey was conducted in each field during the Summer of 2007. For each field, a transect was defined (Northern France: mean length 207 ± 15 m; range 139 – 315 m; n = 15; Southern France: mean length 177 ± 21 m; range 87 – 347 m; n = 12; Italy: mean length 442 ± 40 m; range 177 – 813 m; n = 20; Spain: mean length 286 ± 53 m; range 165 – 775 m; n = 11) and a 100 m band centred along the axis of this transect (termed the ‘in-crop transect band’) was surveyed by an observer walking along the centre line. All bird species present within individual in-crop transect bands were recorded and then frequency of occurrence (FO) and dominance determined.

¹⁾ FO: denotes the number of fields in which a defined species was recorded, given as percentage of the total number of fields, regardless of the number of individuals observed. This approach serves as a measure of the spatial frequency of occurrence.

²⁾ Dominance: denotes the relative occurrence of bird species within the bird community. It is reported as the percentage of individuals of the respective species compared to the total number of individuals of all species.

Data recording and analysis :

All data were collated and analysed using standard spreadsheet applications. Individual species were ranked according to potential focal candidate importance by considering the number of fields in which individual species were present (FO) and dominance. A list of observed species was then compiled according to FO. Those species with FO values greater than 10 % were deemed focal species and assigned to foraging guilds, diet guilds and size classes.

Findings:**Focal species candidates :**

A total of 292 individual bird contacts comprising eleven species were recorded in Northern France, 25 individual bird contacts comprising six species in Southern France, 216 individual bird contacts comprising nine species in Italy and 48 individual bird contacts comprising seven species in Spain. From these data, FO values in excess of 10 % were calculated for eight species in Northern France, three species in Southern France, five species in Italy and five species in Spain which were subsequently deemed candidates for focal bird species for the observed cabbage fields (see tables below).

Table B.9.1.9-1 : Candidates for focal species in Northern France

Bird species	FO n = 15 [%]	Dominance n = 15 [%]
Barn swallow (<i>Hirundo rustica</i>)	60.0	5.8
Black-headed gull (<i>Larus ridibundus</i>)	33.3	52.4
Herring gull (<i>Larus argentatus</i>)	33.3	25.7
White wagtail (<i>Motacilla alba</i>)	20.0	2.7
Carrion crow (<i>Corvus corone</i>)	20.0	2.1
Magpie (<i>Pica pica</i>)	20.0	1.0
Jackdaw (<i>Corvus monedula</i>)	13.3	1.7
Wood pigeon (<i>Columba palumbus</i>)	13.3	1.4

Table B.9.1.9-2 : Candidates for focal species in Southern France

Bird species	FO n = 12 [%]	Dominance n = 12 [%]
Barn swallow (<i>Hirundo rustica</i>)	41.7	48.0
Magpie (<i>Pica pica</i>)	25.0	12.0
Kestrel (<i>Falco tinnunculus</i>)	16.7	12.0

Table B.9.1.9-3 : Candidates for focal bird species in Italy

Bird species	FO n = 20 [%]	Dominance n = 20 [%]
Crested lark (<i>Galerida cristata</i>)	70.0	14.8
Barn swallow (<i>Hirundo rustica</i>)	40.0	11.6
Yellow-legged gull (<i>Larus michahellis</i>)	20.0	58.8
Short-toed lark (<i>Calandrella brachydactyla</i>)	15.0	8.3
Kestrel (<i>Falco tinnunculus</i>)	10.0	0.9

Table B.9.1.9-4 : Candidates for focal bird species in Spain

Bird species	FO n = 11 [%]	Dominance n = 11 [%]
Linnet (<i>Carduelis cannabina</i>)	54.5	22.9
Crested lark (<i>Galerida cristata</i>)	54.5	20.8
Carrion crow (<i>Corvus corone</i>)	18.2	20.8
Short-toed lark (<i>Calandrella brachydactyla</i>)	18.2	12.5
Barn swallow (<i>Hirundo rustica</i>)	18.2	10.4

The nominated candidate focal species were assigned to one of following guilds in accordance with the SANCO Guidance Document (ranked by their respective frequency of occurrence and dominance) :

Candidates for focal bird species in Northern France :

Small insectivore: barn swallow (aerial) > white wagtail (ground)

Medium herbivore: wood pigeon (ground)

Medium omnivore: black-headed gull (ground) > magpie (ground/foilage) > jackdaw (ground)

Large omnivore: herring gull > carrion crow (both ground)

Candidates for focal bird species in Southern France :

Small insectivore: barn swallow (aerial)

Medium omnivore: magpie (ground/foilage)

Medium carnivore: kestrel (ground)

Candidates for focal bird species in Italy :

Small insectivore: barn swallow (aerial)

Small omnivore: crested lark > short-toed lark (both ground)

Medium carnivore: kestrel (ground)

Large omnivore: yellow-legged gull (ground)

Candidates for focal bird species in Spain :

Small granivore: linnet (ground/foilage)

Small insectivore: barn swallow (aerial)

Small omnivore: crested lark > short-toed lark (both ground)

Large omnivore: carrion crow (ground)

Conclusions of the RMS :

The barn swallow (aerial insectivorous) was the most characteristic and stable element of the bird community in cabbage fields in Northern and Southern France, the crested lark (herbivorous and earthworm-eating) in Italy and the linnet (granivorous) in Spain. All of these species showed FO values greater than 10 % during the study period. However, all species listed in the tables above can be considered as potential candidates for focal bird species in a refined risk assessment for crop protection products in cabbage fields in Northern or Southern Europe.

Focal bird species in cabbage fields in Europe with regard to granular application of Oncol 8.6G (Dietzen C., 2007).

A total of 21 bird species were recorded, of which 13 species displayed frequencies of occurrence of 10 % or more in at least one study region. Seven species were recorded in at least two study regions. The barn swallow was the only species recorded with notable FO values in all 4 regions.

Since Oncol 8.6G is applied in the form of granules, residues were found in both cabbage seedlings and earthworms. Consequently in addition to the herbivorous scenario, earthworm-eating birds were also considered.

The list of candidate focal species specifically consisted of 3 species (wood pigeon, crested lark and short-toed lark) which include green material in their diet and which were recorded in at least two study regions.

The diet of 7 species (carrion crow, magpie, kestrel, black-headed gull, herring gull, yellow-legged gull and crested lark) includes earthworms.

When selecting focal species it is important that the focal species represent a worst-case and covers all other species occurring in the crop in question. The two following aspects were considered :

- the spatial distribution : only species recorded in at least 2 study regions were considered as good representatives of species occurring in cabbage fields in Europe
- size : species with low body weight tend to exhibit a higher food intake to body weight ratio than heavier species and are likely to be more at risk.

Taking the above considerations into account, the following focal species were chosen

- the **wood pigeon** (herbivorous bird in N and S Europe, (mean b.w. : 490 g); this species is observed in 3 out of 4 regions at FO level of 13.3, 8.3 and 9.1 %
- the **crested lark** (small herbivorous and earthworm-eating bird in S Europe (mean b.w. : 39 g); this species is observed in Spain and Italy at FO level of 70.0 and 54.5 %
- the **black-headed gull** (earthworm-eating bird (mean b.w. : 284 g); this species is observed in N France at FO level of 33.3 %, 2 other gull species are observed in N France and Italy at FO level of 33.3 and 20.0 % respectively for the yellow-legged gull and the herring gull. Although the omnivorous species show lower body weight (magpie, kestrel), these species very occasionally feed on earthworms.

Conclusions of the RMS :

The RMS agrees with the choice of the focal species. The mean body weights of the birds' species are in line with Buxton *et al.*, 1998.

2. Determination of the Food Intake Rates per food item for the 3 focal species :

Fresh food intake (g item/day) and food intake rate (g food/g body weight) per food item were calculated according to the following equations, according to the SANCO/4145/2000 guidance.

$$FIR (kg / kg) = \frac{kg \text{ food item}}{kg BW} \quad (\text{equation 1})$$

$$\text{Fresh food intake per food item (g fw / day)} = \frac{DEE}{\text{yield}} \quad (\text{equation 2})$$

$$\log(DEE) = a + b \times \log(BW) \quad (\text{equation 3})$$

$$\text{yield} = \text{energy content}_{fw} \times (1 - \text{moisture}) \times \text{assimilation efficiency} \% / 100 \quad (\text{equation 4})$$

$$\text{energy content}_{fw} = \frac{\text{energy content}_{dw}}{1 + \frac{\text{moisture \%}/100}{1 - \text{moisture \%}/100}} \quad (\text{equation 5})$$

In these equations, DEE is the daily estimated energy requirement (kJ/day). The DEE is calculated according to Table 1 in Appendix I of SANCO/4145/2000.

SANCO/4145/2000 lists energy contents for a series of food items. For cabbage seedlings, the values listed for non-grass herbs are used. Cabbage seedlings are dicotyledonous crops, and non-grass herbs are dicotyledonous plants. It is considered more appropriate to use the value listed for non-grass herbs than that for dicotyledonous crop leaves, as the latter is based on mature crops and it is assumed that birds will not eat large leaves. Furthermore, seedling vegetation has higher energy content than the mature crop. The choice for non-grass herbs is further justified by the data in Table 10 of Appendix 3 of the draft of the updated guidance document, which shows that the energy of crop leaves including pods is lower than that of “all plants” (i.e. 11.4 and 17.8 kJ/g dw, respectively).

2.1 Crested lark :

The body weight of the crested lark is 39 gram.

$$\log(DEE) = 1.0017 + (0.7034 \times (\log 39)) = 2.12$$

$$DEE = 132 \text{ kJ}$$

Table B.9.1.9-5 : Calculation of the ratio of food intake rate of different food items to body weight for a crested lark per day

Food type	Energy content* (kJ/g dw)	Moisture content* (%)	Energy content (kJ/g ww)	Assimilation efficiency (%)	Yield (kJ/g ww)	Fresh food intake (g/day)	FIR/bw
cabbage seedlings	18.0	82.1	3.2	76	2.45	54	1.38
weed seeds	21.0	11.9	18.5	80	14.8	8.9	0.23
arthropods	21.9	70.5	6.5	76	4.91	27	0.69
earthworms	19.3	84.6	3.0	76	2.26	58	1.50

* Values taken from Table 3 in Appendix I of SANCO/4145/2000

The assimilation efficiencies of 76 % for cabbage seedlings, arthropods, earthworms and 80 % for weed seeds were proposed by the notifier and are in agreement with the Appendix I of the Guidance Document SANCO/4145/2000.

2.2 Wood pigeon :

The body weight of the wood pigeon is 490 gram.
 $\log(\text{DEE}) = 0.6768 + (0.7723 \times (\log 490)) = 2.75$
 DEE = 568 KJ

As outlined for the crested lark above, the energy values listed for non-grass herbs are used for cabbage seedlings.

Table B.9.1.9-6 : Calculation of the ratio of food intake rate of different food items to body weight for a wood pigeon per day

Food type	Energy content* (kJ/g dw)	Moisture content* (%)	Energy content (kJ/g ww)	Assimilation efficiency (%)	Yield (kJ/g ww)	Fresh food intake (g/day)	FIR/bw
cabbage seedlings	18.0	82.1	3.2	52.5	1.69	336	0.69
weed seeds	21.0	11.9	18.5	76	14.1	40.4	0.08
cereal seeds	16.7	13.3	14.5	76	11.0	51.6	0.11
arthropods	21.9	70.5	6.5	78	5.04	113	0.23

* Values taken from Table 3 in Appendix I of SANCO/4145/2000

The assimilation efficiencies of 52.5 % for cabbage seedlings, 76 % for weed seeds, cereal seeds and 78 % for arthropods were proposed by the notifier and are in agreement with the Appendix I of the Guidance Document SANCO/4145/2000.

2.3 Black-headed gull :

The body weight of the black-headed gull is 284 gram.
 $\log(\text{DEE}) = 1.1482 + (0.6521 \times (\log 284)) = 2.75$
 DEE = 560 KJ

Table B.9.1.9-7: Calculation of the ratio of food intake rate of different food items to body weight for a black-headed gull per day

Food type	Energy content* (kJ/g dw)	Moisture content* (%)	Energy content (kJ/g ww)	Assimilation efficiency (%)	Yield (kJ/g ww)	Fresh food intake (g/day)	FIR/bw
earthworms	19.3	84.6	3.0	79	2.35	238	0.84
arthropods	21.9	70.5	6.5	79	5.10	110	0.39
cereal seeds	16.7	13.3	14.5	75	10.9	51.5	0.18

* Values taken from Table 3 in Appendix I of SANCO/4145/2000

The assimilation efficiencies of 79 % for earthworms, arthropods and 75 % for cereal seeds were proposed by the notifier and are in agreement with the Appendix I of the Guidance Document SANCO/4145/2000.

Conclusions of the RMS :

The RMS agrees with the parameters that were used to determine the FIR/b.w. ratio for the 3 focal bird species.

3. Determination of the proportions of different food types in the diet (PD) of the focal species :

The acute risk assessment may be refined using PD data. The Guidance Document on Risk Assessment for Birds and Mammals (SANCO/4145/2000) considers indicator species for the Tier I risk assessment, which in Tier II may need to be refined based on the use pattern specific to the substance in question.

In a field study conducted in 2007, the crested lark, the wood pigeon and the black-headed gull were considered as focal species. These species are relevant with regards to consumption of cabbage seedlings and earthworms. These species are used for refinement of the risk assessment. An extensive literature search has been performed in order to determine the composition of the diet of the 3 focal species. As the available information is derived from bird crop or faeces examination of birds commuting between treated fields and untreated areas, the determination of an accurate PD factor is difficult and only helpful on a qualitative level.

3.1 Crested lark :

Notifier's proposal : "There are not a lot of quantitative data regarding the diet of crested larks available. Cramp (1998) reports earthworms (mainly small ones) found in the diet of crested larks, but no further details are given. Quantitative data on the proportion of earthworms in the diet are currently not available. However, the comprehensive monograph by Abs (1963) provides some data on the diet composition, which contains mainly weed seeds (62.3 %), cereals (8.7 %) and invertebrates (29 %) including cucurionidae (20 %), carabidae (6 %), ants (45 %), caterpillars (9 %) and "others" (20 %). But he cites one study providing evidence that the diet composition of crested larks is very similar to the diet of skylarks and woodlarks. Due to the lack of specific data for the crested lark, it is considered appropriate to assume a proportion of earthworms in the diet of crested larks to range between 1.5-6.1 % as in the skylark (Bösenberg K., 1969; Collinge W.E., 1927; Donald P.F., Evans A.D., Buckingham D.L., Muirhead L.B. & Wilson J.D., 2001; Jeromin K., 2002). Consequently, PD values of 23 % for insects and 6 % for earthworms are appropriate.

For estimation of the PD for cabbage seedlings, the diet of the skylark is again considered. Skylarks potentially foraging on fields of cabbage treated with carbofuran would preferentially consume the dicotyledonous crop seedlings, but also weed seeds on the soil surface and ground-dwelling arthropods. Adult skylarks always feed on a mixed diet with the compounds varying strongly with the season. Green (1978) conducted a detailed study on the diet composition of skylarks in agricultural areas in the UK. The consumption data for herbivorous feed items have been estimated from Green (1978) for the relevant period of exposure, correlating to March - April (see Table B.9.1.9-8).

Table B.9.1.9-8 : Percentage of dicotyledonous leaves, weed seeds and arthropods in the diet of skylarks in the UK (estimated from Green (1978))

Month	Dicotyledonous leaves	Weed seeds	Arthropods
March	10 %	22 %	3 %
April	9 %	19 %	15 %

For the refinement of the risk assessment, the PD of earthworms is set to 6 %. In a worst-case approach, dicotyledonous leaves in the diet are assumed to consist only of cabbage seedlings, resulting in a PD for cabbage seedlings of 10 %. For the remaining diet, 23 % is assumed to be arthropods (insects) and 61 % weed seeds. As the crested lark consumes seedlings as well as earthworms (both contaminated food items), the refined risk assessment covers both routes of exposure. "

Table B.9.1.9-9 : Percentages of broadleaf leaves and earthworms in skylark diet (from Buxton *et al.*, 1998)

Environmental conditions	Broadleaf leaves and earthworms contribution in the diet (%)	Reference
May June, chick faecal sacks	No earthworm, nor plant material Insects : 100 % of the diet	Brooks <i>et al.</i> , 1995
No seasonal data, nestling diet	Earthworms : 2 % Leaves : 1 %	Collinge, 1924-1927
October-March, faecal samples in cereal fields	Broadleaf leaves : 24 % Earthworms : 1 %	Donald <i>et al.</i> , 2001a
October-March, faecal samples in broadleaf crops	Broadleaf leaves : 96 % Earthworms : -	Donald <i>et al.</i> , 2001b
October-March, faecal samples in permanent pasture	Broadleaf leaves : 51 % Earthworms : -	Donald <i>et al.</i> , 2001c
April – June, New Zealand	Dicotyledons : 15-100 % (results unclear)	Garrick, 1981
Arable land, UK	50 % leaves, especially cereals leaves. (Very limited information is reported in the summary by Buxton <i>et al.</i> , 1998)	Green, 1978
UK, sugar beet field	Weed and sugar beet seedlings : 63 %	Green, 1980
April June, nestling diet, Switzerland	No earthworm, nor plant material Insects : 100 % of the diet	Jenny, 1990

Conclusion of the RMS :

As comprehensive data are not available for crested lark, the RMS agrees to base the PD for cabbage seedlings on skylark data. Skylarks occur wherever farming is practiced. They prefer flat open fields with grasses and low herbage. They avoid areas with too high vegetation. They are considered as pest of sugar beet, lettuce and pea seedlings (Buxton *et al.*, 1998). These observations on the behaviour confirm that larks can be found in almost bare fields planted with young cabbage seedlings.

The notifier has based the PD determination on the study of Green (1978). In this study the diet of skylarks has been determined in 3 arable fields areas located in UK (67 to 110 ha areas, main crops are cereals, sugar beets and vegetables species). Skylarks faeces have been analyzed and the proportion of invertebrates, cereal grains, grass flowers and seeds, dicotyledonous weed seeds, monocotyledonous leaves, dicotyledonous leaves has been determined. Monthly data have been collected during 2.5 years. A graphical presentation of the results is available in the study report. Depending on time of the year, the proportion of dicotyledonous leaves reached up to 30 % of the total diet.

The RMS has considered the **PD of 33 % for cabbage seedlings** as acceptable and representative of the feeding behaviour of the species. The assessment is mainly based on the studies by Green (1978) and (1980), Donald *et al.* (2001b). This factor has been determined according to a weight of evidence approach and is only likely to help on a qualitative basis. It is obvious that the determination of a “mathematically exact” figure is not feasible. The RMS agrees with the **PD of 6 % for earthworms** that has been set by the notifier. This figure is an acceptable worst-case. For the remaining diet, **PD of 23 % for arthropods** and **PD of 38 % for weed seeds** is set.

3.2 Wood pigeon :

Notifier's proposal : "Wood pigeons feed on plant material (green leaves, seeds, berries, buds, flowers, and root crops); occasionally invertebrates are taken. However, the diet of the adult wood pigeon was shown to be dominated by high-calorific seeds, e.g. cereals, peas, chickpeas, acorns, etc. The amount of those feed items in the diet varies greatly according to their availability in the particular habitats. Agricultural seeds are taken mainly around sowing and harvest time. But in the course of the year the wood pigeon always takes some green plant material like leaves, buds, etc.

There are no studies dealing with the exact amount of consumption of cabbage seedlings. However, green leaves of cabbage and other kind of leafy crops are listed in the diet of wood pigeons by several authors (Snow D. and Perrins C., 1998; Colquhoun M.K., 1951; Ljunggren L., 1968). From these studies it is possible to estimate the fraction of cabbage seedlings in diet.

As mentioned above, the diet of adult wood pigeons is dominated by high-calorific seeds. However, the amount of those feed items in the diet varies greatly according to time period and habitat characteristics. Since wood pigeons exhibit an opportunistic foraging behaviour it is highly unlikely that birds will exclusively exploit one single food source over a longer time period. Hence, for the short-term scenario the fraction of each food type in the diet can be reduced (from 100 %). Several studies analysing the crop content of wood pigeons were conducted that allow an estimation of the fraction of food type (cabbage seedlings) in diet (see Table B.9.1.9-10).

Table B.9.1.9-10 : Proportion of Brassica leaves in the diet of the wood pigeon (from Snow D. and Perrins C., 1998)

Food item	Proportion in the diet	Period	Location	Reference
Brassica leaves	8 % (% fresh weight)	January–March	Oxford (England)	Colquhoun, 1951
Legume or Brassica leaves	13 % (% of items)	January–July	Cambridgeshire (England)	Murton R.K. <i>et al.</i> , 1963
Rape leaves	21 % (% of frequency)	January–April	South-west Sweden	Ljunggren L., 1968
Brassica leaves	51 % (% of frequency)	December–April	Rhine valley (West Germany)	Bettman H., 1965
Vegetables, mainly Brassica	31 % (% of frequency)	All year	West Germany	Bettmann H., 1966

Furthermore, a comprehensive study on the diet composition of wood pigeons in Belgium (Schnock G., Seutin E., 1970, 1973 and Seutin G., Schnock E., 1971) showed that the diet components of wood pigeons varied due to changes in food availability. A close relationship between the food components found in the crops and the phenological development of the main components of the agro-forest landscape inhabited by the wood pigeons was found. Thus, the annual feeding cycle of the wood pigeons could be divided into distinct phases each corresponding to a well-defined phenological stage of the habitat.

During the sowing period (April to mid-May) agricultural seeds formed the main part of the diet (nearly 91 % by dry weight). Hence, in this period a maximum of 10 % of food may be green leaves. During the second phase (mid-May to mid-June) the diet was dominated by seeds, fruits and vegetative material. In this period, vegetative material originating from different plants constituted 32.5 % by dry weight of the diet. Earlier in the year, during the phase from mid-October to April the diet of the wood pigeons principally consisted of seeds with vegetative material making up about 17 % by dry weight.

From the above it can be concluded that the fraction of cabbage seedlings in the diet of the woodpigeon can be conservatively reduced to 33 % (PD = 0.33).

PD values for the remaining part of the diet are based on data from the same studies, in the second phase (mid-May to mid-June). In this phase, cereal seeds and arthropods accounted for 6 % and 3 % of the diet, respectively, while 58 % of the diet consisted of non-agricultural seeds and fruits (mainly *Ranunculus sp.* and chickweeds), rhizomes of *Anemone sp.*, bulbs of *Ficaria sp.* and flower buds (beech, buttercup). Energy data are available for weed seeds, but not for rhizomes, bulbs and flower buds. As these items are expected to be rich in energy, they are grouped with the weed seeds for this risk assessment. Furthermore, as these food items do not contain any residues of carbofuran, the exposure assessment is not affected by this assumption. Therefore, PD values used for the other parts in the diet of the wood pigeon are 58 %, 6 % and 3 % for weed seeds (including rhizomes, bulbs and flower buds), cereal seeds and arthropods, respectively.”

Table B.9.1.9-11 : Percentages of broadleaf leaves in wood pigeon diet (from Buxton *et al.*, 1998)

Environmental conditions	Leaves contribution in the diet (%) (*)	Reference
November-January	Brassica : 8 %	Colquhoun, 1951
December-January	Leaves : 23 %	Durroy <i>et al.</i> , 1984
January-April	Plant leaves : 52 %	Ljunggren L., 1968
May-August	Plant leaves : 13 %	
September-November	Plant leaves : 9 %	
February-April	Plant leaves : 23 %	Murton <i>et al.</i> , 1963
May-July	Plant leaves : 40 %	
August-October	Plant leaves : 3 %	
November-January	Plant leaves : 20 %	
May	Weed leaves and flowers : 20 %	Murton <i>et al.</i> , 1963a
June	Weed leaves and flowers : 7 %	
July	Weed leaves and flowers : 4 %	

(*) : leaf species are not mentioned in these studies. The presence of earthworms is not reported in these studies

Conclusion of the RMS :

Wood pigeons exhibit an opportunistic foraging behaviour. They consume different food items in different habitats (agricultural/non agricultural, woodlands/fields/pastures,...) depending on the time of the year. They mainly feed on high-calorific seeds (cereals seeds at sowing and round harvest) and on a large variety of green plant material collected in agricultural and non-agricultural habitats (green leaves, berries, buds, flowers, and root crops). They occasionally take invertebrates. The RMS has considered the **PD value of 33 % for cabbage seedlings** as acceptable and representative of the feeding behaviour of the species. This factor has been determined according to a weight of evidence approach and is only likely to help on a qualitative basis. It is obvious that the determination of a “mathematically exact” figure is not feasible. **PD values** used for the other parts in the diet of the wood pigeon are **58 %, 6 % and 3 % for weed seeds (including rhizomes, bulbs and flower buds), cereal seeds and arthropods, respectively.”**

3.3 Black-headed gull :

Notifier's proposal : "The diet of a black-headed gull consists of earthworms, insects, seeds, fish, fruits and refuse, depending on the time of the year. According to Cramp (1998) the following qualitative data on the diet of black-headed gulls are available : In breeding season, earthworms and insects predominate in diet, with earthworms comprising as much as 50 % of total food mass, and insects *ca.* 15 %. Insects, which may comprise *ca.* 80 – 90 % of total number of items, are mainly ground-dwelling beetles and their larvae, tipulid fly larvae, and aquatic insects and their larvae (especially those living on or near surface, those of shallow margins, and those of relatively slow flight near water). In summer and autumn, when vegetation is high and the ground often hard, earthworms and ground-dwelling insects are taken less often, while aquatic insects whose breeding season is finished are not available. At this time, other insects are taken, together with fish, fruit, seeds, and refuse. In winter, insects are taken less frequently, and other foods exploited, e.g. fish (by food-piracy and from drained fish-ponds) and refuse. Under certain conditions earthworms and insects still figure highly in the winter diet. A study in Switzerland by Cuendet (1979) in Glutz von Blotzheim U.N., Bauer K.M. and Bezzel W. (2001) revealed a diet composition of 92.3 % for earthworms, 1.7 % for insects, 5.7 % for cereal seeds and 0.2 % for other seeds. For the refined risk assessment, the PD values for earthworms, insects and cereal seeds are taken to be 92 %, 2 % and 6 %, respectively."

Table B.9.1.9-12 : Percentages of earthworms in the black-headed gull diet (from Buxton *et al.*, 1998)

Environmental conditions	Earthworms' contribution in the diet (%)	Reference
No seasonal data	50 %	Christensen <i>et al.</i> , 1996
No seasonal data, data probably collected in a coastal area	36 % (crustaceans and annelids)	Collinge, 1924-1927
No seasonal data, Swiss farmland	92 %	Cuendet, 1980
Jul-sept, estuarine area in UK	9 %	Curtis & Thompson, 1980
No seasonal data, Czech Republic	Presence of earthworms reported but not measured	Honza & Modry, 1994
May-June	38 % (occurrence in stomachs)	Vernon, 1972
June-July	22 %	
August	0 %	
September	67 %	
October-February	29 %	

Conclusion of the RMS :

The notifier has proposed a **PD value of 92 % for earthworms** in the black-headed gull diet. The RMS considers that this figure is a worst-case assumption. The **PD values of 2 % for arthropods and 6 % for cereal seeds** were agreed upon.

4. Determination of the proportions of the diet in the treated area (PT) of the focal species :

The notifier proposed the following argumentation for the determination of PT factors for crested lark and wood pigeon.

4.1 Southern Europe (crested lark) :

For further refinement of the risk assessment, PT data may be used. Currently, no data are available for determination of a PT value for crested lark but data for the skylark (a related species) may be used. The home range of a skylark is 1-8 ha, depending on habitat structure (Donald P.F., 2004), which may cover several fields containing brassica crops. On this basis, the PT for skylarks feeding in carbofuran treated cabbage fields may be set at 0.3. Using this data, the margin of safety for Southern Europe would be even higher than that calculated in the Tier II risk assessment. Therefore, the long-term risk for birds due to consumption of contaminated cabbage seedlings and earthworms is considered acceptable for Southern Europe.

4.2 Northern Europe (wood pigeon) :

For further refinement of the risk assessment, PT data may be used. It is unlikely that birds would obtain their complete intake of brassica crops for four weeks from the same cabbage plot, treated with Oncol 8.6G. In France, only 10 % of all cabbage grown is treated with Oncol 8.6G (communication by DuPont, distributor of Oncol 8.6G in France). A PT value (PT = Proportion of diet in Treated area) value of 0.1 however might underestimate the risk since this would assume that birds will cover a very large area during foraging. The maximum PT that would result in a TER value > 5 can however be calculated to be 0.75 (TER would be 5.4 using a PT of 0.70). This PT value is not considered unrealistic, considering the home range of a wood pigeon, which is 250-300 ha (Haynes P.J., Inglis I.R., Isaacson T.J., Fryday S.L., 2003). This home range could cover several fields with brassica crops. The PT for wood pigeons feeding in carbofuran treated cabbage fields may therefore conservatively be set at 0.5, yielding a long-term TER of 7.5. Therefore, the long-term risk for birds due to consumption of contaminated cabbage seedlings and earthworms is considered acceptable for Northern Europe.”

Conclusion of the RMS :

According to the RMS, the PT figures that have been calculated by the notifier seem to have been back calculated in order to provide an acceptable TER. Due to the large uncertainty in the determination of these data, the RMS considers that the risk assessment should not take these figures into consideration.

The RMS has proposed to base the determination of PT factor “proportion of the diet obtained in the treated” on an evaluation of the available food sources (% cabbage fields, % other vegetables, % other field crops) under real environmental conditions.

The total European production of cauliflowers (the most important cabbage type) is concentrated in a few countries. In Italy (25 %), Spain (17 %), France (16 %), Poland (9 %), Germany (7 %), United Kingdom (9 %), Belgium (3 %) and other countries (14 %).

In the 3 first countries, the entire production is localized in relatively small areas as shown by the Table B.9.1.1-13. The following table confirms that the regions taken into consideration in field survey for the determination of focal species are representative of the supported GAP.

Table B.9.1.9-13 : Overview of the total European production of cauliflowers (the most important cabbage type)

	Nb of hectares cauliflower and cabbage in the main production regions of France, Italy and Spain	Main regions of production of cauliflower (% of the total national acreage) (*)
Nord-Pas de Calais	1477 (cauliflower)	13
Bretagne (Finistère, Côtes-d'Armor, Ille-et-Vilaine), Manche	21282 (cauliflower)	78
Bouches-du-Rhône	592 (cauliflower)	2.3
France	24033 (cauliflower)	100
Puglia	8.500 + 2500 (cauliflower and cabbages)	37.0
Sicilia	2.400 (cauliflower)	10.4
Abbruzzo	2.350 (cauliflower)	10.2
Campania	2.300 (cauliflower)	10.0
Marche	2.300 + 950 (cauliflower and cabbages)	10.0
Calabria	900 (cauliflower)	3.9
Veneto	1.500 (cabbage)	-
Lazio	1.200 (cabbage)	-
Piemonte	1.050 (cabbage)	-
Campania	550 (cabbage)	-
Italia	23000 + 11000 (cauliflower and cabbages)	100
Navarra	6124 (cauliflower)	25.0
La Rioja	1050 (cauliflower)	4.3
C. Valenciana	3638 (cauliflower)	14.8
R. de Murcia	9765 (cauliflower) 22268 (all cabbage, broccoli and cauliflower types)	39.9
Andalucia	1325 (cauliflower)	5.4
Espana	24500 (cauliflower)	100

(*) Complete statistical information is available for the cauliflower, which is the most cultivated cabbage type. In consequence the calculation has only been made for this crop type.

Web site of Fertirrigazione :

Cavolo - Orticole - Colture - Fertirrigazione_it.htm ;
Cavolfiore - Orticole - Colture - Fertirrigazione_it.htm

Web site of Ministerio de Agricultura, Pesca y Alimentacion
Superficies y producciones agricolas (Enero 2008)

Web site of Región de Murcia, Consejería de Agricultura y Agua
Distribucion regional de cultivos

Web site of Direction Régionale de l'Agriculture et de la Forêt de Bretagne

Service Régional de l'Information Statistique et Économique

Agreste Bretagne - Tableaux de l'Agriculture Bretonne 2007

Agreste Bretagne – Mémento de la statistique agricole - Edition 2007

Agreste Conjoncture – légumes (janvier 2007)

Agreste Conjoncture – légumes (mai 2006)

Web site of Direction Départementale de l'Agriculture et de la Forêt

Service de la Statistique agricole (Manche)

5. The production of cauliflower, broccoli and cabbages in Bretagne (France) :

A detailed evaluation of the distribution of crops in Bretagne (region with highly concentrated production of open field vegetables) has been performed by the RMS in order to derive a PT factor in an extreme worst-case situation. This evaluation has been based on publicly available statistical information.

Table B.9.1.9-14 : Distribution of cabbage production in Bretagne (year 2006)

	Côtes-d'Armor	Finistère	Ille-et-Vilaine	Morbihan	Bretagne
Main areas of vegetables production in the Département	Paimpol	St-Pol de Léon	St-Malo	Pontivy	
Cauliflower (in ha)	5962	12208	2015	149	20334
Broccoli (in ha)	659	1680	231	250	2820
Other cabbages (in ha)	130	390	620	100	1240
Total cabbages (in ha)	6751	14278	2866	499	24394
Total vegetables (in ha) (*)	13646	20723	5426	13799	53594
Acreage used for agriculture (**)	479611	420931	492183	398343	1791068
Acreage vegetables/acreage used for agriculture (in %)	2.8	4.9	1.1	3.5	3.0
All cabbages/total vegetables crops (in %)	49.5	68.9	52.8	3.6	45.5
All cabbages/acreage used for agriculture (in %)	1.4	3.4	0.6	0.1	1.4

(*) Main vegetable crops of this region are artichoke, peas, beans and spinach

(**) "Acreage used for agriculture" stands for fields, pastures, all types of orchards, amateur gardens. Woodlands, surface water bodies, non agricultural soils are not included in the acreage used for agriculture

The following map represents the distribution of vegetables production in % of the “acreage used for agriculture” (14.4 %, 10.6 %, 6.2 %, 3.3 %). It is reasonable to assume that the cabbages represent around 50 % of vegetables cultivated in Bretagne. (see Table B.9.1.9-14 : 49.5 %, 68.9 %, 52.8 %).

Figure B.9.1.9-1 : Distribution of vegetables production in % of “acreage used for agriculture”

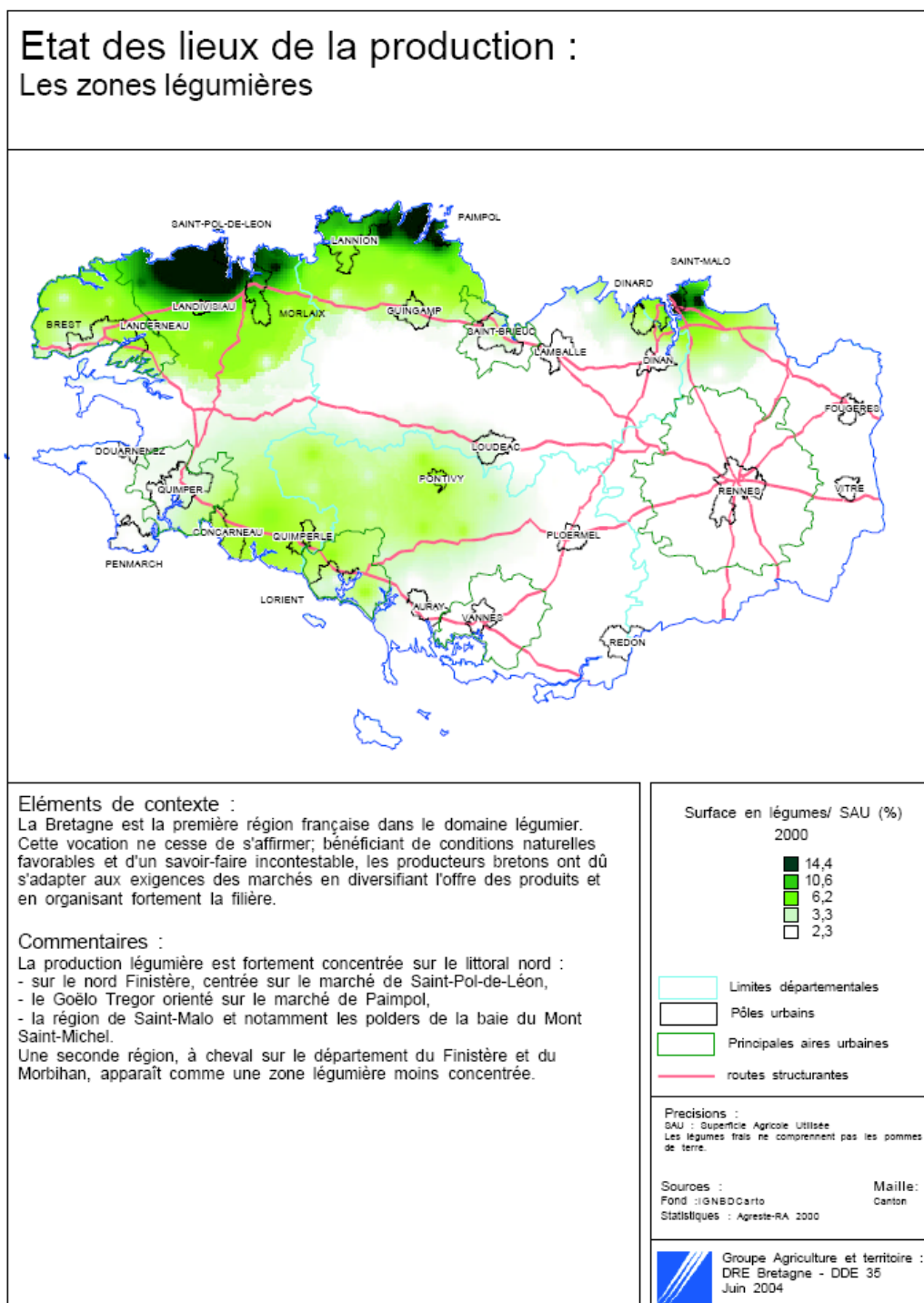


Table B.9.1.9-15 : Explanation of the colour index

Vegetables production in % of the “acreage used for agriculture”	Cabbages production in % of the ”acreage used for agriculture”
14.4	7.2
10.6	5.3
6.2	3.1
3.3	1.65
2.3	1.15

Conclusions of the RMS on the PT determination :

The PT factor “proportion of the diet obtained in the treated area” has been determined by an evaluation of the available food sources (% cabbage fields, % other vegetables, % other field crops) under real environmental conditions. Bretagne represents a worst case scenario in terms of cabbage availability.

Cabbage represents 50 % of the vegetables in this region. Except in very restricted areas, cabbage fields represent less than 3.1 % of the total acreage used for agriculture. In regions with high cabbage production, the plantations are performed at regular intervals (from January to begin September in Northern France) in different fields in order to have a continuous production all the year round. In consequence, this figure should be further mitigated by the proportion of fields at the critical growth stage (seedlings at BBCH 12-19, with potentially high residue level).

This evaluation does not take into account the proportion of the fields that would be treated with benfuracarb (cabbage fields, extension of the use to other crops), nor the impact of the use of other pesticides with the same mode of action.

B.9.1.10 Monitoring of pesticide poisoning incidents

Pesticide poisoning of animals 1998 to 2006 : Investigations of suspected incidents in the United Kingdom (Fletcher M.R., Hunter K., Barnett E.A., Sharp E.A., 1999 to 2007).

The reports of the poisoning incidents between 1998 and 2006 have been submitted by the notifier. They indicated that the incidents related to benfuracarb (1 sample) and carbofuran are abuse. The RMS however considers that this information does not demonstrate the safety on Oncol 8.6G to birds under normal agricultural practice. Moreover the annual sales of Oncol 8.6G in the UK is rather limited (it amounted to 5000-19000 kg formulation/year from 1997 up to 2005, with an estimated use area of 833-3170 hectares/year).

B.9.1.11 Summary of effects on birds - exposure and risk assessment for birds (Annex IIIA 10.1) revised in August 2008**Exposure route for the active substance :**

Birds are exposed to benfuracarb via the consumption of granules (accidental or as grit). Since the residue levels of benfuracarb in cabbage seedlings and earthworms are negligible, no TER calculation is necessary for benfuracarb in those food matrices.

Exposure route for the metabolites :

Since residue levels of the metabolites carbofuran and 3-OH-carbofuran in cabbage seedlings and earthworms were relevant and since these metabolites are both more toxic than the active substance, the risk to birds from exposure to these metabolites has been assessed.

I. Choice of toxicological endpoints :

The RMS has proposed the following endpoints as relevant for the risk assessment for birds.

Table B.9.1.11-1 : Summary of effects of benfuracarb on birds (Otsuka studies)

Test species	Test system	Endpoints	References
<i>Coturnix coturnix japonica</i>	acute oral toxicity	LD _{50,male} = 48.3 mg a.s./kg b.w. LD _{50,female} = 39.9 mg a.s./kg b.w.	Tadashi Jyonouchi, 1982
<i>Anas platyrhynchos</i>		LD₅₀ = 19.8 mg a.s./kg b.w.	Robert Fink, Joann B. Beavers, 1982
<i>Colinus virginianus</i>	5-day dietary toxicity	LC ₅₀ = 179 mg a.s./kg b.w./day	Robert Fink, Joann B. Beavers, 1982
<i>Anas platyrhynchos</i>		LC₅₀ = 15 mg a.s./kg b.w./day	Robert Fink, Joann B. Beavers, 1982
<i>Colinus virginianus</i>	22 weeks reproduction study	NOEC = 8.93 mg a.s./kg b.w./day	Teunissen M.S., 2001

Table B.9.1.11-2 : Summary of effects of carbofuran on birds (Otsuka studies)

Test species	Test system	Endpoints	References
<i>Anas platyrhynchos</i>	acute oral toxicity	LD₅₀ = 0.76 mg Carbofuran/kg b.w. NOEL = 0.19 mg Carbofuran/kg b.w.	Roberts N.L., Fairley C., 1987
<i>Anas platyrhynchos</i>	5-day dietary	LC ₅₀ = 10 mg Carbofuran/kg b.w./day NOEC < 6 mg Carbofuran/kg b.w./day	Roberts N.L., Fairley C., 1987

<i>Colinus virginianus</i>	toxicity	LC ₅₀ = 114 mg Carbofuran/kg b.w./day NOEC = 5.25 mg Carbofuran/kg b.w./day	Roberts N.L., Fairley C., 1987
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Table B.9.1.11-3 : Toxicological endpoints of carbofuran for birds (entire database available in the original DAR of carbofuran)

Test species	Time-scale	Endpoints
<i>Anas platyrhynchos</i>	Acute effects	<p>1) LD₅₀ = 0.76 mg a.s./kg b.w. NOEL = 0.19 mg a.s./kg b.w.</p> <p>2) LD_{50,m} = 0.71 mg a.s./kg b.w. LD_{50,f} = 0.86 mg a.s./kg b.w.</p>
<i>Anas platyrhynchos</i>	Short-term effects	<p>1) LC₅₀ (5 d) = 10 mg a.s./kg b.w./day, derived from 91 mg a.s./kg feed, based on a mean food consumption of 9.7 g/bird/day and a mean body weight of 87 g/bird NOEC < 6 mg a.s./kg b.w./day, derived from < 32 mg a.s./kg feed, based on a mean food consumption of 20 g/bird/day and a mean body weight of 107 g/bird. In this experiment, the NOEC determination is based on the food consumption reduction and body weight loss that were observed at all carbofuran dosages. Birds were subdued and very thin from 64 mg a.s./kg feed onwards.</p> <p>2) LC₅₀ (5 d) = 17 mg a.s./kg b.w./day, derived from 79 mg a.s./kg feed, based on a mean food consumption of 65 g/bird/day and a mean body weight of 301 g/bird NOEC (5 d) = 4.5 mg a.s./kg b.w./day, derived from 22 mg a.s./kg feed, based on a mean food consumption of 63 g/bird/day and a mean body weight of 308 g/bird In this experiment, the NOEC determination is based on mortality observed at 46 mg a.s./kg feed and onwards. No food consumption reduction nor body weight loss were observed at all carbofuran dosages.</p> <p>3) LC₅₀ (14 d) = 1.6 mg a.s./kg b.w./day, derived from 21 mg a.s./kg feed, based on a mean food consumption of 24 g/bird/day and a mean body weight of 313 g/bird – LC₁₀ (14 d) = 0.64 mg a.s./kg b.w./day (see below the determination of the long-term endpoint)</p>
<i>Colinus virginianus</i>	Acute effects	<p>LD_{50,m} = 8.0 mg a.s./kg b.w. LD_{50,f} = 8.0 mg a.s./kg b.w.</p>
<i>Colinus virginianus</i>	Short-term effects	<p>1) LC₅₀ (5 d) = 114 mg a.s./kg b.w./day, derived from 855 mg a.s./kg feed, based on a mean food consumption of 2 g/bird/day and a mean body weight of 15 g/bird NOEC = 5.25 mg a.s./kg b.w./day, derived from 30 mg a.s./kg feed, based on a mean food consumption of 3.5 g/bird/day and a mean body weight of 20 g/bird. The NOEC is based on the mortality observed at 84 mg a.s./kg feed</p> <p>2) LC₅₀ (14 d) = 15.8 mg a.s./kg b.w./day derived from 158 mg a.s./kg feed, based on a mean food consumption of 6.1</p>

		g/bird/day and a mean body weight of 61 g/bird NOEC < 127 mg a.s./kg feed, based on mortality observed at all dosages 3) LC ₅₀ (7 d) = 20.8 mg a.s./kg b.w./day, derived from 1000 mg a.s./kg feed, based on a mean food consumption of 3 g/bird/day and a mean body weight of 144 g/bird NOEC < 125 mg a.s./kg feed, based on behaviour : birds fed with treated diets were extremely lethargic but also hyper-reactive to noise stimuli.
<i>Coturnix coturnix japonica</i>	Acute effects	LD _{50,m} = 4.9 mg a.s./kg b.w. LD _{50,f} = 3.5 mg a.s./kg b.w.
<i>Phasianus colchicus</i>	Acute effects	LD _{50,m} = 4.0 mg a.s./kg b.w. LD _{50,f} = 6.2 mg a.s./kg b.w.
<i>Anas platyrhynchos</i>	Reproduction study	NOEC (adult mortality, 12 weeks pre-egg laying) < 0.30 mg a.s./kg b.w./day, derived from < 2 mg a.s./kg feed, based on a mean food consumption of 168 g/bird/day and a mean body weight of 1107 g/bird

The notifier has disagreed and proposed the following endpoints as relevant for the risk assessment for birds.

1.1 Acute and short-term endpoints :

According to the notifier, the LD₅₀ was determined in a gavage study, where carbofuran dissolved in corn oil was intubated into the stomach of fasted animals. This route of exposure is not considered to be representative for the scenario where birds are exposed to carbofuran in cabbage seedlings. A justification is given below. "Carbofuran is a carbamate and the toxic effects of carbamates are due to inhibition of the enzyme acetylcholinesterase (AChE) which causes rapid accumulation of acetylcholine (ACh) in neuromuscular junctions and certain neural synapses. The excess of ACh results in over-stimulation of receptors of the central nervous system, organs and skeletal muscles. With carbamates the enzyme-inhibition is reversible. In rats, the time of maximum plasma concentration after oral gavage was already reached after < 7 minutes, and the elimination half-life was 29 minutes (Ferguson P., Michael S., Dey S., Jewell S.A. and Krieger R., 1984, evaluated in the toxicological section). In all acute toxicity studies with carbofuran in rats, complete recovery was observed within 24 hours after dosing, which indicates that the effects are reversible within hours from onset. The high blood level of carbofuran that occurs immediately after direct dosing of the animal (gavage) will not occur when carbofuran is ingested via the diet resulting in a similar dose. This is also apparent for birds when comparing the acute oral toxicity LD₅₀ of carbofuran in mallard duck (0.76 mg carbofuran/kg b.w.) with the LC₅₀ from a 5-day dietary study in mallard duck, which was 91 mg carbofuran/kg diet, equivalent to 10 mg carbofuran/kg b.w./day (Roberts N.L., Fairley C., 1987b, evaluated in the DAR of carbofuran). The 5-day LC₅₀ (exposure to treated diet) is a factor of 13.2 higher than the acute oral LD₅₀ (exposure by gavage). The LC₅₀ determined from dietary exposure rather than the LD₅₀ determined from oral gavage is the relevant parameter that should be used for the evaluation of the acute risk assessment. This approach follows the recommendations of EFSA in relation to the evaluation of another carbamate, pirimicarb (EFSA Journal (2005) 240: page 1-21)."

According to the notifier, the discrepancy between the LD₅₀ and the LC₅₀ would mainly be due to the mode of exposure, respectively by gavage and to the treated diet. The notifier considered therefore that the acute risk assessment is not relevant for the final risk assessment and took the LC₅₀ of 10mg carbofuran/kg b.w./day as relevant endpoint for short-term risk assessment.

1.2 Long-term endpoint :

The notifier has proposed the following statement for the determination of the long term endpoint :

“The NOEC from a reproduction study in mallard duck is < 0.30 mg carbofuran/kg b.w./day (Roberts N.L. *et al*, 1983, evaluated in the toxicological section). In this study, there was a 24-week exposure period (12 weeks pre-egg laying and 12 weeks egg production) to carbofuran in the diet. The dominant observed effect was dose-related mortality (16/35 ducks at the lowest dose of 2 mg carbofuran/kg diet during the 12 weeks pre-egg laying), but the DAR stated that the reproductive capacity of birds that survived appeared not to be adversely affected in any way. Considering the specific mode of action of carbofuran (acetyl-cholinesterase inhibitor, see above), mortality is expected to be the dominant effect, occurring at dose levels which are much lower than those causing effects on other parameters including reproduction parameters. Furthermore, the duration of exposure of the reproduction study in mallard greatly exceeds the duration of exposure to carbofuran in treated cabbage seedlings, which is about 4 weeks. The DAR of carbofuran summarises 4-week dietary feeding studies in 5-7 days old mallard duck and bobwhite quail, in which the former species was far more sensitive (2-week LC₅₀ values were 21 and 158 mg carbofuran/kg diet respectively) (Shellenberger T.E., 1972, evaluated in the toxicological section). The study with mallard duck again confirmed that the dominant effect is mortality. The mortality was 10 %, 30 %, 55 %, 90 %, 65 % and 95 % at 0, 17, 23, 33, 45 and 65 mg carbofuran/kg diet, respectively. The NOEC for mortality was thus < 17 mg carbofuran/kg diet, whereas the NOEC for food consumption was 23 mg carbofuran/kg diet. In the absence however of effects on body weight at 23 mg carbofuran/kg diet, the NOEC for effects other than mortality may be set at 33 mg carbofuran/kg diet. Based on the above mortality data, 4-week LC₀, LC₁₀ and LC₅₀ values (estimated by probit analysis using Toxstat version 3.5) were 1.5, 8.4 and 22.2 mg carbofuran/kg diet. Based on food consumption data in the DAR (24 g of food per bird per day, mean body weight of birds 313 g), these values are equivalent to 0.12, 0.64 and 1.7 mg carbofuran/kg b.w./day, respectively. In this study, 10 % mortality occurred in the untreated control and 10 % mortality in the control is considered to be acceptable by the OECD 205 guideline for short-term dietary toxicity studies. The LC₁₀ may therefore be considered as the overall NOEC from this 4-week dietary feeding study, and is considered to be the correct ecotoxicological endpoint for the risk assessment of exposure of birds to treated cabbage seedlings. “

Conclusion of the RMS on setting of the endpoints relevant for the risk assessment :

1.1 Acute and short-term endpoints :

The RMS has evaluated the possibility to review the acute dose estimation based on the recommendations of the opinion of the SCP on pirimicarb (EFSA Journal (2005) 240: page 1-21). However, there is not enough information in the dossier of benfuracarb to determine the avoidance threshold dose, the avoidance delay time, the feeding rate per minute and the absorption/deuration rate constant in birds. We also have considered that this method of calculation is lacking validation and uncertainty determination. In consequence, it was not possible to recalculate the acute endpoint according to the SCP opinion.

The LD₅₀ values have been determined in 5 studies for 4 bird species to be in the range of 0.71 to 8 mg carbofuran/kg b.w. The **LD₅₀ of 0.76 mg carbofuran/kg b.w.** that has been proposed by the notifier Otsuka is an acceptable worst-case.

According to Special review of Carbofuran insecticide : Effects on avian fauna and value to agriculture (Plant Industry Directorate, Agricultura Canada, Ottawa, Ontario, 1993), the LD₅₀ values for *Anas platyrhynchos* (0.370 – 0.628 mg carbofuran/kg b.w.) are in the same order of magnitude as the proposed LD₅₀ of 0.76 mg carbofuran/kg b.w.

The LC₅₀ values have been determined in 6 studies for 2 bird species to be in the range of 1.6 to 114 mg carbofuran/kg b.w. Considering the entire database of Table B.9.1.11-3, the RMS is of the opinion that **LC₅₀ (14 d) = 1.6 mg carbofuran/kg b.w./day** is the most appropriate value for the risk assessment.

1.2 Long-term endpoint :

The RMS agrees with the fact that, considering the specific mode of action of carbofuran (acetyl-cholinesterase inhibitor), mortality is expected to be the dominant effect, occurring at dose levels which are much lower than those causing effects on other parameters including reproduction parameters. The RMS considers that a new long-term study (reproduction study or “long term” dietary study) would not bring new valuable information on the long term NOEC. The **LC₁₀ of 0.64 mg carbofuran/kg b.w./day** may therefore be considered as an overall NOEC.

2. Avoidance behaviour :

Under the conditions of the acceptance study (Teunissen M., 2004) no avoiding behaviour of Japanese quail from seed scattered on granules containing Oncol 8.6G during 24-hours was noted. Avoidance factor cannot be used for risk refinement.

3. Supported uses :

The risk assessment for birds is based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002.

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the furrow at a single application rate of 1 kg a.s./ha.

As the original GAP proposal was application in-furrow and in the plant-hole and as residue trials were also available for the use in plant-hole, the RMS included calculations to demonstrate that this particular use in the plant-hole is not safe.

Considering the high residue level in cabbage seedlings observed with plant-hole application, the notifier does therefore no longer support this type of use of benfuracarb granules.

4. Risk assessment for ingestion of granules :

The calculation of conventional TER is not possible for granules.

For information the acute LD₅₀ and the dietary LC₅₀ of benfuracarb for the most sensitive species (*Anas platyrhynchos*) and the reproductive NOEC for *Colinus virginianus* were recalculated in number of granules for different sizes of birds. The weight of one granule of Oncol 8.6G is 0.064 mg, which corresponds with an amount of 0.0055 mg a.s./granule. The diameter of the granules is assumed to be 0.25 – 0.71 mm.

Table B.9.1.11-4 : LD₅₀, LC₅₀ and NOEC of benfuracarb expressed in number of granules for different sizes of birds

Time scale	Number of granules for a 15 g bird	Number of granules for a 50 g bird	Number of granules for a 200 g bird	Number of granules for a 500 g bird
Acute LD ₅₀	54	180	720	1800
Dietary LC ₅₀	41	136	545	1364
Reproductive NOEC	24	81	325	812

Conclusion:

According to the EPPO scheme, further risk assessment for ingestion on granular formulation is necessary when only one or a few granules would be sufficient to achieve a lethal dose. The risk for birds consuming granules containing benfuracarb as grit or accidentally has been considered acceptable since at least 24-54 granules are necessary to reach the relevant toxicological endpoints in the case of a bird weighting 15 g. Moreover, the risk assessment that has been performed for bird species in the range 15-500 g b.w. covers the entire list of focal species candidates identified in Dietzen C. (2007).

Benfuracarb : Statement on acceptance of granules by birds. (de Roode D.F., 2007).

See appendix 1 to this chapter B9.

5. Risk assessment for consumption of contaminated drinking water :

Benfuracarb is applied as a granular formulation. Therefore, it can be expected that the risk of consumption of contaminated drinking water is low.

6. Risk assessment of consumption of contaminated earthworms and treated seedlings :**6.1 First tier risk assessment :**

The first tier risk assessment has not been performed for birds consuming cabbage seedlings and earthworms containing benfuracarb. The analytical results of the field trials (seedlings and earthworms) clearly demonstrate the absence of the a.s. itself in these matrices.

The first tier risk assessment for carbofuran is based on a medium herbivorous bird of 300 g body weight feeding exclusively on cabbage seedlings, with a daily food intake of 228 g fresh material/day (equivalent to a FIR/bw of 0.76).

Since the main route of exposure is via the consumption of treated vegetation, the data on residues were used first. The residue levels in cabbage seedlings are derived from the concentrations observed in the field trials. The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran, conjugated carbofuran and 3-OH carbofuran.

The residue levels for the various risk assessments were calculated following the recommendations of the Guidance document on Risk Assessment for Birds and Mammals, with some adaptations taking into account that the initial residue is not the maximum residue in the case of a granule containing a systemic a.s.

- For the acute assessment : the 90th percentile (or equivalent) of maximum residues
- For the short-term assessment : the arithmetic means of the maximum residues
- For the long-term assessment : the mean time-weighted-average residues (averaging has been done by considering the observed area under-curve).

Table B.9.1.11-5 : Estimated oral uptake of carbofuran by herbivorous birds and first tier Toxicity Exposure Ratios (TERs) for use in cabbage crop (12 kg Oncol 8.6G/ha)

Application rate (kg a.s./ha)	Crop	Bird type	Time-scale	FIR/ bw	Residue level (mg carbofuran equivalents/kg food)	ETE (mg a.s./kg b.w./day)	TER	Annex VI Trigger value
1 × 1.00, in-furrow application	leafy crop/ early (cabbage seedlings)	medium herbivorous	acute	0.76	3.92	2.98	0.255	10
			short-term	0.76	3.08	2.34	0.684	10
			long-term	0.76	1.14	0.87	0.739	5
1 × 1.00, in plant-hole application (*)	leafy crop/ early (cabbage seedlings)	medium herbivorous	acute	0.76	60.00	45.60	0.017	10
			short-term	0.76	51.58	39.20	0.041	10
			long-term	0.76	22.80	17.33	0.037	5

*: the notifier does not support the GAP with plant-hole application

No first tier standard scenario is available for earthworm-eating birds. Only the higher tier risk assessment has been performed.

Conclusion of the RMS :

The first tier risk assessment is based on a medium herbivorous bird of 300 g body weight feeding exclusively on cabbage seedlings, with a daily food intake of 228 g fresh material/day (equivalent to a FIR/bw of 0.76). Since the main route of exposure is via the consumption of treated vegetation, the data on residues were used first. The residue levels in cabbage seedlings are derived from the concentrations observed in the field trials. The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran, conjugated carbofuran and 3-OH carbofuran.

This first tier assessment shows that the risk to birds consuming cabbage seedlings is unacceptable. In consequence higher tier risk assessment is required.

This assessment also demonstrates that the residue level in seedlings, and consequently the risk to birds, is highly depending on the mode of application of the granules.

When evaluating the risk at national level for uses on cabbage seedlings or other crops, the evaluators should carefully consider the actual application amount of a.s. available at the foot of each individual plant, and not only the whole application rate per hectare. This rate is depending on the mode of application (broadcast, in-furrow or plant-hole), the distance between the plants in the row and between the rows. The residue level in young plants is also depending on the growth rate, plantation time,... It is therefore advisable to perform specific residue trials for each crop/use.

In order to reduce the risk to birds and mammals (by ingestion of granules or earthworms), to non-target soil organisms (arthropods, earthworms, micro-organisms), to groundwater and surface water contamination, the application in the plant-hole, at lower dosage is advisable. This technique would provide the same protection of the crop to target insects and highly reduces the amount of a.s. used per hectare.

6.2 Higher tier risk assessment :

The higher tier risk assessment (worst-case approach, deterministic) has been calculated using the following input parameters :

- Measured residue concentrations in cabbage seedlings and in earthworms, collected respectively in a total of 8 and 4 fields. Field management and application of the formulation was done in accordance with the supported GAP. The residue levels were expressed in sum of free and bound carbofuran + 3-OH carbofuran (See B.9.1.8 : PEC_{FEED} (residue concentrations in cabbage seedlings and earthworms).
- The focal species (crested lark, wood pigeon and black-headed gull) were chosen by means of a survey of bird communities in a total of 58 fields in Brittany (Northern France), Provence (Southern France), Apulia (Italy) and Murcia (Spain). The 4 regions are representative in terms of the cultivation of cabbage in Northern and Southern Europe. (See B.9.1.9 : focal species).
- Fresh food intake (g item/day) and food intake rate (g food/g body weight) per food item were calculated according to the SANCO/4145/2000 guidance.
- PD determination : An extensive literature search has been performed in order to determine the composition of the diet of the 3 focal species. As the available information is derived from bird crop or faeces examination of birds commuting between treated fields and untreated areas, the determination of an accurate PD factor is difficult and only helpful on a qualitative level.
- the choice of the toxicological endpoints is based on the re-assessment of the entire database (see B.9.1.11 : choice of the toxicological endpoints).

Table B.9.1.11-6 : Sources of uncertainty identified in the risk assessment

Sources of uncertainty	Input data used in the refined risk assessment	Identified variability
Toxicological endpoints of carbofuran	<p>Worst-case LD₅₀ = 0.76 mg carbofuran/kg b.w.</p> <p>Extreme worst-case LC₅₀ = 1.6 mg carbofuran/kg b.w./day (14 d dietary study)</p> <p>NOEC = 0.74 mg carbofuran/kg b.w./day (EC₁₀ of a 14 d dietary study)</p>	<p>LD₅₀ in 5 studies for 4 bird species in the range of 0.71 to 8 mg carbofuran/kg b.w.</p> <p>LC₅₀ in 6 studies for 2 bird species in the range of 1.6 to 114 mg carbofuran/kg b.w./day.</p> <p>The mode of exposure (gavage, in the diet), the type of diet used (in comparison with the diet of wild animals) the duration of the study, the tested species,... are sources of variability.</p> <p>The steepness of the mortality curve, level at which clinical, behavioural effects occur (NOEC level).</p>
Residues of carbofuran in food (cabbage seedlings)	<p>Worst-case for the acute and short-term RA</p> <p>acute : 3.92 mg/kg, 90th percentile of maximum residues</p> <p>short-term : 3.08 mg/kg, arithmetic means of the maximum residues</p> <p>long-term : 1.14 mg/kg, mean time-weighted-average residues</p>	<p>The residue levels in cabbage seedlings are derived from the concentrations observed in 8 field trials (supported GAP). The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran, conjugated carbofuran and 3-OH carbofuran.</p> <p>High variability is observed in terms of residues in food items (peak concentrations in cabbage seedlings in the range of 0.327-10.566 µg/kg.</p> <p>High variability in terms of residue levels depending on the application technique (in plant-hole, in-furrow application), the growth rate of the crop depending on the environmental conditions.</p>

Sources of uncertainty	Input data used in the refined risk assessment	Identified variability
Residues of carbofuran in food (earthworms)	Worst case for the acute and short-term RA acute : 0.56 mg/kg, maximum residue value short-term : 0.15 mg/kg, arithmetic means of the maximum residues long-term : 0.095 mg/kg, mean time-weighted-average residues	The residue levels in earthworms are derived from the concentrations observed in 4 field trials (supported GAP). The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of carbofuran and 3-OH carbofuran. High variability is observed in terms of residues in food items (peak concentrations in earthworms in the range of 0.004-0.558 µg/kg).
Food avoidance (granules)	Worst-case (food avoidance not considered)	No avoidance was observed in the Avoidance study of Japanese quail from seed scattered on granules containing Oncol 8.6G. The validity of this type of study is questionable to evaluate the avoidance of the a.s. included in the relevant food sources (in this case, systemic absorption of carbofuran in plants or earthworms).
FIR determination	Calculated endpoint (mean b.w. of the species, other factors taken from the Guid. Doc.)	Calculated endpoint with several sources of variability (variability of the relationship b.w. – DEE, parameters used for the calculation: weight of the animal, assimilation efficiency, moisture content of the food).
Focal species	Worst-case: Crested lark (species with low b.w., high plant consumption) Wood pigeon (present in 3 out of 4 regions, high plant consumption) Black-headed gull (very high earthworm consumption)	Choice of the species is based on the observations made in 4 regions of high cabbage productions. - the crested lark (small herbivorous and earthworm-eating bird in S Europe (mean b.w. : 39 g); this species is observed in Spain and Italy at FO level of 70.0 and 54.5 % - the wood pigeon (herbivorous bird in N and S Europe, (mean b.w. : 490 g); this species is observed in 3 out of 4 regions at FO level of 13.3, 8.3 and 9.1 % - the black-headed gull (earthworm-eating bird (mean b.w. : 284 g); this species is observed in N France at FO level of 33.3 %; 2 other gull species are observed in N France and Italy at FO level of 33.3 % and 20.0 % respectively for the yellow-legged gull and the herring gull. Although the omnivorous species show lower body weight (magpie, kestrel), these species very occasionally feed on earthworms.
PD determination	Worst-case (it is assumed that the entire leaves contribution is made of cabbage seedlings) PD = 33 %	Quality of the literature studies that are considered (the aim of the study was not the PD determination, type of protocol, measurements that have been done). Variability of the birds diet depending on the availability of food sources, the type of environment, ... Leaves in crested lark diet : 24, 96, 51, 50-63 %

Sources of uncertainty	Input data used in the refined risk assessment	Identified variability
	<p>PD = 33 %</p> <p>PD = 92 % (close to 100 %)</p>	<p>Leaves in wood pigeon diet : 8, 13, 21, 51, 31, 9-52, 3-40, 4-20 %</p> <p>Earthworms in black-headed gull diet : 50, 92, 9, 0-67 %</p>
PT determination	<p>Worst-case : PT = 100 %</p>	<p>The PT factor “proportion of the diet obtained in the treated area” has been determined by an evaluation of the available food sources (% cabbage fields, % other vegetables, % other field crops) under real environmental conditions. Bretagne represents a worst-case scenario in terms of cabbage availability.</p> <p>Cabbage represents 50 % of the vegetables in this region. Except in very restricted areas, cabbage fields represent less than 3.1 % of the total acreage used for agriculture. In regions with high cabbage production, the plantations are performed at regular intervals (from January to begin September in Northern France) in different fields in order to have a continuous production all the year round. In consequence, this figure should be further mitigated by the proportion of fields at the critical growth stage (seedlings at BBCH 12-19, with potentially high residue level).</p> <p>This evaluation does not take into account the proportion of the fields that would be treated with benfuracarb (cabbage fields, extension of the use to other crops), nor the impact of the use of other pesticides with the same mode of action.</p>

In Tables B.9.1.11-7 to B.9.1.11-15, the TER calculations are presented for the 3 focal species for the use of benfuracarb in-furrow.

6.2.1 Crested lark :

Table B.9.1.11-7 : Diet composition, carbofuran concentration in each food item and acute TER value for the whole diet of crested lark feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LD ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	1.38	3.92	0.33	1.79			
weed seeds	0.23	0	0.38	0			
arthropods	0.69	0	0.23	0			
earthworms	1.50	0.56	0.06	0.05			
Total				1.84	0.76	0.41	10

Table B.9.1.11-8 : Diet composition, carbofuran concentration in each food item and short-term TER value for the whole diet of crested lark feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LC ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	1.38	3.08	0.33	1.41			
weed seeds	0.23	0	0.38	0			
arthropods	0.69	0	0.23	0			
earthworms	1.50	0.15	0.06	0.01			
Total				1.42	1.60	1.13	10

Table B.9.1.11-9 : Diet composition, carbofuran concentration in each food item and long-term TER value for the whole diet of crested lark feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	NOEC (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	1.38	1.14	0.33	0.52			
weed seeds	0.23	0	0.38	0			
arthropods	0.69	0	0.23	0			
earthworms	1.50	0.095	0.06	0.01			
Total				0.53	0.64	1.21	5

6.2.2 Wood pigeon :

Table B.9.1.11-10 : Diet composition, carbofuran concentration in each food item and acute TER value for the whole diet of wood pigeon feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LD ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	0.69	3.92	0.33	0.89			
weed seeds	0.08	0	0.58	0			
cereal seeds	0.11	0	0.06	0			
arthropods	0.23	0	0.03	0			
Total				0.89	0.76	0.86	10

Table B.9.1.11-11 : Diet composition, carbofuran concentration in each food item and short-term TER value for the whole diet of wood pigeon feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LC ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	0.69	3.08	0.33	0.70			
weed seeds	0.08	0	0.58	0			
cereal seeds	0.11	0	0.06	0			
arthropods	0.23	0	0.03	0			
Total				0.70	1.60	2.30	10

Table B.9.1.11-12 : Diet composition, carbofuran concentration in each food item and long-term TER value for the whole diet of wood pigeons feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha In-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	NOEC (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	0.69	1.14	0.33	0.26			
weed seeds	0.08	0	0.58	0			
cereal seeds	0.11	0	0.06	0			
arthropods	0.23	0	0.03	0			
Total				0.26	0.64	2.49	5

6.2.3 Black-headed gull :

Table B.9.1.11-13 : Diet composition, carbofuran concentration in each food item and acute TER value for the whole diet of black-headed gulls feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LD ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
earthworms	0.84	0.56	0.92	0.43			
arthropods	0.39	0	0.02	0			
cereal seeds	0.18	0	0.06	0			
Total				0.43	0.76	1.76	10

Table B.9.1.11-14 : Diet composition, carbofuran concentration in each food item and short-term TER value for the whole diet of black-headed gulls feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LC ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
earthworms	0.84	0.15	0.92	0.12			
arthropods	0.39	0	0.02	0			
cereal seeds	0.18	0	0.06	0			
Total				0.12	1.60	13.6	10

Table B.9.1.11-15 : Diet composition, carbofuran concentration in each food item and long-term TER value for the whole diet of black-headed gulls feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	NOEC (mg/kg b.w./day)	TER	Annex VI Trigger value
earthworms	0.84	0.095	0.92	0.074			
arthropods	0.39	0	0.02	0			
cereal seeds	0.18	0	0.06	0			
Total				0.074	0.64	8.69	5

Conclusions of the RMS on the risk assessment for birds :

The RMS has performed a deterministic worst-case risk assessment as required in the current guidance documents. The calculated TER values should be read in a balanced way considering the various sources of uncertainty of the input parameters and the worst-case assumptions that were used.

The higher tier risk assessment was based on :

- the following toxicological endpoints ($LD_{50} = 0.76$ mg carbofuran/kg b.w., $LC_{50} = 1.6$ mg carbofuran/kg b.w./day, $NOEC = 0.74$ mg carbofuran/kg b.w./day),
- measured residue levels in cabbage seedlings and earthworms,
- the determination of focal species by means of field surveys,
- PD refinement based on a literature search

The refined acute TER values (0.41, 0.86, 1.76) are below the trigger of 10 for the 3 focal species (namely crested lark, wood pigeon and black-headed gull).

The refined short-term TER values (1.13, 2.30) are below the trigger of 10 for the crested lark and wood pigeon. The refined short-term TER is 13.6 for black-headed gull.

The refined long-term TER values (1.21, 2.49) are below the trigger of 5 for the crested lark and wood pigeon. The refined long-term TER is 8.69 for black-headed gull.

Additional refinements of the risk such as the revision of the acute dose based on the opinion of the SCP on pirimicarb, the PT factor determined in a region of high cabbage production (Bretagne), the proportion of fields at the critical growth stage (seedlings at BBCH 12-19, with potentially high residue level) could be envisaged.

Cabbage represents 50 % of the vegetables in this region. Except in very restricted areas, cabbage fields represent less than 3.1 % of the total acreage used for agriculture. In regions with high cabbage production, the plantations are performed at regular intervals (from January to begin September in Northern France) in different fields in order to have a continuous production all the year round. In consequence, this figure should be further mitigated by the proportion of fields at the critical growth stage (seedlings at BBCH 12-19, with potentially high residue level).

This information was not yet taken into account for the TER calculations. RMS is of the opinion that such information can only be used as a weight of evidence approach, rather than for a quantitative risk assessment. This type of refinement could be envisaged at MS level in a region with high cabbage production.

B.9.2 Effects on aquatic organisms (fish, aquatic invertebrates, algae) (Annex IIA 8.2; Annex IIIA 10.2)

B.9.2.1 Acute toxicity of the active substance and metabolites, degradation or reaction products to fish (Annex IIA 8.2.1)

96-hour acute toxicity study in rainbow trout (*Oncorhynchus mykiss*) with Benfuracarb and [ring-¹⁴C] Benfuracarb (semi-static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.1."Acute toxicity for fish"

OECD Guideline for Testing of Chemicals No. 203:"Fish acute toxicity test"

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96, water solubility : 8 - 9 mg/L
[ring-¹⁴C]benfuracarb, radiochemical purity : > 99.0 %

Test species : rainbow trout (*Oncorhynchus mykiss*)

Number of organisms, weight, length : 7 fish per replicate, 1 replicate per treatment, 1.02 ± 0.14 g, 3.79 ± 0.23 cm. The fish loading was 0.71 g body weight/L (7 fish with mean body weight of 1.02 g in 10 L of test medium).

Type of test : 96 hours semi-static test, renewal of test solutions after each 24-hour test period

Applied and measured concentrations :

nominal : solvent control; 22/30, 46, 100, 220, 460 µg a.s./L

measured concentrations ranging from 67 - 79 % of the nominal concentrations

Due to the low solubility of benfuracarb in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 100 µL/L.

Test conditions :

temperature : 15.0 – 16.1 °C

pH : 8.5 – 8.7

oxygen content : 79 - 103 % O₂ saturation (7.9 – 10.3 mg O₂/L)

total hardness : 2.5 mmol/L (200 mg/L CaCO₃)

photoperiod : 16/8 hours light/dark cycle

Analytical methods : radioactivity measurements, TLC analysis

Findings :

Mortality : No fish died in the control group and in the treatment groups of 18 and 32 µg a.s./L. There was 29 % mortality observed in the treatment group of 75 µg a.s./L. In both treatments of 170 and 363 µg a.s./L 100 % mortality was observed. The LC₅₀ (96 h) of pentachlorophenol was 0.34 mg/L.

Behavioural observations : The fish in the control group and in the test groups of 18 and 32 µg a.s./L showed no abnormalities. In the treatment group of 75 µg a.s./L the surviving fish were hypoactive at the bottom of the tank and were snapping for air.

Conclusions :

The study is acceptable. Minor deviations occurred in recovery analysis and solution preparation.

Endpoints :

LC₅₀ (*Oncorhynchus mykiss*, 96 h) = 0.083 mg a.s./L (measured)

NOEC (*Oncorhynchus mykiss*, 96 h) = 0.032 mg a.s./L (measured)

96-hour acute toxicity study in bluegill sunfish (*Lepomis macrochirus*) with Benfuracarb and [ring-14C] Benfuracarb (semi-static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.1."Acute toxicity for fish"

OECD Guideline for Testing of Chemicals No. 203:"Fish acute toxicity test"

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96, water solubility : 8 - 9 mg/L
[ring-¹⁴C]benfuracarb, radiochemical purity : > 99.0 %

Test species : bluegill sunfish (*Lepomis macrochirus*)

Number of organisms, weight, length : 7 fish per replicate, 1 replicate per treatment, 0.86 ± 0.25 g, 3.28 ± 0.25 cm. The fish loading was 0.35 g body weight/L (7 fish with mean body weight of 0.86 g in 17 L of test medium).

Type of test : 96 hours semi-static test, renewal of test solutions after each 24-hour test period

Applied and measured concentrations :

nominal : solvent control; 4.6, 10, 22, 46, 100 µg a.s./L

measured concentrations ranging from 74 - 93 % of the nominal concentrations

Due to the low solubility of benfuracarb in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 100 µL/L.

Test conditions :

temperature : 21.5 – 22.7 °C

pH : 7.9 – 8.3

oxygen content : 60 – 109 % O₂ saturation (5.3 – 9.6 mg O₂/L)

total hardness : 2.5 mmol/L (200 mg/L CaCO₃)

photoperiod : 16/8 hours light/dark cycle

Analytical methods : radioactivity measurements, TLC analysis

Findings :

Mortality : No fish died in the control group and in the treatment group of 3.4 µg a.s./L. There was 29 % mortality observed in the treatment group of 8.6 µg a.s./L and 25 % mortality in the treatment group of 18 µg a.s./L. In both treatments of 39 and 93 µg a.s./L, 100 % mortality was observed.

Behavioural observations : The fish in the control group and in the test group of 3.4 µg a.s./L showed no abnormalities. In the treatment groups of 8.6 and 18 µg a.s./L the surviving fish were swimming hypoactive.

Conclusions :

The study is acceptable however the LC₅₀ (96 h) of pentachlorophenol was 0.41 mg/L. The bluegill sunfish originating from this batch can be considered as relatively insensitive to toxic substances. Minor deviations occurred in recovery analysis.

Endpoints :

LC₅₀ (*Lepomis macrochirus*, 96 h) = 0.017 mg a.s./L (measured)

NOEC (*Lepomis macrochirus*, 96 h) = 0.0034 mg a.s./L (measured)

96-hour acute toxicity study in rainbow trout (*Salmo gairdneri*) with Carbofuran (semi-static). (Douglas M.T., Handley J.W., Macdonald I.A., 1987).

Guidelines :

OECD Guideline for Testing of Chemicals No. 203: "Fish acute toxicity test"

EPA Test Guideline No. EG-9

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 96.7 %, batch n° : 6M 11

Test species : rainbow trout (*Salmo gairdneri* or *Oncorhynchus mykiss*)

Number of organisms, weight, length : 10 fish per replicate, 2 replicates per treatment, 1.8 g (SD = 0.5 g), 5.1 cm (SD = 0.54 cm). The fish loading was 0.45 g body weight/L (10 fish with mean body weight of 1.8 g in 40 L of test medium).

Type of test : 96 hours semi-static test, renewal of test solutions after each 24-hour test period

Applied and measured concentrations :

nominal : control; solvent control; 0.10, 0.18, 0.32, 0.56, 1.0 mg carbofuran/L

measured concentrations ranging from 88 – 142 % of the nominal concentrations

Due to the low solubility of carbofuran in water a solubilising agent was used to prepare stock solutions. The maximum amount of Tween 80-acetone in the final test solutions was 50 µL/L.

Test conditions :

temperature : 12.0 °C

pH : 7.8 – 8.6

oxygen content : 79 - 102 % O₂ saturation (8.5 – 10.9 mg O₂/L)

total hardness : 350 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle

Analytical methods : gas chromatography

Findings :

Mortality : In one replicate of the control treatment 10 % mortality was observed. In the other replicate of the control and in both replicates of the solvent control no mortality occurred. No fish died at test concentrations up to 0.32 mg/L. 10 % mortality was recorded in both replicates of 0.56 mg/L. 80 % mortality was observed in both replicates of 1 mg/L.

Behavioural observations : Marked reactions to exposure were increased pigmentation, loss of equilibrium, swimming at the surface and lethargy from test concentrations of 0.10 up to 1.0 mg/L.

Conclusions :

The study is acceptable.

Endpoints :

LC₅₀ (*Oncorhynchus mykiss*, 96 h) = 0.82 mg carbofuran/L (nominal)

NOEC (*Oncorhynchus mykiss*, 96 h) < 0.10 mg carbofuran/L (nominal)

96-hour acute toxicity study in bluegill sunfish (*Lepomis macrochirus*) with Carbofuran (semi-static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.1."Acute toxicity for fish"

OECD Guideline for Testing of Chemicals No. 203:"Fish acute toxicity test"

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 99.9 %, batch n° : 1B87

Test species : bluegill sunfish (*Lepomis macrochirus*)

Number of organisms, weight, length : 7 fish per replicate, 1 replicate per treatment, 0.46 ± 0.10 g, 2.7 ± 0.23 cm. The fish loading was 0.64 g body weight/L (7 fish with mean body weight of 0.46 g in 5 L of test medium).

Type of test : 96 hours semi-static test, renewal of test solutions after each 24-hour test period

Applied and measured concentrations :

nominal : control; solvent control; 0.10, 0.18, 0.32, 0.56, 1.0 mg carbofuran/L

measured concentrations ranging from 94 – 133 % of the nominal concentrations

Due to the low solubility of carbofuran in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 100 μ L/L.

Test conditions :

temperature : 20.8 – 21.5 °C

pH : 7.0 – 7.4

oxygen content : 62 - 110 % O₂ saturation (5.6 – 9.9 mg O₂/L)

total hardness : 2.5 mmol/L (200 mg/L CaCO₃)

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC

Findings :

Mortality : No mortality was observed in the control, solvent control and the 0.10 mg/L test group. At 0.18 mg/L 43 % mortality was recorded. From test concentration 0.32 mg/L onwards 100 % mortality occurred.

Behavioural observations : The fish in the control and solvent control showed no abnormalities. Clinical effects such as discoloration, hypoactive swimming, snapping at the surface and loss of equilibrium were observed from test concentration of 0.10 up to 0.32 mg/L.

Conclusions :

The study is acceptable however the LC₅₀ (96 h) of pentachlorophenol was 0.41 mg/L. The bluegill sunfish originating from this batch can be considered as relatively insensitive to toxic substances.

Endpoints :

LC₅₀ (*Lepomis macrochirus*, 96 h) = 0.18 mg carbofuran/L (nominal)

NOEC (*Lepomis macrochirus*, 96 h) < 0.10 mg carbofuran/L (nominal)

96-hour acute toxicity study in bluegill sunfish (*Lepomis macrochirus*) with Carbofuran-7-phenol (semi-static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.1."Acute toxicity for fish"

OECD Guideline for Testing of Chemicals No. 203:"Fish acute toxicity test"

GLP :

Yes

Material and Methods :

Test substance : 7-phenol, chemical purity : 99.8 %, batch n° : 10222AS

Test species : bluegill sunfish (*Lepomis macrochirus*)

Number of organisms, weight, length : 7 fish per test vessel, 1 replicate per treatment, 0.46 ± 0.10 g, 2.7 ± 0.23 cm. The fish loading was 0.64 g body weight/L (7 fish with mean body weight of 0.46 g in 5 L of test medium).

Type of test : 96 hours semi-static, renewal of test solutions after each 24-hour test period

Applied and measured concentrations :

nominal : control; 10, 18, 32, 56, 100 mg 7-phenol/L

measured concentrations ranging from 76 – 105 % of the nominal concentrations

Test conditions :

temperature : 20.2 – 22.0 °C

pH : 7.0 – 8.0

oxygen content : 62 - 109 % O₂ saturation (5.6 – 9.8 mg O₂/L)

total hardness : 2.5 mmol/L (200 mg/L CaCO₃)

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC

Findings :

Mortality : No mortality was observed in the control and in the treatment groups up to 56 mg/L. All fish died in the treatment group of 100 mg/L.

Behavioural observations : All fish of the treatment groups of 32 and 56 mg/L were discoloured. After 2 hours all fish in the test group of 100 mg/L showed loss of equilibrium.

Conclusions :

The study is acceptable however the LC₅₀ (96 h) of pentachlorophenol was 0.41 mg/L. The bluegill sunfish originating from this batch can be considered as relatively insensitive to toxic substances.

Endpoints :

LC₅₀ (*Lepomis macrochirus*, 96 h) = 75 mg 7-phenol/L (nominal)

NOEC (*Lepomis macrochirus*, 96 h) = 18 mg 7-phenol/L (nominal)

B.9.2.2 Fish early life stage toxicity (Annex IIA 8.2.2.1)

A fish juvenile growth test is available.

B.9.2.3 Fish juvenile growth test (Annex IIA 8.2.2.2)

A study on the juvenile growth inhibition of Carbofuran to fresh water fish (rainbow trout, *Oncorhynchus mykiss*). (Egeler Ph., Gilberg D., Baumann J., 2002).

Guidelines :

OECD Guideline for Testing of Chemicals, No. 215: “Fish, Juvenile Growth Test”

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 97.6 %, batch n° : 1H25

Test species : rainbow trout (*Oncorhynchus mykiss*)

Number of organisms, weight : 12 fish per replicate, 1 replicate per treatment, 2 replicates for the control, 1.01 – 1.09 g. The fish loading was 0.72 g body weight/L.

Type of test : 28 day flow-through test, the turn-over rate was at least 6 L per g fish per day

Applied and measured concentrations :

nominal : control; 8.7, 24.0, 66.1, 181.8, 500.0 µg carbofuran/L

measured concentrations ranging from 68.8 – 95.4 % of the nominal concentrations

Test conditions :

temperature : 14.0 – 15.5 °C

pH : 6.9 – 7.2

oxygen content : 80 – 104 % O₂ saturation (8.1 – 10.3 mg O₂/L)

total hardness : 244.5 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC/Fluorescence

Findings :

Mortality: After 28 d there was 8.3 % mortality in the control treatment. No mortality occurred in the treatment group of 8.7 µg/L. After 28 d the mortality in the treatment groups 24.0, 66.1, 181.8 and 500.0 µg/L was 16.7 %, 8.3 %, 83.3 % and 100 % respectively.

Behavioural observations : In all concentration levels, behavioural differences from the control were observed such as different swimming activities and decreased feeding activities. Differences in tank-average specific growth rate compared to the control were observed at test concentration of 181.8 µg/L. Differences in “pseudo” specific growth rate compared to the control were observed at test concentration of 181.8 µg/L. Reduction of weight was 33.1 % at the highest concentration with fish alive at the end of the test (181.8 µg/L). At all concentrations tested up to the highest concentration tested with fish alive at the end of the test (181.8 µg/L) there was a reduction of length ranging from 1.8 to 14.7 %.

Conclusions :

The study is acceptable. Minor deviations occurred in recovery analysis.

Endpoints :

LC₅₀ (*Oncorhynchus mykiss*, 28 d) = 0.0963 mg carbofuran/L (nominal)

NOEC (*Oncorhynchus mykiss*, 28 d) based on mortality = 0.0087 mg carbofuran/L (nominal)

NOEC (*Oncorhynchus mykiss*, 28 d) based on behaviour < 0.0087 mg carbofuran/L (nominal)

NOEC (*Oncorhynchus mykiss*, 28 d) based on tank-average specific growth rate = 0.0661 mg carbofuran/L (nominal)

NOEC (*Oncorhynchus mykiss*, 28 d) based on “pseudo” specific growth rate = 0.0661 mg carbofuran/L (nominal)

EC₅₀ (*Oncorhynchus mykiss*, 28 d) based on weight = 0.2299 mg carbofuran/L (nominal)

The overall NOEC is lower than 0.0087 mg carbofuran/L. In order to define a NOEC a fish early life stage toxicity study should be performed at lower concentrations.

Added in August 2008

Rainbow trout, juvenile growth test - 28 days with Carbofuran (flow-through). (Migchielsen M.H.J., 2005).

Guidelines :

OECD Guideline for Testing of Chemicals, No. 215: "Fish, Juvenile Growth Test"

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : > 98 %, batch n° : 4I20

Test species : rainbow trout (*Oncorhynchus mykiss*)

Number of organisms, weight : 16 fish per replicate, 1 replicate per treatment, 1.92 – 5.53 g.

The fish loading was 0.19 g body weight/L/day at start of the test.

Type of test : 28 day flow-through test, the renewal flow rate was 12 L/hour/treatment

Applied and measured concentrations :

nominal : control; 1.0, 2.2, 4.8, 10, 22 µg carbofuran/L

measured concentrations ranging from 80 - 122.5 % of the nominal concentrations

Test conditions :

temperature : 14.4 – 15.3 °C

pH : 7.7 - 8.1

oxygen content : 75 – 107 % O₂ saturation (7.6 – 10.9 mg O₂/L)

total hardness : 1.2 mmol/L

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC with spectrophotometric detection (wavelength 281 nm)

Findings :

Mortality: After 28 days there was no mortality in the control treatment. No mortality occurred in the treatment groups of 2.2 and 4.8 µg carbofuran/L. After 28 days the mortality in the treatment groups 1.0, 10 and 22 µg carbofuran/L was 1/16, 2/16 (+1/16 euthanased) and 1/16 (euthanased) respectively. The two fish that were euthanased were observed to be discoloured and missing their tail fin. This last feature is probably due to aggressive behaviour of other fish which is probably not treatment-related.

Behavioural observations : There were no changes in behaviour related to slow swimming, decreased feeding or changed respiration of the fish. There were no visible treatment-related effects in any of the carbofuran treated groups.

Body weight, body length:

Table B.9.2.3-1 : Fish body weight, growth rate and fish body length

Evaluation criteria	Nominal test concentration (μg carbofuran/L)					
	Control	1.0	2.2	4.8	10	22
Average fish weight (0 d)	3.31 \pm 0.74	3.43 \pm 0.82	3.48 \pm 0.66	3.47 \pm 0.69	3.45 \pm 0.71	3.43 \pm 0.78
Average fish weight (14 d)	4.71 \pm 1.27	4.60 \pm 0.91	4.92 \pm 0.99	4.86 \pm 1.26	4.62 \pm 1.06	4.82 \pm 1.13
Average fish weight (28 d)	6.75 \pm 1.71	5.91 \pm 1.47	6.26 \pm 1.30	6.82 \pm 2.02	6.37 \pm 1.43	6.43 \pm 1.59
% increase on day 28	204	172	180	197	185	187
Average growth rate (0-14 d)	2.297 \pm 0.438	1.954 \pm 0.366	2.319 \pm 0.382	2.151 \pm 0.536	1.894 \pm 0.449	2.240 \pm 0.442
Average growth rate (0-28 d)	2.440 \pm 0.216	1.836 \pm 0.235	2.018 \pm 0.192	2.209 \pm 0.352	2.091 \pm 0.259	2.136 \pm 0.233
Average length (at 0 d)	5.71 \pm 0.43	5.81 \pm 0.41	5.78 \pm 0.41	5.76 \pm 0.30	5.71 \pm 0.54	5.73 \pm 0.41
Average length (at 28 d)	7.34 \pm 0.62	6.93 \pm 0.67	7.11 \pm 0.52	7.29 \pm 0.82	7.15 \pm 0.63	7.11 \pm 0.58

Conclusions :

The study is acceptable.

Endpoints :

LC₅₀ (*Oncorhynchus mykiss*, 28 d) > 0.022 mg carbofuran/L (nominal)

NOEC (*Oncorhynchus mykiss*, 28 d) based on body weight, body length, behaviour = 0.022 mg carbofuran/L (nominal)

Benfuracarb – statement on the NOEC of Carbofuran in juvenile growth testing. (de Roode D.F., 2007).

The outcome of the two studies that have been submitted by Otsuka differs: changes in fish behaviour were noted at 8.7 μg carbofuran/L and above in the first study, none in the second study at concentrations up to and including 22 μg carbofuran/L.

The only remarkable difference in the performance and conduct of the two studies, that could explain the different outcomes, is the size of the fish. The mean fish weight at the beginning of the test was 1.01-1.07 g in study 1, but 3.43 g in study 2. The OECD 215 guideline (2000) recommends the fish weight to be in the range 1-5 g. The much smaller trouts in the first study are likely to have been more sensitive to carbofuran than the larger ones in the second.

The notifier considered that “the conduct of another juvenile growth test with fish weighing 1.0 g is not desirable nor advisable. Firstly, the sacrifice of more vertebrates to generate a test result, where the results of two valid guideline compliant tests are already available, should be avoided. The Animal Ethical Commission may not give permission for such a test, since all possible ways to address the issue have not been explored.

Secondly, in study 1, fish weights encompassed a very narrow range, near the lower limit of what is acceptable according to the guideline. If a study is to be repeated using fish of almost the same weight (1.0 g), it would probably be necessary to select the smaller fish from a population with greater variation in fish weight. This selection would not be impartial, and would render the study validity questionable. “

The notifier therefore proposed to revise the NOEC in the study by Egeler Ph., Gilberg D., Baumann J. (2002) and to base the overall chronic endpoint on an EC₁₀ estimation of the behavioural effects (reduced swimming (E) activity, changes in ventilation rate and respiration (I)).

Observation K (reduced feeding activity) was only observed on one single occasion at 8.7 µg carbofuran/L, namely on day 2. The notifier has considered that this unique occurrence early in the study of a symptom also observed in untreated fish is not treatment related. The NOEC for symptom K may be set at 8.7 µg carbofuran/L.

Data processing :

Observation E and I were considered separately. For every study day, the number of fish for which a particular observation was made, was divided by the number of live fish present on that day. This gave the incidence per day, expressed as a fraction. The average incidence over the study period was then calculated by summing up the incidences for all study days, and dividing by the number of study days. Multiplication of this value by 100 gave the average percentage incidence.

Hence, $Y = 100 * (B1 + B2 + \dots + Bn) / n$

Where:

Y = percent overall mean incidence of abnormal behaviour B

Bx = no. of fish with abnormal behaviour B on study day x / total no. of live fish on study day x

n = total no. of study days.

The concentration data were log-transformed. Observation E was also observed in the control, and log-transformation of a value of 0 is not possible. To account for the observations in the control, the incidences of observation E in the test item groups were corrected for the incidence in the control (average of two replicates) using the Abbot formula (Abbot, 1925 [4]):

$P = 100 * (Y - Z) / (100 - Z)$

Where:

P = corrected percent overall mean incidence of abnormal behaviour

Y = mean % effect per live fish/day (treated)

Z = mean % effect per live fish/day (control)

EC₁₀ for reduced swimming activity :

The notifier has provided results of the regression analysis based on test concentrations up to and including 500 µg carbofuran/L. A good first order fit was obtained (r^2 0.97). The EC₁₀ was 5.39 µg carbofuran/L. As the dose response curve levelled off at the highest test concentration, the EC₁₀ was also calculated after omission of this data point. Omitting the result for the highest test concentration gave a slightly higher EC₁₀ (6.44 µg carbofuran/L), with a comparable fit (r^2 0.96).

EC₁₀ for changes in ventilation rate and respiration :

The notifier has provided results of the regression analysis. A reasonable first order fit was obtained (r^2 0.90). The EC₁₀ was 6.55 µg carbofuran/L. This is considered to be a conservative value, since it was based on the data for 8.7 - 66 µg carbofuran/L, and there was no dose-response in the range 24 - 500 µg carbofuran/L i.e. a plateau had been reached. This would justify EC-calculation based on the data for 8.7 and 24 µg carbofuran/L only, which would have given a higher EC₁₀ value (8.58 µg carbofuran/L).

Table B.9.2.3-2 : Observed behavioural differences of fish compared to the control animals as sum of the observations throughout the exposure phase; numbers indicate number of affected fish; K: numbers indicate number of occasions behaviour observed

Concentration µg/L	symptom:								sum per treatment	dead
	A	B	C	D	E	I	J	K		
0	2	0	0	0	42	0	0	0	44	1
0	0	0	0	0	39	0	0	0	39	1
8.7	0	0	0	0	77	36	0	1	114	0
24.0	7	1	0	0	194	259	0	7	468	2
66.1	1	0	0	39	212	293	0	6	551	1
181.8	9	0	1	0	159	126	3	27	325	10
500.0	37	0	1	0	100	71	7	25	241	12

- A: Fish were lying on the bottom of the test vessel.
 B: Fish were swimming on the lateral side (loss of equilibrium).
 C: Fish were swimming upside down.
 D: Fish were showing enhanced swimming activity compared to the control.
 E: Fish were showing reduced swimming activity compared to the control.
 I: Fish were showing changes in ventilation rate and respiration.
 J: Fish were showing curved spine.
 K: Fish were showing reduced feeding activity.

Discussion :

Reduced swimming activity is a phenomenon which is also observed in populations of untreated fish. In study 1, it was recorded 39 - 42 times as an observation in both control replicates during the study (although the report stated that this observation was made in comparison with the control). In order to avoid this observation being unnecessarily recorded as an effect, it is advisable to tap the wall of the fish tank prior to observing the fish. This procedure however was not followed during study 1 (communication from Study Director). The toxicological relevance of this parameter is therefore doubtful, in particular at those test concentrations where the incidences that are recorded are of a comparable order of magnitude to those in the control. For these reasons, the EC₁₀ values for this observation (5.39 - 6.44 µg carbofuran/L) should be treated with caution. Changes in ventilation rate and respiration are considered to be the most critical and sensitive endpoint, and this behaviour was not observed in the control. The EC₁₀ for this parameter (6.55 µg carbofuran/L) is considered to be a more robust and toxicologically relevant value. It is proposed to set the EC₁₀ (and hence the overall NOEC) for 28-day juvenile fish testing at 6.55 µg carbofuran/L.

Conclusion of the notifier :

The overall NOEC in 28-day juvenile fish testing is proposed to be 6.55 µg carbofuran/L, i.e. equivalent to the EC₁₀ for fish observations (changes in ventilation rate and respiration). This is supported by the results of study 2, in which the NOEC was determined to be higher (22 µg carbofuran/L).

Conclusion of the RMS on the establishment of the chronic fish endpoint :

There were 4 acceptable chronic fish studies that have been submitted by Otsuka (benfuracarb dossier) and by FMC (carbofuran dossier).

The RMS considers that the information on chronic toxicity to fish is sufficient to perform the risk assessment. For the TER calculations, we have considered that the figure of 0.00655 mg carbofuran/L that has been proposed by Otsuka is equivalent to the worst case NOEC (0.006 mg carbofuran/L) of the entire database on carbofuran.

Table B.9.2.3-3 : Summary of acceptable chronic fish studies with carbofuran

Test species	Test substance	Test system	Endpoints	References
<i>Oncorhynchus mykiss</i>	carbofuran	28 d juvenile	NOEC < 0.0087 mg/L (nominal) EC ₁₀ (behaviour) = 0.00655 mg/L (nominal)	Egeler Ph., Gilberg D., Baumann J., 2002 (dossier benfuracarb Otsuka)
<i>Oncorhynchus mykiss</i>	carbofuran	28 d juvenile	NOEC = 0.022 mg/L (nominal)	Migchielsen, M.H.J., 2005 (dossier benfuracarb Otsuka)
<i>Oncorhynchus mykiss</i>	carbofuran	90 d fish early life stage	NOEC = 0.0248 mg/L (nominal)	McAllister W.A., 1981 (dossier carbofuran FMC)
<i>Cyprinodon variegatus</i>	carbofuran	35 d fish early life stage	NOEC = 0.006 mg/L (mean measured)	Boeri R.L., Ward T.J., 1994 (dossier carbofuran FMC)

B.9.2.4 Fish life cycle test (Annex IIA 8.2.2.3)

Not required.

B.9.2.5 Bioaccumulation potential in fish (Annex IIA 8.2.3)

The assessment of bioaccumulation of ^{14}C -Benfuracarb in rainbow trout (*Oncorhynchus mykiss*). (Hawkins D.R., Mayo B.C., Sykes A., Douglas M., 1989).

Guidelines :

OECD Guideline for Testing of Chemicals, No. 305: "Bioconcentration: Flow-through Fish Test"

GLP :

Yes

Material and Methods :

Test substance : ^{14}C -benfuracarb, radiochemical purity : 96 %

Test species : rainbow trout (*Oncorhynchus mykiss*)

Number of organisms, weight, length, age : 50 fish per replicate, 1 replicate per treatment, 7.18 ± 1.78 g, 7.6 ± 0.5 cm, approximately 1 year old

Type of test : bioaccumulation test (6 days exposure period, 12 days depuration period) in a flow-through system

Applied and measured concentrations :

nominal : solvent control; 0.6, 6.0 $\mu\text{g a.s./L}$

measured concentrations ranging from 68 - 167 % of the nominal concentrations (mean recovery 102 %)

Test conditions :

temperature : 14.0 – 14.5 °C

pH : 8.0 – 8.1

oxygen content : 89 - 98 % O_2 saturation (9.3 – 10.2 mg O_2/L)

photoperiod : 16/8 hours light/dark cycle

Analytical methods : radioactivity measurements (LSC), TLC analysis

Findings :

Table B.9.2.5-1 : Bioaccumulation potential of benfuracarb in fish

	Water		Fillet (edible part)		Viscera (non-edible part)		Whole fish	
	0.6 µg/L	6.0 µg/L	0.6 µg/L	6.0 µg/L	0.6 µg/L	6.0 µg/L	0.6 µg/L	6.0 µg/L
Mean residue concentration during 6 days exposure period	0.62 ± 0.19 µg/L	6.1 ± 0.96 µg/L	0.016-0.026 µg eq/g	0.24 - 0.32 µg eq/g	0.039 - 0.081 µg eq/g	0.44 - 0.68 µg eq/g	0.025 - 0.045 µg eq/g	0.33 - 0.40 µg eq/g
Mean residue concentration after depuration	< 0.2 µg/L	< 0.3 µg/L	0.001 µg eq/g after 1 day	< 0.002 µg eq/g after 12 days	0.001 µg eq/g after 3 days	0.005 µg eq/g after 12 days	0.006 µg eq/g after 1 day	< 0.002 µg eq/g after 12 days
Depuration rate constant k_1 (days)*	-	-	-	2.61	-	1.43	-	1.58
Half-life $t_{1/2}$ (days)*	-	-	-	0.27	-	0.48	-	0.44
Depuration rate constant k_2 (days)*	-	-	-	0.067	-	0.067	-	0.067
Half-life $t_{1/2}$ (days)*	-	-	-	10	-	10	-	10
BCF _{SS} (exposure)	-	-	20 - 48	45	61 - 172	96	38 - 90	61

* biphasic depuration curve

Radioactivity in viscera and fillet samples were too low for extraction at test concentration of 0.6 µg/L.

Table B.9.2.5-2 : Proportions of radioactive components extracted by dichloromethane and methanol, TLC determination

Components	% radioactivity (mean of days 2, 4 and 6)	
	Fillet (edible part)	Viscera (non-edible part)
Component A (polar)	8	44
Component B	4	2
3-hydroxy-carbofuran-phenol	22	-
3-hydroxy-carbofuran and N-hydroxymethyl-carbofuran	39	27
carbofuran	-	9
7-phenol	14	2
benfuracarb	-	3
3-keto-carbofuran-phenol	2	-
Others	6	5

Conclusions :

The study is acceptable.

The maximum BCF was 48 in fillet, 172 in viscera and 90 in the whole fish.

The depuration half-lives in the whole fish were 0.44 days and 10 days (k_1 and k_2).

Exploring QSAR, Hydrofobic, electronic and steric constants. (Hansch C., Leo A., Hoekman D., 1995).

The study is not acceptable. The list of QSAR from the open literature cannot be used in the final assessment.

B.9.2.6 Acute toxicity to aquatic invertebrates (Annex II A 8.2.4)

Acute toxicity study in *Daphnia magna* with Benfuracarb and [ring-¹⁴C]Benfuracarb (static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.2. "Acute Toxicity for *Daphnia*"

OECD Guideline for Testing of Chemicals, No. 202 Part I: "*Daphnia sp.*, Acute Immobilisation Test"

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96, water solubility : 8 – 9 mg/L
[ring-¹⁴C]benfuracarb, radiochemical purity : > 99.0 %

Test species : *Daphnia magna*

Number of organisms, age : 10 daphnids per replicate, 2 replicates per treatment, less than 24 hours old

Type of test : 48 hours static toxicity test

Applied and measured concentrations :

nominal : control; solvent control; 2.2, 4.6, 10, 22, 46 µg a.s./L

measured concentrations ranging from 78 - 83 % of the nominal concentrations

Due to the low solubility of benfuracarb in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 83 µL/L.

Test conditions :

temperature : 19.7 – 20.4 °C

pH : 7.7 – 8.0

oxygen content : 93 - 99 % O₂ saturation (8.6 – 9.1 mg O₂/L)

total hardness : 250 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle

Analytical methods : radioactivity measurement, TLC analysis

Findings :

Mortality : No immobilization was observed in the control, the solvent control and the treatments up to 3.9 µg a.s./L. At 8.8 µg a.s./L an immobilization of 20 % and 30 % was observed in the respective replicates. 100 % immobilization occurred in the treatment groups of 19 and 40 µg a.s./L. The EC₅₀ (48 h) of potassium dichromate was 0.55 mg/L.

Conclusions :

The study is acceptable.

Endpoints :

EC₅₀ (*Daphnia magna*, 48 h) = 0.0099 mg a.s./L (measured)

NOEC (*Daphnia magna*, 48 h) = 0.0039 mg a.s./L (measured)

Acute toxicity study in *Daphnia magna* with Carbofuran (static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.2. "Acute Toxicity for *Daphnia*"

OECD Guideline for Testing of Chemicals, No. 202 Part I: "*Daphnia sp.*, Acute Immobilisation Test"

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 99.9 %, batch n° : 1B87

Test species : *Daphnia magna*

Number of organisms, age : 10 daphnids per replicate, 2 replicates per treatment, less than 24 hours old

Type of test : 48 hours static toxicity test

Applied and measured concentrations :

nominal : control; solvent control; 7, 10, 18, 32, 56 µg carbofuran/L

measured concentrations ranging from 92 – 117 % of the nominal concentrations

Due to the low solubility of carbofuran in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 100 µL/L.

Test conditions :

temperature : 19.7 – 20.2 °C

pH : 6.9 – 7.6

oxygen content : 75 - 100 % O₂ saturation (6.9 – 9.2 mg O₂/L)

total hardness : 250 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC

Findings :

Mortality : No immobilization was observed in the control, the solvent control and the 7 µg/L treatment. At 10 µg/L 80 % and 50 % immobility was observed in the respective replicates. From 18 µg/L and higher test concentrations 100 % immobilization occurred. The EC₅₀ (48 h) of potassium dichromate was 0.55 mg/L.

Conclusions :

The study is acceptable.

Endpoints :

EC₅₀ (*Daphnia magna*, 48 h) = 0.0094 mg carbofuran/L (nominal)

NOEC (*Daphnia magna*, 48 h) = 0.007 mg carbofuran/L (nominal)

Acute toxicity study in *Daphnia magna* with Carbofuran-7-phenol (static). (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.2. "Acute Toxicity for *Daphnia*"

OECD Guideline for Testing of Chemicals, No. 202 Part I: "*Daphnia sp.*, Acute Immobilisation Test"

GLP :

Yes

Material and Methods :

Test substance : 7-phenol, chemical purity : 99.5 %, batch n° : 1B88

Test species : *Daphnia magna*

Number of organisms, age : 10 daphnids per replicate, 2 replicates per treatment, less than 24 hours old

Type of test : 48 hours static toxicity test

Applied and measured concentrations :

nominal : control; 10, 18, 32, 56, 100 mg 7-phenol/L

measured concentrations ranging from 100 - 117 % of the nominal concentrations

Test conditions :

temperature : 18.9 – 19.2 °C

pH : 8.0 – 8.1

oxygen content : 94 - 103 % O₂ saturation (8.8 – 9.1 mg O₂/L)

total hardness : 250 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC

Findings :

Mortality : No immobilization occurred in the control and in the treatment groups up to 18 mg/L. At 32 mg/L 100 % and 90 % immobilization was observed in the respective replicates. At both test concentrations of 56 and 100 mg/L an immobilization of 100 % was observed. The EC₅₀ (48 h) of potassium dichromate was 0.55 mg/L.

Conclusions :

The study is acceptable.

Endpoints :

EC₅₀ (*Daphnia magna*, 48 h) = 25 mg 7-phenol/L (nominal)

NOEC (*Daphnia magna*, 48 h) = 18 mg 7-phenol/L (nominal)

B.9.2.7 Chronic toxicity to aquatic invertebrates (Annex IIA 8.2.5)

Benfuracarb degrades rapidly to the major metabolite Carbofuran. Therefore chronic toxicity to aquatic invertebrates is tested with Carbofuran.

A study on the chronic toxicity of Carbofuran to *Daphnia magna*. (Egeler Ph., Gilberg D., Baumann J., 2002).

Guidelines :

OECD Guideline for Testing of Chemicals, No. 211: “*Daphnia magna*, Reproduction test”

GLP :

Yes

Material and Methods :

Test substance: carbofuran, chemical purity : 97.6 %, batch n° : 1H25

Test species: *Daphnia magna*

Number of organisms, age : 1 daphnid per replicate, 10 replicates per treatment, less than 24 hours old

Type of test : 21 day semi-static toxicity test

Applied and measured concentrations :

nominal : control; 0.205, 0.512, 1.28, 3.2, 8.0, 20.0 µg carbofuran/L

measured concentrations ranging from 88 – 103 % of the nominal concentrations

Test conditions :

temperature : 20.38 – 20.48 °C

pH : 7.21 – 7.28

oxygen content : 97 – 99 % O₂ saturation (8.96 – 9.07 mg O₂/L)

total hardness : 306 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle

Analytical methods : HPLC/Fluorescence

Findings:

Table B.9.2.7-1 : Major effects of carbofuran observed during the reproduction study of *Daphnia magna*

	Nominal test concentration (µg/L)						
	control	0.205	0.512	1.28	3.2	8.0	20.0
% mortality of parental <i>Daphnia magna</i>	10	0	10	10	10	0	10
mean cumulative number of born juveniles per surviving female	160.7	174.5	144.9	169.9	150.0	155.4	146.6
mean cumulative number of dead juveniles per surviving female	1	0.78	0.22	1.22	2.22	1.33	17.22*
mean length of surviving adults at day 21 (mm)	4.17	4.41*	4.19	4.34	4.23	4.32	4.35

Conclusions:

The study is acceptable.

No significant effects were observed for the mean cumulative number of born juveniles per surviving female compared to the control. A significant difference was noted for the mean cumulative number of dead juveniles per surviving female for the test concentration of 20 µg/L compared to the control. There were no treatment-related effects observed for the mean length of the surviving adults at day 21.

Endpoints :

NOEC (*Daphnia magna*, 21 d) based on the number of dead juveniles per surviving female = 0.008 mg carbofuran/L (nominal)

B.9.2.8 Effects on algal growth (Annex IIA 8.2.6)

Fresh water algal growth inhibition test (*Selenastrum capricornutum*) with Benfuracarb. (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, C-3: "Algal Inhibition Test"

OECD Guideline for Testing of Chemicals, No. 201: "Algae, Growth Inhibition Test"

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96, water solubility : 8 – 9 mg/L

Test species : green alga (*Selenastrum capricornutum* or *Pseudokirchneriella subcapitata*)

Number of replicates, initial cell density : 6 replicates per treatment, 1 x 10⁴ cells/mL

Type of test : 72 hours static toxicity test

Applied and measured concentrations :

Due to the low solubility of benfuracarb in water the solutions with the test substance were prepared at the limit of solubility. The average exposure concentration over the 72-hour test period was 2.2 mg a.s./L.

Test conditions :

temperature : 23.0 – 24.1 °C

pH : 7.9 – 9.3

light : continuous, 60 – 82 µE.m⁻².s⁻¹

Analytical methods : HPLC

Findings and conclusions :

The study is acceptable. The E_bC₅₀ (72 h) of potassium dichromate was 0.64 mg/L and the E_rC₅₀ (72 h) of potassium dichromate was 0.96 mg/L.

No inhibitory effects were observed at test concentration of 2.2 mg a.s./L. The EC₅₀ for inhibition of algal cell growth and reduction of growth rate exceeded the maximum solubility limit in test medium.

Endpoints :

EC₅₀ (*Pseudokirchneriella subcapitata*, 72 h) > 2.2 mg a.s./L (measured)

NOEC (*Pseudokirchneriella subcapitata*, 72 h) = 2.2 mg a.s./L (measured)

Fresh water algal growth inhibition test (*Selenastrum capricornutum*) with Carbofuran. (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, C-3: “Algal Inhibition Test”

OECD Guideline for Testing of Chemicals, No. 201: “Algae, Growth Inhibition Test”

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 99.9 %, batch n° : 1B87

Test species : green alga (*Selenastrum capricornutum* or *Pseudokirchneriella subcapitata*)

Number of replicates, initial cell density : 3 replicates per treatment, 1×10^4 cells/mL

Type of test : 72 hours static toxicity test

Applied and measured concentrations :

nominal : control; solvent control; 2.2, 4.6, 10, 22, 46, 100 mg carbofuran/L

measured concentrations ranging from 57 - 82 % of the nominal concentrations after 3 days

Due to the low solubility of carbofuran in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 100 µL/L.

Test conditions :

temperature : 22.0 – 23.0 °C

pH : 7.2 – 8.7

light : continuous, 79 – 98 µE.m⁻².s⁻¹

Analytical methods : HPLC

Findings and conclusions :

The study is acceptable. The E_bC₅₀ (72 h) of potassium dichromate was 0.83 mg/L and the E_rC₅₀ (72 h) of potassium dichromate was 1.6 mg/L.

Endpoints :

E_bC₅₀ (*Pseudokirchneriella subcapitata*, 72 h) = 6.5 mg carbofuran/L (measured)

E_rC₅₀ (*Pseudokirchneriella subcapitata*, 72 h) = 19 mg carbofuran/L (measured)

NOEC (*Pseudokirchneriella subcapitata*, 72 h) = 1.9 mg carbofuran/L (measured)

Fresh water algal growth inhibition test (*Selenastrum capricornutum*) with Carbofuran-7-phenol. (Migchielsen M.H.J., 2002).

Guidelines :

EEC Directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, C-3: “Algal Inhibition Test”

OECD Guideline for Testing of Chemicals, No. 201: “Algae, Growth Inhibition Test”

GLP :

Yes

Material and Methods :

Test substance : 7-phenol, chemical purity : 99.5 %, batch n° : 1B88

Test species : green alga (*Selenastrum capricornutum* or *Pseudokirchneriella subcapitata*)

Number of replicates, initial cell density : 3 replicates per treatment, 6 replicates for the control group, 1×10^4 cells/mL

Type of test : 72 hours static toxicity test

Applied and measured concentrations :

nominal : control; 10, 18, 32, 56, 100 mg 7-phenol/L

measured concentrations ranging from 96 - 104 % of the nominal concentrations

Test conditions :

temperature : 22.2 – 23.0 °C

pH : 8.1 – 9.9

light : continuous, 77 – 99 $\mu\text{E}\cdot\text{m}^{-2}\cdot\text{s}^{-1}$

Analytical methods : HPLC

Findings and conclusions :

The study is acceptable. The E_bC_{50} (72 h) of potassium dichromate was 0.83 mg/L and the E_rC_{50} (72 h) of potassium dichromate was 1.6 mg/L.

Endpoints :

E_bC_{50} (*Pseudokirchneriella subcapitata*, 72 h) = 63 mg 7-phenol/L (nominal)

E_rC_{50} (*Pseudokirchneriella subcapitata*, 72 h) > 100 mg 7-phenol/L (nominal)

NOEC (*Pseudokirchneriella subcapitata*, 72 h) = 32 mg 7-phenol/L (nominal)

B.9.2.9 Effects on sediment dwelling organisms (Annex IIA 8.2.7)

Effects of Benfuracarb on the development of sediment-water dwelling larvae of *Chironomus riparius* in a water-sediment system. (Desmares-Koopmans M.J.E., van de Waart E.J., 1998).

Guidelines :

BBA Guideline (Final Draft): “Effects of plant protection products on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system”

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.0 %, batch n° : 7C81-S, water solubility : 8.0 mg/L
[Ring-¹⁴C]benfuracarb, radiochemical purity : > 99 %

Test species : *Chironomus riparius*

Number of organisms, age : 25 larvae per treatment, 2 replicates per test concentration, 3 replicates for the control group, first-instar midge larvae

Type of test : sediment-water Chironomid toxicity test using spiked water

Applied and measured concentrations :

nominal : contro; solvent control; 1.0, 2.2, 4.6, 10, 22, 46, 100 µg a.s./L

measured concentrations in water column ranging from 61 – 92 % of nominal concentrations

Due to the low solubility of benfuracarb in water a solubilising agent was used to prepare stock solutions. The maximum amount of acetone in the final test solutions was 100 µL/L.

Test conditions :

temperature : 20.6 – 21.0 °C

pH : 7.0 – 8.0

oxygen content : 78 - 104 % O₂ saturation (7.0 – 9.4 mg O₂/L)

total hardness : 250 mg/L CaCO₃

photoperiod : 16/8 hours light/dark cycle, 900 – 1000 lux

sediment/water ratio : 1 : 9

Analytical methods : radioactivity measurements (LSC)

Conclusions :

The study is acceptable. Minor deviations were observed for total hardness of the test water, the sediment to water ratio and the number of replicates per treatment.

A decreasing concentration in the water column was observed with a corresponding increase in sediment and interstitial water.

Endpoints :

EC₅₀ (*Chironomus riparius*, 28 d) based on emergence of midges = 0.0041 mg a.s./L (nominal)

NOEC (*Chironomus riparius*, 28 d) based on emergence rate and development rate = 0.001 mg a.s./L (nominal)

Added in August 2008

Benfuracarb – Statement on risk to sediment dwelling organisms. (de Roode D.F., 2007).

According to the notifier, no data are available on the toxicity of carbofuran to sediment-dwelling organisms. Benfuracarb is rapidly degraded to carbofuran in the water phase of water-sediment systems. Therefore, the overall NOEC for *Chironomus riparius* of 1.0 µg/L can be used for carbofuran.

The RMS agrees with this approach, considering the fact that *Chironomus riparius* has been exposed to carbofuran which is rapidly formed in water. Moreover, the TER calculations based on FOCUS step 4 modelling indicate that the risk to *Chironomus riparius* is negligible (see B.0.2.16).

B.9.2.10 Effects on aquatic plants (Annex IIA 8.2.8)

Not required. (Benfuracarb is an insecticide).

B.9.2.11 Acute toxicity of the preparations (Annex IIIA 10.2.1)

Not required. (The formulation Oncol 8.6G contains only one active substance and no direct spray application of Oncol 8.6G is intended).

B.9.2.12 Microcosm and mesocosm study (Annex IIIA 10.2.2)

Not available.

B.9.2.13 Residue data in fish (Annex IIIA 10.2.3)

Not required. (Studies on bioconcentration give sufficient information on the nature and the level of residues).

B.9.2.14 Supplementary studies of toxicity to fish and aquatic invertebrates (Annex IIIA 10.2.4)

Not available.

B.9.2.15 Summary of effects on aquatic organisms (Annex IIA 8.2, Annex IIIA 10.2)

Table B.9.2.15-1 : Summary of effects of benfuracarb on aquatic organisms

Test species	Test substance	Test system	Endpoints	References
<i>Oncorhynchus mykiss</i>	benfuracarb	96 h semi-static	LC ₅₀ = 0.083 mg a.s./L (measured)	Migchielsen M.H.J., 2002
<i>Lepomis macrochirus</i>	benfuracarb	96 h semi-static	LC ₅₀ = 0.017 mg a.s./L (measured)	Migchielsen M.H.J., 2002
<i>Daphnia magna</i>	benfuracarb	48 h static	EC ₅₀ = 0.0099 mg a.s./L (measured)	Migchielsen M.H.J., 2002
<i>Pseudokirchneriella subcapitata</i>	benfuracarb	72 h static	EC ₅₀ > 2.2 mg a.s./L (measured)	Migchielsen M.H.J., 2002
<i>Chironomus riparius</i>	benfuracarb	28 d static	EC ₅₀ = 0.0041 mg a.s./L NOEC = 0.001 mg a.s./L (*) (nominal)	Desmares-Koopmans M.J.E., van de Waart E.J., 1998

(*) endpoint used for carbofuran

Table B.9.2.15-2 : Summary of effects of metabolites of benfuracarb on aquatic organisms

Test species	Test substance	Test system	Endpoints	References
<i>Oncorhynchus mykiss</i>	carbofuran	96 h semi-static	LC ₅₀ = 0.82 mg/L (nominal)	Douglas M.T., Handley J.W., Macdonald I.A., 1987
<i>Lepomis macrochirus</i>	carbofuran	96 h semi-static	LC₅₀ = 0.18 mg/L (nominal)	Migchielsen M.H.J., 2002
<i>Oncorhynchus mykiss</i>	carbofuran	28 d fish juvenile growth	NOEC < 0.0087 mg/L (nominal) EC₁₀ = 0.00655 mg/L (nominal)	Egeler Ph., Gilberg D., Baumann J., 2002 (*)
<i>Oncorhynchus mykiss</i>	carbofuran	28 d fish juvenile growth	NOEC = 0.022 mg/L (nominal)	(Migchielsen, M.H.J., 2005) (*)
<i>Daphnia magna</i>	carbofuran	48 h static	EC₅₀ = 0.0094 mg/L (nominal)	Migchielsen M.H.J., 2002
<i>Daphnia magna</i>	carbofuran	21 d semi-static	NOEC = 0.008 mg/L (nominal)	Egeler Ph., Gilberg D., Baumann J., 2002
<i>Pseudokirchneriella</i>	carbofuran	72 h static	E_bC₅₀ = 6.5 mg/L (measured) E _r C ₅₀ = 19 mg/L (measured)	Migchielsen M.H.J., 2002

<i>subcapitata</i>				
<i>Lepomis macrochirus</i>	7-phenol	96 h semi-static	LC ₅₀ = 75 mg/L (nominal)	Migchielsen M.H.J., 2002
<i>Daphnia magna</i>	7-phenol	48 h static	EC ₅₀ = 25 mg/L (nominal)	Migchielsen M.H.J., 2002
<i>Pseudokirchneriella subcapitata</i>	7-phenol	72 h static	E _b C ₅₀ = 63 mg/L (nominal) E _r C ₅₀ > 100 mg/L (nominal)	Migchielsen M.H.J., 2002

(*) An overall worst case NOEC of 0.006 mg/L carbofuran has been derived from the 4 acceptable chronic fish studies. These studies have been submitted by Otsuka (benfuracarb dossier) and by FMC (carbofuran dossier). (See point B.9.2.3). For the TER calculations, we have considered that the figure of 0.00655 mg/L that has been proposed by Otsuka is equivalent to the NOEC of 0.006 mg/L

The notifier did not submit acute toxicity tests with the formulation:

- Since Oncol 8.6G is a granular formulation, direct exposure of aquatic organisms to the formulation is not expected. Therefore the risk could be assessed by means of the active substance data.
- The labeling of Oncol 8.6G has been based on the active substance data. (R50 justified for both the active substance and Oncol 8.6G)

B.9.2.16 Exposure and risk assessment for aquatic organisms (Annex IIIA 10.2) (revised in August 2008)

The risk assessment for aquatic organisms is based on the Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC of October 2002.

Due to the rapid conversion of benfuracarb to carbofuran (DT_{50} in water = 0.25 – 0.625 days), the risk assessment will be based on the TER calculations for carbofuran.

The PEC values for benfuracarb and carbofuran in surface water and in sediment were calculated in the section on fate and behaviour. Drainage is the most relevant route of exposure for surface water.

The calculation of the acute and chronic risk of benfuracarb and carbofuran to aquatic organisms is worst-case :

- The most sensitive species were used in the calculation.
- Both acute and chronic risk was calculated using the maximum PEC values in surface water or sediment for different scenarios (FOCUS step 3 and 4). These maximum values represent worst-case scenarios for acute and chronic exposure.

The TER values indicated in bold are those which do not meet the respective trigger value.

Table B.9.2.16-1 : Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to benfuracarb for the intended use in brassicas (1 x 1.0 kg a.s./ha) based on FOCUS Step 3 calculations

Scenario	Water body type	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	TER
D3	Ditch	0.000	0.000	Not relevant
D4	Pond	0.000	0.000	Not relevant
D4	Stream	0.000	0.000	Not relevant
D6	Ditch	0.000	0.000	Not relevant

Table B.9.2.16-2 : Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to benfuracarb for the intended use in brassicas (1 x 1.0 kg a.s./ha) based on FOCUS Step 4 (*) calculations

Scenario	Water body type	PEC _{sw} (µg/L)	PEC _{sed} (µg/kg)	TER
R1	Pond	0.000	0.000	Not relevant
R1	Stream	0.000	0.000	Not relevant
R2	Stream	0.000	0.000	Not relevant
R3	Stream	0.000	0.000	Not relevant
R4	Stream	0.000	0.000	Not relevant

(*) Referred to as STEP 4 calculations because defaults for CAM and DEPI were adjusted to reflect granule incorporation at exactly 2.5 cm

Table B.9.2.16-3 : Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to carbofuran for the intended use in brassicas (1 x 1.0 kg a.s./ha) based on FOCUS Step 3 calculations

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC _{sw} (µg/L)	TER	Annex VI trigger
D3	Ditch	<i>Lepomis macrochirus</i>	96 h	180	0.0493	3651	100
D4	Pond				0.0196	9184	100
D4	Stream				0.0608	2961	100
D6	Ditch				0.123	1463	100
D3	Ditch	<i>Daphnia magna</i>	48 h	9.4	0.0493	191	100
D4	Pond				0.0196	480	100
D4	Stream				0.0608	155	100
D6	Ditch				0.123	76	100
D3	Ditch	<i>Pseudokirchneriella subcapitata</i>	72 h	6500	0.0493	131846	10
D4	Pond				0.0196	331633	10
D4	Stream				0.0608	106908	10
D6	Ditch				0.123	52846	10
D3	Ditch	<i>Oncorhynchus mykiss</i>	28 d	6.55	0.0493	133	10
D4	Pond				0.0196	334	10
D4	Stream				0.0608	108	10
D6	Ditch				0.123	53	10
D3	Ditch	<i>Daphnia magna</i>	21 d	8.0	0.0493	162	10
D4	Pond				0.0196	408	10
D4	Stream				0.0608	132	10
D6	Ditch				0.123	65	10
D3	Ditch	<i>Chironomus riparius</i>	28 d	1.0	0.0493	20	10
D4	Pond				0.0196	51	10
D4	Stream				0.0608	16	10
D6	Ditch				0.123	8.1	10

Table B.9.2.16-4 : Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to carbofuran for the intended use in brassicas (1 x 1.0 kg a.s./ha) based on FOCUS Step 4 calculations

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC _{sw} (µg/L)	TER	Annex VI trigger
R1	Pond	<i>Lepomis macrochirus</i>	96 h	180	<0.001	>180000	100
R1	Stream				<0.001	>180000	100
R2	Stream				<0.001	>180000	100
R3	Stream				<0.001	>180000	100
R4	Stream				<0.001	>180000	100
R1	Pond	<i>Daphnia magna</i>	48 h	9.4	<0.001	>9400	100
R1	Stream				<0.001	>9400	100
R2	Stream				<0.001	>9400	100
R3	Stream				<0.001	>9400	100
R4	Stream				<0.001	>9400	100
R1	Pond	<i>Pseudokirchneriella subcapitata</i>	72 h	6500	<0.001	>6500000	10
R1	Stream				<0.001	>6500000	10
R2	Stream				<0.001	>6500000	10
R3	Stream				<0.001	>6500000	10
R4	Stream				<0.001	>6500000	10
R1	Pond	<i>Oncorhynchus mykiss</i>	28 d	6.55	<0.001	>6550	10
R1	Stream				<0.001	>6550	10
R2	Stream				<0.001	>6550	10
R3	Stream				<0.001	>6550	10
R4	Stream				<0.001	>6550	10
R1	Pond	<i>Daphnia magna</i>	21 d	8.0	<0.001	>8000	10
R1	Stream				<0.001	>8000	10
R2	Stream				<0.001	>8000	10
R3	Stream				<0.001	>8000	10
R4	Stream				<0.001	>8000	10
R1	Pond	<i>Chironomus riparius</i>	28 d	1.0	<0.001	>1000	10
R1	Stream				<0.001	>1000	10
R2	Stream				<0.001	>1000	10

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PEC _{sw} (µg/L)	TER	Annex VI trigger
R3	Stream				<0.001	>1000	10
R4	Stream				<0.001	>1000	10

(*) Referred to as STEP 4 calculations because defaults for CAM and DEPI were adjusted to reflect granule incorporation at exactly 2.5 cm

Conclusions of the RMS :

The most sensitive species were used to calculate the acute and chronic risk of benfuracarb and carbofuran. Both acute and chronic risk was calculated using the maximum PEC values for benfuracarb and carbofuran in surface water or sediment for different scenarios (FOCUS steps 3 and 4). These maximum values represent worst-case scenarios for acute and chronic exposure.

The acute and chronic risk of benfuracarb and its metabolite carbofuran to aquatic organisms is acceptable for the majority of FOCUS scenarios considering the representative use (soil incorporation of 12 kg Oncol 8.6G granule/ha (equivalent to 1 kg a.s./ha) in cabbage).

The PEC_{SED} values of the metabolite carbofuran-7-phenol are 1 order of magnitude lower than the corresponding PEC_{SED} values for carbofuran. Carbofuran-phenol is 4 orders of magnitude less toxic than carbofuran to aquatic organisms. Therefore, the risk of the metabolite carbofuran-7-phenol to aquatic organisms is acceptable.

In conclusion, the risk of benfuracarb, carbofuran and carbofuran-7-phenol to aquatic organisms is acceptable for the intended use in brassicas (1 x 1.0 kg a.s./ha).

B.9.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3) revised in August 2008**Exposure route for the active substance :**

Mammals are exposed to benfuracarb via the accidental consumption of granules.

Since the residue levels of benfuracarb in cabbage seedlings and earthworms are negligible, no TER calculation is necessary for benfuracarb in those food matrices.

Exposure route for the metabolites :

Since residue levels of the metabolites carbofuran and 3-OH-carbofuran in cabbage seedlings and earthworms were relevant and since these metabolites are both more toxic than the active substance, the risk to mammals from exposure to these metabolites has been assessed.

The risk assessment for mammals is based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002.

I. Choice of toxicological endpoints :

The RMS has proposed the following endpoints as relevant for the risk assessment for mammals.

Table B.9.3-1 : Summary of effects of benfuracarb on mammals

Test species	Test system	Endpoints	References
Rat	acute oral	LD ₅₀ = 205 mg a.s./kg b.w.	Masaaiiki Shirai, 1996a
Rat	2-generation study	NOAEL = 1.2 mg a.s./kg b.w./day	Schroeder, 1984

For the determination of the acute endpoint for carbofuran several studies are available. Acute oral toxicity in the rat ranged from 5.3 mg carbofuran/kg b.w. (Fletcher, 1983a) to 13.3 mg carbofuran/kg b.w. (Fletcher, 1983b). Acute oral mice toxicity was in the range of 9.1 - 26.3 mg carbofuran/kg b.w. As a worst-case scenario, the lowest endpoint of 5.3 mg carbofuran/kg b.w. was chosen for the acute risk assessment.

The determination of the relevant long-term endpoint is based on the reproductive toxicity and teratogenicity studies.

Following list of endpoints are the lowest NOAELs derived from the studies :

2 generation rat study : NOAEL parental tox = 1.169 mg carbofuran/kg b.w./day (Schardein, 1990)

3 generation rat study : NOAEL parental tox = 1.2 mg carbofuran/kg b.w./day (Goldenthal, 1979b)

developmental rat study : NOAEL maternal tox = 0.3 mg carbofuran/kg b.w./day (Schardein, 1989)

developmental rat study : NOAEL maternal tox = 0.1 mg carbofuran/kg b.w./day (Rao, 1978a)

developmental rat study : NOAEL maternal tox > 1.2 mg carbofuran/kg b.w./day (Rodwell, 1980)

developmental rat study : NOAEL maternal tox = 1.47 mg carbofuran/kg b.w./day (Rodwell, 1981)

developmental rat study : NOAEL maternal tox = 1.71 mg carbofuran/kg b.w./day (Ponnock, 1994)

rabbit study (gavage) : NOAEL maternal tox = 0.2 mg carbofuran/kg b.w./day (Schardein, 1990)

rabbit study (gavage) : NOAEL maternal tox = 0.6 mg carbofuran/kg b.w./day (Rao, 1978b)

rabbit study (gavage) : NOAEL maternal tox = 0.5 mg carbofuran/kg b.w./day (Laveglia, 1981)

60-day rat study : NOAEL = 0.1 mg carbofuran/kg b.w./day (Pant *et al.*, Human Exp. Toxicol., 1995, 14, 889-894)

rat study (in utero and lactational exposure) : NOAEL = 0.2 mg carbofuran/kg b.w./day (Pant *et al.*, Human Exp. Toxicol., 1997, 16, 267-272)

reproductive toxicity in mice : NOAEL = 0.7 mg carbofuran/kg b.w./day (Baligar and Kaliwal, Indust. Health, 2002, 40, 345-352)

developmental rat study : NOAEL maternal tox = 0.5 mg carbofuran/kg b.w./day (Courtney *et al.*, J. Environ. Sci. Health, 1985, B(20)4, 373-406)

As a reasonable worst-case scenario the mean value of former NOAEL values was used for the long-term risk assessment, mean NOAEL = 0.71 mg carbofuran/kg b.w./day.

Table B.9.3-2 : Summary of effects of carbofuran on mammals

Test species	Test system	Endpoints	References
Rat	acute oral	LD ₅₀ = 5.3 – 5.6 mg carbofuran/kg b.w.	Fletcher, 1983a and b
Rat	reproductive toxicity and teratogenicity	mean NOAEL = 0.71 mg carbofuran/kg b.w./day	-

The notifier has disagreed and proposed the following endpoints as relevant for the risk assessment for mammals.

1.1 Acute endpoint :

The notifier proposed to use an LC₅₀ = 600 mg carbofuran/kg b.w./day, originating from a 4-week neurotoxicity study with rat (Freeman, 1993, study from FMC) for acute risk assessment.

The notifier considered that it is more appropriate to use toxicity data from dietary feeding studies instead of toxicity data from gavage studies to select the ecotoxicological endpoints for the risk assessment. Carbofuran is a carbamate and the toxic effects of carbamates are due to inhibition of the enzyme acetylcholinesterase (AChE) which causes rapid accumulation of acetylcholine (ACh) in neuromuscular junctions and certain neural synapses. The excess of ACh results in over-stimulation of receptors of the central nervous system, organs and skeletal muscles. With carbamates the enzyme-inhibition is reversible. In rats, the time of maximum plasma concentration after oral gavage was already reached after <7 minutes, and the elimination half-life was 29 minutes (Ferguson P., Michael S., Dey S., Jewell S.A. and Krieger R., 1984, evaluated in the toxicological section). In all acute toxicity studies with carbofuran in rats, complete recovery was observed within 24 hours after dosing, which indicates that the effects are reversible within hours from onset. The high blood level of carbofuran that occurs immediately after direct dosing of the animal (gavage) will not occur when carbofuran is ingested via the diet resulting in a similar dose.

From the short-term 4-week neurotoxicity study with rat (Freeman, 1993, study from FMC), the LC₅₀ was determined > 6000 mg carbofuran/kg diet (2/10 rats died at that dose, which was the highest tested), equivalent to about 600 mg carbofuran/kg b.w./day (assuming that a rat consumes an amount of food equivalent to about 10 % of its own body weight every day, as a reasonable worst-case).

1.2 Long-term endpoint :

The notifier proposed a NOAEL = 1.2 mg carbofuran/kg b.w./day, originating from a 3-generation reproduction study with rat (Goldenthal, 1979b) as the relevant toxicological endpoint for long term risk assessment.

The notifier considered that it is more appropriate to use toxicity data from dietary feeding studies instead of toxicity data from gavage studies to select the ecotoxicological endpoints for the risk assessment (see above).

The lowest ecotoxicological NOAEL from long-term toxicity and carcinogenicity (dietary feeding) studies was 0.462 mg carbofuran/kg b.w./day from a 2-year dietary study in rat (Spicer, 1991), but the duration of the exposure in this study was too long to be relevant for the scenario under consideration (exposure period of about 4 weeks). The next lowest NOAEL is that of a 13-week short-term toxicity (dietary feeding) study with rat, giving NOAEL < 1 mg carbofuran/kg b.w./day (Abe, 1986). The only effect observed at the lowest tested dose was a reduction of brain AChE by 13 % relative to the control. Since however, this reduction was not accompanied by any other sign of toxicity throughout the study, including those typical for carbamate poisoning (e.g. no clinical signs), this effect is considered to be without toxicological relevance. The next lowest NOAEL from dietary feeding studies is 1.2 mg carbofuran/kg b.w./day, originating from a 3-generation reproduction study in the rat with 61 days of exposure (Goldenthal, 1979b). The notifier considers this latter endpoint as the ecotoxicological relevant endpoint for the risk assessment for mammals.

Conclusion of the RMS on setting of the endpoints relevant for the risk assessment :

1.1 Acute endpoint :

The RMS cannot agree with the statement of the notifier on the setting of the acute endpoint of 600 mg carbofuran/kg b.w. The RMS has evaluated the possibility to review the acute dose estimation based on the recommendations of the opinion of the SCP on pirimicarb (EFSA Journal (2005) 240: page 1-21). However, there is not enough information in the dossier of benfuracarb to determine the avoidance threshold dose, the avoidance delay time, the feeding rate per minute and the absorption/depuration rate constant in mammals. We also have considered that this method of calculation is lacking validation and uncertainty determination. In consequence, it was not possible to recalculate the acute endpoint according to the SCP opinion.

1.2 Long-term endpoint :

The RMS cannot agree with the statement of the notifier and believes that the ecotoxicological relevant long-term endpoint should be based on reproductive toxicity and teratogenicity studies, since the endpoints of these kind of studies are related to reproduction, which is not the case for long-term toxicity and carcinogenicity studies or short-term studies.

2. Supported uses :

The risk assessment for mammals is based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002.

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the furrow at a single application rate of 1 kg a.s./ha.

As the original GAP proposal was application in-furrow and in the plant-hole and as residue trials were also available for the use in plant-hole, the RMS included calculations to demonstrate that this particular use in the plant-hole is not safe.

Considering the high residue level in cabbage seedlings observed with plant-hole application, the notifier does therefore no longer support this type of use of benfuracarb granules.

3. The production of cauliflower, broccoli and cabbages in Bretagne (France) :

A detailed evaluation of the distribution of crops in Bretagne (region with highly concentrated production of open field vegetables) has been performed in order to derive a PT factor in an extreme worst-case situation. This evaluation has been based on publicly available statistical information.

More details are given in the chapter on birds.

4. Risk assessment for ingestion of granules :

The calculation of conventional TER is not possible for granules.

For information the acute oral LD₅₀ and the two generation NOAEL of benfuracarb for the most sensitive species (rat) were recalculated in number of granules for different sizes of mammals. The weight of one granule of Oncol 8.6G is 0.064 mg, which corresponds with an amount of 0.0055 mg a.s./granule. The diameter of the granules is assumed to be 0.25 – 0.71 mm.

Table B.9.3-3 : LD₅₀ and NOAEL of benfuracarb expressed in number of granules for different sizes of mammals

Time scale	Number of granules for a 10 g mammal	Number of granules for a 25 g mammal	Number of granules for a 100 g mammal
Acute oral LD ₅₀	373	932	3727
Two generation NOAEL	2	5	22

Conclusion :

The number of granules that have to be ingested by a mammal to reach the LD₅₀ of benfuracarb is high. It can be expected that the acute risk is limited for small mammals like shrews and mice.

Granules are not attractive to mammals since there is no grit consumption and the granule does not resemble a natural food source (insect, seed grain).

The acute risk of benfuracarb is more relevant than the long-term risk. There is a rapid decomposition of the granule and also benfuracarb rapidly transforms into carbofuran.

Benfuracarb : Statement on long-term risk assessment for mammals from uptake of granules. (de Roode D.F., 2007).

See appendix 2 to this chapter B9.

5. Risk assessment for consumption of contaminated drinking water :

Benfuracarb is applied as a granular formulation. Therefore, it can be expected that the risk of consumption of contaminated drinking water is low.

6. Risk assessment of consumption of contaminated earthworms :

Benfuracarb : Statement on risk assessment for mammals from uptake of contaminated earthworms. (de Roode D.F., 2007).

6.1 First tier risk assessment :

The first tier risk assessment has not been performed for mammals consuming earthworms containing benfuracarb. The analytical results of the field trials (earthworms) clearly demonstrate the absence of the a.s. itself in these matrices.

The first tier risk assessment for carbofuran is based on a mammal of 10 g body weight feeding exclusively on earthworms, with a daily food intake of 14 g fresh material/day (equivalent to a FIR/bw of 1.4).

Since the main route of exposure is via the consumption of earthworms, the data on residues were used first. The residue levels in earthworms are derived from the concentrations observed in the field trials. The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran and 3-OH carbofuran.

The residue levels for the various risk assessments were calculated following the recommendations of the Guidance document on Risk Assessment for Birds and Mammals, with some adaptations taking into account that the initial residue is not the maximum residue in the case of a granule containing a systemic a.s.

- For the acute assessment : the 90th percentile (or equivalent) of maximum residues
- For the short-term assessment : the arithmetic means of the maximum residues
- For the long-term assessment : the mean time-weighted-average residues (averaging has been done by considering the observed area under-curve).

More details are given in the chapter on birds.

Table B.9.3-4 : Estimated oral uptake of carbofuran and first tier Toxicity Exposure Ratios (TERs) for vermivorous mammals feeding in cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Mammals type	Time-scale	Endpoint (mg a.s./kg bw/d)	FIR/bw	Residue level in earthworms (mg a.s. eq./kg)	ETE (mg a.s./kg b.w./day)	TER	Annex VI Trigger Value
vermivorous	acute	5.3	1.4	0.56	0.78	6.78	10
	long-term	0.71	1.4	0.095	0.13	5.32	5

Conclusions of the RMS :

The acute risk from consumption of earthworms contaminated with carbofuran needs to be further refined.

6.2 Higher tier risk assessment :**6.2.1 Determination of species of ecological relevance :**

The **common shrew** (*Sorex araneus*) was found to be a suitable focal species for mammals foraging in cabbage fields on earthworms.

The feeding habitat for common shrew is wherever low vegetation provides cover, particularly in thick grass and scrub, hedgerows and deciduous woodland.

The common shrew is an opportunistic predator feeding on a wide range of common invertebrates, particularly earthworms, woodlice, spiders, slugs, snails and insect larvae. Although showing preferences between prey types, items tend to be taken in proportion to their availability. Small amounts of plant material including seeds are also taken (From the documentation “Mammals and farming : information for risk assessment. Gurney J.E., Perrett J., Crocker D.R. and Pascual J.A., 1998”).

6.2.2 Determination of the proportion of earthworms in the diet (PD value) :

From a study of shrews inhabiting watercress beds in UK (Churchfield, 1984) faeces were analysed and the proportion of earthworms in the diet was determined.

Table B.9.3-5 : Seasonal data on proportion of earthworms in the diet (Churchfield, 1984)

Month	Feb	Mar	May	Jun	Jul	Sep	Oct	Dec
Proportion of earthworms in the diet (%)	62	72	72	50	80	74	33	40

Pernetta (1976a) confirmed that the dominant components of the diet of common shrew were earthworms, adult coleopteran and opiliones. Earthworms were more important in winter than in summer. Data from analysis of gut and stomach contents from shrews inhabiting Oxfordshire grassland are presented in the table below.

Table B.9.3-6 : Seasonal data on proportion of earthworms in the diet (Pernetta, 1976b)

Months	Jan – Mar	Apr – Jun	Jul – Sep	Oct – Dec
Proportion of earthworms in the diet (%)	29	19	28	65

Based on the data of Churchfield (1984), the maximum value of **PD** was determined as **80 %**. This is a worst-case scenario, compared to values of Rudge (1968a, b, c).

Table B.9.3-7 : Seasonal data on proportion of earthworms in the diet (Rudge, 1968a)

Months	Jan – Feb	Apr – May	Jun – Aug	Sept
Proportion of earthworms in the diet (%)	4	14	6	9

Table B.9.3-8 : Seasonal data on proportion of earthworms in the diet (Rudge, 1968b)

Months	Jan	Mar – Apr	Jun – Jul	Sept – Oct
Proportion of earthworms in the diet (%)	6	10	8	11

Table B.9.3-9 : Seasonal data on proportion of earthworms in the diet (Rudge, 1968c)

Months	Mar - May	Jun - Aug	Sept - Nov	Dec - Feb
Proportion of earthworms in the diet (%)	22	11	10	13

6.2.3 Determination of the food intake rate for earthworms for common shrew :

Fresh food intake (g item/day) and food intake rate (g food/g body weight) were calculated according to the following equations, according to the SANCO/4145/2000 guidance.

$$FIR (kg / kg) = \frac{kg \text{ food item}}{kg \text{ BW}} \quad (\text{equation 1})$$

$$\text{Fresh food intake per food item (g fw / day)} = \frac{DEE}{\text{yield}} \quad (\text{equation 2})$$

$$\log(DEE) = a + b \times \log(BW) \quad (\text{equation 3})$$

$$\text{yield} = \text{energy content}_{fw} \times (1 - \text{moisture}) \times \text{assimilation efficiency} \% / 100 \quad (\text{equation 4})$$

$$\text{energy content}_{fw} = \frac{\text{energy content}_{dw}}{1 + \frac{\text{moisture \%}/100}{1 - \text{moisture \%}/100}} \quad (\text{equation 5})$$

In these equations, DEE is the daily estimated energy requirement (kJ/day). The DEE is calculated according to Table 2 in Appendix I of SANCO/4145/2000.

The common shrew is classified as other eutherians and has a body weight of 8.1 g.

$$\log(DEE) = 0.8459 + 0.7050 \times (\log 8.1) = 1.49$$

$$DEE = 30.65 \text{ kJ}$$

SANCO/4145/2000 lists energy content and moisture content for soil invertebrates. The assimilation efficiency for shrews and bats eating insects is 88 %. Since there are no data on assimilation efficiency for soil invertebrates, the value for insects was chosen in the calculations.

Table B.9.3-10 : Calculation of the ratio of food intake rate of different food items to body weight for the common shrew

Food type	Energy content (kJ/g dw)	Moisture content (%)	Energy content (kJ/g ww)	Assimilation efficiency (%)	Yield (kJ/g ww)	Fresh food intake (g/day)	FIR/bw
earthworms	19.3	84.6	2.97	88	2.62	11.7	1.45

6.2.4 Higher tier TER calculations :

Table B.9.3-11 : Estimated oral uptake of carbofuran and higher tier Toxicity Exposure Ratios (TERs) for vermivorous mammals feeding in cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Mammals type	Time-scale	Endpoint (mg a.s./kg bw/d)	FIR/bw	Residue level in earthworms (mg a.s. eq./kg)	PD	ETE (mg a.s./kg b.w./day)	TER	Annex VI Trigger Value
vermivorous	acute	5.3	1.45	0.56	0.80	0.65	8.19	10
	long-term	0.71	1.45	0.095	0.80	0.11	6.42	5

7. Risk assessment of consumption of treated seedlings :

Benfuracarb : Statement on risk assessment for mammals from uptake of treated seedlings. (de Roode D.F., 2007).

7.1 First tier risk assessment :

The first tier risk assessment has not been performed for mammals consuming cabbage seedlings containing benfuracarb. The analytical results of the field trials (seedlings) clearly demonstrate the absence of the a.s. itself in these matrices.

The first tier risk assessment for carbofuran is based on a herbivorous mammal of 3000 g body weight feeding exclusively on cabbage seedlings, with a daily food intake of 832 g fresh material/day (equivalent to a FIR/bw of 0.28).

Since the main route of exposure is via the consumption of treated vegetation, the data on residues were used first. The residue levels in cabbage seedlings are derived from the concentrations observed in the field trials. The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran, conjugated carbofuran and 3-OH carbofuran.

The residue levels for the various risk assessments were calculated following the recommendations of the Guidance document on Risk Assessment for Birds and Mammals, with some adaptations taking into account that the initial residue is not the maximum residue in the case of a granule containing a systemic a.s.

- For the acute assessment : the 90th percentile (or equivalent) of maximum residues
- For the short-term assessment : the arithmetic means of the maximum residues
- For the long-term assessment : the mean time-weighted-average residues (averaging has been done by considering the observed area under-curve).

More details are given in the chapter on birds.

Table B.9.3-12 : Estimated oral uptake of carbofuran by herbivorous mammals and first tier Toxicity Exposure Ratios (TERs) for use in cabbage crop (12 kg Oncol 8.6G/ha)

Application rate (kg a.s./ha)	Crop	Mammal type	Time-scale	FIR/bw	Residue level (mg carbofuran equivalents/kg food)	ETE (mg a.s./kg b.w./day)	TER	Annex VI Trigger value
1 × 1.00, in-furrow application	leafy crop/early (cabbage seedlings)	medium herbivorous	acute	0.28	3.92	1.10	4.83	10
			long-term	0.28	1.14	0.32	2.23	5
1 × 1.00, in plant-hole application (*)	leafy crop/early (cabbage seedlings)	medium herbivorous	acute	0.28	60.00	16.8	0.32	10
			long-term	0.28	22.80	6.38	0.11	5

*: the notifier does not support the GAP with plant-hole application

Conclusions of the RMS :

The first tier risk assessment is based on a medium herbivorous mammal of 3000 g body weight feeding exclusively on cabbage seedlings, with a daily food intake of 832 g fresh material/day (equivalent to a FIR/bw of 0.28). Since the main route of exposure is via the consumption of treated vegetation, the data on residues were used first. The residue levels in cabbage seedlings are derived from the concentrations observed in the field trials. The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran, conjugated carbofuran and 3-OH carbofuran.

This first tier assessment shows that the risk to mammals consuming cabbage seedlings is unacceptable. In consequence higher tier risk assessment is required.

This assessment also demonstrates that the residue level in seedlings, and consequently the risk to mammals, is highly depending on the mode of application of the granules.

When evaluating the risk at national level for uses on cabbage seedlings or other crops, the evaluators should carefully consider the actual application amount of a.s. available at the foot of each individual plant, and not only the whole application rate per hectare. This rate is depending on the mode of application (broadcast, in-furrow or plant-hole), the distance between the plants in the row and between the rows. The residue level in young plants is also depending on the growth rate, plantation time,... It is therefore advisable to perform specific residue trials for each crop/use.

In order to reduce the risk to birds and mammals (by ingestion of granules or earthworms), to non-target soil organisms (arthropods, earthworms, micro-organisms), to groundwater and surface water contamination, the application in the plant-hole, at lower dosage is advisable. This technique would provide the same protection of the crop to target insects and highly reduces the amount of a.s. used per hectare.

7.2 Higher tier risk assessment :

7.2.1 Determination of species of ecological relevance :

The **brown hare** (*Lepus europaeus*) was found to be a suitable focal species for herbivorous mammals foraging in cabbage fields.

Argumentation from the notifier :

The European Hare (*Lepus europaeus*) is a native species to Europe and western Asia. It is a mammal of temperate open country. The species mainly inhabits agricultural grassland in Western Europe. The body weight of the hares ranges between 3.5 and 5 kg (Niethammer J. and Pegel M., 2003). Hence, for the risk assessment the body weight can be set to 3.5 kg.

The brown hare is predominantly nocturnal and it is strictly herbivorous. Hares graze on the young shoots of grasses and herbs as well as on agricultural crops during the summer months and include twigs, bark and the buds of young trees in winter. However, green plant parts always form the main part of their food – up to 92 % in spring and summer (Zörner H., 1990).

In arable lands, field crops make a large part of the hare's diet. Food composition changes with availability in different habitats and over the course of the year (Niethammer J. and Pegel M., 2003). In general, hares select saplings and young plant parts for food (Niethammer J. and Pegel M., 2003). No significant differences have been found between the diets eaten by males and females (Homolka M., 1987).

Literature studies on the hare (*Lepus europaeus*) :

Lepus europaeus Pallas, 1778 – Feldhase. (Averianov A., Niethammer J., Pegel M.).

The habitat of the hare is situated in agricultural areas. The diet of the hare consists of 90.1 % of green plant material, 5.5 % of wood and hardened plant material and 4.4 % of fruits.

The reproduction period of the hare lasts from December/January till September/October. The pregnancy time takes 42 – 43 days. One female hare can have 3 litters per year, with 1 to 3 young per litter. At birth, the young hares weigh 100 – 150 g.

Feldhase, *Lepus europaeus* (Pallas). (Zörner H.).

Hares spend time in surfaces of 20, 40 till 70 ha. There were 60 % of the hares found in agricultural lands. One hare feeds on about 500 – 1400 g feed per day, giving 120 – 150 cm³.

The body weight of young just after birth is 100 – 150 g, after 16 days 300 g, after 40 days 1000 g and after 4 months the hare weighs 2.5 kg. After 10 days of age, the young hare starts eating green plant material, after 20 days the young hare is independent from the mother.

Vegetation has 2 functions, it acts as a feed source and it serves for camouflage.

Problems associated with investigations into the diet of the European hare. (Homolka M., 1987).

In this study, 2000 faecal and 104 stomach content samples were investigated microscopically. Food items were identified in the diet of the hare in three different habitat types (a beet field, a lucerne field and a spruce forest) and in three regions (central Bohemia, the lowlands and the highlands of Southern Moravia).

The sufficient number of samples from different habitat types was determined to be 5 – 10. In the environment of agrocoenoses as a whole, with environmental diversity higher than that in individual habitat types, the sufficient number of samples was 15 – 20. Fragments of individual food items whose frequency attained over 15 % were evenly distributed in the preparations. Fragments of those food items which occurred with a frequency of 1–15 % were partly distributed evenly, the rest was distributed unevenly.

In agrocoenoses, the hare utilizes essentially the same food sources throughout the year. It consumes mostly just a few kinds of cultivated plants which, in the study area, occupy 90 % of the total arable land, besides several species of weeds (mainly *Chenopodium* and *Amaranthus* spp.) which grow abundantly at the edges of fields and along field tracks (Homolka, 1982 a). The number of food items consumed by the hare in agrocoenoses and in the woodland environment did not differ significantly in successive seasons of the year. This means that the hare consumes, in most habitat types, approximately equal numbers of food items whose quality, however, changes

considerably in the course of the year. Also, the composition of the diet of the hare can differ greatly amongst different habitats. No dietary differences have been demonstrated between male and female hares.

Wildfutterpflanzengesellschaften und futterwert der von Feldhasen (*Lepus europaeus* Pallas) genutzten Pflanzen. (Brüll U., 1973).

Nahrungsbiologische Studien am Feldhasen in Schleswig – Holstein. Ein Beitrag zur Äsungsverbesserung. (Brüll U., 1976).

The hare feeds mainly in the morning and in the late afternoon until the evening. In spring, fall and winter, the hare feeds up to 90 % of its diet on Gramineae. During late spring, summer and early fall, the hare feeds on dicotyledones for 40 – 60 % of its diet. During winter, the hare feeds up to 80 % of its diet on *Hordeum vulgare* and *Triticum aestivum*.

Methodische Untersuchungen zur Identifizierbarkeit und Quantifizierbarkeit von Nahrungsresten im Kot von Feldhasen. (Thiele M., 1990).

The reliability of the microscopic analysis of faeces as a technique for ascertaining the food composition of hares (*Lepus europaeus*) has been examined. This method is based on the identification of epidermis of leaves and stems of plants recovered from faeces. Fragments of plant epidermis found in the faeces were compared with reference slides prepared from leaves of known plants. Feeding experiments on a rabbit (*Oryctolagus cuniculus*) were carried out to ascertain that apart from desintegration, no changes of the characteristic anatomical epidermis pattern of the plant species took place due to digestion. Two field studies were undertaken to test the applicability of this method.

The advantage of this method is that it does not interfere with the normal habit of the animal. However, this study revealed that its applicability was limited to only a qualitative analysis of the diet of the animal. The quantitative analysis proved to be imprecise due to different digestibilities of plant species, which leads to inaccuracies in weighing correctly the actual quantity of a plant eaten and the proportional number of fragments of that plant species found in the faeces. Dicotyledones were considerably underrated, monocotyledones generally overrated and a large number of fragments were rendered unidentifiable, some were probably completely digested.

Comparison of the diets of two sympatric lagomorphs, *Lepus europaeus* (Pallas) and *Oryctolagus cuniculus* (L.) in an agroecosystem of the Ile-de-France. (Chapus J.L., 1990).

The diets of the European hare (*Lepus europaeus* Pallas) and wild rabbit (*Oryctolagus cuniculus* L.) in an agrosystem of Ile-de-France are compared. The results are based on analysis of faeces collected at least monthly at 4 sites over one or two annual cycles.

Hares and rabbits had very similar diets. Grasses made up the base of their diet (50 to 100 % of the fragments found in the faeces) of which wheat was the preferred food item throughout the year. Their diet was more varied in summer and fall, and included maize, inflorescences of grasses, and various dicotyledones, as well as *Equisetum arvense* for the hare. The difference between two species' food choices are related to the behaviour of food selection : the proximity of food resources to the warrens for the rabbits and, on a larger scale, the repartition of fields for the hare.

These results show that the rabbit is a generalist compared with the hare which is more selective. Although feeding on the same plants in certain seasons, the two Lagomorphs exploit different areas, and are therefore unlikely to compete for food under these circumstances.

Zustandserfassung von Wintergetreide und Zuckerrüben während des Wachstums mit Hilfe des C-Band Radars der ERS-1 und ERS-2 Satelliten. (Hamacher M., 2000).

The primary aim of remote sensing in agriculture is to determine landuse inventories of arable regions. Optical sensors have been successful in classification and monitoring the vitality of plants using the NDVI (Normalized Difference Vegetation Index). However, they are sensitive to clouds, weather conditions and dependant on daylight. The main advantage of radar systems in comparison to optical sensors is the capability to acquire images of the earth's surface independent of daytime and cloud cover.

Multitemporal radar backscatter characteristics of crops were analyzed for an agricultural area located in the western part of Germany using ERS-1 and ERS-2 SAR imagery from 1996 until 1998. From the calibrated data, SAR temporal backscatter profiles were generated for winter wheat, winter barley, winter rye and sugar beet. The SAR imageries have been ordered every 35 days, during the main vegetation period every 17.5 days.

One of the main results is that each crop has its own distinctive backscatter profile. Therefore it is possible to identify different crops at optimum acquisition dates. The best time period to distinguish between winter barley, winter wheat and winter rye is from the end of may until the beginning of july. Sugar beet can be distinguished from winter cereal in may and august.

C-band radar with VV-polarisation is suitable to monitor the growth of winter cereals. However, it is impossible for sugar beet.

The backscatter profiles of winter cereals showed a clear decline during tillering and shooting and reached a minimum at the stages ear emergence and flowering respectively. This minimum was followed by an increase at the time of grain filling and ripening.

Until ear emergence the crop parameters plant height, fresh biomass, dry matter and water content were highly correlated with radar backscatter. Thereafter no correlations between these parameters and the backscatter could be found.

Comments of the RMS :

From the documentation "Mammals and farming : information for risk assessment. (Gurney J.E., Perrett J., Crocker D.R. and Pascual J.A., 1998)" information was found for risk refinement.

The brown hare prefers as feeding habitat arable land where cereals predominate but with available grass fields for summer feeding. The hare prefers shorter crops with more open vegetation. Also it requires wooded areas and hedgerows for resting areas during day.

The diet of the brown hare consists of grasses, herbs and arable crops, especially cereals in early growth stages. It prefers wild grasses and herbs, when available, to cultivated forms. In summer, herbs form the diet. Grasses predominate in winter when shrubs may also be browsed. The associated crops are cereals, rape, barley, turnip and grassland. The foraging behaviour of the brown hare is nocturnal, but crepuscular during summer months. Home ranges possibly 20 – 40 ha in size but do not show strong territorial activity. Movements of up to 1.7 km recorded per day.

A study of 21 radio-collared hares on French arable land recorded an average range size of about 100 ha both in winter and summer. Cereal fields were avoided before harvest but became more attractive as stubble (Reitz and Leonard, 1994). A similar study by Marboutin and Aebischer (1996) calculated mean home range of 20 radio-collared hares to be 190 ha. Hares made greater use of cultivated areas than would be expected by chance and less use of non-cultivated areas (woodland, hedges, grass fields, set-aside).

In a study of hares on mixed arable farm in Hampshire, Tapper and Barnes (1986) noted that the study population preferred to feed on short crops and their preference for cereals declined as crops developed beyond the tillering stage (see also Pepin, 1985). Pastures were important feeding areas throughout the year. Hares shifted their activities between fields according to crop development, in particular, moving from winter cereals in the spring to grassland at other times. Hares generally preferred grass without livestock (see also Barnes *et al.*, 1983).

In Poland, Lewandowski and Nowakowski (1993) observed that hares tended to use different crops in proportion to their availability, apart from oilseed rape which they avoided and stubble fields which they preferred.

7.2.2 Determination of the proportion of food type in the diet (PD value) :

Argumentation from the notifier :

Hares feed predominantly on monocotyledonous plants (Poaceae 50-70 %) but several dicotyledonous plant species (from the families of Fabaceae, Asteraceae, Brassicaceae and Plantaginaceae) may also form part of the diet over the course of the year (Niethammer J. and Pegel M., 2003; Zörner H., 1990). In a study from Schleswig-Holstein, Germany, the proportion of dicotyledonous plants was greatest in spring with 40-60 % (Brüll U., 1973; Brüll U., 1976). Hence, for the long-term risk assessment a reduction of PD to at least 50 % can be made on the basis of this information.

A further reduction can be made on the basis of studies that analysed individual food items in the stomach of hares. Plant parts from the genus Brassica (including unidentified food items) amount to 17.1 % stomach content annual average in Austria (Onderscheka *et al.*, 1981 in Zörner H., 1990). Homolka (1987) found in eastern Bohemia that plant parts from the genus Brassica (including unidentified food items) amount to only 6 % stomach volume annual average. Hence a further reduction to 25 % (PD = 0.25 for cabbage seedlings) is justified.

The portion of monocotyledonous plants in the diet of hares is derived from the following data on their general diet. Monocotyledonous plant species were found to account for 59.2 and 82 % (frequency of occurrence) in stomachs from Sweden (Niethammer J. and Pegel M., 2003; Zörner H., 1990) and for 26.3 % (frequency of occurrence) in central Bohemia (Homolka M., 1987). Monocotyledonous represented 63.6 % volume of the hares diet in central Bohemia Poacea (Homolka M., 1987). In autumn, winter and spring, 70 % of the plant parts analysed were monocotyledons in the German Rhine valley (Thiele M., 1990). In a study from the Czech Republic, faecal analysis demonstrated monocotyledons to account for 60 % (Homolka, 1984 in Zörner H., 1990). In Austria, monocotyledons represented 69.3 % of stomach content at different study sites (Onderscheka in Zörner H., 1990). Finally, more than 70 % (relative abundance of identified plant parts) was identified as monocotyledons in France from October to June (Niethammer J. and Pegel M., 2003). From these data, a PD value for monocotyledons of 0.60 can be derived.

For the refinement of the risk assessment, the PD of cabbage seedlings (dicotyledonous crop leaves) is set to 25 %. For the remaining diet, 60 % is assumed to be monocotyledonous plants (grasses) and 15 % other dicotyledonous plants.

Comments of the RMS :

From the documentation “Mammals and farming : information for risk assessment. (Gurney J.E., Perrett J., Crocker D.R. and Pascual J.A., 1998)” information was found for risk refinement.

A study of winter diet of hares (October – December) was conducted in relation to agricultural land use. Among cultivated plants, wheat was most frequently eaten in mixed farmland and in monoculture land. Rape was well represented in mixed farmland but was less often eaten. Rape was highly utilized in monoculture land. Wild sweet grasses play an important role. Agricultural land use determines food intake. Data from monoculture (Frylestam, 1986a) give following results, expressed as % frequency in stomach contents : 48.5 % wheat, 37.8 % rape, 4.7 % *Deschampsia caespitosa*, 3 % other herbs and woody plants). Data from mixed farmland (Frylestam, 1986b) : 20.5 % wheat, 18 % Graminae sp. and 12.2 % rape. Data from pasture (Frylestam, 1986c) : 21 % Graminae sp., 12 % other herbs and woody plants, 7.6 % wheat, 1 % rape.

7.2.3 Determination of the food intake rate for cabbage seedlings for hare :

Fresh food intake (g item/day) and food intake rate (g food/g body weight) were calculated according to the following equations, according to the SANCO/4145/2000 guidance.

$$FIR (kg / kg) = \frac{kg \text{ food item}}{kg \text{ BW}} \quad (\text{equation 1})$$

$$\text{Fresh food intake per food item (g fw / day)} = \frac{DEE}{\text{yield}} \quad (\text{equation 2})$$

$$\log(DEE) = a + b \times \log(BW) \quad (\text{equation 3})$$

$$\text{yield} = \text{energy content}_{fw} \times (1 - \text{moisture}) \times \text{assimilation efficiency} \% / 100 \quad (\text{equation 4})$$

$$\text{energy content}_{fw} = \frac{\text{energy content}_{dw}}{1 + \frac{\text{moisture \%}/100}{1 - \text{moisture \%}/100}} \quad (\text{equation 5})$$

In these equations, DEE is the daily estimated energy requirement (kJ/day). The DEE is calculated according to Table 2 in Appendix I of SANCO/4145/2000.

The brown hare is classified as other eutherians and has a body weight of 3230 g (males) to 3430 g (females).

$$\log(DEE) = 0.8459 + 0.7050 \times (\log 3500) = 3.34$$

$$DEE = 2210 \text{ kJ}$$

SANCO/4145/2000 lists energy contents for a series of food items. For cabbage seedlings, the values listed for non-grass herbs are used. Cabbage seedlings are dicotyledonous crops, and non-grass herbs are dicotyledonous plants. It is considered more appropriate to use the value listed for non-grass herbs than that for dicotyledonous crop leaves, as the latter is based on mature crops and it is assumed that mammals will not eat large leaves. Furthermore, seedling vegetation has higher energy content than the mature crop. The choice for non-grass herbs is further justified by the data in Table 10 of Appendix 3 of the draft of the updated guidance document, which shows that the energy of crop leaves including pods is lower than that of “all plants” (i.e. 11.4 and 17.8 kJ/g dw, respectively). For monocotyledonous plants, the values listed for grasses and cereals shoots are used.

Table B.9.3-13 : Calculation of the ratio of food intake rate of different food items to body weight for a brown hare per day

Food type	Energy content* (kJ/g dw)	Moisture content* (%)	Energy content (kJ/g ww)	Assimilation efficiency (%)	Yield (kJ/g ww)	Fresh food intake (g/day)	FIR/bw
cabbage seedlings	18.0	82.1	3.22	74	2.38	927	0.26
other dicotyledonous plants	18.0	82.1	3.22	74	2.38	927	0.26
monocotyledonous plants	18.0	76.4	4.25	46	1.95	1131	0.32

* Values taken from Table 3 in Appendix I of SANCO/4145/2000

7.2.4 Higher tier TER calculations :

Table B.9.3-14 : Diet composition, carbofuran concentration in each food item and acute TER value for the whole diet of brown hare feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	LD ₅₀ (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	0.26	3.92	0.25	0.26			
other dicotyledonous plants	0.32	0	0.15	0			
monocotyledonous plants	0.26	0	0.60	0			
Total				0.26	5.3	20.42	10

Table B.9.3-15 : Diet composition, carbofuran concentration in each food item and long-term TER value for the whole diet of brown hare feeding on cabbage fields treated with Oncol 8.6G (12 kg formulation/ha in-furrow)

Food type	FIR/b.w.	Residue level (mg/kg)	PD	ETE (mg/kg b.w./day)	NOEC (mg/kg b.w./day)	TER	Annex VI Trigger value
cabbage seedlings	0.26	1.14	0.25	0.08			
other dicotyledonous plants	0.32	0	0.15	0			
monocotyledonous plants	0.26	0	0.60	0			
Total				0.08	0.71	9.42	5

8. Comments of the RMS on the higher tier risk assessment for consumption on contaminated earthworms and treated seedlings :

The higher tier risk assessment (worst-case approach, deterministic) has been calculated using the following input parameters:

- Measured residue concentrations in cabbage seedlings and in earthworms, collected respectively in a total of 8 and 4 fields. Field management and application of the formulation was done in accordance with the supported GAP. The residue levels were expressed in sum of free and bound carbofuran + 3-OH carbofuran (See B.9.1.8: PEC_{FEED} (residue concentrations in cabbage seedlings and earthworms)).

- The focal species (common shrew and hare) were chosen on the basis of literature review provided by the notifier and from the documentation "Mammals and farming : information for risk assessment. (Gurney J.E., Perrett J., Crocker D.R. and Pascual J.A., 1998)".

- Fresh food intake (g item/day) and food intake rate (g food/g body weight) per food item were calculated according to the SANCO/4145/2000 guidance.

- PD determination: An extensive literature search has been performed in order to determine the composition of the diet of the 2 focal species. As the available information is derived from stomach or faeces examination of mammals commuting between treated fields and untreated areas, the determination of an accurate PD factor is difficult and only helpful on a qualitative level.

- the choice of the toxicological endpoints is based on the re-assessment of the entire database .

Table B.9.3-15 : Sources of uncertainty identified in the risk assessment

Sources of uncertainty	Input data used in the refined risk assessment	Identified variability
Toxicological endpoints of carbofuran	Worst case LD ₅₀ = 5.3 mg carbofuran/kg b.w./day, NOAEL = 0.71 mg carbofuran/kg b.w./day)	LD ₅₀ in 8 studies for 2 mammal species (rat and mice) in the range of 5.3 to 13.3 mg carbofuran/kg b.w./day The determination of the relevant long-term endpoint is based on the reproductive toxicity and teratogenicity studies. As a reasonable worst-case scenario the mean value of NOAEL values was used for the long-term risk assessment. The mode of exposure (gavage, in the diet), the type of diet used (in comparison with the diet of wild animals) the duration of the study, the tested species, ... are sources of variability. The steepness of the mortality curve, level at which clinical, behavioural effects occur (NOEC level).
Residues of carbofuran in food (cabbage seedlings)	Worst-case for the acute RA : acute : 3.92 mg/kg, 90 th percentile of maximum residues long-term : 1.14 mg/kg, mean time-weighted-average residues	The residue level in cabbage seedlings are derived from the concentrations observed in 8 field trials (supported GAP). The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of free carbofuran, conjugated carbofuran and 3-OH carbofuran. High variability is observed in terms of residue in food items (peak concentrations in cabbage seedlings in the range of 0.327-10.566 µg/kg). High variability in terms of residue levels depending on the application technique (in-plant hole, in-furrow application), the growth rate of the crop depending on the environmental conditions.
Residues of carbofuran in food (earthworms)	Worst-case for the acute RA : acute : 0.56 mg/kg, maximum residue value long-term : 0.095 mg/kg, mean time-weighted-average residues	The residue levels in earthworms are derived from the concentrations observed in 3 field trials (supported GAP). The residue is expressed in carbofuran equivalents/kg food and takes into account the contributions of carbofuran and 3-OH carbofuran. High variability is observed in terms of residues in food items (peak concentrations in earthworms in the range of 0.004-0.558 µg/kg).
FIR determination	Calculated endpoint (mean b.w. of the species, other factors taken from the Guid. Doc.)	Calculated endpoint with several sources of variability (variability of the relationship b.w. – DEE, parameters used for the calculation: weight of the animal, assimilation efficiency, moisture content of the food).
Focal species	2 common species were chosen as focal species. Also, the common shrew and the hare are recommended by the Guidance Document SANCO/4145/2000.	Choice of the species is based on literature review. - the common shrew (vermivorous mammal, (mean b.w. : 8.1 g); this species is observed in agricultural land. - the brown hare (herbivorous mammal (mean b.w. : 3500 g); this species is observed in agricultural land.

Sources of uncertainty	Input data used in the refined risk assessment	Identified variability
PD determination	Worst-case : PD = 0.80 for earthworms; PD = 0.25 for cabbage seedlings	<p>- the PD value for common shrew is very worst-case, it was the maximum % of earthworms in the diet found.</p> <p>- the PD value for brown hare is worst-case, the amount of dicotyledonous plants was estimated in the range 40 – 60 % of the diet. It was assumed that the brown hare would consume 60 % dicotyledonous plants (containing no carbofuran residues) and 25 % treated cabbage seedlings.</p> <p>Variability of the mammals diet depending on the availability of food sources, the type of environment, ...</p>
PT determination	Worst-case : PS = 100 %	<p>The PT factor “proportion of the diet obtained in the treated area” has been determined by an evaluation of the available food sources (% cabbage fields, % other vegetables, % other field crops) under real environmental conditions. Bretagne represents a worst-case scenario in terms of cabbage availability.</p> <p>Cabbage represents 50 % of the vegetables in this region. Except in very restricted areas, cabbage fields represent less than 3.1 % of the total acreage used for agriculture. In regions with high cabbage production, the plantations are performed at regular intervals (from January to begin September in Northern France) in different fields in order to have a continuous production all the year round. In consequence, this figure should be further mitigated by the proportion of fields at the critical growth stage (seedlings at BBCH 12-19, with potentially high residue level).</p> <p>This evaluation does not take into account the proportion of the fields that would be treated with benfuracarb (cabbage fields, extension of the use to other crops), nor the impact of the use of other pesticides with the same mode of action.</p> <p>The hare is known to have a large territory to feed (20, 40 till 70 ha).</p>

Conclusions of the RMS on the risk assessment for mammals :

The RMS has performed a deterministic worst-case risk assessment as required in the current guidance documents. The calculated TER should be read in a balanced way considering the various sources of uncertainty of the input parameters and the worst-case assumptions that were used.

The higher tier risk assessment was based on :

- the following toxicological endpoints ($LD_{50} = 5.3$ mg carbofuran/kg b.w./day, mean NOAEL = 0.71 mg carbofuran/kg b.w./day),
- measured residue level in cabbage seedlings and earthworms,
- the determination of focal species by means of literature review,
- PD refinement based on a literature search.

The refined acute TER value (8.19) is below the trigger of 10 for common shrew. The refined long-term TER for common shrew is 6.42.

The refined acute TER value is 20.42 and the refined long-term TER value is 9.42 for brown hare.

Based on worst-case refinement parameters, the TER values are close to and above the trigger values. Also, the refinement option of PT was not taken into consideration.

Therefore, RMS is of the opinion that the risk of benfuracarb and carbofuran is acceptable for mammals for the intended use in brassicas (1 x 1.0 kg a.s./ha).

B.9.4 Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.4)

B.9.4.1 Acute toxicity to bees (Annex IIA 8.3.1.1)

Acute contact and oral toxicity study in the honeybee (*Apis mellifera*) with Benfuracarb (laboratory test). (Geuijen W.H.C., 2002).

Guidelines :

EPPO Guideline No. 170: "Guideline on test methods for evaluating the side-effects of plant protection products on honeybees"

OECD Guideline for Testing of Chemicals No. 213: "Honeybees, Acute Oral Toxicity Test"

OECD Guideline for Testing of Chemicals No. 214: "Honeybees, Acute Contact Toxicity Test"

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96

Test species, age : honeybees (*Apis mellifera* L.), worker bees, 3 - 6 weeks

Number of organisms : 10 bees per replicate, 3 replicates per test concentration in the contact toxicity test
10 bees per replicate, 3 replicates per test concentration in the oral toxicity test

Type of test : 96 hours acute contact and oral toxicity test

Applied concentrations :

Contact test : blank control; solvent control (acetone); positive control (dimethoate); 0.03, 0.06, 0.10, 0.18, 0.32 µg a.s./bee (nominal, corrected for impurity of the test compound)

Oral test : blank control; solvent control (1 % acetone); positive control (dimethoate); 0.10, 0.20, 0.40, 0.80, 1.60 µg a.s./bee (nominal, corrected for impurity of the test compound)

Due to the low water solubility of benfuracarb, acetone was used to prepare stock solutions.

Exposure route :

Contact test : The bees were anaesthetised with CO₂. A 1 µL droplet of the prepared solution of the test substance was applied on the ventral side of the thorax of each bee.

Oral test : The active substance was dissolved in acetone and was added to the 50 % sucrose solution. A single dose of 100 µL of sucrose solution containing the test substance was administered to each replicate of 10 bees.

Feeding : 50 % aqueous sucrose solution

Test conditions :

Contact test : temperature : 23 – 26 °C, relative humidity : 70 – 83 %

Oral test : temperature : 23 – 27 °C, relative humidity : 67 – 82 %

Findings :

Mortality :

Contact test : No mortality was observed in the control groups. Benfuracarb did not induce biological significant mortality (> 15 % after 96 hours) at concentrations up to 0.10 µg a.s./bee. At 0.18 µg a.s./bee 50 % mortality was observed after 96 hours. 83.3 % mortality occurred at 0.32 µg a.s./bee after 96 hours. The LD₅₀ (24 h) of dimethoate was 0.163 µg a.s./bee.

Oral test : No mortality was observed in the control groups. Benfuracarb did not induce biological significant mortality (> 15 % after 96 hours) at concentrations up to 0.20 µg a.s./bee. At 0.40 µg a.s./bee 33 % mortality was recorded after 96 hours. After 96 hours 15 % mortality was observed at 0.80 µg a.s./bee. At the highest tested benfuracarb dosage (1.60 µg a.s./bee) cumulative mortality was 50.0 % after 96 hours. The LD₅₀ (24 h) of dimethoate was 0.133 µg a.s./bee.

Conclusion :

The study is acceptable. Minor deviations occurred in relative humidity compared to the guidelines.

Endpoints :

LD₅₀ (*Apis mellifera*, 96 h) contact = 0.19 µg a.s./bee (nominal, corrected for impurity of test compound)

NOEC (*Apis mellifera*, 96 h) contact = 0.10 µg a.s./bee (nominal, corrected for impurity of test compound, based on abnormal behaviour (> 15 % after 96 hours))

LD₅₀ (*Apis mellifera*, 96 h) oral = 2.1 µg a.s./bee (nominal, corrected for impurity of test compound)

NOEC (*Apis mellifera*, 96 h) oral = 0.20 µg a.s./bee (nominal, corrected for impurity of test compound, based on abnormal behaviour (> 15 % after 96 hours))

Acute toxicity study in the honeybee (*Apis mellifera*) with Benfuracarb (laboratory test, supplement). (Geuijen W.H.C., 2002).

Guidelines :

EPPO Guideline No. 170: "Guideline on test methods for evaluating the side-effects of plant protection products on honeybees"

OECD Guideline for Testing of Chemicals No. 213: "Honeybees, Acute Oral Toxicity Test"

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96

Test species, age : honeybees (*Apis mellifera* L.), worker bees, 3 - 6 weeks

Number of organisms : 10 bees per replicate, 3 replicates per test concentration

Type of test : 48 hours acute oral toxicity test

Applied concentrations :

blank control; solvent control (0.1 mL/100 mL acetone); positive control (dimethoate); 0.20, 0.40, 0.80, 1.60, 3.20, 6.40 µg a.s./bee (nominal, corrected for impurity of the test compound)

Exposure route : The active substance was dissolved in acetone and was added to the 50 % sucrose solution. A single dose of 100 µL of sucrose solution containing the test substance was administered to each replicate of 10 bees.

Feeding : 50 % aqueous sucrose solution

Test conditions : temperature : 24 – 27 °C, relative humidity : 52 – 92 %

Findings :

Mortality : No mortality was observed in the control groups. The results of mortality at 48 hours were already reached after 24 hours. Mortalities after 24 hours at 0.20, 0.40, 0.80, 1.60, 3.20, 6.40 µg a.s./bee were 6.67, 13.3, 60.0, 73.3, 76.7 and 100 % respectively. The LD₅₀ (24 h) of dimethoate was 0.176 µg a.s./bee.

Conclusion :

The study is acceptable. Minor deviations occurred in relative humidity compared to the guidelines.

Endpoints :

LD₅₀ (*Apis mellifera*, 48 h) oral = 0.92 µg a.s./bee (nominal, corrected for impurity of test compound)

NOEC (*Apis mellifera*, 48 h) oral = 0.20 µg a.s./bee (nominal, corrected for impurity of test compound, based on abnormal behaviour)

B.9.4.2 Bee brood feeding test (Annex IIA 8.3.1.2)

Not required. Benfuracarb has no growth regulating properties.

B.9.4.3 Acute toxicity of the preparations to bees (Annex IIIA 10.4.1)

Not required. The formulation Oncol 8.6G contains only one active substance.

B.9.4.4 Effects on bees of residues on crops (Annex IIIA 10.4.2)

Not required. The exposure of bees to benfuracarb in brassicas is not relevant.

B.9.4.5 Cage tests (Annex IIIA 10.4.3)

Not required. The exposure of bees to benfuracarb in brassicas is not relevant.

B.9.4.6 Field tests to investigate special effects (Annex IIIA 10.4.4)

Not required. The exposure of bees to benfuracarb in brassicas is not relevant.

B.9.4.7 Tunnel testing to investigate effects of feeding on contaminated honey (Annex IIIA 10.4.5)

Not required. The exposure of bees to benfuracarb in brassicas is not relevant.

B.9.4.8 Exposure and risk assessment for bees (Annex IIIA 10.4)

Table B.9.4.8-1 : Summary of effects of benfuracarb on bees

<i>Test species</i>	Test system	Endpoints	References
<i>Apis mellifera</i> L.	96 h acute contact and oral toxicity test	LD₅₀ contact = 0.19 µg a.s./bee LD ₅₀ oral = 2.1 µg a.s./bee	Geuijen W.H.C., 2002
<i>Apis mellifera</i> L.	48 h acute oral toxicity test	LD₅₀ oral = 0.92 µg a.s./bee	Geuijen W.H.C., 2002

First tier risk assessment for bees :

The risk assessment for bees is based on the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC of October 2002.

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the sowing bed as a single application rate of 1 kg a.s./ha.

Table B.9.4.8-2 : Hazard quotients of the formulation Oncol 8.6G for bees

Application rate	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
1 kg a.s./ha	brassicas	contact	5263	50
1 kg a.s./ha	brassicas	oral	1087	50

The calculated hazard quotients are not relevant for granule incorporation use. Also, the exposure of bees to benfuracarb in brassicas is not relevant. Cabbage is not attractive for pollinating insects : no flower in the production crop. Moreover weeds are controlled and no flowering weeds are present in cabbage fields.

In conclusion, the risk of benfuracarb to bees in brassicas is negligible.

B.9.5 Effects on other arthropods species (Annex IIA 8.3.2; Annex IIIA 10.5)**B.9.5.1 Effects of the active substance on non-target terrestrial arthropods (Annex IIA 8.3.2)**

Studies were performed with appropriate formulations.

B.9.5.2 Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests) (Annex IIIA 10.5.1)

Extended laboratory test on adults of *Aphidius rhopalosiphi* exposed to oat plants. (Bruhnke C., 2001).

Guidelines :

Mead-Briggs *et al.* (2000)

GLP :

Yes

Material and Methods :

Test substance : Oncol 20EC, formulation containing 216 g/L benfuracarb, batch n° : 0181117

Test species : *Aphidius rhopalosiphi* (parasitic wasp), adult females, surviving females for reproduction test were between 48 and 96 hours old

Number of organisms : 6 replicates per treatment and control (4 replicates for the reference item) each with 5 adult female wasps for the exposure phase, 15 replicates with 1 female wasp for the reproduction phase

Type of test : acute extended laboratory toxicity test

Applied and measured concentrations :

water control; positive control: ADimethoat 40 EC (414 g/L dimethoate); 3.2, 10, 32, 100, 320 mL Oncol 20EC/ha (equivalent to 0.69, 2.16, 6.9, 21.6, 69.1 g a.s./ha)

Exposure route :

The wasps were exposed to treated oat plants in cylinders for 48 hours. For the parasitization phase, females were individually transferred to pots with oat seedlings infested with aphids of *Rhopalosiphum padi*. The aphids were parasitized within 24 hours by one female. The number of aphid mummies per female wasp were assessed after 11 days.

Test conditions :

temperature : 19 – 20 °C (exposure phase), 14 – 25 °C (parasitization phase)

relative humidity : 75 – 100 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 2023 ± 614 lux (exposure phase), 2023 ± 614 lux (parasitization phase)

Findings :

Table B.9.5.2-1 : Effects of the formulation Oncol 20EC on *Aphidius rhopalosiphi*

Evaluation criteria	Control	Positive control	Treatment (g a.s./ha)				
			0.69	2.16	6.9	21.6	69.1
Corrected mortality (%)	0.0 ± 0.0	100 ± 0.00	10 ± 10.95	13 ± 20.66	10 ± 10.95	100 ± 0.00	100 ± 0.00
Reproduction (mummies per female)	10.7 ± 8.3	-	4.5 ± 2.9	4.3 ± 4.0	3.9 ± 3.2	-	-
Reproduction relative to control	-	-	-58 %	-60 %	-64 %	-	-

No reproduction phase was performed at concentrations of 100 and 320 mL Oncol 20EC/ha and for the toxic standard due to high mortality in those replicates.

Conclusion :

The study is acceptable. Minor deviations occurred in relative humidity in both phases and in temperature and light intensity during the parasitization phase.

Endpoints :

LD₅₀ (*Aphidius rhopalosiphi*, 48 h) = 43 mL Oncol 20EC/ha = 9.3 g a.s./ha

The reproduction rates were significantly different to the control group (58 % reduction at 3.2 mL Oncol 20 EC/ha).

Extended laboratory test on *Typhlodromus pyri* exposed on apple tree leaves. (Bruhnke C., 2000).

Guidelines :

Blümel *et al.* (2000): "Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) for regulatory testing of plant protection products"

Louis and Ufer (1995): "Methodical improvements of standard laboratory tests for determining the side-effects of agrochemicals on predatory mites (Acari: Phytoseiidae)"

GLP :

Yes

Material and Methods :

Test substance : Oncol 20EC, formulation containing 216 g/L benfuracarb, batch n° : 0181117

Test species : *Typhlodromus pyri* (predacious mite), protonymphs

Number of organisms : 5 replicates per treatment each with 20 protonymphs

Type of test : acute extended laboratory toxicity test

Applied and measured concentrations :

water control; positive control: ADimethoat 40 EC (414 g/L dimethoate); 16, 25, 40, 63, 100 mL Oncol 20EC/ha (equivalent to 3.46, 5.40, 8.64, 13.6, 21.6 g a.s./ha)

Exposure route :

Protonymphs were exposed to treated apple tree leaves for 14 days. Mortality was assessed on days 1, 2, 4 and 7. The number of surviving females and males, eggs laid and hatched juveniles was recorded on days 7, 9, 11 and 14.

Test conditions :

temperature : 23 – 27 °C

relative humidity : 70 – 100 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 675 – 735 lux

Findings :

Table B.9.5.2.-2: Effects of the formulation Oncol 20EC on *Typhlodromus pyri*

Evaluation criteria	Control	Positive control	Treatment (g a.s./ha)				
			3.46	5.40	8.64	13.6	21.6
Corrected mortality (%)	10.0 ± 7.9	92.0 ± 15.2	14.0 ± 10.8	36.0 ± 16.0	52.0 ± 11.5	73.0 ± 20.2	91.0 ± 7.4
Reproduction (mummies/female)	6.18 ± 1.82	-	5.64 ± 1.65	3.86 ± 2.43	1.75 ± 0.95	-	-
Reproduction relative to control	-	-	-8.7 %	-38 %	-72 %	-	-

No reproduction phase was performed at concentrations of 63 and 100 mL Oncol 20EC/ha and for the toxic standard due to high mortality in those replicates.

Conclusion :

The study is acceptable. Minor deviations occurred in relative humidity.

Endpoints :

LD₅₀ (*Typhlodromus pyri*, 7 d) = 42.4 mL Oncol 20EC/ha = 9.2 g a.s./ha

The mean reproduction rate of the test item group 40 mL Oncol 20 EC/ha was statistically significantly different when compared to the control.

Effects of Oncol 20 EC on the ladybird *Coccinella septempunctata* under laboratory conditions. (Kühner Ch., 1991).

Guidelines :

BBA, Pinsdorf W. (1989): Auswirkung von Pflanzenschutzmitteln auf *Coccinella septempunctata*. Richtlinie für die Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren, Teil VI, April 1989, 23-2.1.5.

GLP :

Yes

Material and Methods :

Test substance : Oncol 20EC, formulation containing 200 g/L benfuracarb, batch n° : not reported

Test species : *Coccinella septempunctata* L., 2 - 3 days old larvae

Number of organisms : 3 replicates per treatment each with 15 larvae

Type of test : acute laboratory toxicity test

Applied and measured concentrations :

water control; 0.5 mL Oncol 20EC/100 mL water or 1 L Oncol 20 EC/ha in 200 L water (equivalent to 216 g a.s./ha)

Exposure route :

The larvae were exposed to treated glass plates and daily fed with aphids.

Test conditions :

temperature : 22 – 25 °C (day), 16 – 18 °C (night)

relative humidity : 50 ± 10 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 300 lux

Findings :

Table B.9.5.2-3 : Effects of the formulation Oncol 20EC on *Coccinella septempunctata*

Evaluation criteria	Control	216 g a.s./ha
Mortality (%)	33.3	100
Corrected mortality (%)	-	100

No reproduction phase was performed due to 100 % mortality in the treatment group.

Conclusion :

The study is acceptable. Minor deviations occurred to the temperature at night, the relative humidity, the light intensity and the mortality criterion in the control.

Side effects on the larve of the green lacewing *Chrysoperla carnea* (Neuroptera, Chrysopidae) exposed on apple tree leaves. (Bruhnke C., 2000).

Guidelines :

IOBC, Bigler F. (1988)

Vogt H. *et al.* (2000)

GLP :

Yes

Material and Methods :

Test substance : Oncol 20EC, formulation containing 215.6 g/L benfuracarb, batch n° : 0181117

Test species : *Chrysoperla carnea*, 2 – 3 days old larvae

Number of organisms : 30 replicates per test item concentration each with 1 larva and 50 replicates for the control and the reference item each with 1 larva for the exposure phase, 2 replicates each containing 5 – 14 females and 7 – 9 males for the reproduction phase

Type of test : acute extended laboratory toxicity test

Applied and measured concentrations :

water control; positive control: ADimethoat 40 EC (415 g/L dimethoate); 0.01, 0.032, 0.1, 0.32, 1.0 L Oncol 20EC/ha (equivalent to 2.16, 6.91, 21.6, 69.1, 216 g a.s./ha)

Exposure route :

The lacewing larvae were exposed to treated apple tree leaves layed on glass plates up to formation of cocoons. All insects reaching adult stage were transferred to untreated reproduction units to assess oviposition and egg viability.

Test conditions :

temperature : 22 – 27 °C (exposure phase), 23 – 29 °C (reproduction phase)

relative humidity : 58 – 85 % (exposure phase), 52 – 90 % (reproduction phase)

photoperiod : 16/8 hours light/dark cycle

light intensity : 2163 ± 329 lux

Findings :

Table B.9.5.2-4: Effects of the formulation Oncol 20EC on *Chrysoperla carnea*

Evaluation criteria	Control	Positive control	Treatment (g a.s./ha)				
			2.16	6.91	21.6	69.1	216
Mortality (%)	6	96	13	43	100	100	100
Corrected mortality (%)	-	-	7.4	39	100	100	100
Fertile eggs per female per day	29.4 ± 6.3	-	27.9 ± 9.2	24.5 ± 1.3	-	-	-
Hatching rate (%)	96.6 ± 1.6	-	94.9 ± 5.5	92.7 ± 4.9	-	-	-
Reproduction relative to control	-	-	-6.7 %	-20 %	-	-	-

$F = ((\text{number of eggs per female}) \times \text{hatching rate in } \%) / 100$

F_1 = average number of fertile eggs per female in the treatment group 2.16 g a.s./ha = 26.5

F_2 = average number of fertile eggs per female in the treatment group 6.91 g a.s./ha = 22.7

F_c = average number of fertile eggs per female in the control group = 28.4

No reproduction phase was performed at concentrations of 0.1, 0.32 and 1.0 L Oncol 20EC/ha and for the toxic standard due to high mortality in those replicates.

Conclusion :

The study is acceptable. Minor deviations occurred for temperature.

Endpoints :

LD₅₀ (*Chrysoperla carnea*, 20 d) = 24 mL Oncol 20EC/ha = 5.2 g a.s./ha

No effect on reproduction occurred.

Effects of Oncol 8.6 G on survival and food consumption of the carabid beetle *Poecilus cupreus* (extended laboratory test for granulates). (Geuijen W.H.C., 2002).

Guidelines :

Barrett K.L. *et al.*: SETAC: Guidance document on regulatory testing procedures with non-target arthropods (1994)

Hassan S.A.: Meeting of the working group “pesticides and beneficial organisms”, University of Southampton, UK, September 1991, IOBC/WPRS XV/3: 1-3 (1992)

BBA Guideline part VI, 23-2.1.8: Auswirkungen von Pflanzenschutzmitteln auf Images von *Poecilus cupreus* L. als Vertreter der Familie Carabidae (=Laufkäfer) im Laboratorium (1991)

Heimbach U.: Laboratory method to test effects of pesticides on *Poecilus cupreus* (Coleoptera, Carabidae), IOBC WPRS Working Group “Pesticides and Beneficial Organisms”, IOBC/WPRS Bull. 1992 XV/3: 103-109 (1992)

Heimbach U *et al.*: A method for testing effects of plant protection products on the carabid beetle *Poecilus cupreus* (Coleoptera, Carabidae) under laboratory and semi-field conditions. In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (IOBC, BART and EPPO Joint Initiative), Gandolfi M.P. *et al.*, 2000, 87-106. Publication available in 2001 (2000)

GLP :

Yes

Material and Methods :

Test substance : Oncol 8.6G, formulation containing 9.14 % benfuracarb, batch n° : 22CA1E

Test species : *Poecilus cupreus*, 6^{1/2} weeks old adult beetles

Number of organisms : 5 replicates per treatment each with 3 male and 3 female beetles

Type of test : acute extended laboratory test for granulates

Applied and measured concentrations :

blank control (blank granulate formulation: Gypsum Granule, 12 kg/ha); positive control: Holland Fyto Pyrazofos (294 g/L pyrazofos); 12 kg/ha Oncol 8.6G (Maximum Recommended Label Rate) (equivalent to 1.0 kg a.s./ha). For the positive control a spray application was used equivalent to a volume application of 400 L/ha.

Exposure route :

The beetles in the blank control and in the treatment group were exposed to granular application in sand boxes at 1 cm depth. The beetles in the positive control were exposed to sprayed sand boxes. The food consisted out of 3 perforated *Delia*-pupae/beetle. Mortality, behaviour and food consumption were monitored for 14 days.

Test conditions :

temperature : 17 – 22 °C

relative humidity : 69 – 98 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 857 – 1300 lux

Findings :Table B.9.5.2-5: Effects of the formulation Oncol 8.6G on *Poecilus cupreus*

Evaluation criteria	Blank control	Positive control	Oncol 8.6G
Cumulative mortality (%) after 14 days	3.33 ± 7.45	100 ± 0.00	0.00 ± 0.00
Corrected mortality (%)	-	-	-3.4
Abnormal behaviour (%) after 14 days	0.00 ± 0.00	100 ± 0.00	0.00 ± 0.00
Mean pupae consumed per beetle after 14 days	10.0	-	10.0
Food consumption relative to control (%)	-	-	0 %

During the first week food consumption of beetles exposed to Oncol 8.6G was 3.33 % less compared to the blank control, in the second week consumption in the test substance group was more (4.00 %) than in the blank control. So, over the whole test period consumption in the Oncol 8.6G group was comparable with the blank control.

Conclusion :

The study is acceptable. Minor deviations occurred for temperature, relative humidity, moisture content and food addition.

Oncol 8.6 G did not induce mortality at a dosage of 12 kg/ha. Total mean cumulative food consumption at the end of the test was comparable to the blank control.

Effects of Oncol 8.6 G on Staphylinid beetle *Aleochara bilineata* (extended laboratory test for granulates). (Geuijen W.H.C., 2002).

Guidelines :

Barrett K.L. *et al.* : SETAC : Guidance document on regulatory testing procedures with non-target arthropodes (1994)

Hassan S.A.: Meeting of the working group “pesticides and beneficial organisms”, university of Southampton, UK, September 1991, IOBC/WPRS XV/3: 1-3 (1992)

Grimm C. *et al.*: A test for evaluating the chronic effects of plant protection products on the rove beetle *Aleochara bilineata* Gyll (Coleoptera: Staphylinidae) under laboratory and extended laboratory conditions. In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (IOBC, BART and EPPO Joint Initiative), Gandolfi M.P. *et al.*, 2000, 1-12. Publication available in 2001 (2000)

GLP :

Yes

Material and Methods :

Test substance : Oncol 8.6G, formulation containing 9.14 % benfuracarb, batch n° : 22CA1E

Test species : *Aleochara bilineata*, 1 – 4 days old

Number of organisms : 4 replicates per treatment each with 10 male and 10 female beetles

Type of test : acute extended laboratory test for granulates

Applied and measured concentrations :

blank control (blank granulate formulation: Gypsum Granule, 12 kg/ha); positive control: Holland Fyto Pyrazofos (294 g/L pyrazofos); 12 kg/ha Oncol 8.6G (Maximum Recommended Label Rate) (equivalent to 1.0 kg a.s./ha). For the positive control a spray application was used equivalent to a volume application of 400 L/ha.

Exposure route :

The beetles in the blank control and in the treatment group were exposed to granular application in boxes filled with soil at 1 cm depth. The beetles in the positive control were exposed to sprayed soil. During the exposure phase the beetles were fed with red mosquito larvae (*Chironomus* sp.). During the hatching phase the host species was the onion fly *Delia antiqua* Meigen (Diptera, Anthomyiidae).

Test conditions :

temperature : 18 – 22 °C

relative humidity : 62 – 97 % (exposure phase), 25 – 53 % (drying phase), 34 – 91 % (hatching phase)

photoperiod : 16/8 hours light/dark cycle

light intensity : 900 – 1150 lux

Findings :Table B.9.5.2-6: Effects of the formulation Oncol 8.6G on *Aleochara bilineata*

<i>Evaluation criteria</i>	Blank control	Positive control	Oncol 8.6G
Mean corrected mortality (%) of parental generation during exposure phase	-	45.6	59.5
Mean hatching rate (%) of <i>Aleochara bilineata</i>	44.3 ± 5.96	27.0 ± 4.76	18.8 ± 2.79
Reproduction relative to control	-	-	-58 %

Mortality in the test substance group was statistically significant from the blank control and comparable with the positive control. Mean beetle hatching rate in the Oncol 8.6G treatment was significantly lower than in the blank control and comparable with the positive control.

Conclusion :

The study is acceptable. Minor deviations occurred for temperature, relative humidity and moisture content.

Exposure of the parental generation to Oncol 8.6G induced a mean (corrected) mortality of 59.5 %. The cumulative mean hatching rate of *Aleochara bilineata* (F1 generation) at the end of the test was 18.8 %. This was a reduction of 57.6 % compared to the blank control.

Effects of Carbofuran on survival and food consumption of the carabid beetle *Poecilus cupreus* (extended laboratory test for seed dressings). (Geuijen W.H.C., 2002).

Guidelines :

Barrett K.L. *et al.*: SETAC: Guidance document on regulatory testing procedures with non-target arthropods (1994)

BBA Guideline part VI, 23-2.1.8: Auswirkungen von Pflanzenschutzmitteln auf Images von *Poecilus cupreus* L. als Vertreter der Familie Carabidae (=Laufkäfer) im Laboratorium (1991)

Heimbach U.: Laboratory method to test effects of pesticides on *Poecilus cupreus* (Coleoptera, Carabidae), IOBC WPRS Working Group "Pesticides and Beneficial Organisms", IOBC/WPRS Bull. 1992 XV/3: 103-109 (1992)

Dohmen G.P.: Testing side effects of pesticides on carabid beetles: a standardized method for testing ground dwelling predators in the laboratory for registration purposes. In: Ecotoxicology: Pesticides and beneficial organisms, Haskell P.T. and McEwen P. (eds), 1998, 98-106 (1998)

Heimbach U *et al.*: A method for testing effects of plant protection products on the carabid beetle *Poecilus cupreus* (Coleoptera, Carabidae) under laboratory and semi-field conditions. In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (IOBC, BART and EPPO Joint Initiative), Gandolfi M.P. *et al.*, 2000, 87-106. Publication available in 2001 (2000)

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 99.9 %, batch n° : 1B87

Test species : *Poecilus cupreus*, 3 – 4 weeks old adult beetles

Number of organisms : 5 replicates per treatment each with 3 male and 3 female beetles

Type of test : acute extended laboratory test

Applied and measured concentrations :

water control; solvent control (acetone); positive control: Asepthion (8.275 µg parathion-ethyl/g quartz sand); treatment at 0.13 mg carbofuran/g quartz sand

Exposure route :

The test substance was dissolved in acetone, mixed with sand, distributed evenly over 3 small holes in each test unit and covered with soil. Speyer 2.1 soil was used instead of quartz sand. For the solvent control acetone was mixed thoroughly with quartz sand. For the parathion-ethyl control a solution was prepared and mixed thoroughly with quartz sand. The food consisted out of 3 perforated *Delia antiqua* pupae/beetle. Mortality, behaviour and food consumption were monitored for 14 days.

Test conditions :

temperature : 18 – 20 °C

relative humidity : 57 – 92 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 800 – 1000 lux

Findings :Table B.9.5.2-7: Effects of carbofuran on *Poecilus cupreus*

Evaluation criteria	Water control	Solvent control	Parathion-ethyl	carbofuran
Cumulative mortality (%) after 14 days	6.67 ± 9.13	3.33 ± 7.45	3.33 ± 7.45	0.00 ± 0.00
Corrected mortality (%)	-	-	-	-7.1
Mean pupae consumed per beetle after 14 days	8.27	6.59	6.03	4.60
Food consumption relative to pooled control (%)	-	-	-	-38 %

During the first week food consumption of beetles exposed to carbofuran was 46 % less compared to the solvent control, in the second week consumption in the test substance group was 1 % more than in the solvent control.

Conclusion :

The study is not acceptable. The mode of application is not relevant for the proposed intended use (incorporation of the granules in the sowing bed). The mortality with the parathion-ethyl control met not the validity criteria. Minor deviations occurred for relative humidity, moisture content and food addition.

Exposure to carbofuran induced no mortality. Over the whole test period food consumption was reduced by 38% (statistically significant reduction).

Effects of Carbofuran on the Staphylinid beetles *Aleochara bilineata* (extended laboratory test for seed dressings). (Geuijen W.H.C., 2001).

Guidelines :

Barrett K.L. *et al.*: SETAC: Guidance document on regulatory testing procedures with non-target arthropods (1994)

Moreth L. and Naton E.: Richtlinie zur Prüfung der Nebenwirkung von Pflanzenschutzmitteln auf *Aleochara bilineata* Gyll. (Col., Staphylinidae) (erweiterter Laborversuch), IOBC WPRS Working Group "Pesticides and Beneficial Organisms", IOBC/WPRS Bull. 1992 XV/3: 152-158 (1992)

Grimm C. *et al.*: A test for evaluating the chronic effects of plant protection products on the rove beetle *Aleochara bilineata* Gyll (Coleoptera: Staphylinidae) under laboratory and extended laboratory conditions. In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (IOBC, BART and EPPO Joint Initiative), Gandolfi M.P. *et al.*, 2000, 1-12. Publication available in 2001 (2000)

GLP :

Yes

Material and Methods :

Test substance : carbofuran, chemical purity : 99.9 %, batch n° : 1B87

Test species : *Aleochara bilineata*, 2 - 3 days old

Number of organisms : 4 replicates per treatment each with 10 male and 10 female beetles

Type of test : acute extended laboratory test

Applied and measured concentrations :

water control; solvent control (acetone); positive control: Asepthion (8.28 mg parathion-ethyl/g quartz sand); treatment at 0.13 mg carbofuran/g quartz sand. Due to a mistake the 1000-folded target concentration of the positive control was tested.

Exposure route :

The test substance was dissolved in acetone, mixed with sand, distributed evenly over 2 small holes in each test unit and covered with soil. Speyer 2.1 soil was used instead of quartz sand. For the solvent control acetone was mixed thoroughly with quartz sand. For the parathion-ethyl control a solution was prepared and mixed thoroughly with quartz sand. During the exposure phase the beetles were fed with red mosquito larvae (*Chironomus* sp.). During the hatching phase the host species was the onion fly *Delia antiqua* Meigen (Diptera, Anthomyiidae).

Test conditions :

temperature : 18 – 20 °C (exposure phase), 18 – 21 °C (reproduction phase)

relative humidity : 60 – 82 % (exposure phase), 34 – 76 % (drying phase), 60 – 90 % (reproduction phase)

photoperiod : 16/8 hours light/dark cycle

light intensity : 225 – 350 lux (exposure phase), 300 – 400 lux (reproduction phase)

Findings :

Table B.9.5.2-8: Effects of carbofuran on *Aleochara bilineata*

Evaluation criteria	Pooled control	Parathion-ethyl	carbofuran
Mean corrected mortality (%) of parental generation during exposure phase	-	98.7	11.3
Mean hatching rate (%) of <i>Aleochara bilineata</i>	47.7 ± 9.80	0.13 ± 0.27	39.2 ± 5.52
Reproduction relative to control	-	-	-18 %

Since the blank and acetone control data were normally distributed with equal variances, data were pooled. Corrected mortality in the test substance group and positive control was calculated with reference to the pooled control data.

In the pooled control the hatching rate was 47.7 %. Hatching in the carbofuran treatment and the pooled control was not statistically significant. The reduction of beneficial capacity in the test substance group with reference to the pooled control was 18 %.

Conclusion :

The study is not acceptable. The mode of application is not relevant for the proposed intended use (incorporation of the granules in the sowing bed). Minor deviations occurred for temperature, relative humidity and moisture content.

Added in August 2008

Effects of aged residue of Oncol 8.6G on the staphylinid beetle *Aleochara bilineata* (extended laboratory test for granulates with aged residue). (Geuijen I., 2005a).

Guidelines :

Barrett K.L. *et al.* : SETAC : Guidance document on regulatory testing procedures with non-target arthropods (1994)

Hassan S.A.: Meeting of the working group “pesticides and beneficial organisms”, university of Southampton, UK, September 1991, IOBC/WPRS XV/3: 1-3 (1992)

Grimm C. *et al.*: A test for evaluating the chronic effects of plant protection products on the rove beetle *Aleochara bilineata* Gyll (Coleoptera: Staphylinidae) under laboratory and extended laboratory conditions. In: Guidelines to evaluate side-effects of plant protection products to non-target arthropods (IOBC, BART and EPPO Joint Initiative), Gandolfi M.P. *et al.*, 2000, 1-12. Publication available in 2001 (2000)

GLP :

Yes

Material and Methods :

Test substance : Oncol 8.6G, formulation containing 9.39 % benfuracarb, batch n° : 4D80

Test species : *Aleochara bilineata* (polyphagous predator), 1 – 4 days old

Number of organisms : 4 replicates per treatment, per aging period, each with 10 male and 10 female beetles

Type of test : acute extended laboratory test for granulates

Applied and measured concentrations :

The formulation Oncol 8.6G was applied at the dosage of 12 kg formulation/ha (equivalent to 1.0 kg a.s./ha) in soil containers and incubated in the laboratory for 0, 7, 14, 21, 28, 56 and 119 days. With a test unit area of 145 cm² this dosage corresponded with 17.4 mg per test unit. The granules were evenly spread in the 2.5 cm deep furrow made in the soil of each test unit and were covered with soil of the test unit. The Speyer 2.1 soil (batch F214104, sand (according to USDA), 34.7 g/100 g WHC, pH CaCl₂ of 6.1, organic carbon content of 1.21 ± 0.27 %) was used. The moisture of the soil in each test unit was readjusted daily to 40 % MWHC.

A blank control consisted of a blank granulate formulation, Calcium sulfate dihydrate Granule, applied at 12 kg/ha by soil incorporation similar as the formulation Oncol 8.6G. Also a positive control Aseptia Dimethoat (400 g/L dimethoate) was applied by spraying at 1.8 L dimethoate in 400 L water/ha. Both blank control and positive control were subjected to the same aging procedure as for the formulation Oncol 8.6G. Further positive controls were applied at higher dosage (3.1 L dimethoate in 400 L water/ha at day 0 and 4.4 L dimethoate in 400 L water/ha at day 0 and with 120 day aging).

Exposure route :

The beetles in the blank control and in the treatment group were exposed to granular application in boxes filled with soil at 2.5 cm depth. The beetles in the positive control were exposed to sprayed soil. During the exposure phase (5 weeks) the beetles were fed every 1-2 days with red mosquito larvae (*Chironomus* sp.). During the hatching phase (5-6 weeks) the host species was the onion fly *Delia antiqua* Meigen (Diptera, Anthomyiidae). On day 7, 14 and 21 DAT approximately 500 pupae (totally 1500 pupae) were added for parasitisation to each test unit. Pupae were put in the hole and covered with the soil.

Test conditions :

temperature : 19.0 – 22.1 °C (soil aging), 19.0 – 21.8 °C (exposure phase), 21.6 – 22.8 °C (drying phase), 19.0 – 21.2 °C (hatching phase)

relative humidity : 19.7 - 85.1 % (soil aging), 47.3 - 85.3 % (exposure phase), 18.6 - 44.3 % (drying phase), 19.7 - 85.3 % (hatching phase)

Average daily relative humidity was mainly between 60 and 85 %. Deviations occurred and were mostly caused by the very low relative humidity of the incoming (outside) air during some periods. Relative humidity values below 45 % were only present for a few hours.

photoperiod : 16/8 hours light/dark cycle

light intensity : 1350-1900 lux (exposure and aging till day 28), 280-610 (exposure and aging from day 28 onwards), 390-530 (drying) and 340-580 lux (hatching). The high light intensity caused problems with maintaining temperature and caused algae growth on the soil. If algae growth was observed on the soil, algae were removed just before readjustment of humidity.

Assessment parameters :

Mean mortality of parental generation : On 28 DAT the soil of the test units was searched and the number of dead and alive beetles of the parental generation were counted. Beetles present on the substrate within the next days (till 34 – 36 DAT) were removed.

Hatching rate of *Aleochara bilineata* beetles (hatched beetles/added pupae) : Hatched beetles were counted and removed from the units.

Hatching of onion flies : Hatched onion flies were counted and removed from the units.

Findings :

Table B.9.5.2-9 : Effects of the formulation Oncol 8.6G on *Aleochara bilineata*, after soil aging during 0, 7, 14, 21, 28, 56 and 119 days

Treatment	Soil aging period (days)	Mean corrected mortality (%) of parental generation during exposure phase	Mean hatching rate (%) of <i>Aleochara bilineata</i>	Hatching rate reduction (%) of <i>Aleochara bilineata</i> in comparison to blank control	Mean hatching rate (%) of <i>Delia antiqua</i>
Blank control	0	-	54.8	-	6.6
Oncol 8.6G		8.5	50.2	8.5	9.7
1.8 L dimethoate/ha		53.5	41.4	24.4	20.6
Blank control	7	-	54.9	-	9.2
Oncol 8.6G		7.0	53.4	2.7	7.2
1.8 L dimethoate/ha		52.1	49.4	10.0	12.8
Blank control	14	-	53.5	-	9.5
Oncol 8.6G		31.8	42.9	19.8	16.4
1.8 L dimethoate/ha		15.2	50.2	6.2	6.8
Blank control	21	-	42.9	-	8.1
Oncol 8.6G		18.3	42.6	0.8	21.9
1.8 L dimethoate/ha		63.4	42.1	1.9	24.3
Blank control	28	-	45.6	-	12.7
Oncol 8.6G		42.0	35.1	23.0	28.0
1.8 L dimethoate/ha		21.7	50.9	-11.5 (*)	11.1
Blank control	56	-	54.8	-	11.3
Oncol 8.6G		17.6	41.8	23.7	32.3
1.8 L dimethoate/ha		40.5	55.3	-0.9 (*)	16.7
Blank control	119	-	56.4	-	6.1
Oncol 8.6G		20.8	23.8	57.8	49.4
1.8 L dimethoate/ha		51.9	52.3	7.3	14.5
3.1 L dimethoate/ha	0	93.5	20.7	63.3	58.3
4.4 L dimethoate/ha	0	97.4	3.3	94.1	83.2
4.4 L dimethoate/ha	120	88.3	15.0	73.5	70.2

(*): negative values mean more beetles hatched than in the blank control

Mortality in the blank control and Oncol 8.6G treatment were comparable after 0 and 7 days of aging, later on mortality in the Oncol 8.6G treatment was significantly higher in comparison to the blank control, with mortality ranging between 23.8 and 50 %. Mortality in all dimethoate treatments was significantly higher in comparison with the blank control.

Hatching of *Aleochara* beetles in the Oncol 8.6G treatment ranged from 35.1 to 53.4 % when beetles were exposed to residue aged for 56 days or less, but the hatching rate dropped to 23.8 % when beetles were exposed to 119 day old residue. Number of beetles hatched when exposed to 56 days and 119 days aged Oncol 8.6G residue was significantly lower as compared to the blank control. Hatching rate reduction in the treatments with 119 days aged Oncol 8.6G as compared to the blank control was 57.8 %, reduction in the other Oncol 8.6G treatments as compared to the blank control was 23.7 % or less.

Hatching rate reduction in the dimethoate controls (1.8 L/ha) as compared to the blank control was highest when sprayed on fresh soil, later on reduction was less or even more beetles hatched compared to the blank control. At 3.1 L/ha and 4.4 L dimethoate/ha, significantly less beetles hatched compared to the blank control and 1.8 L dimethoate/ha controls. When exposed to a dosage of 4.4 L dimethoate/ha on fresh soil, significantly less beetles hatched than when the same dosage was sprayed on aged soil or when a lower dosage (3.1 L dimethoate/ha) was sprayed on fresh soil.

In case of a lower *Aleochara* hatching rate as compared to the blank control, a higher *Delia* hatching rate was reached.

Conclusion :

The study is acceptable.

The formulation Oncol 8.6G was applied at the dosage of 12 kg formulation/ha (equivalent to 1.0 kg a.s./ha) in soil containers and incubated in the laboratory for 0, 7, 14, 21, 28, 56 and 119 days. The beetles were then introduced in the soil containers. Mortality of the adults and hatching rate was monitored.

Mortality in the blank control and Oncol 8.6G treatment were comparable after 0 and 7 days of aging, later on mortality in the Oncol 8.6G treatment was significantly higher to the blank control with corrected mortality ranging between 17.6 and 42.0 %. The formulation Oncol 8.6G is harmless (< 25 % hatching rate reduction) to beetles when introduced 0, 7, 14, 21, 28 and 56 days after application of the formulation to the test units, but slightly harmful (58 % hatching rate reduction) when introduced 119 days after application of the formulation

The notifier provided an argumentation why the effect of carbofuran observed after 119 days of aging is not considered to be treatment-related. The motivation is based on following considerations of exposure :

- release rate of benfuracarb from granules
- degradation of benfuracarb to carbofuran
- degradation of carbofuran
- fresh soil, 20 °C, 40 % MWHC (maintained)
- DT₅₀ of benfuracarb in soil = 0.13 – 0.83 days (laboratory)
- DT₅₀ of carbofuran in soil = 6.1 – 19.3 days (laboratory)
- release rate from granules : not known, but normally fast (days)

The notifier provided simulations of the level of benfuracarb and carbofuran in soil over time assuming following scenarios :

- immediate release of benfuracarb from granule, DT₅₀ (benfuracarb) = 0.83 days, DT₅₀ (carbofuran) = 19.3 days
- release of benfuracarb from granule after 28 days, DT₅₀ (benfuracarb) = 0.83 days, DT₅₀ (carbofuran) = 19.3 days
- release of benfuracarb from granule after 42 days, DT₅₀ (benfuracarb) = 0.83 days, DT₅₀ (carbofuran) = 19.3 days
- immediate release of benfuracarb from granule, DT₅₀ (benfuracarb) = 0.83 days, DT₅₀ (carbofuran) = 50 days (worst-case)
- release of benfuracarb from granule after 28 days, DT₅₀ (benfuracarb) = 0.83 days, DT₅₀ (carbofuran) = 50 days (worst-case)
- release of benfuracarb from granule after 42 days, DT₅₀ (benfuracarb) = 0.83 days, DT₅₀ (carbofuran) = 50 days (worst-case)

Following conclusions could be drawn :

- Maximum exposure to carbofuran at the end of the release period of benfuracarb from the granule (assuming linear release), is not dependent on the DT₅₀ of carbofuran.
- Even at release periods of 42 days (extremely unlikely for a moist soil) and long DT₅₀ value for carbofuran, the exposure at days 7, 14, 21, 28 and 56 exceeds the exposure at day 119.
- The effect observed at 119 days cannot be treatment-related and is an experimental artifact.

Conclusion of RMS :

RMS agrees with the argumentation of the notifier and concludes that the effect observed at 119 days is not treatment-related.

Added in August 2008

An extended laboratory test to determine the effects of Oncol 8.6G (= Oncol S), containing 8.6 % w/w benfuracarb, on the predatory mite, *Hypoaspis aculeifer* (Acari, Laelapidae).

Guidelines :

OECD Guideline : Predatory mite reproduction test in soil (*Hypoaspis (Geolaelaps) aculeifer*). (draft 2007).

GLP :

Yes

Material and Methods :

Test substance : Oncol 8.6G, formulation containing 8.9 % w/w benfuracarb, batch n° : 22LG1E

Test species : *Hypoaspis aculeifer* (predatory mite), adult females

Number of organisms : 6 replicates per treatment, each containing 10 female mites

Type of test : acute extended laboratory toxicity test for granules

Test substrate : natural soil (LUF 2.1), batch n° : F2.11508, sandy soil, 0.88 % organic matter content, pH : 5.1

Applied concentrations :

untreated control;

positive control : Posse 10G, formulation containing 10 % w/w carbosulfan, applied at 16 kg Posse 10G/ha.

treatment : applied at 12 kg Oncol 8.6G/ha (equivalent to 1 kg a.s./ha).

The test item was incorporated into the soil substrate at a depth of approximately 2.5 cm below the surface, the positive control was incorporated up to a depth of 1 cm below the surface. The surface area of soil in the individual test arenas was 15.2 cm² and so aliquots of 1.8 mg Oncol 8.6G and 2.4 mg Posse 10G were incorporated in each arena to achieve the target rate of 12 kg Oncol 8.6G/ha and 16 kg Posse 10G/ha.

Exposure route :

Within 1 hour of the soil being treated, 10 female *Hypoaspis aculeifer* (approximately 7-14 days from becoming adult) were placed in each test arena. Both the number of surviving adults and the number of offspring produced per treatment were assessed at 14 DAT (days after treatment). The predatory mites were separated from the soil substrate by heat extraction.

Feeding : Cheese mites (*Tyrophagus putrescentiae*) and juvenile springtails (*Folsomia candida*) were added to the soil surface at the beginning of the test and *ad libitum* (every 1-4 days) throughout the test.

Test conditions :

temperature : 19.6 – 23.8 °C

relative humidity : 61 – 89 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 450 – 610 lux

Findings :Table B.9.5.2-10 : Effects of the formulation Oncol 8.6G on *Hypoaspis aculeifer* in an extended laboratory test

Evaluation criteria	Control	Positive control	Oncol 8.6G
% mortality after 14 days	0	55*	7
% corrected mortality	-	55	7
Mean number of progeny/replicate	83.0	31.8*	81.3
% reproduction relative to control	-	-62	-2

* statistically significantly different from the control

Conclusions :

The study is acceptable.

In an extended laboratory test where the predatory mite, *Hypoaspis aculeifer*, were exposed to a natural sandy soil treated with Oncol 8.6G at a rate equivalent to 12 kg formulation/ha (the treatment being incorporated into the soil at a uniform depth of 2.5 cm), no harmful effects on the survival or reproductive activity of the mites were observed over a 14-day assessment period.

Added in August 2008

An extended laboratory test to determine the effects of Oncol 8.6G (= Oncol S), containing 8.6 % w/w benfuracarb, on spiders of the genus *Pardosa* (Araneae, Lycosidae).

Guidelines :

Heimbach *et al.* (2000). A method for testing effects of plant protection products on spiders of the genus *Pardosa* (Araneae : Lycosidae) under laboratory conditions.

GLP :

Yes

Material and Methods :

Test substance : Oncol 8.6G, formulation containing 8.9 % w/w benfuracarb, batch n° : 22LG1E

Test species : *Pardosa* (100 species of *Pardosa pullata*, 2 female species of *Pardosa proxima*) (spiders), adults

Number of organisms, life stage, age : 34 replicates per treatment, each containing 1 spider

Type of test : acute extended laboratory toxicity test for granules

Test substrate : natural soil (LUFA 2.1), batch n° : F2.10208, sandy soil, 0.88 % organic matter content, pH : 5.1

Applied concentrations :

untreated control;

positive control : Posse 10G, formulation containing 10 % w/w carbosulfan, applied at 16 kg Posse 10G/ha.

treatment : applied at 12 kg Oncol 8.6G/ha (equivalent to 1 kg a.s./ha).

The test item was incorporated into the soil substrate at a depth of approximately 2.5 cm below the surface, the positive control was incorporated up to a depth of 1 cm below the surface. The surface area of soil in the individual test arenas was 75.4 cm² and so aliquots of 9 mg Oncol 8.6G and 12 mg Posse 10G were incorporated in each arena to achieve the target rate of 12 kg Oncol 8.6G/ha and 16 kg Posse 10G/ha.

Pre-conditioning of the spiders :

Three days prior to the application of the treatments, the spiders were weighed to confirm that they were within the range of 12 – 35 mg. Any that were outside of this range were replaced. None of the females had egg sacs at this time. The spiders were placed into the pots containing the fully-moistened soil. The spiders were deprived of food from this time until the start of the test.

Exposure route :

The spiders were temporarily removed from the pots, the applications of Oncol 8.6G and Posse 10G were made and the spiders were reintroduced. Mortality of the spiders was assessed 1-2 hours after reintroduction in the treated pots and then 1, 2, 3, 4, 7, 10 and 14 DAT (days after treatment). To assess any changes in the feeding activity of the spiders, five food items (i.e. pea aphids) were placed in each arena approximately 1-2 hours after

test initiation and again after 1, 2, 3, 7 and 10 days. In each instance, an assessment of the number of items consumed was made after approximately 24 hours (i.e. at 1, 2, 3, 4, 8 and 11 DAT) and any remains (live or dead aphids) were removed.

Since the feeding activity of spiders may be reduced in the period prior to moulting, and their sensitivity to effects of plant protection products may be increased in the period after moulting, the presence of any moulted skins in the pots was recorded at the same time that any of the other assessments were being made. The skins were then removed. In addition, the development of egg sacs by females was noted.

Feeding : large (third- to fourth-instar) pea aphids reared on dwarf broad beans (*Vicia faba*)

Test conditions :

temperature : 19 – 20 °C

relative humidity : 61 – 89 %

photoperiod : 16/8 hours light/dark cycle

light intensity : 500 – 680 lux

Findings :

Table B.9.5.2-11 : Effects of the formulation Oncol 8.6G on *Pardosa* in an extended laboratory test

Evaluation criteria	Control	Positive control	Oncol 8.6G
% mean mortality after 14 days	6	100	6
% corrected mortality	-	100	0
Mean number prey items taken/spider/feeding occasion	3.1	0.0	3.3
% feed consumption relative to control	-	-	6
% of food items provided that were consumed	62	0	66

* statistically significantly different from the control

Conclusions :

The study is acceptable.

In an extended laboratory test where lycosid spiders of the genus *Pardosa* were exposed to a natural sandy soil treated with Oncol 8.6G at a rate equivalent to 12 kg formulation/ha (the treatment being incorporated into the soil at a uniform depth of 2.5 cm), no harmful effects on the survival or feeding activity of the spiders were observed over a 14-day assessment period.

B.9.5.3 Effects of the formulations on non-target terrestrial arthropods (field tests) (Annex IIIA 10.5.2)

Not available.

B.9.5.4 Summary of effects, exposure and risk assessment for non-target terrestrial arthropods (revised in August 2008)

Table B.9.5.4-1: Summary of effects and risk assessment of the formulations Oncol 20EC and Oncol 8.6G to non-target terrestrial arthropods

Species	Life stage	Test substance, substrate and duration	Dose	Endpoint	% effect	Trigger value
Laboratory tests						
<i>Coccinella septempunctata</i>	larvae	Oncol 20EC, glass plates	216 g a.s./ha	Corrected mortality	100 %	50 %
Extended laboratory tests						
<i>Aphidius rhopalosiphi</i>	adult females	Oncol 20EC, oat plants, 48 h + 11 d	0.69 g a.s./ha	Corrected mortality	10 %	50 %
				Reproduction	-58 %	50 %
			2.16 g a.s./ha	Corrected mortality	13 %	50 %
				Reproduction	-60 %	50 %
			6.9 g a.s./ha	Corrected mortality	10 %	50 %
				Reproduction	-64 %	50 %
			21.6 g a.s./ha	Corrected mortality	100 %	50 %
				Reproduction	-	50 %
			69.1 g a.s./ha	Corrected mortality	100 %	50 %
				Reproduction	-	50 %
			LD ₅₀ = 9.3 g a.s./ha			
<i>Typhlodromus pyri</i>	proto-nymphs	Oncol 20EC, apple tree leaves, 7 d + 7 d	3.46 g a.s./ha	Corrected mortality	14 %	50 %
				Reproduction	-8.7 %	50 %
			5.40 g a.s./ha	Corrected mortality	36 %	50 %
				Reproduction	-38 %	50 %
			8.64 g a.s./ha	Corrected mortality	52 %	50 %
				Reproduction	-72 %	50 %
			13.6 g a.s./ha	Corrected mortality	73 %	50 %
				Reproduction	-	50 %
			21.6 g a.s./ha	Corrected mortality	91 %	50 %
				Reproduction	-	50 %
			LD ₅₀ = 9.2 g a.s./ha			
<i>Chrysoperla carnea</i>	larvae	Oncol 20EC, apple tree leaves	2.16 g a.s./ha	Corrected mortality	7.4 %	50 %
				Reproduction	-6.7 %	50 %
			6.91 g a.s./ha	Corrected mortality	39 %	50 %
				Reproduction	-20 %	50 %
			21.6 g a.s./ha	Corrected mortality	100 %	50 %
				Reproduction	-	50 %

Species	Life stage	Test substance, substrate and duration	Dose	Endpoint	% effect	Trigger value
			69.1 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			216 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			LD ₅₀ = 5.2 g a.s./ha			
<i>Poecilus cupreus</i>	adults	Oncol 8.6G, sand, 14 d	1.0 kg a.s./ha	Corrected mortality Food consumption	-3.4 % 0 %	50 % 50 %
<i>Aleochara bilineata</i>	adults	Oncol 8.6G, soil	1.0 kg a.s./ha	Corrected mortality Reproduction	59.5 % -58 %	50 % 50 %
<i>Hypoaspis aculeifer</i>	adults	Oncol 8.6G, sand, 14 d	1 kg a.s./ha	Corrected mortality Reproduction	7 % -2 %	50 % 50 %
<i>Pardosa</i>	adults	Oncol 8.6G, sand, 14 d	1 kg a.s./ha	Corrected mortality Food consumption	0 % 6 %	50 % 50 %
Aged residue laboratory test						
<i>Aleochara bilineata</i>	adults	Oncol 8.6G, soil	1.0 kg a.s./ha, 0 DAT	Corrected mortality Reproduction	8.5 % -8.5 %	50 % 50 %
			1.0 kg a.s./ha, 7 DAT	Corrected mortality Reproduction	7.0 % -2.7 %	50 % 50 %
			1.0 kg a.s./ha, 14 DAT	Corrected mortality Reproduction	31.8 % -19.8 %	50 % 50 %
			1.0 kg a.s./ha, 21 DAT	Corrected mortality Reproduction	18.3 % -0.8 %	50 % 50 %
			1.0 kg a.s./ha, 28 DAT	Corrected mortality Reproduction	42.0 % -23.0 %	50 % 50 %
			1.0 kg a.s./ha, 56 DAT	Corrected mortality Reproduction	17.6 % -23.7 %	50 % 50 %
			1.0 kg a.s./ha, 119 DAT *	Corrected mortality Reproduction	20.8 % -57.8 %	50 % 50 %

Oncol 20EC : formulation containing 216 g/L benfuracarb

Oncol 8.6G : formulation containing 8.9 - 9.14 % benfuracarb

* the effect on reproduction at 119 DAT is not treatment-related

Corrected mortality : positive values : adverse effects; negative values : no adverse effects

Effect on reproduction, food consumption : negative values : adverse effects; positive values : no adverse effects

First tier risk assessment for non-target arthropods :

The risk assessment for non-target arthropods is based on the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC of October 2002.

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the sowing bed as a single application rate of 1 kg a.s./ha.

Standard test species :

In extended laboratory tests with the formulation Oncol 20EC and with the two standard species (*Aphidius rhopalosiphii* and *Typhlodromus pyri*), effects were observed at a dose equivalent to 0.69 g a.s./ha (reproduction for *Aphidius rhopalosiphii*) and at 8.64 g a.s./ha (mortality and reproduction for *Typhlodromus pyri*).

Foliage dwelling species :

In a laboratory test with the formulation Oncol 20EC and with *Coccinella septempunctata*, severe effects were observed at a dose equivalent to 216 g a.s./ha (100 % mortality).

In an extended laboratory test with the formulation Oncol 20EC and with *Chrysoperla carnea*, severe effects were observed at a dose equivalent to 21.6 g a.s./ha (100 % mortality).

However, leaf dwelling species are not at risk since the intended use is by granular application.

Soil dwelling species :

In an extended laboratory test with the formulation Oncol 8.6G and with *Poecilus cupreus*, no effects on mortality or reproduction were observed at a dose equivalent to 1.0 kg a.s./ha.

In an extended laboratory test with the formulation Oncol 8.6G and with *Aleochara bilineata*, effects on mortality and reproduction were observed at a dose equivalent to 1.0 kg a.s./ha.

In an extended laboratory test with carbofuran and with *Poecilus cupreus*, no effects on mortality or reproduction were observed at a dose equivalent to 0.13 g/kg.

In an extended laboratory test with carbofuran and with *Aleochara bilineata*, no effects on mortality and reproduction were observed at a dose equivalent to 0.13 g/kg.

In an aged residue study with the formulation Oncol 8.6G and with *Aleochara bilineata*, no effects on mortality or reproduction were observed at a dose equivalent to 1.0 kg a.s./ha and soil aged for 0, 7, 14, 21, 28, 56 and 119 days.

In an extended laboratory test with Oncol 8.6G and with *Hypoaspis aculeifer*, no effects on mortality or reproduction were observed at a dose equivalent to 1 kg a.s./ha.

In an extended laboratory test with Oncol 8.6G and with *Pardosa*, no effects on mortality or food consumption were observed at a dose equivalent to 1 kg a.s./ha.

In conclusion, severe effects were observed for the two standard species (*Aphidius rhopalosiphii* and *Typhlodromus pyri*) at doses below the intended application rate.

The risk of benfuracarb and carbofuran to several soil dwelling species (*Poecilus cupreus*, *Aleochara bilineata*, *Hypoaspis aculeifer* and *Pardosa*) is acceptable for the intended use of benfuracarb in brassicas (1 x 1.0 kg a.s./ha).

B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.6.1)

B.9.6.1 Acute toxicity to earthworms (Annex IIA 8.4.1)

Added in August 2008

Acute toxicity study in the earthworm *Eisenia fetida fetida* with Benfuracarb. (Geuijen W.H.C., 2005b).

Guidelines :

OECD Guideline for Testing of Chemicals No. 207: "Earthworm, acute toxicity tests"

European Economic Community (EEC) directive 87/302/EEC adapting for the ninth time Council Directive 67/548/EEC, Toxicity for earthworms. EEC publication no. L 133 (1988)

International Standard ISO 11268-1 (1993), Soil quality – Effects of pollutants on earthworms (*Eisenia foetida*) – Part 1: determination of acute toxicity using artificial soil substrate.

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 94.15 %, batch n° : 4I75

Test species : earthworms (*Eisenia fetida fetida*)

Number of organisms, age, weight : 4 replicates per treatment group each with 10 earthworms, 300 – 600 mg at start, adult worms, at least 2 months old with clitellum

Type of test : acute laboratory toxicity test

Test substrate : artificial soil (70 % industrial sand, 20 % kaolin clay, 10 % sphagnum peat, pH was adjusted by addition of CaCO₃)

Applied concentrations :

nominal : water control; solvent control (acetone); 10, 18, 32, 56, 100 mg a.s./kg substrate

Exposure route : The test substance was thoroughly mixed with the substrate.

Test conditions :

temperature : 19.8 – 20.3 °C

pH : 6.3 – 6.5

water content : 44.4 – 46.2 % (at start), 43.6 – 45.3 % (at end) of soil d.w.

light regime : continuous light

light intensity : 450 – 700 lux

Findings :Table B.9.6.1-1 : Effects of benfuracarb on *Eisenia fetida fetida*

Evaluation criteria	Control	Solvent control	Nominal Test Concentration (mg a.s./kg soil d.w.)				
			10	18	32	56	100
Total mortality after 14 days (%)	0	0	0	0	22.5	42.5	80.0
Surviving earthworms with abnormal behaviour (mean %) after 14 days	0	0	100	100	100	100	100
Mean individual earthworm weight on day 0 (mg)	368	370	372	367	370	372	374
Mean individual earthworm weight on day 14 (mg)	316	325	235	232	214	188	174
Reduction of initial weight after 14 days (mean %)	13.9	11.9	37*	37*	42*	49*	54*

* statistically significantly different from the control

After 14 days of exposure, benfuracarb induced mortality of *Eisenia fetida fetida* at concentrations above 18 mg a.s./kg substrate, which was significantly higher as compared to the controls.

Reduction in mean earthworm biomass at all treatment levels was biologically (> 20 %) and statistically ($\alpha = 0.01$) significantly higher as compared to control. Biomass reductions were 37 %, 37 %, 42 %, 49 % and 54 %, respectively at 10, 18, 32, 56 and 100 mg a.s./kg substrate.

Behavioural effects were observed at all treatment levels (10 - 100 mg a.s./kg substrate) on 100 % of the earthworms. Symptoms ranged from stiffness, stretching of segments shortly after removal from the soil at observations, malformation, small earthworms, sometimes body fluid deposition, body parts cut off to hardly moving.

The reference test proved the sensitivity of the test organisms (LC_{50} (*Eisenia fetida fetida*, 14 d) = 15 mg 2-chloroacetamide/kg substrate).

Conclusions :

The study is acceptable.

Endpoints :

LC_{50} (*Eisenia fetida fetida*, 14 d) = 58 mg a.s./kg substrate

NOEC (*Eisenia fetida fetida*, 14 d) < 10 mg a.s./kg substrate, due to important biomass reduction and symptoms at all treatment doses.

The endpoints were corrected for purity of benfuracarb (94.15 %).

B.9.6.2 Sublethal effects on earthworms (Annex IIA 8.4.2)

According to the triggers for persistence and number of applications set in the Guidance document on terrestrial ecotoxicology, sublethal effects on earthworms are not required for carbofuran, the metabolite of benfuracarb :

- The laboratory DT₅₀ of benfuracarb (geomean DT₅₀, at reference temperature and moisture conditions : 0.31 days) and its active metabolite carbofuran (geomean DT₅₀, at reference temperature and moisture conditions : 10.73 days, range : 6.1-17.4 days) are less than 60 days. According to the directive, field dissipation studies are therefore not required. The DT₉₀ field of carbofuran (in the dossier of FMC, another notifier) are < 100 days, i.e. 4.4 - 91 days.
- Oncol 8.6G is applied as granule at planting. One application per year is expected.

However, the guidance document on terrestrial ecotoxicology states that a study on sublethal effects is also required if the acute TER < 10.

The acute TER (based on LC₅₀) were 22 and 26, respectively for the active substance and for the formulation. However important biomass reduction (biologically and statistically significant) and symptoms were observed at all treatment doses on 100 % of the surviving earthworms, for both the a.s. and the formulation tests. The RMS considers that these effects have to be taken into account in the final risk assessment. The sublethal effects should be evaluated in a laboratory study or a field study performed according to the supported use conditions.

B.9.6.3 Acute toxicity of the formulations to earthworms (Annex IIIA 10.6.1.1)

Acute toxicity of Oncol 20 EC on the earthworm *Eisenia foetida* (Akute Toxizität von Oncol 20 EC auf den Kompostwurm, *Eisenia foetida* (Artificial Soil Test). (Kühner Ch., 1990).

Guidelines :

OECD Guideline for Testing of Chemicals No. 207: "Earthworm, acute toxicity tests"

Verfahrensvorschlag der Ad hoc Arbeitsgruppe der BBA zur Entwicklung ökotoxikologischer Verfahren im terrestrischen Bereich. (= Procedure proposal of the Ad hoc workgroup of the BBA for the development of ecotoxicology procedures in the terrestrial field)

GLP :

Yes

Material and Methods :

Test substance : Oncol 20EC, formulation containing 200 g/L benfuracarb, batch n° : not reported

Test species : earthworms (*Eisenia foetida*)

Number of organisms, weight, age : 4 replicates per treatment group each with 10 worms, 250 – 600 mg at start, adult worms

Type of test : acute laboratory toxicity test

Applied concentrations : water control; 10, 18, 32, 56, 100 mg Oncol 20EC/kg substrate (nominal) (equivalent to 2.0, 3.6, 6.4, 11.2, 20 mg a.s./kg substrate)

Soil type and test conditions :

test substrate : 69 % quartz sand, 20 % kaoline, 10 % sphagnum peat, 1 % CaCO₃

water content : 37.4 – 40.8 % of dry weight in the final test

temperature : 20 ± 2 °C

light regime : continuous, 300 – 400 lux

Findings :

Mortality : After 14 days a mortality of 10 % was observed in the water control. The mean mortality for the treatments 10, 18, 32, 56 and 100 mg Oncol 20EC/kg substrate were respectively 10.0 %, 27.5 %, 30.0 %, 77.5 % and 75.0 %.

Observations : The mean body weight at the end of the test for the water control, 10, 18 and 32 mg Oncol 20EC/kg substrate was 279 mg, 246 mg, 207 mg and 205 mg respectively.

Conclusion :

The study is acceptable. Minor deviations occurred for the minimum individual weight at start of the test.

Endpoints :

LC₅₀ (*Eisenia foetida*, 14 d) = 46.58 mg Oncol 20EC/kg substrate = 9.3 mg a.s./kg substrate

Added in August 2008

Acute toxicity study in the earthworm *Eisenia fetida fetida* with ONCOL 8.6G. (Geuijen W.H.C., 2005c).

Guidelines :

OECD Guideline for Testing of Chemicals No. 207: "Earthworm, acute toxicity tests"

European Economic Community (EEC) directive 87/302/EEC adapting for the ninth time Council Directive 67/548/EEC, Toxicity for earthworms. EEC publication no. L 133 (1988)

International Standard ISO 11268-1 (1993), Soil quality – Effects of pollutants on earthworms (*Eisenia foetida*) – Part 1: determination of acute toxicity using artificial soil substrate.

GLP :

Yes

Material and Methods :

Test substance : Oncol 8.6G, formulation containing 9.39 % w/w benfuracarb, batch n° : 4D80

Test species : earthworms (*Eisenia fetida fetida*)

Number of organisms, age, weight : 4 replicates per treatment group each with 10 earthworms, 300 – 600 mg at start, adult worms, at least 2 months old with clitellum

Type of test : acute laboratory toxicity test

Test substrate : artificial soil (70 % industrial sand, 20 % kaolin clay, 10 % sphagnum peat, pH was adjusted by addition of CaCO₃)

Applied concentrations :

nominal : water control; 100, 180, 320, 560, 1000 mg Oncol 8.6g/kg substrate (equivalent to 9.4, 17, 30, 53, 94 mg a.s./kg substrate)

Exposure route : The test substance was thoroughly mixed with the substrate.

Test conditions :

temperature : 20 – 21 °C

pH : 6.4 – 6.5

water content : 45.3 – 45.7 % (at start), 43.4 – 44.7 % (at end) of soil d.w.

light regime : continuous

light intensity : 500 – 630 lux

Findings :Table B.9.6.3-1 : Effects of the formulation Oncol 8.6G on *Eisenia fetida fetida*

Evaluation criteria	Control	Nominal Test Concentration (mg Oncol 8.6G/kg soil d.w.)				
		100	180	320	560	1000
Total mortality after 14 days (%)	0.0	0.0	2.5	10	40	65
Surviving earthworms with abnormal behaviour after 14 days (%)	0.	100	100	100	100	100
Mean individual earthworm weight on day 0 (mg)	460	462	462	461	462	462
Mean individual earthworm weight on day 14 (mg)	441	328	344	293	302	262
Reduction of initial weight after 14 days (%)	4.2	29*	26*	36*	35*	43*

* statistically significantly different from the control

After 14 days of exposure, mortality was above the natural mortality threshold (i.e. > 10 %) and statistically significant from the blank control at 560 and 1000 mg Oncol 8.6G/kg substrate (40 and 65 % mortality, respectively).

Reduction in mean earthworm biomass at all treatment levels was biologically (> 20 %) and statistically (alpha = 0.01) significantly higher as compared to control. Biomass reductions were 29 %, 26 %, 26 %, 36 %, 35 % and 43 % respectively at 100, 180, 320, 560 and 1000 mg Oncol 8.6G/kg substrate.

Behavioural effects were observed at all treatment levels (100 - 1000 mg Oncol 8.6G/kg substrate) on 100 % of the earthworms. The following symptoms were observed : stiffness, stretching of segments shortly after removal from the soil at observations, malformation and/or small earthworms and sometimes body fluid deposition.

The reference test proved the sensitivity of the test organisms (LC_{50} (*Eisenia fetida fetida*, 14 d) = 15 mg 2-chloroacetamide/kg substrate).

Conclusions :

The study is acceptable.

Endpoints :

LC_{50} (*Eisenia fetida fetida*, 14 d) = 730 mg Oncol 8.6G/kg substrate = 69 mg a.s./kg substrate

NOEC (*Eisenia fetida fetida*, 14 d) < 100 mg Oncol 8.6G/kg substrate = 9.4 mg a.s./kg substrate, due to important biomass reduction and symptoms at all treatment doses.

B.9.6.4 Sublethal effects of the formulation on earthworms (Annex IIIA 10.6.1.2)

See point B.9.6.2

B.9.6.5 Field tests - residue content of earthworms (Annex IIIA 10.6.1.3)

Field study to evaluate the toxicity to earthworms in arable soils of Oncol 10 G when applied at the maximum recommended UK sugar beet rate of 3.0 g product/10 m of row (equivalent to 6.56 kg product/ha at 18"/46 cm inter-row spacing), and followed by wet conditions. (Partington Keith, 1997).

Guidelines :

ISO/TC190/SC4WG2-Field method to determine the effect of substances on earthworms

GLP :

Yes

Material and Methods :

Test substance : Oncol 10G, formulation containing 10.34 % benfuracarb, batch n° : 0087/FEB/95

Type of test : field study

Applied concentrations : 6.56 kg Oncol 10G/ha, equivalent to 650 g a.s./ha (maximum recommended UK sugar beet rate of 3.0 g product/10 m of row at 46 cm inter-row spacing); untreated control; positive control : Benlate Fungicide (benomyl at 2000 g a.s./ha); each treatment was replicated 4 times. Oncol 10G was applied in granular form as supplied, whilst Benlate was diluted with water prior to application (250 L/ha at 3.0 bar).

Test conditions :

Table B.9.6.5-1 : Characteristics of the test soils for the field study

	Soil 1: Clay	Soil 2: Sandy loam
Location	Wilson, Derbyshire	Weston-on-Trent, Derbyshire
Previous crop	Grass	Leeks (seedbed production of transplants only)
Other pesticides applied during previous crop	None	Stomp (pendimethalin)
pH in water	5.6	7.0
% OC	2.9	2.4
Water holding capacity (% gravimetric mass)	54.31	38.7
Trial design	Randomized complete block	Randomized complete block
Number of replicates	4	4
Plot size width x length	7.5 m x 14 m	7.5 m x 14 m
Earthworm density	18/m ²	7/m ²
Total on-site precipitation in field phase (rainfall + irrigation)	524.2 mm	554.5 mm
Cultivators/fertilisers	Soil surface lightly cultivated to about 5 cm with power harrow before drilling, to allow granules to be placed 28.03.95 – N:P:K applied at 60:30:30 kg/ha	Soil surface lightly cultivated to about 5 cm with power harrow before drilling, to allow granules to be placed
Other pesticides applied	20.04.95 – Gramoxone 100 (paraquat) at 5.5 L/ha 28.05.95 – Stefes Glyphosate at 3.0 L/ha 31.10.95 – Roundup (glyphosate) at 6.0 L/ha	28.05.95 – Stefes Glyphosate at 3.0 L/ha 31.10.95 – Roundup (glyphosate) at 6.0 L/ha

The soil was wetted by application of approximately 20 mm of irrigation 6 – 8 days before application of the test substances, then from 1 day after application for a total of 5 weeks irrigation was used to supplement the level of rainfall, to ensure as far as possible that a total of at least 30 mm of water fell onto the soil during each 10 day period.

Sampling method :

To quantify the number of earthworms dying on the soil surface of the plots, early morning casualty searches were carried out. Dead earthworms were collected and counted from the central 10.5 m x 6.9 m surface of each of the treated plots.

To quantify the number of earthworms in the plots, small areas of each plot pre-designated in the study plan (2 x 1 m²/timing) were treated with a solution of formaldehyde to force the earthworms to the soil surface. This was carried out 2 – 3 days before application of the test treatments and again 1, 6 and 12 months after application; each sample area was used only once. For each marked quadrat 2 batches of 0.2 % formaldehyde solution were applied, at an interval of 10 – 15 minutes. Each of the 2 batches was 15 L (an edge frame quadrat was used, designed to retain the solution on the marked area whilst it soaked into the soil). Following earthworm species were looked for: *Lumbricus terrestris*, *Lumbricus rubellus*, *Lumbricus castaneus*, *Lumbricus eiseni*, *Lumbricus*,

Aporrectodea caliginosa, *Aporrectodea longa*, *Aporrectodea rosea*, *Allolobophora chlorotica*, *Dendrodrilus rubida*, *Epilobous* juvenile, *Tanylobous* juvenile

Sampling dates :

- pre-application (after relatively dry winter/spring)
- 1 month after treatment (after simulated wet weather)
- 6 months after treatment (autumn)
- 12 months after treatment

Residue analysis :

The sampling method of the earthworms was the same as described before. The sample from each plot was retained frozen for residue analysis. Test samples were prepared by hand using a knife to cut into small pieces prior to analysis. Samples for benfuracarb and carbofuran analysis were extracted by homogenizing in a phosphate buffer/methanol mix. Samples for 3-hydroxy carbofuran analysis were refluxed with hydrochloric acid and extracts filtered and partitioned into dichloromethane.

Quantitation of residues was by gas chromatography and the limit of determination for benfuracarb, carbofuran and 3-hydroxy carbofuran (determined as 3-ethoxy carbofuran) was 0.02 mg/kg.

Procedural recoveries for benfuracarb and carbofuran performed concurrently with test samples over the range 0.02 mg/kg – 0.2 mg/kg gave mean recoveries for benfuracarb of 108 % and carbofuran of 94 %. Procedural recoveries for 3-hydroxy carbofuran performed concurrently with test samples over the range 0.02 mg/kg – 0.2 mg/kg gave a mean recovery of 105 %.

Findings :

Table B.9.6.5-2 : Cumulative number of dead earthworms, number of total live earthworms and number of dominant species *Aporrectodea longa* in soil 1 (clay) per 2 m² (mean, (range), statistically significant)

	Untreated control	Oncol 10G	Benlate fungicide
Cumulative number of dead earthworms			
14 days after treatment	1.50 (0 – 2) b	9.25 (6 – 13) a	10.75 (7 – 17) a
Total number of live earthworms			
Pre-application	35.5 (27 – 43) a	35.0 (14 – 55) a	35.0 (17 – 59) a
1 month after treatment	62.3 (42 – 87) a	41.0 (31 – 54) a	50.3 (20 – 70) a
6 months after treatment	39.25 (22 – 52) a	32.25 (13 – 63) a	15.75 (7 – 32) a
12 months after treatment	98.25 (91 – 114) a	80.50 (67 – 92) a	55.75 (38 – 69) b
Mean number of dominant species <i>Aporrectodea longa</i>			
Pre-application	8.0 (4 – 12) a	7.0 (4 – 13) a	11.5 (4 – 21) a
1 month after treatment	14.5 (6 – 20) a	12.0 (3 – 21) a	15.0 (3 – 25) a
6 months after treatment	11.5 (7 – 18) a	10.0 (6 – 13) a	1.3 (1 – 2) b
12 months after treatment	16.3 (10 – 26) a	12.3 (9 – 18) a	1.0 (0 – 2) b

Table B.9.6.5-3 : Cumulative number of dead earthworms, number of total live earthworms and number of dominant species *Aporrectodea longa* in soil 2 (sandy loam) per 2 m² (mean, (range), statistically significant)

	Untreated control	Oncol 10G	Benlate fungicide
Cumulative number of dead earthworms			
14 days after treatment	3.25 (1 – 6) a	10.75 (1 – 25) a	8.25 (5 – 15) a
Total number of live earthworms			
Pre-application	13.8 (7 – 26) a	15.3 (8 – 24) a	13.5 (9 – 23) a
1 month after treatment	7.0 (3 – 12) a	7.8 (1 – 17) a	2.5 (1 – 4) a
6 months after treatment	98.5 (45 – 141) a	70.0 (46 – 91) a	28.0 (23 – 39) b
12 months after treatment	70.75 (56 – 88) a	57.50 (29 – 118) a	48.50 (14 – 92) a
Mean number of dominant species <i>Aporrectodea longa</i>			
Pre-application	0.5 (0 – 2) b	3.0 (2 – 5) a	0.3 (0 – 1) b
1 month after treatment	0.0 a	0.8 (0 – 2) a	0.0 a
6 months after treatment	0.3 (0 – 1) a	2.8 (0 – 6) a	1.0 (0 – 2) a
12 months after treatment	0.0 a	0.5 (0 – 1) a	0.5 (0 – 1) a

On both soils, benfuracarb and carbofuran residues after application of Oncol 10G were highest 3 days after application, being at 0.52 mg/kg and 0.55 mg/kg respectively on soil 1 and 0.03 mg/kg and 1.46 mg/kg respectively on soil 2. After 1 month, residues of carbofuran and benfuracarb declined to below the limits of determination, and subsequent samples were not analyzed for these analytes. No 3-hydroxy carbofuran residues above the limit of determination were detected in earthworms from soil 1 or 2 after 1 month and after 6 months.

Conclusions :

According to the ISO 11268-3 Guideline at least four replicates should be used, and four random samples taken per replicate (i.e. 16 individual samples per test variant). A suitable grassland test area should have an earthworm density of at least 100 individuals per square meter. On grassland, a sampling area of 0.25 m² per individual sample is sufficient. On arable land, the sample area will normally have to be increased to 1 m² due to low population density or non-homogeneous distribution of the worms.

The study has deficiencies. In this study, 2 samples of 1 m² were taken per replicate for both soils.

Soil 1 (grassland) should have been sampled with four random samples whereas now only two random samples were taken. Only 18 earthworms per sample were tested instead of the recommended 25 earthworms in the guideline.

Soil 2 (arable land) should have been sampled with four random samples. Only 7 earthworms per sample of 1 m² were tested for soil 2. The sample area should be increased so that at least 25 earthworms could be collected per sample, as recommended by the guideline.

So, due to the low population density of the soils 1 and 2 in the study, more samples and larger sample areas should have been taken to get enough statistical power.

Because of the deficiencies described above, the RMS has considered that the field study cannot be taken into account for the final risk assessment.

B.9.6.6 Summary and risk assessment for earthworms (Annex III, 10.6.1.1) revised in August 2008**First tier risk assessment for earthworms :**

The risk assessment for earthworms is based on the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC of October 2002.

Two acute toxicity studies were performed using the active substance benfuracarb and the representative formulation Oncol 8.6G as test material.

The LC₅₀ (*Eisenia fetida*) of the active substance is experimentally determined as 58 mg a.s./kg substrate. Corrected for the organic matter content of the test soil (log Pow of benfuracarb = 4.22), the LC₅₀ is 29 mg a.s./kg.

The LC₅₀ (*Eisenia fetida*) of the formulation Oncol 8.6G is experimentally determined to be 730 mg formulation/kg substrate, equivalent to 69 mg a.s./kg. Hence the toxicity of the product is very similar to that of the active ingredient. Corrected for the organic matter content of the test soil (log Pow of benfuracarb = 4.22), the LC₅₀ is 34.5 mg a.s./kg.

Table B.9.6.6-1: Summary of effects of benfuracarb and the formulations Oncol 20EC and Oncol 8.6G on earthworms

Test species	Test substance	Test system	Endpoints	References
<i>Eisenia fetida</i>	benfuracarb	14 d acute	LC ₅₀ = 58 mg a.s./kg substrate LC _{50 corr} = 29 mg a.s./kg substrate NOEC < 10 mg a.s./kg substrate, due to important biomass reduction and symptoms at all treatment doses	Geuijen W.H.C., 2005b
<i>Eisenia foetida</i>	Oncol 20EC	14 d acute	LC ₅₀ = 46.58 mg/kg substrate (9.3 mg a.s./kg substrate)	Kühner Ch., 1990
<i>Eisenia fetida</i>	Oncol 8.6G	14 d acute	LC ₅₀ = 730 mg/kg substrate (69 mg a.s./kg substrate) LC _{50 corr} = 34.5 mg a.s./kg substrate NOEC < 100 mg Oncol 8.6G/kg substrate (50 mg a.s./kg substrate), due to important biomass reduction and symptoms at all treatment doses	Geuijen W.H.C., 2005c

Oncol 20EC : formulation containing 200 g/L benfuracarb

Oncol 8.6G : formulation containing 9.39 % benfuracarb

The initial PEC_{SOIL} concentration for a single application of 1 kg a.s./ha (12 kg Oncol 8.6G/ha) in brassicas is 1.33 mg a.s./kg soil.

Table B.9.6.6-2 : First Tier Toxicity Exposure Ratio's for earthworms exposed to benfuracarb and the formulation Oncol 8.6G for the intended use in brassicas (1 × 1.0 kg a.s./ha)

Test species	Test substance	Time-scale	Endpoint (mg a.s./kg)	Max PEC _{soil} (mg a.s./kg)	TER	Annex VI Trigger Value
<i>Eisenia foetida</i>	benfuracarb	14 d	29	1.33	22	10
<i>Eisenia foetida</i>	Oncol 8.6G	14 d	34.5	1.33	26	10

The acute TER values (based on LC₅₀) were 22 and 26, respectively for the active substance and for the formulation. However important biomass reduction (biologically and statistically significant) and symptoms were observed at all treatment doses on 100 % of the surviving earthworms, for both the a.s. and the formulation tests. The RMS considers that these effects have to be taken into account in the final risk assessment. The sublethal effects should be evaluated in a laboratory study or a field study performed according to the supported use conditions.

Moreover the effects of carbofuran and other metabolites would be completely assessed in this type of studies.

A field study exhibiting several deficiencies was submitted. The field study did not cover the actual dose rate of 1 kg a.s./ha. Therefore, this study cannot be taken into account for the final risk assessment.

In conclusion, the risk of benfuracarb and carbofuran to earthworms in brassicas is not yet fully addressed.

B.9.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)

Added in August 2008

Not required according to the Guidance Document on Terrestrial ecotoxicology, since the maximum DT₉₀ in field of carbofuran is < 100 days. However, a study with *Hypoaspis aculeifer* is reported under point B.9.5.2.

B.9.8 Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)

B.9.8.1 Impact of the active substance on soil microbial activity (Annex IIA 8.5)

Effect of Benfuracarb on Nitrification in Soil. (Vonk J.W. and van Veendendaal F., 1986).

Guidelines :

Guidelines given in form A, Commissie Toelating Bestrijdingsmiddelen (Dutch Commission for Registering Pesticides), modified appendix H.4.1, September 1984

GLP :

No

Material and methods :

Test substance : benfuracarb, chemical purity : 92 %, batch n° : not reported

Soils : humic sandy soil (84.5 % sand; 3.1 % clay; 7.9 % loam; 2.6 % OC; pH 5.4) and loam soil (26.7 % sand; 22.7 % clay; 40.6 % loam; 1.2 % OC; pH 7.3)

Applied concentrations :

untreated control; 3.5 and 17.5 mg a.s./kg soil

no information on number of replicates

Type of test : 28 days nitrogen transformation test

Test conditions :

Soil moisture : pF 2.5 (0.32 bar), less than 40 % of the maximum water holding capacity

Soil amendment : ammonium sulphate solution (100 mg NH₄⁺-N/kg soil)

Soil samples were incubated at 20 ± 1 °C in conical flasks in the dark

Sampling scheme : 0, 3, 7, 14 and 28 days after treatment samples for nitrogen transformation

Findings :

Graphs of ammonium disappearance and nitrate formation showed no difference between control and test substance treatments.

Conclusions :

The study is not acceptable. Deviations occurred in the sand content of both soils, the organic carbon content for the humic sandy soil and the moisture content for both soils. No data were given for the microbial biomass and its organic carbon content. The validity criterion could not be checked since there is no information on replicates. Benfuracarb at concentrations of 3.5 and 17.5 mg a.s./kg soil did not affect nitrification in a humic sandy soil and a loam soil to a significant extent.

B.9.8.2 Impact of the formulations on soil microbial activity (laboratory) (Annex IIIA 10.7.1)

Effects on the activity of soil microflora (Auswirkungen auf Aktivität der Bodenmikroflora (nach Richtlinie Teil VI 1-1)) (Littmann and Maas, 1988).

Guidelines :

BBA Guideline, part VI 1-1

GLP :

No

Material and methods :

Test substance : Oncol 20EC, formulation containing 200 g/L benfuracarb, batch n° : not reported

Soils : sandy loam soil (54.1 % sand; 6.9 % clay; 39.0 % silt; 0.95 % OC; pH 6.8) and clay loam soil (34.6 % sand; 29.5 % clay; 35.9 % silt; 2.42 % OC; pH 7.1)

Applied concentrations :

untreated control; 2 mg a.s./kg soil (corresponding to 7.5 L formulation/ha), 20 mg a.s./kg soil (corresponding to 75 L formulation/ha); positive control: dinoseb-acetate-containing preparation (2 kg a.s./ha and 10 kg a.s./ha) *Type of test* : 60 days nitrogen transformation test, 60 days carbon transformation test

Test conditions :

Soil moisture : 60 % of the maximum water holding capacity

Soil amendment : ammonium sulphate solution (10 mg NH₄⁺-N/100 g soil) for nitrogen transformation, no data on soil amendment for carbon transformation

Soil samples were incubated at 20 °C

Sampling scheme : 7, 14, 21, 28 and 60 days after treatment samples for nitrogen transformation were taken;

0, 14, 28 and 60 days after treatment samples for carbon transformation were taken

Test principle : Steam distillation according to Bremmer (1965) for nitrogen transformation; Dehydrogenase activity determination according to Thalmann

Findings :

Table B.9.8.2-1 : Influence of benfuracarb on nitrogen transformation in sandy loam soil

Incubation (days)	Mean NO ₂ ⁻ + NO ₃ ⁻ (mg N/100 g dry weight soil) and % deviation from Control								
	Control	Test substance (2 mg a.s./kg soil)		Test substance (20 mg a.s./kg soil)		Positive control (2 kg a.s./ha)		Positive control (10 kg a.s./ha)	
	(mg/100 g)	(mg/100 g)	(%)	(mg/100 g)	(%)	(mg/100 g)	(%)	(mg/100 g)	(%)
sandy loam soil (54.1 % sand; 6.9 % clay; 39.0 % silt; 0.95 % OC; pH 6.8)									
0	1.13	1.13	-	1.13	-	1.13	-	1.13	-
7	3.54	3.27	-7.65	1.80	-49.25	1.96	-44.76	1.41	-60.27
14	6.33	5.60	-5.53	3.82	-39.66	3.67	-41.97	1.61	-74.53
21	8.30	8.17	-1.52	6.36	-23.40	6.27	-24.44	1.57	-81.06
28	9.86	9.48	-3.88	8.41	-14.74	8.44	-14.47	1.87	-81.04
60	11.54	11.7	+1.37	10.92	-5.38	11.53	-0.11	6.28	-45.56

Table B.9.8.2-2 : Influence of benfuracarb on nitrogen transformation in clay loam soil (not acceptable)

Incubation (days)	Mean NO ₂ ⁻ + NO ₃ ⁻ (mg N/100 g dry weight soil) and % deviation from Control								
	Control	Test substance (2 mg a.s./kg soil)		Test substance (20 mg a.s./kg soil)		Positive control (2 kg a.s./ha)		Positive control (10 kg a.s./ha)	
	(mg/100 g)	(mg/100 g)	(%)	(mg/100 g)	(%)	(mg/100 g)	(%)	(mg/100 g)	(%)
clay loam soil (34.6 % sand; 29.5 % clay; 35.9 % silt; 2.42 % OC; pH 7.1)									
0	1.94	1.94	-	1.94	-	1.94	-	1.94	-
7	10.97	10.94	-0.26	11.02	+0.45	11.12	+1.40	10.97	+0.06
14	11.29	11.37	+0.68	11.44	+1.36	11.66	+3.23	11.84	+4.91
21	11.59	11.55	-0.37	11.75	+1.33	11.86	+2.29	12.61	+8.77
28	11.94	11.95	+0.12	12.24	+2.59	12.31	+3.18	13.17	+10.35

The results of Table B.9.8.2-2 are not acceptable since the positive control showed no reliable results.

Conclusions :

The study is acceptable for nitrogen transformation in the sandy loam soil. No data were given for the microbial biomass and its organic carbon content. Benfuracarb had no long-term influence on nitrogen transformation in the sandy loam soil (at 2 mg a.s./kg soil, no effect; at 20 mg a.s./kg soil, less than 25 % deviation in 21 days). The study is not acceptable for carbon transformation. More information on the dehydrogenase test is necessary, in particular the relation between dehydrogenase and respiration. No data were available on soil amendment for carbon transformation.

Nitrification study with Oncol 10 G. (Marcio Adriani Gava, Reinaldo Alcarde, Roberto Bonetti, 1995).

Guidelines :

This study was conducted in compliance with the Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renovaveis – IBAMA, under the Toxic Substance Control Act N 139 of 12/21/94.

GLP :

No

Material and methods :

Test substance : Oncol 10G, formulation containing 101 g/kg benfuracarb, batch n° : not reported

Soils : LE (Typic Haplorthox): clay soil (20.0 % sand; 69.0 % clay; 11.0 % silt; 1.33 % OC; pH 6.0)

Applied concentrations :

untreated control; inhibition control: 100 ppm Maneb (a fungicide which inhibits the conversion of ammonium ions to nitrate); 20 kg/ha (the maximum use rate MUR in the field) and 200 kg/ha (10 times the maximum use rate)

Type of test : 28 days nitrogen transformation test

Test conditions :

Soil moisture : 65 % of field capacity

Soil amendment : ammonium sulphate solution (100 mg NH₄⁺-N/kg soil)

Soil samples were incubated at 24 ± 2 °C in covered glass jars in the dark

Sampling scheme : 0, 7, 14, 21 and 28 days after treatment samples for nitrogen transformation were taken

Conclusions :

The study is not acceptable. The Brazilian soil is not representative for European soils, the sand content is too low. No data were given for the microbial biomass and its organic carbon content. Ammonium sulphate was used for soil amendment which is not an organic substrate as recommended by the OECD Guideline 216.

Respiration study with Oncol 10 G. (Alvaro August T. Vargas, Roberto Bonetti, 1995).

Guidelines :

The methods used were in-house methods.

GLP :

No

Material and methods :

Test substance : Oncol 10G, formulation containing 101 g/kg benfuracarb, batch n° : not reported

Soils : LE (Typic Haplorthox): clay soil (20.0 % sand; 69.0 % clay; 11.0 % silt; 1.33 % OC; pH 6.0)

Applied concentrations :

untreated control; inhibition control: 50 ppm HgCl₂ (microflora inhibitor); 20 kg/ha (the maximum use rate MUR in the field) and 200 kg/ha (10 times the maximum use rate)

Type of test : 28 days carbon transformation test

Test conditions :

Soil moisture : 65 % of field capacity

Soil amendment : no data

Soil samples were incubated at 24 °C in covered glass jars in the dark

Sampling scheme : 0, 7, 14, 21 and 28 days after treatment samples for carbon transformation were taken

Conclusions :

The study is not acceptable. The Brazilian soil is not representative for European soils, the sand content is too low. No data were given for the microbial biomass and its organic carbon content. No data were available on soil amendment for carbon transformation.

Added in August 2008

Carbofuran : Determination of effects on soil microflora respiration and nitrogen transformations. (Rix S., 2005).

Guidelines :

OECD Guideline 216 : Soil Microorganisms : Nitrogen Transformation Test

OECD Guideline 217 : Soil Microorganisms : Carbon Transformation Test

GLP :

Yes

Materials and Methods :

Test substance : Carbofuran PESTANAL[®], chemical purity : 99.9 %, batch n° : 3036X

Test organisms : microflora indigenous to a sample of LUFA 2.3 soil

Test substrate : LUFA 2.3 soil, batch n° : F235004, no organic fertilization or pesticides during sampling year and two former years, previous planting : 2004 pumpkins, 2003 fallow, 2002 pumpkins, 2001 fallow, 2000 fallow, sampling depth : 20 cm, sieved to 2 mm, sand content : 52.8 – 65.4 % w/w, pH : 5.76 – 5.80, organic carbon content : 1.02 ± 0.2 % w/w, mean microbial biomass : 1.28 % of the total organic carbon content

Test design :

3 replicates of 500 g d.w. soil for nitrogen transformation, the soils were amended with 1 mm sieved ground lucerne at a rate of 0.5 % w/w (mean total carbon content : 43.21 % w/w, total nitrogen content : 2.98 % w/w giving a C:N ratio of 15:1);

3 replicates of 1000 g d.w. soil for carbon transformation, soil sub-samples (100 g d.w. soil) were amended with glucose to stimulate respiration

Applied concentrations : control (water); positive control (1 and 10 mg dinoseb/kg d.w. soil); treatment at 0.7 and 3.5 mg carbofuran/kg d.w. soil

Test conditions :

temperature : 20.0 ± 2 °C

pH : 6.00 – 6.10 (at start), 6.19 – 6.35 (at end)

water content : 41 % MWHC (at start), 38.6 – 39.5 % MWHC (at end)

light regime : darkness

Sampling : Extractions for nitrogen transformation were made within the first 6 hours of dosing and again after 7, 14 and 28 days. Measurements of nitrogen transformations were carried out by removing 50 g d.w. soil sub-samples from the 3 replicate vessels for each treatment and extraction with KCl solution. Analysis of the extracts was done to determine the content of ammonium-nitrogen, nitrite-nitrogen and nitrate-nitrogen.

Measurements for soil respiration were made within the first 6 hours of dosing and again after 7, 14 and 28 days. Soil sub-samples (100 g d.w. soil) were placed in separate stainless steel tubes. Air stripped of CO₂ was drawn through each tube approximately 100 mL per minute. The exiting air was diverted from each tube in turn by a gas handling unit (GHU) to an infrared analyser (IGA). CO₂ content of the exiting air was measured and recorded by the IGA for a period of greater than 12 hours for each soil sample. Each tube was measured at least once an hour for a six-minute period and measurements of CO₂ were logged every minute during that period.

Findings :

Table B.9.8.2-3 : Influence of carbofuran on nitrogen transformation

Day	Mean nitrate-nitrogen concentration (mg NO ₃ ⁻ -N/kg d.w. soil)				
	Control	Treatment with carbofuran			
		0.7 mg a.s./kg d.w. soil		3.5 mg a.s./kg d.w. soil	
	mg N/kg	mg N/kg	%	mg N/kg	%
0	9.72	9.49	- 2.42	9.82	+ 1.03
7	9.82	10.2	+ 3.87	10.1	+ 2.85
14	22.8	24.2	+ 6.14	24.8	+ 8.77
28	37.0	38.0	+ 2.70	38.8	+ 4.86

Table B.9.8.2-4 : Influence of carbofuran on soil nitrate-nitrogen transformation rates

Days	Mean nitrate-nitrogen transformation rate (mg NO ₃ ⁻ -N/kg d.w. soil/day)				
	Control	Treatment with carbofuran			
		0.7 mg a.s./kg d.w.soil		3.5 mg a.s./kg d.w. soil	
	mg N/kg/day	mg N/kg/day	%	mg N/kg/day	%
0 – 7	0.015	0.101	+ 583	0.042	+ 183
7 – 14	1.85	2.00	+ 8.1	2.10*	+ 13*
14 – 28	1.02	0.986	- 2.9	0.996	- 1.9

* statistically significantly different from the control

Table B.9.8.2-5 : Influence of carbofuran on carbon transformation

Day	Mean respiration rate (mg CO ₂ /kg d.w. soil/h)				
	Control	Treatment with carbofuran			
		0.7 mg a.s./kg d.w. soil		3.5 mg a.s./kg d.w. soil	
	mg CO ₂ /kg/h	mg CO ₂ /kg/h	%	mg CO ₂ /kg/h	%
0	7.03	7.11	+ 1.14	7.80	+ 11.0*
7	6.06	6.38	+ 5.28	6.74	+ 11.2*
14	6.21	6.46	+ 4.03	6.76	+ 8.86
28	6.77	7.14	+ 5.47	7.65	+ 13.0*

* statistically significantly different from the control

Results of the positive control :

By day 28 the mean soil nitrate-nitrogen transformation rates at 1 and 10 mg dinoseb/kg d.w. soil deviated by -3.7 % and +163 % from the control mean, respectively, and both showed statistically significant effects on nitrate-nitrogen transformations between days 0 and 14. Between days 14 and 28 only the 10 mg dinoseb/kg d.w. soil treatment was statistically different from the control mean.

Soil microbial respiration in soil treated at 1 mg and 10 mg dinoseb/kg d.w. soil showed the greatest response at the start of exposure (day 0) with inhibition in mean respiration rates relative to the mean control value of 20 % and 62 % respectively. By day 28, the inhibition of soil respiration rate at 1 and 10 mg dinoseb/kg d.w. soil relative to the control mean was 3.6 % and 23 %, respectively.

At day 0 and day 14 the mean soil respiration rates at both dinoseb concentrations were significantly different from the control mean. At day 28 the mean soil respiration rate at 10 mg dinoseb/kg d.w. soil (but not 1 mg dinoseb/kg d.w. soil) was significantly different from the control mean.

The results of this study are consistent with former observations, which were that effects should be seen at 10 mg dinoseb/kg d.w. soil, and confirms the sensitivity of the test soil (LUFA 2.3) for further soil side-effects studies.

Conclusions :

The study is acceptable.

By day 28, the mean soil nitrate-nitrogen transformation rates at 0.7 and 3.5 mg carbofuran/kg d.w. soil differed by -2.9 % and -1.9 %, respectively, from the control mean. These variations are below the 25 % criterion for effect as stated in the test guideline OECD 216 (2000).

By day 28, the mean soil respiration rates at 0.7 and 3.5 mg carbofuran/kg d.w. soil differed by +5.5 % and +13 %, respectively, from the control mean. These variations are below the 25 % criterion for effect as stated in the test guideline OECD 217 (2000).

B.9.8.3 Further laboratory, glasshouse or field testing to investigate impact on soil microbial activity (Annex IIIA 10.7.2)

Not required.

B.9.8.4 Summary of studies on non-target micro-organisms - exposure and risk assessment for non-target micro-organisms

Revised in August 2008

Risk assessment for non-target soil micro-organisms :

The risk assessment for non-target soil micro-organisms is based on the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC of October 2002.

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the sowing bed at a single application rate of 1 kg a.s./ha.

Since benfuracarb is rapidly degraded to carbofuran, the risk assessment is based on studies performed with carbofuran as test item.

From the section on fate and behaviour the initial PEC_{soil} for carbofuran was determined as 0.72 mg/kg soil.

The soil nitrogen transformation rates at 0.7 and 3.5 mg carbofuran/kg d.w. soil differed by less than 25 % from the untreated control. The soil respiration rates at 0.7 and 3.5 mg carbofuran/kg d.w. soil differed by less than 25 % from the untreated control. No effects were observed at the initial PEC_{soil} and at 5 x initial PEC_{soil} . Therefore, the risk of benfuracarb and carbofuran to soil non-target micro-organisms is acceptable.

B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6; Annex IIIA 10.8)*Added in August 2008*

An evaluation of the efficacy of Oncol 10G and Oncol 20CS for the control of cabbage root fly in vegetable brassicas. (Thorpe A.P., 2000).

Materials and Methods :**Test substances :**

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : 97745 Feb 97

Oncol 20CS : EC formulation containing 200 g/L benfuracarb, batch n° : 8AB04

Temik 10G : GR formulation containing 10 % w/w aldicarb, batch n° : -

Yaltox : GR formulation containing 5 % w/w carbofuran, batch n° : 298908129/6

Test sites :

624A : clay loam, cabbage, 35000 plants/ha, 4 replicates, 1.0 x 8.0 cm (2 rows x 8.0 cm)

624B : clay loam, Brussels sprout, 30000 plants/ha, 4 replicates, 1.0 x 8.0 cm (2 rows x 8.0 cm)

Application timing : BBCH 13 for site 624 A and BBCH 16 for site 624B**Treatment rates :**

Untreated control

Oncol 10G : 2.5, 5.0, 10.0 kg/ha

Oncol 20CS : 1.25, 2.5, 5.0 L formulation in 400 L water/ha (drench)

Temik 10G : 3.8, 5.1 g/10 m row

Yaltox : 12.5 g/10 m row

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death, assessments at 16-17, 30-31, 47-48 DAT.

Vigour : 100 = most vigorous, < 100 = less vigorous, assessments at 16-17, 30-31, 47-48, 96-97 DAT.

Cabbage root fly damage : 20 plants/pot were pulled up at 145-147 DAT to assess for the presence/absence of mining damage by cabbage root fly larvae. The area between the base of the stem and top of the root was assessed for damage.

Findings :

Table B.9.9-1 : Effects of the formulations Oncol 10G, Oncol 20CS, Temik 10G and Yaltox on phytotoxicity for vegetable brassicas (0 = no damage, 100 = complete crop death)

Treatment	Rate (ha)	Site A, 17 DAT	Site B, 16 DAT	Site A, 31 DAT	Site B, 30 DAT	Site A, 48 DAT	Site B, 47 DAT
Control	-	0.0	0.0	0.0	0.0	0.0	0.0
Oncol 10G	2.5 kg	0.0	0.0	0.0	0.0	0.0	0.0
	5.0 kg	0.0	0.0	0.0	0.0	0.0	0.0
	10.0 kg	0.0	0.0	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L	0.0	0.0	0.0	0.0	0.0	0.0
	2.5 L	0.0	0.0	0.0	0.0	0.0	0.0
	5.0 L	0.0	0.0	0.0	0.0	0.0	0.0
Temik 10G	7.6 kg	0.0	0.0	0.0	0.0	0.0	0.0
	10.2 kg	0.0	0.0	0.0	0.0	0.0	0.0
Yaltox	25.0 kg	0.0	0.0	0.0	0.0	0.0	0.0

Table B.9.9-2 : Effects of the formulations Oncol 10G, Oncol 20CS, Temik 10G and Yaltox on crop vigour of vegetable brassicas (100 = most vigourous, < 100 = less vigourous)

Treatment	Rate (/ha)	Site A, 17 DAT	Site B, 16 DAT	Site A, 31 DAT	Site B, 30 DAT	Site A, 48 DAT	Site B, 47 DAT	Site A, 97 DAT	Site B, 96 DAT
Control	-	100.0	100.0	100.0	100.0	100.0	100.0	95.0	98.3
Oncol 10G	2.5 kg	100.0	100.0	100.0	100.0	100.0	100.0	98.5	97.5
	5.0 kg	100.0	100.0	100.0	100.0	100.0	100.0	99.5	96.3
	10.0 kg	100.0	100.0	100.0	100.0	100.0	100.0	97.8	97.0
Oncol 20CS	1.25 L	100.0	100.0	100.0	100.0	100.0	100.0	98.8	96.3
	2.5 L	100.0	100.0	100.0	100.0	100.0	100.0	97.0	97.5
	5.0 L	100.0	100.0	100.0	100.0	100.0	100.0	97.8	99.5
Temik 10G	7.6 kg	100.0	100.0	100.0	100.0	100.0	100.0	100.0	97.5
	10.2 kg	100.0	100.0	100.0	100.0	100.0	100.0	98.3	100.0
Yaltox	25.0 kg	100.0	100.0	100.0	100.0	100.0	100.0	99.5	98.3

Table B.9.9-3 : Effects of the formulations Oncol 10G, Oncol 20CS, Temik 10G and Yaltox on cabbage root fly damage in vegetable brassicas (number of plants with roots damaged by cabbage root fly mining/20 plants; % efficacy to control)

Treatment	Rate (/ha)	Site A, 147 DAT	Site B, 145 DAT
Control	-	0.3 (0 %)	8.0 (0 %)
Oncol 10G	2.5 kg	0.8 (0 %)	5.0 (38 %)
	5.0 kg	0.3 (0 %)	4.0 (50 %)
	10.0 kg	0.5 (0 %)	5.5 (31 %)
Oncol 20CS	1.25 L	0.5 (0 %)	1.0 (88 %)
	2.5 L	1.0 (0 %)	1.5 (81 %)
	5.0 L	0.3 (0 %)	0.5 (94 %)
Temik 10G	7.6 kg	0.5 (0 %)	7.0 (13 %)
	10.2 kg	1.3 (0 %)	3.5 (56 %)
Yaltox	25.0 kg	1.0 (0 %)	4.0 (50 %)

Conclusions :

The study is acceptable.

None of the treatments caused any phytotoxic damage to the crop.

Plots treated with Oncol 20CS at 2.5 L/ha produced plants of similar vigour levels to untreated plots at site A at 97 DAT. All of the remaining plots treated with Oncol 10G and Oncol 20CS produced plants with similar levels of vigour to the Temik 10G and Yaltox treated plots at site A at 97 DAT. All of the treatments at site B had plants that had statistically similar levels of vigour.

Cabbage root fly damage was significantly reduced at site B in plots treated with Oncol 20CS and Temik 10G at 10.2 kg/ha compared to the untreated controls. Plants in plots treated with Oncol 10G, Temik at 7.6 kg/ha and Yaltox displayed significantly similar levels of mining to those in untreated plots.

An evaluation of the efficacy of Oncol 10G and 20EC for the control of cabbage root fly in cauliflower and cabbage. (Carr D.E., 2003).

Material and Methods :

Test substances :

- Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : -
- Oncol 20EC : EC formulation containing benfuracarb, batch n° : -
- Oncol 20CS : CS formulation containing benfuracarb, batch n° : -
- Posse 10G : GR formulation containing carbosulfan, batch n° : -
- Spannit granules : GR formulation containing 6 % w/w chlorpyrifos, batch n° : -

Test sites :

- NUF959A : gravelly silt loam, cabbage, 30000 plants/ha, 4 replicates, 2.5 x 10.0 m²
- NUF959B : sandy loam, Brussels sprouts, 14000 plants/ha, 4 replicates, 2.5 x 10.0 m²
- NUF959C : sandy loam, cauliflower, 30000 plants/ha, 4 replicates, 2.5 x 10.0 m²
- NUF959D : sandy loam, cabbage, 26500 plants/ha, 4 replicates, 2.5 x 10.0 m²
- NUF959E : sandy loam, cabbage, 26500 plants/ha, 4 replicates, 2.5 x 10.0 m²

Application timing : BBCH 09 for site NUF959A, BBCH 15 for site NUF959B, BBCH 14 for sites NUF959C, NUF959D and NUF959E

Treatment rates :

Untreated control

The treatments were applied at planting in the root zone and incorporated.

Oncol 10G : 3.0, 5.0, 10.0 g/10 m row (granules applied with “pepper pot” to soil surface)

Oncol 20EC : 1.5, 3.0, 6.0 L formulation in 200 L water/ha (applied as spray in solution with conventional small plot sprayer)

Oncol 20CS : 3.0 L formulation in 200 L water/ha (applied as spray in solution with conventional small plot sprayer)

Posse 10G : 7.0 g/10 m row (granules applied with “pepper pot” to soil surface)

Spannit granules : 12.0 g/10 m row (granules applied with “pepper pot” to soil surface)

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death, assessments at 16-17, 30-31, 47-48 DAT.

Vigour : 100 = most vigorous, < 100 = less vigorous, 0 = dead, assessments at 16-17, 30-31, 47-48, 96-97 DAT.

Crop mortality : the number of dying or dead plants after application.

Cabbage root fly damage : 20 roots were sampled and graded into 4 categories (0 = no damage, 1 = slight damage, 2 = moderate damage, 3 = severe damage).

Cabbage root fly mining damage index =

$$\frac{(no\ plants\ in\ class\ 0 \times 0) + (no\ plants\ in\ class\ 1 \times 1) + (no\ plants\ in\ class\ 2 \times 2) + (no\ plants\ in\ class\ 3 \times 3)}{no\ plants\ assessed} \times$$

$$\frac{100}{3}$$

The number of living larvae per 20 plants was also counted.

Findings :

Table B.9.9-4 : Effects of the formulations Oncol 10G, Oncol 20EC, Oncol 20CS, Posse 10G and Spannit granules on phytotoxicity for vegetable brassicas (0 = no damage, 100 = complete crop death) at harvest

Treatment	Rate	Site A 86 DAT	Site B 78 DAT	Site C 84 DAT	Site D 78 DAT	Site E 21 DAT
Control	-	0.0	0.0	0.0	0.0	0.0
Oncol 10G	30 g/100 m row	0.0	0.0	0.0	0.0	0.0
	50 g/100 m row	0.0	0.0	0.0	0.0	0.0
	100 g/100 m row	0.0	0.0	0.0	0.0	0.0
Oncol 20EC	1.5 L/ha	0.0	0.0	0.0	0.0	0.0
	3.0 L/ha	0.0	0.0	0.0	0.0	0.0
	6.0 L/ha	0.0	0.0	0.0	0.0	0.0
Oncol 20CS	3.0 L/ha	0.0	0.0	0.0	0.0	0.0
Posse 10G	70 g/100 m row	0.0	0.0	0.0	0.0	0.0
Spannit granules	120 g/100 m row	0.0	0.0	0.0	0.0	0.0

Table B.9.9-5 : Effects of the formulations Oncol 10G, Oncol 20EC, Oncol 20CS, Posse 10G and Spannit granules on crop vigour of vegetable brassicas (100 = most vigorous, < 100 = less vigorous) at harvest

Treatment	Rate	Site A 86 DAT	Site B 78 DAT	Site C 84 DAT	Site D 78 DAT	Site E 21 DAT
Control	-	91.8	93.5	100.0	100.0	100.0
Oncol 10G	30 g/100 m row	94.3	96.5	100.0	100.0	100.0
	50 g/100 m row	95.3	98.8	100.0	100.0	100.0
	100 g/100 m row	95.3	98.8	100.0	100.0	100.0
Oncol 20EC	1.5 L/ha	96.3	96.3	100.0	100.0	100.0
	3.0 L/ha	94.8	97.0	100.0	100.0	100.0
	6.0 L/ha	92.8	96.5	100.0	100.0	100.0
Oncol 20CS	3.0 L/ha	96.3	96.8	100.0	100.0	100.0
Posse 10G	70 g/100 m row	96.3	98.8	100.0	100.0	100.0
Spannit granules	120 g/100 m row	92.5	98.3	100.0	100.0	100.0

The number of plants was variable across the trials with a few percent differences but the products appeared to have no detrimental effect on the crop. Similarly, apart from the odd random dead or dying plant in some plots, mortality rate was unaffected by the treatments.

Table B.9.9-6 : Effects of the formulations Oncol 10G, Oncol 20EC, Oncol 20CS, Posse 10G and Spannitt granules on cabbage root fly damage in vegetable brassicas (cabbage root fly mining damage index; % efficacy to control)

Treatment	Rate	Site A 86 DAT	Site B 78 DAT	Site C 84 DAT	Site D 78 DAT	Site E 71 DAT
Control	-	18.3 (0%)	36.7 (0%)	41.3 (0%)	50.0 (0%)	19.6 (0%)
Oncol 10G	30 g/100 m row	11.3 (38%)	42.5 (-16%)	20.4 (50%)	26.3 (47%)	12.9 (34%)
	50 g/100 m row	7.1 (61%)	37.5 (-2%)	20.0 (52%)	27.1 (46%)	11.6 (40%)
	100 g/100 m row	10.4 (43%)	36.7 (0%)	31.3 (24%)	24.1 (52%)	11.7 (40%)
Oncol 20EC	1.5 L/ha	11.6 (36%)	62.5 (-70%)	29.6 (28%)	35.8 (28%)	12.1 (38%)
	3.0 L/ha	12.5 (32%)	45.0 (-23%)	27.9 (32%)	26.6 (47%)	1.3 (42%)
	6.0 L/ha	5.8 (68%)	45.0 (-23%)	26.7 (35%)	19.6 (61%)	5.0 (74%)
Oncol 20CS	3.0 L/ha	9.1 (50%)	43.3 (-18%)	27.9 (32%)	33.3 (33%)	7.9 (60%)
Posse 10G	70 g/100 m row	10.4 (43%)	33.3 (9%)	34.2 (17%)	45.8 (8%)	14.2 (28%)
Spannitt granules	120 g/100 m row	7.1 (61%)	34.2 (7%)	32.5 (21%)	44.2 (12%)	11.2 (43%)

Conclusions :

The study is acceptable.

No phytotoxic effects were seen at any of the test sites, vigour differences were statistically insignificant and plant numbers remained constant across the trials.

Oncol 10G and 20EC appeared to produce similar control of cabbage root fly with the exception of Oncol 20EC at 6.0 L/ha which was, with the exception of site C, slightly superior to the other Oncol treatments (over 60 % root fly control at three sites).

Oncol 20CS, Posse 10G and Spannitt granules were average and at a few of the sites produced slightly reduced efficacy on root fly compared with the higher rate 10G and 20EC treatments.

An evaluation of the efficacy of Oncol 10G for the control of cabbage root fly in brassicas. (Thorpe A.P., 2001).

Materials and Methods :

Test substances :

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : 97145

Oncol 20CS : CS formulation containing 200 g/L benfuracarb, batch n° : OAC01

Posse 10G : GR formulation containing 10 % w/w carbosulfan, batch n° : 805

Spannitt granules : GR formulation containing 6 % w/w chlorpyrifos, batch n° : -

Test sites :

728A : clay loam, Brussels sprouts, 32000 plants/ha, 4 replicates, 2.0 x 6.0 m²

728B : gravelly silt, cabbage, 70000 plants/ha, 4 replicates, 2.0 x 5.0 m²

728C : sandy loam, Brussels sprouts, 25000 plants/ha, 4 replicates, 3.0 x 5.0 m²

728D : loamy fine sand, cauliflower, 32000 plants/ha, 4 replicates, 3 x 12 m²

728E : sandy loam, Brussels sprouts, 30000 plants/ha, 4 replicates, 3 x 12 m²

Application timing : BBCH 15 for sites 728A and C; pre-drilling and incorporated for site 728B; BBCH 13 (at transplanting) for sites 728D and E

Treatment rates :

Untreated control
 Oncol 10G : 2.5, 5.0, 10.0 kg /ha
 Oncol 20CS : 1.25, 2.5, 5.0 L formulation in 200 L water/ha (drench)
 Posse 10G : 7.0 g/10 m row
 Spannit granules : 12.5 g/10 m row

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death, assessments at 4-14, 21-42, 55, 88-152 DAT.
 Vigour : 100 = most vigorous, < 100 = less vigorous, assessments at 4-14, 21-42, 55-84, 88-152 DAT.

Crop yellowing due to *Brevicoryne brassicae* infection : 0 = normal healthy green crop, >0 = yellowing due to virus infection, 100 = dead crop, assessment at 45 DAT.

Number of plants per pot : assessment at 66-152 DAT.

Cabbage root fly damage : 15-20 plants/pot were pulled up at 66-160 DAT to assess for the presence/absence of mining damage by cabbage root fly larvae; the area between the base of the stem and top of the root was assessed for damage where 0 = no mining damage, 1 = slight damage, 2 = moderate damage and 3 = severe damage

Cabbage root fly mining damage index =

$$\frac{(no\ plants\ in\ class\ 0 \times 0) + (no\ plants\ in\ class\ 1 \times 1) + (no\ plants\ in\ class\ 2 \times 2) + (no\ plants\ in\ class\ 3 \times 3)}{no\ plants\ assessed} \times$$

$$\frac{100}{3}$$

Findings :

Table B.9.9-7 : Effects of the formulations Oncol 10G, Oncol 20CS, Posse 10G and Spannit granules on phytotoxicity for vegetable brassicas (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site 728A, 25 DAT	Site 728B, 21 DAT	Site 728C, 28 DAT	Site 728D, 24 DAT	Site 278E, 42 DAT
Control	-	0.0	0.0	0.0	0.0	0.0
Oncol 10G	2.5 kg/ha	0.0	0.0	0.0	0.0	0.0
	5.0 kg/ha	0.0	0.0	0.0	0.0	0.0
	10.0 kg/ha	0.0	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L/ha	0.0	0.0	0.0	0.0	0.0
	2.5 L/ha	0.0	0.0	0.0	0.0	0.0
	5.0 L/ha	0.0	0.0	0.0	0.0	0.0
Posse 10G	7.0 g/10 m row	0.0	0.0	0.0	0.0	0.0
Spannit granules	12.0 g/10 m row	0.0	0.0	0.0	0.0	0.0

Table B.9.9-8 : Effects of the formulations Oncol 10G, Oncol 20CS, Posse 10G and Spannitt granules on crop vigour of vegetable brassicas (100 = most vigorous, < 100 = less vigorous)

Treatment	Rate	Site 728A, 152 DAT	Site 728B, 84 DAT	Site 728C, 88 DAT	Site 728D, 66 DAT	Site 278E, 42 DAT
Control	-	95.8	90.8	94.5	100.0	91.5
Oncol 10G	2.5 kg/ha	97.0	93.8	96.3	100.0	94.5
	5.0 kg/ha	98.3	92.5	99.0	100.0	98.0
	10.0 kg/ha	95.3	94.0	97.0	100.0	99.3
Oncol 20CS	1.25 L/ha	97.8	93.0	96.5	100.0	99.3
	2.5 L/ha	96.3	92.8	95.0	100.0	99.5
	5.0 L/ha	95.0	93.8	97.0	100.0	100.0
Posse 10G	7.0 g/10 m row	96.3	94.3	95.8	100.0	99.0
Spannitt granules	12.0 g/10 m row	96.8	92.0	97.3	100.0	99.3

All the treatments have a favourable effect on yellowing due to infection of virus transmitted by *Brevicoryne brassicae*.

Table B.9.9-9 : Effects of the formulations Oncol 10G, Oncol 20CS, Posse 10G and Spannitt granules on cabbage root fly damage in vegetable brassicas (cabbage root fly mining damage index)

Treatment	Rate	Site 728A, 152 DAT	Site 728B, 84 DAT	Site 728C, 88 DAT	Site 728D, 66 DAT	Site 278E, 42 DAT
Control	-	46.2 (0%)	26.6 (0%)	46.6 (0%)	38.7 (0%)	29.9 (0%)
Oncol 10G	2.5 kg/ha	37.5 (19%)	26.0 (2%)	32.9 (29%)	19.5 (50%)	25.0 (17%)
	5.0 kg/ha	33.3 (28%)	21.1 (21%)	20.0 (57%)	13.3 (66%)	13.3 (56%)
	10.0 kg/ha	20.4 (56%)	19.9 (25%)	20.0 (57%)	13.4 (66%)	22.5 (25%)
Oncol 20CS	1.25 L/ha	27.9 (40%)	32.7 (0%)	31.3 (33%)	20.0 (48%)	25.8 (14%)
	2.5 L/ha	25.4 (45%)	27.2 (0%)	22.9 (51%)	25.0 (35%)	20.8 (30%)
	5.0 L/ha	18.8 (59%)	17.2 (35%)	25.4 (46%)	11.6 (70%)	20.0 (33%)
Posse 10G	7.0 g/10 m row	30.8 (33%)	21.6 (19%)	32.9 (29%)	19.6 (49%)	32.5 (0%)
Spannitt granules	12.0 g/10 m row	18.3 (60%)	28.3 (0%)	17.9 (62%)	17.5 (55%)	20.0 (33%)

Conclusions :

The study is acceptable.

There were no phytotoxic effects. Small differences in crop vigour were observed.

An aphid-borne virus was well controlled at one site, with a good dose response.

Most sites showed a good dose response to the Oncol formulations for cabbage root fly control with the two highest rates broadly comparable to Spannit granules.

The lowest rate of each formulation was comparable to Posse 10G.

An evaluation of the efficacy of Oncol 10G and Oncol 20CS for the control of carrot fly in carrots. (Massie R.B., 2000).

Materials and Methods :

Test substances :

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : -

Oncol 20CS : CS formulation containing 200 g/L benfuracarb, batch n° : -

Temik : GR formulation containing 10 % w/w aldicarb, batch n° : -

Yaltox : GR formulation containing 5 % w/w carbofuran, batch n° : -

Test sites :

623A : peaty loam, carrots, 1800000 seeds/ha, 4 replicates, 2.0 x 7.0 m²

623B : sand, carrots, 2250000 seeds/ha, 4 replicates, 2.0 x 7.0 m²

Application timing : pre-planting and at BBCH 16 for sites 623A and B

Treatment rates :

Untreated control

Oncol 10G : 2.5, 5.0, 10.0 kg /ha

Oncol 20CS : 1.25, 2.5, 5.0 L formulation in 200 L water/ha

Temik : 33.6 kg/ha

Yaltox : 12.5 kg/ha

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death.

Vigour : 100 = most vigorous, 0 = complete crop death.

Carrot fly damage : During each vigour assessment and at harvest, 25 roots from each plot were cut open and assessed for signs of carrot fly damage.

Findings :

Table B.9.9-10 : Effects of the formulations Oncol 10G, Oncol 20CS, Temik and Yaltox on phytotoxicity for carrots for site 623A (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site 623A, 42 DAT 1	Site 623A, 30 DAT 2	Site 623A, 69 DAT 2	Site 623A, 97 DAT 2
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	2.5 kg/ha	0.0	0.0	0.0	0.0
	5.0 kg/ha	0.0	0.0	0.0	0.0
	10.0 kg/ha	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L/ha	0.0	0.0	0.0	0.0
	2.5 L/ha	0.0	0.0	0.0	0.0
	5.0 L/ha	0.0	0.0	0.0	0.0
Temik	33.6 kg/ha	0.0	0.0	0.0	0.0
Yaltox	12.5 kg/ha	0.0	0.0	0.0	0.0

Table B.9.9-11 : Effects of the formulations Oncol 10G, Oncol 20CS, Temik and Yaltox on phytotoxicity for carrots for site 623B (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site 623B, 41 DAT 1	Site 623B, 30 DAT 2	Site 623B, 69 DAT 2	Site 623B, 97 DAT 2
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	2.5 kg/ha	0.0	0.0	0.0	0.0
	5.0 kg/ha	0.0	0.0	0.0	0.0
	10.0 kg/ha	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L/ha	0.0	0.0	0.0	0.0
	2.5 L/ha	0.0	0.0	0.0	0.0
	5.0 L/ha	0.0	0.0	0.0	0.0
Temik	33.6 kg/ha	0.0	0.0	0.0	0.0
Yaltox	12.5 kg/ha	0.0	0.0	0.0	0.0

Table B.9.9-12 : Effects of the formulations Oncol 10G, Oncol 20CS, Temik and Yaltox on carrot fly number

Treatment	Rate	Site 623A, 97 DAT 2	Site 623B, 96 DAT 2
Control	-	0.0	0.0
Oncol 10G	2.5 kg/ha	0.0	0.0
	5.0 kg/ha	0.0	0.0
	10.0 kg/ha	0.0	0.0
Oncol 20 CS	1.25 L/ha	0.0	0.0
	2.5 L/ha	0.0	0.0
	5.0 L/ha	0.0	0.0
Temik	33.6 kg/ha	0.0	0.0
Yaltox	12.5 kg/ha	0.0	0.0

Conclusions :

The study is acceptable.

No phytotoxicity or vigour differences were seen during any of the assessments at either site.

No carrot fly damage was seen in any of the treated or untreated plots at either site.

An evaluation of the efficacy of Oncol 10G and Oncol 20EC compared to Temik 10G and Posse 10G for the control of wireworm in sugar beet. (Scholey J.M., 2003).

Materials and Methods :

Test substances :

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : -
 Posse 10G : GR formulation containing 10 % w/w carbosulfan, batch n° : -
 Temik 10G : GR formulation containing 10 % w/w aldicarb, batch n° : -
 Oncol 20EC : EC formulation containing benfuracarb, batch n° : -
 Oncol 20SC : SC formulation containing benfuracarb, batch n° : -

Test sites :

952A : loamy sand, sugar beet, 1 unit seeds/ha, 4 replicates, 2.0 x 10 m²
 952B : organic sandy loam, sugar beet, 1 unit seeds/ha, 4 replicates, 2 x 10 m²
 952C : clay loam, sugar beet, 1 unit seeds/ha, 4 replicates, 2 x 10 m²
 952D : loamy sand, sugar beet, 1 unit seeds/ha, 4 replicates, 2 x 10 m²

Application timing : pre-emergence

Treatment rates :

Untreated control
 Oncol 10G : 30, 45, 60, 100 g/100 m row
 Posse 10G : 30 g/100 m row
 Temik : 38 g/100 m row
 Oncol 20EC : 1.5, 3.0, 6.0 L formulation in 200 L water/ha
 Oncol 20SC : 3.0 L formulation in 200 L water/ha

Assessments :

Vigour : 10 = most vigorous, 0 = totally dead.

Plant populations were assessed by counting the number of sugar beet in the two central, 10 metre, rows in each plot.

Findings :

Table B.9.9-13 : Effects of the formulations Oncol 10G, Posse, Temik, Oncol 20EC and Oncol 20SC on crop emergence count of sugar beet/10 m

Treatment	Rate	Site 952A, 24 DAT	Site 952B, 18 DAT	Site 952C, 15 DAT	Site 952D, 16 DAT
Control		52.3	22.3	33.4	43.5
Oncol 10G	30 g/100 m	54.3	22.0	36.3	51.3
	45 g/100 m	58.5	34.3	34.6	51.5
	60 g/100 m	55.5	27.3	36.4	45.3
	100 g/100 m	58.8	26.3	34.0	45.8
Posse 10G	30 g/100 m	53.3	26.5	32.1	44.5
Temik	38 g/100 m	57.3	28.5	36.3	47.0
Oncol 20EC	1.5 L/ha	54.3	19.8	35.9	49.0
	3.0 L/ha	57.3	24.0	35.4	50.3
	6.0 L/ha	48.8	26.0	33.8	51.0
Oncol 20SC	3.0 L/ha	57.8	24.5	34.0	51.8

Table B 9.9-14 : Effects of the formulations Oncol 10G, Posse, Temik, Oncol 20EC and Oncol 20SC on crop vigour of sugar beet (4-6 weeks after application) (10 = most vigorous, 0 = totally dead)

Treatment	Rate	Site 952A, 39 DAT	Site 952B, 29 DAT	Site 952C, 42 DAT	Site 952D, 34 DAT
Control	-	9.5	5.1	8.9	9.0
Oncol 10G	30 g/100 m	9.6	6.5	9.7	9.4
	45 g/100 m	9.6	7.3	9.3	9.4
	60 g/100 m	9.7	7.5	9.3	9.3
	100 g/100 m	9.7	6.5	9.5	9.0
Posse 10G	30 g/100 m	9.6	7.0	9.3	9.5
Temik	38 g/100 m	9.8	7.5	9.7	9.5
Oncol 20EC	1.5 L/ha	9.5	5.3	9.5	9.5
	3.0 L/ha	9.8	6.6	9.4	9.3
	6.0 L/ha	9.5	6.1	9.2	9.0
Oncol 20SC	3.0 L/ha	9.8	6.4	9.3	9.4

Table B 9.9-15 : Effects of the formulations Oncol 10G, Posse, Temik, Oncol 20EC and Oncol 20SC on crop vigour of sugar beet (8-12 weeks after application) (10 = most vigorous, 0 = totally dead)

Treatment	Rate	Site 952A, 80 DAT	Site 952B, 52 DAT	Site 952C, 77 DAT	Site 952D, 69 DAT
Control	-	10.0	7.7	10.0	10.0
Oncol 10G	30 g/100 m	10.0	8.1	10.0	10.0
	45 g/100 m	10.0	9.1	10.0	10.0
	60 g/100 m	10.0	9.5	10.0	10.0
	100 g/100 m	10.0	7.4	10.0	10.0
Posse 10G	30 g/100 m	10.0	8.8	10.0	10.0
Temik	38 g/100 m	10.0	9.3	10.0	10.0
Oncol 20EC	1.5 L/ha	10.0	7.6	10.0	10.0
	3.0 L/ha	10.0	9.0	10.0	10.0
	6.0 L/ha	10.0	8.0	10.0	10.0
Oncol 20SC	3.0 L/ha	10.0	8.9	10.0	10.0

Table B.9.9-16 : Effects of the formulations Oncol 10G, Posse, Temik, Oncol 20EC and Oncol 20SC on crop counts of sugar beet/10 m (4-6 weeks after application)

Treatment	Rate	Site 952A, 39 DAT	Site 952B, 29 DAT	Site 952C, 42 DAT	Site 952D, 34 DAT
Control	-	51.0	14.0	30.8	37.3
Oncol 10G	30 g/100 m	53.8	26.0	35.4	49.3
	45 g/100 m	57.5	29.8	35.0	51.3
	60 g/100 m	52.5	31.3	38.3	43.8
	100 g/100 m	57.0	28.0	35.5	45.0
Posse 10G	30 g/100 m	53.5	26.3	34.3	43.3
Temik	38 g/100 m	55.5	27.8	39.0	45.0
Oncol 20EC	1.5 L/ha	52.5	19.3	37.1	48.3
	3.0 L/ha	58.0	23.0	36.5	48.5
	6.0 L/ha	47.8	26.5	34.9	50.5
Oncol 20SC	3.0 L/ha	56.0	28.3	35.9	50.8

Conclusions :

The study is acceptable.

At site 952B, where damage to all treatments was high, the plot vigour was low because of severe wireworm damage. Also, the plant numbers were lower at site 952B because of wireworm attack.

There was no indication from the trials that Oncol 10G, Oncol 20EC and Oncol 20SC were less efficacious than Posse 10G and Temik 10G against wireworm in sugar beet.

An evaluation of Oncol 10G for the control of aphid in sugar beet. (Scholey J.M., 2001).

Materials and Methods :

Test substances :

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : -

Temik 10G : GR formulation containing 10 % w/w aldicarb, batch n° : -

Test sites :

701A : silt, sugar beet, 1 unit seeds/ha, 4 replicates, 2.0 x 10 m²

701B : silt, sugar beet, 1 unit seeds/ha, 4 replicates, 2 x 10 m²

701C : sandy clay loam, sugar beet, 1 unit seeds/ha, 4 replicates, 2 x 10 m²

701D : sandy loam, sugar beet, 1 unit seeds/ha, 4 replicates, 2 x 10 m²

Application timing : pre-planting

Treatment rates :

Untreated control

Oncol 10G : 30, 45, 60, 100 g/100 m row

Temik : 38 g/100 m row

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death.

Vigour : 100 = most vigourous, 0 = totally dead.

Aphid control was assessed by counting the number of aphids on 20 plants per plot.

Virus yellows was assessed by counting the number of plants per plot showing symptoms of the disease.

Findings :

Table B.9.9-17 : Effects of the formulations Oncol 10G and Temik on phytotoxicity for sugar beet (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site 701A, 26 DAT	Site 701B, 27 DAT	Site 701C, 40 DAT	Site 701D, 40 DAT
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	30.0 g/100 m row	0.0	0.0	0.0	0.0
	45.0 g/100 m row	0.0	0.0	0.0	0.0
	60.0 g/100 m row	0.0	0.0	0.0	0.0
	100.0 g/100 m row	0.0	0.0	0.0	0.0
Temik	26.0 g/100 m row	0.0	0.0	0.0	0.0
	38.0 g/100 m row	0.0	0.0	0.0	0.0

Table B 9.9-18 : Effects of the formulations Oncol 10G and Temik on crop vigour of sugar beet (100 = most vigorous, 0 = totally dead)

Treatment	Rate	Site 701A, 26 DAT	Site 701B, 27 DAT	Site 701C, 40 DAT	Site 701D, 40 DAT
Control	-	100.0	100.0	100.0	100.0
Oncol 10G	30.0 g/100 m row	100.0	100.0	100.0	100.0
	45.0 g/100 m row	100.0	100.0	100.0	100.0
	60.0 g/100 m row	100.0	100.0	100.0	100.0
	100.0 g/100 m row	100.0	100.0	100.0	100.0
Temik	26.0 g/100 m row	100.0	100.0	100.0	100.0
	38.0 g/100 m row	100.0	100.0	100.0	100.0

Table B.9.9-19 : Effects of the formulations Oncol 10G and Temik on aphid control (/plant; % efficacy to control)

Treatment	Rate	Site 701A, 48 DAT	Site 701B, 49 DAT	Site 701C, 70 DAT	Site 701D, 70 DAT
Control	-	112.8 (0%)	42.8 (0%)	0.0	0.0
Oncol 10G	30.0 g/100 m row	42.8 (62%)	39.5 (8%)	0.0	0.0
	45.0 g/100 m row	28.8 (75%)	51.5 (0%)	0.0	0.0
	60.0 g/100 m row	26.8 (76%)	48.5 (0%)	0.0	0.0
	100.0 g/100 m row	18.5 (82%)	44.5 (0%)	0.0	0.0
Temik	26.0 g/100 m row	20.3 (82%)	42.0 (2%)	0.0	0.0
	38.0 g/100 m row	14.8 (87%)	39.3 (8%)	0.0	0.0

Table B.9.9-20 : Effects of the formulations Oncol 10G and Temik on incidence of virus infected plants

Treatment	Rate	Site 701A, 48 DAT	Site 701B, 49 DAT	Site 701C, 70 DAT	Site 701D, 70 DAT
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	30.0 g/100 m row	0.0	0.0	0.0	0.0
	45.0 g/100 m row	0.0	0.0	0.0	0.0
	60.0 g/100 m row	0.0	0.0	0.0	0.0
	100.0 g/100 m row	0.0	0.0	0.0	0.0
Temik	26.0 g/100 m row	0.0	0.0	0.0	0.0
	38.0 g/100 m row	0.0	0.0	0.0	0.0

Table B.9.9-21 : The control of wireworm expressed in terms of increase in plant numbers (untreated = 100 %)

Treatment	Rate	Site 701A, 33 DAT
Control	-	41.3 (100%)
Oncol 10G	30.0 g/100 m row	62.0 (150%)
	45.0 g/100 m row	65.5 (159%)
	60.0 g/100 m row	70.3 (170%)
	100.0 g/100 m row	69.5 (168%)
Temik	26.0 g/100 m row	59.3 (144%)
	38.0 g/100 m row	63.5 (154%)

Conclusions :

The study is acceptable.

No symptoms of crop phytotoxicity were seen from any of the treatments used in the trial.

The treatments used in the trial had no adverse effect on crop vigour.

For the aphid control, the results showed good consistency over the four trials, with a dose response to Oncol 10G and Temik 10G at each site.

No symptoms of virus yellows were seen at any of the four sites.

At site 701A, wireworm caused a reduction in the plant population. Plant counts were therefore an indirect method of assessing wireworm control.

An evaluation of the efficacy of Oncol 10G, 20EC, 20SC and Temik 10G for the control of wireworms in maize. (Thorpe A.P., 2001).

Materials and Methods :**Test substances :**

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : 2588C

Oncol 20EC : EC formulation containing benfuracarb, batch n° : OF84-S

Oncol 20SC : SC formulation containing benfuracarb, batch n° : 9EB07

Temik 10G : GR formulation containing 10 % w/w aldicarb, batch n° : -

Test sites :

NUF948A : clay loam, forage maize, 42000 seeds/ha, 4 replicates, 3.0 (4 rows wide) x 6.0 m²

NUF948B : clay loam, forage maize, 48000 seeds/ha, 4 replicates, 3.0 (4 rows wide) x 6.0 m²

Application timing : pre-emergence**Treatment rates :**

Untreated control

Oncol 10G : 3.0, 4.5, 6.0, 10.0 g/10 m row (applied with pepper pot, incorporated with seeds)

Temik : 2.8, 3.8 g/10 m row (applied with pepper pot, incorporated with seeds)

Oncol 20EC : 1.5, 3.0, 6.0 L formulation in 200 L water/ha (applied to soil surface and incorporated)

Oncol 20SC : 3.0 L formulation in 200 L water/ha (applied to soil surface and incorporated)

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death, assessment at 14 and 28 DAT.

Vigour : 100 = most vigorous, 0 = complete crop death, assessment at 14, 28 and 65 DAT.

Plant height : from the soil surface to the top of the growing point of the plant (mean of 25 plants).

Plant population : visual count of the total number of plants in the two middle rows at 14 and 42 DAT.

This was a way to measure the consequential effect of wireworm attack on the plots.

Findings :

Table B.9.9-22 : Effects of the formulations Oncol 10G, Temik 10G, Oncol 20EC and Oncol 20SC on phytotoxicity for maize (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site NUF948A, 17 DAT	Site NUF948A, 27 DAT	Site NUF948B, 13 DAT	Site NUF948B, 27 DAT
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	3.0 g/10 m	0.0	0.0	0.0	0.0
	4.5 g/10 m	0.0	0.0	0.0	0.0
	6.0 g/10 m	0.0	0.0	0.0	0.0
	10.0 g/10 m	0.0	0.0	0.0	0.0
Temik	2.6 g/10 m	0.0	0.0	0.0	0.0
	3.8 g/10 m	0.0	0.0	0.0	0.0
Oncol 20EC	1.5 L/ha	0.0	0.0	0.0	0.0
	3.0 L/ha	0.0	0.0	0.0	0.0
	6.0 L/ha	0.0	0.0	0.0	0.0
Oncol 20SC	3.0 L/ha	0.0	0.0	0.0	0.0

Table B.9.9-23 : Effects of the formulations Oncol 10G Temik 10G, Oncol 20EC and Oncol 20SC on crop vigour of maize (100 = most vigorous, 0 = complete crop death)

Treatment	Rate	Site NUF948A, 27 DAT	Site NUF948A, 64 DAT	Site NUF948B, 27 DAT	Site NUF948B, 67 DAT
Control	-	100.0	100.0	100.0	92.5
Oncol 10G	3.0 g/10 m	100.0	100.0	100.0	90.0
	4.5 g/10 m	100.0	100.0	100.0	93.8
	6.0 g/10 m	100.0	100.0	100.0	96.3
	10.0 g/10 m	100.0	100.0	100.0	97.0
Temik	2.6 g/10 m	100.0	100.0	100.0	92.5
	3.8 g/10 m	100.0	100.0	100.0	97.5
Oncol 20EC	1.5 L/ha	100.0	100.0	100.0	86.3
	3.0 L/ha	100.0	100.0	100.0	91.3
	6.0 L/ha	100.0	100.0	100.0	88.8
Oncol 20SC	3.0 L/ha	100.0	100.0	100.0	98.8

There was no evidence of plant height variation.

No clear conclusion can be drawn on wireworm control, since variable results were observed.

Conclusions :

The study is acceptable.

There were no symptoms of phytotoxicity nor crop vigour observed. The vigour differences at site NUF948B at 65 DAT were felt to be linked with soil fertility rather than treatment.

An evaluation of Oncol 10G, Oncol 20CS and Atlas Chlorpyrifos for the control of wheat bulb fly. (Massie R.B., 1998).

Materials and Methods :

Test substances :

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : 97/30
Oncol 20CS : CS formulation containing 20 % w/w benfuracarb, batch n° : 8AB04
BASF Dimethoate : EC formulation containing 400 g/L dimethoate, batch n° : E2422
Atlas Chlorpyrifos : EC formulation containing 480 g/L chlorpyrifos, batch n° : BX E2427
Dusban : EC formulation containing 480 g/L chlorpyrifos, batch n° : JR 27272037
Atlas Steward : SC formulation containing 560 g/L gamma-HCH, batch n° : 97023

Test sites :

387A : clay, winter wheat, 180 kg seeds/ha, 4 replicates, 2.5 x 12.0 m²
387B : Black Fen, winter wheat, 180 kg seeds/ha, 4 replicates, 2.5 x 12.0 m²
387C : Peat, winter wheat, 35 kg seeds/ha, 4 replicates, 3.0 x 10.0 m²
387D : Peaty loam, winter wheat, 37 kg seeds/ha, 4 replicates, 3.0 x 10.0 m²

Application timing : BBCH 21 for sites 387A and C, BBCH 11 for site 387B and BBCH 13-14 for site 387D

Treatment rates :

Untreated control
Oncol 10G : 2.5, 5.0, 10.0 kg/ha
Oncol 20CS : 1.25, 2.5, 5.0 L formulation in 200 L water/ha
BASF Dimethoate : 1.7 L formulation in 200 L water/ha
Atlas Chlorpyrifos : 1.5, 3.0 L formulation in 200 L water/ha
Dursban : 1.5 L formulation in 200 L water/ha
Atlas Steward : 2.0 L formulation in 200 L water/ha

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death.

Levels of *Delia coarctata* damage were assessed 2-3 weeks, 5-6 weeks and 8-9 weeks after application. A 0.25 m quadrat was thrown at random within an untreated plot until at least 30 affected plants had been identified. This process was then repeated on the untreated plots of the other replicates to produce the mean number of quadrats needed to give counts in excess of 30. This number of quadrats was then thrown down in the treated plots. If very high levels of damage were seen a minimum of four quadrats were still used within each plot. Levels of damage were recorded as the mean number of affected plants per square metre.

Findings :

Table B.9.9-24 : Effects of the formulations Oncol 10G, Oncol 20CS, BASF Dimethoate, Atlas Chlorpyrifos, Dursban and Atlas Steward on phytotoxicity for winter wheat (8-9 weeks after application) (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site NUF948A, 17 DAT	Site NUF948A, 27 DAT	Site NUF948B, 13 DAT	Site NUF948B, 27 DAT
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	2.5 kg/ha	0.0	0.0	0.0	0.0
	5.0 kg/ha	0.0	0.0	0.0	0.0
	10.0 kg/ha	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L/ha	0.0	0.0	0.0	0.0
	2.5 L/ha	0.0	0.0	0.0	0.0
	5.0 L/ha	0.0	0.0	0.0	0.0
BASF Dimethoate	1.7 L/ha	0.0	0.0	0.0	0.0
Atlas Chlorpyrifos	1.5 L/ha	0.0	0.0	0.0	0.0
	3.0 L/ha	0.0	0.0	0.0	0.0
Dursban 4	1.5 L/ha	0.0	0.0	0.0	0.0
Atlas Steward	2.0 L/ha	0.0	0.0	0.0	0.0

Table B.9.9-25 : Level of *Delia coarctata* damage 8 to 9 weeks after application (mean number of wheat bulb fly damaged plants per m²; % efficacy to control)

Treatment	Rate	Site NUF948A, 66 DAT	Site NUF948A, 61 DAT	Site NUF948B, 63 DAT	Site NUF948B, 63 DAT
Control	-	12.3 (0%)	40.0 (0%)	0.0	17.8 (0%)
Oncol 10G	2.5 kg/ha	10.0 (18%)	31.0 (23%)	0.0	15.5 (13%)
	5.0 kg/ha	7.8 (37%)	30.5 (24%)	0.0	13.5 (24%)
	10.0 kg/ha	5.8 (53%)	32.5 (19%)	0.0	12.8 (28%)
Oncol 20CS	1.25 L/ha	7.3 (41%)	51.0 (0%)	0.0	11.8 (34%)
	2.5 L/ha	8.5 (31%)	37.5 (6%)	0.0	14.3 (20%)
	5.0 L/ha	6.3 (49%)	30.0 (25%)	0.0	12.3 (31%)
BASF Dimethoate	1.7 L/ha	5.3 (57%)	28.0 (30%)	0.0	15.3 (14%)
Atlas Chlorpyrifos	1.5 L/ha	5.5 (55%)	25.5 (36%)	0.0	11.5 (35%)
	3.0 L/ha	4.3 (65%)	27.0 (33%)	0.0	13.3 (25%)
Dursban 4	1.5 L/ha	7.0 (43%)	30.0 (25%)	0.0	10.3 (42%)
Atlas Steward	2.0 L/ha	7.3 (41%)	29.5 (26%)	0.0	13.0 (27%)

Conclusions :

The study is acceptable.

No phytotoxicity was observed at any of the sites.

Over the four test sites, all the treatments were seen to significantly reduce the level of *Delia coarctata* damage compared to the untreated plots.

Field study to evaluate the efficacy of Oncol 20CS for the control of wheat bulb fly in winter wheat. (White R. and Greig I., 2000).

Materials and Methods :

Test substances :

Oncol 20CS : CS formulation containing 200 g/L benfuracarb, batch n° : I22/10595/0100

BASF Dimethoate : EC formulation containing 400 g/L dimethoate, batch n° : I30/10231/0799

Dusban : EC formulation containing 480 g/L chlorpyrifos, batch n° : I30/09851/0499

Test sites :

Trial 1 : loamy sand, winter wheat, 4 replicates, 3 x 10 m²

Trial 2 : sandy loam, winter wheat, 4 replicates, 3 x 12 m²

Trial 3 : sandy clay loam, winter wheat, 4 replicates, 3 x 12 m²

Trial 4 : organic clay, winter wheat, 4 replicates, 3 x 10 m²

Trial 5 : loamy clay, winter wheat, 4 replicates, 3 x 10 m²

Application timing : BBCH 11-13 for trial 1, BBCH 14-15 for trial 2, BBCH 12-13 for trial 3, BBCH 10-11 for trial 4 and BBCH 14-15 for trial 5

Treatment rates :

Untreated control

Oncol 20CS : 1.25, 2.5, 4.0, 5.0, 7.0, 10.0 L formulation in 200 L water/ha

BASF Dimethoate : 1.7 L formulation in 200 L water/ha

Dursban : 1.5 L formulation in 200 L water/ha

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death.

Crop vigour : 10 = most vigorous, 0 = no crop.

Wheat bulb fly control was assessed by counting the number of dead-hearts in 6 x 0.25 m² (0.5 m x 0.5 m) marked quadrats when deadhearts were apparent in the untreated plots.

Findings :

No phytotoxic symptoms were observed on any of the trials at any of the assessment timings.

Table B.9.9-26 : Effects of the formulations Oncol 20CS, BASF Dimethoate and Dursban on crop vigour of winter wheat (10 = most vigorous, 0 = no crop)

Treatment	Rate	Trial 1	
		62 DAT	97 DAT
Control	-	7.50	8.0
Oncol 20 CS	1.25 L/ha	8.00	8.8
	2.5 L/ha	8.13	9.3
	4.0 L/ha	8.88	9.5
	5.0 L/ha	8.38	9.8
	7.0 L/ha	8.75	10.0
	10.0 L/ha	9.38	9.0
BASF Dimethoate	1.7 L/ha	8.25	9.0
Dursban	1.5 L/ha	9.63	10.0

Table B.9.9-27 : Effects of the formulations Oncol 20CS, BASF Dimethoate and Dursban on control of wheat bulb fly (mean % control)

Treatment	Rate	Trial 1, 34 DAT	Trial 2, 40 DAT	Trial 3, 34 DAT	Trial 4, 57 DAT	Trial 5, 43 DAT
Control	-	0.0	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L/ha	34.1	35.0	20.7	17.6	19.8
	2.5 L/ha	35.2	41.6	21.5	14.9	29.0
	4.0 L/ha	36.0	30.0	26.5	2.9	37.2
	5.0 L/ha	37.1	54.3	37.4	9.3	31.0
	7.0 L/ha	33.7	47.2	34.7	27.9	40.2
	5.0 L/ha	51.2	60.9	36.3	20.7	51.0
BASF Dimethoate	1.7 L/ha	23.4	20.3	32.1	13.4	35.6
Dursban	1.5 L/ha	48.4	49.2	31.3	16.9	24.6

Conclusions :

The study is acceptable.

No phytotoxic symptoms were observed on any of the trials at any of the assessment timings.

Slight crop differences were observed at trial 1, where untreated plots were generally less vigorous than the treated plots. Overall a dose response was evident for Oncol 20CS, with the higher rates achieving better crop vigour, comparable with the Dursban standard programme.

At trials 2-5 inclusive, no crop vigour differences were observed at any of the trials at any of the assessment timings.

Whilst moderate levels of control were achieved by all rates of Oncol 20CS, the highest rate (10.0 L product/ha) was the most effective treatment, generally comparable to that achieved by Dursban. BASF Dimethoate was overall the least effective chemical treatment.

An evaluation of Oncol 10G, Oncol 20CS and Atlas Chlorpyrifos formulations for the control of wheat bulb fly in winter wheat. (Massie R.B., 2000).

Materials and Methods :

Test substances :

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : 97745
Oncol 20CS : CS formulation containing 20 % w/w benfuracarb, batch n° : 8AB04
BASF Dimethoate : EC formulation containing 400 g/L dimethoate, batch n° : E2422
Atlas Chlorpyrifos : EC formulation containing 480 g/L chlorpyrifos, batch n° : BX E2427
Dusban : EC formulation containing 480 g/L chlorpyrifos, batch n° : JR 27272037
Atlas Steward : SC formulation containing 560 g/L gamma-HCH, batch n° : 98039

Test sites :

387HA : peat, winter wheat, 4 replicates, 3.0 x 12.0 m²
387MB : loamy sand, winter wheat, 4 replicates, 3.0 x 10.0 m²

Application timing : BBCH 24 for site 387HA, BBCH 21 for site 387MB

Treatment rates :

Untreated control
The treatments were applied post-emergence, when damage begins to show
Oncol 10G : 2.5, 5.0, 10.0 kg/ha
Oncol 20CS : 1.25, 2.5, 5.0 L formulation in 200 L water/ha
BASF Dimethoate : 1.7 L formulation in 200 L water/ha
Atlas Chlorpyrifos : 1.5, 3.0 L formulation in 200 L water/ha
Dursban : 1.5 L formulation in 200 L water/ha
Atlas Steward : 2.0 L formulation in 200 L water/ha

Assessments :

Phytotoxicity : 0 = no damage, 100 = complete crop death.

Levels of *Delia coarctata* damage were assessed 2-3 weeks, 5-6 weeks and 8-9 weeks after application. A 0.25 m quadrat was thrown at random within an untreated plot until at least 30 affected plants had been identified. This process was then repeated on the untreated plots of the other replicates to produce the mean number of quadrats needed to give counts in excess of 30. This number of quadrats was then thrown down in the treated plots. If very high levels of damage were seen a minimum of four quadrats were still used within each plot. Levels of damage were recorded as the mean number of affected plants per square metre.

Findings :

Table B.9.9-28 : Effects of the formulations Oncol 10G, Oncol 20CS, BASF Dimethoate, Atlas Chlorpyrifos, Dursban and Atlas Steward on phytotoxicity for winter wheat (0 = no damage, 100 = complete crop death)

Treatment	Rate	Site 387HA, 29 DAT	Site 387HA, 43 DAT	Site 387MB, 31 DAT	Site 387MB, 55 DAT
Control	-	0.0	0.0	0.0	0.0
Oncol 10G	2.5 kg/ha	0.0	0.0	0.0	0.0
	5.0 kg/ha	0.0	0.0	0.0	0.0
	10.0 kg/ha	0.0	0.0	0.0	0.0
Oncol 20CS	1.25 L/ha	0.0	0.0	0.0	0.0
	2.5 L/ha	0.0	0.0	0.0	0.0
	5.0 L/ha	0.0	0.0	0.0	0.0
BASF Dimethoate	1.7 L/ha	0.0	0.0	0.0	0.0
Atlas Chlorpyrifos	1.5 L/ha	0.0	0.0	0.0	0.0
	3.0 L/ha	0.0	0.0	0.0	0.0
Dursban 4	1.5 L/ha	0.0	0.0	0.0	0.0
Atlas Steward	2.0 L/ha	0.0	0.0	0.0	0.0

Table B.9.9-29 : Level of *Delia coarctata* damage (mean number of wheat bulb fly damaged plants per m²; % efficacy to control)

Treatment	Rate	Site 387HA, 29 DAT	Site 387HA, 43 DAT	Site 387MB, 31 DAT	Site 387MB, 55 DAT
Control	-	138.0 (0%)	91.7 (0%)	204.8 (0%)	49.8 (0%)
Oncol 10G	2.5 kg/ha	109.5 (21%)	76.5 (17%)	136.5 (33%)	30.8 (38%)
	5.0 kg/ha	91.5 (34%)	74.3 (19%)	113.3 (45%)	31.5 (37%)
	10.0 kg/ha	99.8 (28%)	66.9 (27%)	153.0 (25%)	27.0 (46%)
Oncol 20CS	1.25 L/ha	132.8 (4%)	65.9 (28%)	159.0 (22%)	48.0 (4%)
	2.5 L/ha	137.3 (1%)	74.8 (18%)	116.3 (43%)	42.0 (16%)
	5.0 L/ha	120.0 (13%)	80.5 (12%)	138.8 (32%)	40.5 (19%)
BASF Dimethoate	1.7 L/ha	89.3 (35%)	70.3 (23%)	129.0 (37%)	27.8 (44%)
Atlas Chlorpyrifos	1.5 L/ha	103.5 (25%)	63.0 (31%)	105.0 (49%)	43.5 (13%)
	3.0 L/ha	97.5 (29%)	63.0 (31%)	122.3 (40%)	34.5 (31%)
Dursban 4	1.5 L/ha	102.8 (26%)	73.2 (20%)	141.0 (31%)	37.5 (25%)
Atlas Steward	2.0 L/ha	104.3 (24%)	70.3 (23%)	125.8 (39%)	30.8 (38%)

Conclusions :

The study is acceptable.

None of the treatments caused any phytotoxicity.

All the treatments reduced the level of *Delia coarctata* damage compared to the untreated, but over the two sites there were no consistent statistical differences between treatments.

An assessment of the efficacy of Oncol 10G for the control of potato cyst nematode. (Partridge M.A.E., 1999).

Materials and Methods :**Test substances :**

Oncol 10G : GR formulation containing 10 % w/w benfuracarb, batch n° : -

Temic 10G : GR formulation containing 10 % w/w aldicarb, batch n° : -

Nemathorin 10G : GR formulation containing 10 % w/w fosthiazate, batch n° : -

Test sites :

Halsall : organic sandy loam, potato, 4 replicates, 1.83 x 7.5 m²

Risley : loamy peat, potato, 4 replicates, 1.83 x 7.5 m²

Application timing : The chemical was applied to the soil surface just before incorporation.

Treatment rates :

Untreated control

Oncol 10G : 12.0, 24.0, 30.0, 36.0 kg/ha

Temic 10G : 33.6 kg/ha

Nemathorin 10G : 30.0 kg/ha

Assessments :

Phytotoxicity : 9 = equivalent to untreated, 0 = crop death.

Crop emergence counts were carried out on a 5 m section from each plot.

Soil samples were taken for the assessments of cyst and egg counts were carried out.

An assessment of the number of aphids was also carried out.

Findings :

Table B.9.9-30 : Effects of the formulations Oncol 10G, Temic 10G and Nemathorin 10G on phytotoxicity for potato (9 = no damage, 0 = crop death)

Treatment	Rate	Site Halsall, 43 DAT	Site Risley, 30 DAT
Control	-	9.0	9.0
Oncol 10G	12.0 kg/ha	9.0	9.0
	24.0 kg/ha	9.0	9.0
	30.0 kg/ha	9.0	9.0
	36.0 kg/ha	9.0	9.0
Temic 10G	33.6 kg/ha	9.0	9.0
Nemathorin 10G	30.0 kg/ha	9.0	9.0

Table B.9.9-31 : Effects of the formulations Oncol 10G, Temic 10G and Nemathorin 10G on crop emergence (/5 m row)

Treatment	Rate	Site Halsall, 43 DAT	Site Risley, 30 DAT
Control	-	12.0	12.0
Oncol 10G	12.0 kg/ha	12.0	12.0
	24.0 kg/ha	12.0	12.0
	30.0 kg/ha	12.0	12.0
	36.0 kg/ha	12.0	12.0
Temic 10G	33.6 kg/ha	12.0	12.0
Nemathorin 10G	30.0 kg/ha	12.0	12.0

Table B.9.9-32 : Effects of the formulations Oncol 10G, Temic 10G and Nemathorin 10G on aphid counts (/plant)

Treatment	Rate	Site Halsall, 43 DAT	Site Risley, 30 DAT
Control	-	7.3	0.0
Oncol 10G	12.0 kg/ha	4.8	0.0
	24.0 kg/ha	3.5	0.5
	30.0 kg/ha	2.3	0.3
	36.0 kg/ha	2.5	0.5
Temic 10G	33.6 kg/ha	0.3	0.0
Nemathorin 10G	30.0 kg/ha	2.0	0.0

Table B.9.9-33 : Effects of the formulations Oncol 10G, Temic 10G and Nemathorin 10G on potato cyst nematode initial and final population (eggs/g)

Treatment	Rate	Site Halsall		Site Risley	
		Initial population	Final population	Initial population	Final population
Control	-	16.0	116.5	4.25	168.8
Oncol 10G	12.0 kg/ha	15.8	54.0	1.00	197.8
	24.0 kg/ha	18.3	110.3	3.50	242.0
	30.0 kg/ha	24.3	65.3	2.00	184.0
	36.0 kg/ha	19.5	41.8	3.75	223.0
Temic 10G	33.6 kg/ha	20.8	41.3	4.13	37.8
Nemathorin 10G	30.0 kg/ha	18.3	36.0	0.88	128.0

Conclusions :

The study is acceptable.

No phytotoxic effects were noted in the potato plants at either site. No differences in crop emergence were noted between treatments at either site.

The highest number of aphids were noted at site Halsall. Temic 10G at 33.6 kg/ha gave the highest level of control, with a significant reduction in numbers compared to the untreated.

The highest potato cyst nematode initial population counts were noted at site Halsall. There were no significant differences between counts at this stage.

Risk assessment for non-target terrestrial plants :

The risk assessment for non-target terrestrial plants is based on the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC of October 2002.

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the sowing bed at a single application rate of 1 kg a.s./ha.

Based on 11 reports of efficacy trials with formulations containing benfuracarb in a number of crop plant species (vegetable brassicas, cabbage, cauliflower and Brussels sprouts, brassica, carrot, sugar beet, maize, winter wheat and potato), it can be concluded that no phytotoxicity occurred at dose rates of 1.0-1.2 kg a.s./ha, the maximum proposed application rate. In addition, according to the Terrestrial Ecotoxicology guidance document (SANCO/10329/2002), the risk to non-target terrestrial plants applies to the off-crop area. The method of application of benfuracarb as an in-furrow granular formulation means that in this case the relevant exposure (primarily by drift) will be extremely low. Accordingly, it can be concluded that the risk to non-target terrestrial plants from the recommended use of benfuracarb will be low.

B.9.10 Effects on biological methods of sewage treatment (Annex IIA 8.7)

Activated Sludge Respiration Inhibition Test with Benfuracarb (Contact Time: 3 Hours). (Desmares-Koopmans, 2001).

Guidelines :

OECD Guideline for Testing of Chemicals No. 209: "Activated Sludge, Respiration Inhibition Test"

EEC Directive 67/548 amended November 18, 1987 (87/302), Part C: Methods for the determination of ecotoxicity, Publication No. L133, "Biodegradation: Activated sludge respiration inhibition test", adopted May 30, 1988

GLP :

Yes

Material and Methods :

Test substance : benfuracarb, chemical purity : 93.4 %, batch n° : 0D96

Test design : The inhibitory effect of benfuracarb on the oxygen consumption of activated sludge suspension (3.5 g/L dry weight) was determined.

Applied concentrations :

untreated control at start and at end of the test; toxic standard: 1.0, 3.2, 10, 32 mg/L 3,5-dichlorophenol; treatment at concentration of 100 mg a.s./L

Incubation at 20.8 °C for 3 hours.

Findings and conclusions :

The study is acceptable.

The 3-hour EC₅₀ for 3,5-dichlorophenol (7 mg/L) fulfilled the validity criterion relating to the sensitivity to inhibition (acceptable EC₅₀ range 5 to 30 mg/L), and that relating to the respiration rates in the control (variation not greater than 15 %) was also satisfied.

Benfuracarb had no inhibitory effect on the respiration rate of activated sludge at 100 mg a.s./L (nominal).

B.9.11 Batches used for the ecotoxicological studies

Test species	Test substance	Chemical purity / a.s. content	Batch n°	Reference of the study
<i>Coturnix coturnix japonica</i>	benfuracarb	93.03 %	not reported	IIA 8.1.1/01
<i>Anas platyrhynchos</i>	benfuracarb	94.8 %	2A79	IIA 8.1.1/02
<i>Colinus virginianus</i>	benfuracarb	94.8 %	2A79	IIA 8.1.2/01
<i>Anas platyrhynchos</i>	benfuracarb	94.8 %	2A79	IIA 8.1.2/02
<i>Colinus virginianus</i>	benfuracarb	93.4 %	0D96	IIIA 8.1.3
<i>Oncorhynchus mykiss</i>	benfuracarb	93.4 %	0D96	IIA 8.2.1/01
<i>Lepomis macrochirus</i>	benfuracarb	93.4 %	0D96	IIA 8.2.1/02
<i>Oncorhynchus mykiss</i>	carbofuran	96.7 %	6M11	IIA 8.2.1/03
<i>Lepomis macrochirus</i>	carbofuran	99.9 %	1B87	IIA 8.2.1/04
<i>Lepomis macrochirus</i>	7-phenol	99.8 %	10222AS	IIA 8.2.1/05
<i>Oncorhynchus mykiss</i>	carbofuran	97.6 %	1H25	IIA 8.2.2.1/01
<i>Oncorhynchus mykiss</i>	carbofuran	> 98 %	4I20	IIA 8.2.2.1/02
<i>Daphnia magna</i>	benfuracarb	93.4 %	0D96	IIA 8.2.4/01
<i>Daphnia magna</i>	carbofuran	99.9 %	1B87	IIA 8.2.4/02
<i>Daphnia magna</i>	7-phenol	99.5 %	1B88	IIA 8.2.4/03
<i>Daphnia magna</i>	carbofuran	97.6 %	1H25	IIA 8.2.5
<i>Pseudokirchneriella subcapitata</i>	benfuracarb	93.4 %	0D96	IIA 8.2.6/01
<i>Pseudokirchneriella subcapitata</i>	carbofuran	99.9 %	1B87	IIA 8.2.6/02
<i>Pseudokirchneriella subcapitata</i>	7-phenol	99.5 %	1B88	IIA 8.2.6/03
<i>Chironomus riparius</i>	benfuracarb	93.0 %	7C81-S	IIA 8.2.7
<i>Apis mellifera</i>	benfuracarb	93.4 %	0D96	IIA 8.3.1.1/01
<i>Apis mellifera</i>	benfuracarb	93.4 %	0D96	IIA 8.3.1.1/02
<i>Aphidius rhopalosiphi</i>	Oncol 20EC	216 g/L benfuracarb	0181117	IIA 8.3.2/01
<i>Typhlodromus pyri</i>	Oncol 20EC	216 g/L benfuracarb	0181117	IIA 8.3.2/02
<i>Coccinella</i>	Oncol 20EC	200 g/L benfuracarb	not reported	IIA 8.3.2/03

Test species	Test substance	Chemical purity / a.s. content	Batch n°	Reference of the study
<i>septempunctata</i>				
<i>Chrysoperla carnea</i>	Oncol 20EC	215.6 g/L benfuracarb	0181117	IIA 8.3.2/04
<i>Poecilus cupreus</i>	Oncol 8.6G	9.14 % benfuracarb	22CA1E	IIA 8.3.2/05
<i>Aleoachara bilineata</i>	Oncol 8.6G	9.14 % benfuracarb	22CA1E	IIA 8.3.2/06
<i>Poecilus cupreus</i>	carbofuran	99.9 %	1B87	IIA 8.3.2/07
<i>Aleoachara bilineata</i>	carbofuran	99.9 %	1B87	IIA 8.3.2/08
<i>Aleoachara bilineata</i>	Oncol 8.6G	9.39 % benfuracarb	4D80	IIA 8.3.2/09
<i>Hypoaspis aculeifer</i>	Oncol 8.6G	8.9 % benfuracarb	222LG1E	IIA 8.3.2/10
<i>Pardosa</i>	Oncol 8.6G	8.9 % benfuracarb	222LG1E	IIA 8.3.2/11
<i>Eisenia fetida</i>	Oncol 20EC	200 g/L benfuracarb	not reported	IIA 8.4.1/01
<i>Eisenia fetida</i>	benfuracarb	94.15 %	4I75	IIA 8.4.1/02
<i>Eisenia fetida</i>	Oncol 8.6G	9.39 % benfuracarb	4D80	IIIA 10.6.1.1
<i>Eisenia fetida</i>	Oncol 10G	10.34 % benfuracarb	0087/FEB/95	IIIA 10.6.1.3
Soil microflora	benfuracarb	92 %	not reported	IIA 8.5/01
Soil microflora	Oncol 20EC	200 g/L benfuracarb	not reported	IIA 8.5/02
Soil microflora	carbofuran	99.9 %	3036X	IIA 8.5/03
Soil microflora	Oncol 10G	101 g/kg benfuracarb	not reported	IIIA 10.7.1/01
Soil microflora	Oncol 10G	101 g/kg benfuracarb	not reported	IIIA 10.7.1/02
Non-target terrestrial plants	Oncol 10G Oncol 20CS	10 % benfuracarb 200 g/L benfuracarb	97745Feb97 8AB04	IIIA 10.8/01
Non-target terrestrial plants	Oncol 10G Oncol 20EC Oncol 20CS	10 % benfuracarb benfuracarb benfuracarb	not reported not reported not reported	IIIA 10.8/02
Non-target terrestrial plants	Oncol 10G Oncol 20CS	10 % benfuracarb 200 g/L benfuracarb	97145 OAC01	IIIA 10.8/03
Non-target terrestrial plants	Oncol 10G Oncol 20CS	10 % benfuracarb 200 g/L benfuracarb	not reported not reported	IIIA 10.8/04
Non-target terrestrial plants	Oncol 10G Oncol 20EC Oncol 20SC	10 % benfuracarb benfuracarb benfuracarb	not reported not reported not reported	IIIA 10.8/05
Non-target terrestrial plants	Oncol 10G	10 % benfuracarb	not reported	IIIA 10.8/06

Test species	Test substance	Chemical purity / a.s. content	Batch n°	Reference of the study
<i>Non-target terrestrial plants</i>	Oncol 10G	10 % benfuracarb	2588C	IIIA 10.8/07
	Oncol 20EC	benfuracarb	OF84-S	
	Oncol 20SC	benfuracarb	9EB07	
<i>Non-target terrestrial plants</i>	Oncol 10G	10 % benfuracarb	97/30	IIIA 10.8/08
	Oncol 20CS	20 % benfuracarb	8AB04	
<i>Non-target terrestrial plants</i>	Oncol 20 CS	200 g/L benfuracarb	I22/10595/0100	IIIA 10.8/09
<i>Non-target terrestrial plants</i>	Oncol 10G	10 % benfuracarb	97/30	IIIA 10.8/10
	Oncol 20CS	20 % benfuracarb	8AB04	
<i>Non-target terrestrial plants</i>	Oncol 10 G	10 % benfuracarb	not reported	IIIA 10.8/11
<i>Activated sludge</i>	benfuracarb	93.4 %	0D96	IIA 8.7

B.9.12 References relied on**B.9.12.1 Ecotoxicology of the active substance (Annex IIA 8)**

Annex point / reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA, 8.1.1/01	Jyonouchi, T.	1982	Acute oral toxicity of OK-174 in Japanese quail Nippon Dobutsu Toxicology Laboratory, Japan, report --- Non-GLP, unpublished Otsuka File No: T-033	Y	OTS
IIA, 8.1.1/02	Fink, R.F., Beavers, J.B.	1982a	OK-174: Acute oral LD50 - Mallard Duck Wildlife International Ltd., USA, report WI-786 Non-GLP, unpublished Otsuka File No: T-034	Y	OTS
IIA, 8.1.2/01	Fink, R.F., Beavers, J.B.	1982b	Eight-day dietary LC50 of OK-174 - Bobwhite quail Wildlife International Ltd., USA, report WI-786 Non-GLP, unpublished Otsuka File No: T-035	Y	OTS
IIA, 8.1.2/02	Fink, R.F., Beavers, J.B.	1982c	Eight-day dietary LC50 of OK-174 - Mallard duck Wildlife International Ltd., USA, report --- Non-GLP, unpublished Otsuka File No: T-036	Y	OTS
IIA, 8.1.3	Teunissen, M.	2001	Reproduction study in Bobwhite quail with benfuracarb (by dietary mixtures) NOTOX Safety and Environmental Research B.V., The Netherlands, report 295054 GLP, unpublished Otsuka File No: T-522	Y	OTS
IIA, 8.2.1/01	Migchielsen, M.	2002a	96-hour acute toxicity study in rainbow trout with benfuracarb (semi-static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 334564 GLP, unpublished Otsuka File No: T-545	Y	OTS
IIA, 8.2.1/02	Migchielsen, M.	2002b	96-hour acute toxicity study in bluegill with benfuracarb (semi-static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 334575 GLP, unpublished Otsuka File No: T-546	Y	OTS
IIA, 8.2.1/03	Douglas, M., Handley, J., MacDonal d I.	1987	The acute toxicity of Carbofuran to rainbow trout Huntingdon Research Centre Ltd., England, report MCI 103(b)/87227 GLP, unpublished Otsuka File No: T-569	Y	MIT

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA, 8.2.1/04	Migchielsen, M.	2002c	96-hour acute toxicity study in bluegill with carbofuran (static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 341325 GLP, unpublished Otsuka File No: T-560	Y	OTS
IIA, 8.2.1/05	Migchielsen, M.	2002d	96-hour acute toxicity study in bluegill with carbofuran-7-phenol (static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 334586 GLP, unpublished Otsuka File No: T-563	Y	OTS
IIA, 8.2.2.1	Egeler, Ph., Gilberg, D., Baumann, J.	2002a	A study on the juvenile growth inhibition of carbofuran to freshwater fish (Rainbow trout) ECT Oekotoxikologie GmbH, Germany, and Battelle Geneva Research Centres, Switzerland, report W1FQ GLP, Unpublished Otsuka File No: T-567	Y	DIA
<i>Added in August 2008</i> IIA, 8.2.2.1/02 Chronic toxicity to fish -Chronic toxicity test on juvenile fish	Migchielsen, M.H.J.	2005	Rainbow trout, juvenile growth test 28 days with Carbofuran (flow-through) NOTOX, The Netherlands, report 422988 GLP, unpublished Otsuka File No: T-612	Y	OTS DIA
IIA, 8.2.3/01	Hawkins, D., Mayo, B., Sykes, A., Douglas, M.	1989	The assessment of bioaccumulation of 14C-Benfuracarb in rainbow trout Huntingdon Research Centre Ltd., England, report HRC/OCI 85/89402 GLP, unpublished Otsuka File No: T-151	Y	OTS
IIA, 8.2.4/01	Migchielsen, M.	2002e	Acute toxicity study in <i>Daphnia magna</i> with benfuracarb (static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 335914 GLP, unpublished Otsuka File No: T-547	Y	OTS
IIA, 8.2.4/02	Migchielsen, M.	2002f	Acute toxicity study in <i>Daphnia magna</i> with Carbofuran (static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 341336 GLP, unpublished Otsuka File No: T-561	Y	OTS
IIA, 8.2.4/03	Migchielsen, M.	2002g	Acute toxicity study in <i>Daphnia magna</i> with Carbofuran-7-phenol (static) NOTOX Safety and Environmental Research B.V., The Netherlands, report 338862 GLP, unpublished Otsuka File No: T-564	Y	OTS

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA, 8.2.5	Egeler, Ph., Gilberg, D., Baumann, J.	2002b	A study on the chronic toxicity of carbofuran to <i>Daphnia magna</i> ECT Oekotoxikologie GmbH, Germany, and Battelle Geneva Research Centres, Switzerland, report W2DB GLP, Unpublished Otsuka File No: T-568	Y	DIA
IIA, 8.2.6/01	Migchielsen, M.	2002h	Fresh water algal growth inhibition test with benfuracarb NOTOX Safety and Environmental Research B.V., The Netherlands, report 335903 GLP, unpublished Otsuka File No: T-548	Y	OTS
IIA, 8.2.6/02	Migchielsen, M.	2002i	Fresh water algal growth inhibition test with Carbofuran NOTOX Safety and Environmental Research B.V., The Netherlands, report 341347 GLP, unpublished Otsuka File No: T-562	Y	OTS
IIA, 8.2.6/03	Migchielsen, M.	2002j	Fresh water algal growth inhibition test with Carbofuran-7-phenol NOTOX Safety and Environmental Research B.V., The Netherlands, report 338873 GLP, unpublished Otsuka File No: T-565	Y	OTS
IIA, 8.2.7	Desmares-Koopmans, M.J.E.	1998	Effect of Benfuracarb on the development of sediment-water dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system NOTOX Safety and Environmental Research B.V., The Netherlands, report 196504 GLP, unpublished Otsuka File No: T-453	Y	OTS
IIA, 8.3.1/01	Geuijen, I.	2002a	Acute contact and acute oral toxicity study in the honeybee with benfuracarb (laboratory test) NOTOX Safety and Environmental Research B.V., The Netherlands, report 335633 GLP, unpublished Otsuka File No: T-544	Y	OTS
IIA, 8.3.1/02	Geuijen, I.	2002e	Acute oral toxicity study in the honeybee with benfuracarb (laboratory test) NOTOX Safety and Environmental Research B.V., The Netherlands, report 353205 (supplement to 335633) GLP, unpublished Otsuka File No: C-579	Y	OTS

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA, 8.3.2/01	Bruhnke, C.	2001	Extended laboratory test on adults of <i>Aphis rhopalosiphi</i> exposed to oat plants (Oncol20EC) Dr. U. Noack-laboratorium für angewandte Biologie, Germany, report IWE65891 GLP, unpublished Otsuka File No: T-570	Y	SPU
IIA, 8.3.2/02	Bruhnke, C.	1999	Extended laboratory test on <i>Typhlodromus pyri</i> exposed on apple tree leaves (Oncol20EC) Dr. U. Noack-laboratorium für angewandte Biologie, Germany, report IRE65893 GLP, unpublished Otsuka File No: T-571	Y	SPU
IIA, 8.3.2/03	Kühner, Ch.	1991	Effects of Oncol20EC on <i>Coccinella septempunctata</i> (Oncol20EC) (Erfassung der Nebenwirkungen von Oncol20EC auf den Großen Siebenpunkt Marienkäfer, <i>Coccinella septempunctata</i> im Labor) GAB Biotechnologie GmbH, Germany, report SPI 83811I (83811514) GLP, unpublished Otsuka File No: T-572	Y	SPU
IIA, 8.3.2/04	Bruhnke, C.	2000	Side effects on the larve of the green lacewing <i>Chrysoperla carnea</i> exposed on apple tree leaves (Oncol20EC) Dr. U. Noack-laboratorium für angewandte Biologie, Germany, report IFE65892 GLP, unpublished Otsuka File No: T-573	Y	SPU
IIA, 8.3.2/05	Geuijen, I.	2002b	Laboratory toxicity test of Oncol8.6G with <i>Poecilus cupreus</i> NOTOX Safety and Environmental Research B.V., The Netherlands, report 339964 GLP, unpublished Otsuka File No: T-566	Y	OTS
IIA, 8.3.2/06	Geuijen, I.	2002c	Laboratory toxicity test of Oncol8.6G with <i>Aleochara bilineata</i> NOTOX Safety and Environmental Research B.V., The Netherlands, report 339975 GLP, unpublished Otsuka File No: T-555	Y	OTS

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Added in August 2008 IIA, 8.3.2/09 Effect on arthropods - Other arthropods - Laboratory, extended laboratory and semi-field tests	Geuijen, I.	2005a	Effects of aged residue of Oncol 8.6G on the staphylinid beetle <i>Aleochara bilineata</i> (extended laboratory test for granulates with aged residue). NOTOX Safety and Environmental Research B.V., The Netherlands, report 423135 Otsuka file no. T-608F	Y	OTS
Added in August 2008 IIA, 8.3.2/10 Effect on arthropods - Other arthropods - Laboratory, extended laboratory and semi-field tests	Vinall, S.	2008	An extended laboratory test to determine the effects of Oncol 8.6G (= Oncol S) containing 8.6 % w/w benfuracarb, on the predatory mite, <i>Hypoaspis aculeifer</i> (Acari, Laelapidae). Mambo-Tox Study No. NOT-08-1 Report No. NOT-08-1	Y	OTS
Added in August 2008 IIA, 8.3.2/11 Effect on arthropods - Other arthropods - Laboratory, extended laboratory and semi-field tests	Vinall, S	2008	An extended laboratory test to determine the effects of Oncol 8.6G (= Oncol S), containing 8.6 % w/w benfuracarb, on spiders of the genus <i>Pardosa</i> (Araneae, Lycosidae). Mambo-Tox Study No. NOT-08-2 Report No. NOT-08-2	Y	OTS
IIA, 8.4.1	Kühner, Ch.	1990	Acute toxicity of Oncol20EC on the earthworm <i>Eisenia foetida</i> (Artificial soil test) (Akute Toxizität von Oncol20EC auf den Kompostwurm, <i>Eisenia foetida</i>) Institut für Umweltanalytik und Biotechnologie, Germany, report Spi83811I (83811502) Otsuka File No: T-574	Y	SPU
Added in August 2008 IIA, 8.4.1/02 Acute toxicity - earthworms	Geuijen, W.H.C.	2005b	Acute toxicity study in the earthworm <i>Eisenia fetida fetida</i> with Benfuracarb NOTOX Safety and Environmental Research B.V., The Netherlands, report 423078 GLP, unpublished Otsuka File No: C-610	Y	OTS

Annex point / reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA, 8.5/02	Littmann	1987	Effects on the activity of Soil micro-organisms (Auswirkungen auf Aktivität der Bodenmikroflora nach Richtlinie Teil VI 1-1) Labor für Bodenuntersuchungen, Germany, report 83811501 Otsuka File No: T-575	Y	SPU
<i>Added in August 2008</i> IIA, 8.5/03 Effects on soil non-target micro-organisms	Rix, S.	2005	Carbofuran: Determination of effects on soil microflora respiration and nitrogen transformations CEM Analytical Services Limited (CEMAS), England, project CEMR-2514 Otsuka file no. T-614	Y	OTS
IIA, 8.7	Desmares-Koopmans, M.	2001b	Activated sludge respiration inhibition test with benfuracarb (contact time 3 hours) NOTOX Safety and Environmental Research B.V., The Netherlands, report 319578 GLP, unpublished Otsuka File No: C-654	Y	OTS

B.9.12.2 Ecotoxicology of the formulations (Annex IIIA 10)

Annex point / reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIIA, 10.1.4	Partington, K.	1997a	Study to evaluate the palatability to blackbirds (<i>Turdus merula</i>) of earthworms exposed to Oncol10G Agrisearch UK, Ltd., England, report AW/3337/OT GLP, unpublished Otsuka File No: T-449	Y	OTS
<i>Added in August 2008</i> IIIA, 10.1/01 Effects to birds	Fletcher, M.R., Hunter, K., Barnett, E.A., Sharp, E.A.	1999	Pesticide poisoning of animals 1998: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	!
<i>Added in August 2008</i> IIIA, 10.1/02 Effects to birds	Barnett E.A., Hunter K., Fletcher M.R., Sharp E.A.	2000	Pesticide poisoning of animals 1999: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	!

Annex point / reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
<i>Added in August 2008</i> IIIA, 10.1/03 Effects to birds	Barnett, E.A., Fletcher, M.R., Hunter, K., Sharp, E.A.	2001	Pesticide poisoning of animals 2000: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>Added in August 2008</i> IIIA, 10.1/04 Effects to birds	Barnett, E.A., Fletcher, M.R., Hunter, K., Sharp, E.A.	2002	Pesticide poisoning of animals 2001: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>Added in August 2008</i> IIIA, 10.1/05 Effects to birds	Barnett, E.A., Fletcher, M.R., Hunter, K., Sharp, E.A.	2003	Pesticide poisoning of animals 2002: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>Added in August 2008</i> IIIA, 10.1/06 Effects to birds	Barnett, E.A., Fletcher, M.R., Hunter, K., Sharp, E.A.	2004	Pesticide poisoning of animals 2003: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>Added in August 2008</i> IIIA, 10.1/07 Effects to birds	Barnett, E.A., Fletcher, M.R., Hunter, K., Sharp, E.A.	2005	Pesticide poisoning of animals 2004: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>Added in August 2008</i> IIIA, 10.1/08 Effects to birds	Barnett, E.A., Fletcher, M.R., Hunter, K., Sharp, E.A.	2006	Pesticide poisoning of animals 2005: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>Added in August 2008</i> IIIA, 10.1/09 Effects to birds	Barnett E.A., Fletcher M.R., Hunter K., Taylor M.J., Sharp E.A.	2007	Pesticide poisoning of animals 2006: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-

Annex point / reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Added in August 2008 IIIA, 10.1/10 Effects to birds	Nufarm	2005	Oncol sales in the UK Non-GLP, unpublished	N	-
Added in August 2008 IIIA, 10.1/11 Effects to birds	Muenderle, M., Dietzen, C.	2007	Bird species in cabbage fields in Northern and Southern Europe: field data for the determination of focal species. RIFCon, Germany, report: RA07079 Non GLP, unpublished Otsuka file: T-693	Y	OTS
Added in August 2008 IIIA, 10.1/12 Effects to birds	Dietzen, C.	2007	Focal bird species in cabbage fields in Europe with regard to granular application of Oncol 8.6G. RIFCON report no RA07236 Non-GLP, unpublished	Y	OTS
Added in August 2008 IIIA, 10.1/13 Effects to birds	Donald, P.F., Buckingham, D.L., Moorcroft, D., Muirhead, L.B., Evans, A.D., Kirby, W.B.	2001	Habitat use and diet of skylarks <i>Alauda arvensis</i> wintering on lowland farmland in southern Britain. Journal of Applied Ecology 38: 536-547. Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/14 Effects to birds	Donald, P.F.	2004	Mating and territoriality In: The Skylark (Poyser Species Monograph) T&AD Poyser, London, UK, p.95 Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/15 Effects to birds	Cramp, S.	1998	Handbook of the Birds of the Western Palearctic. Optimedia. Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/16 Effects to birds	Abs, M.	1963	Vergleichende Untersuchungen an Haubenlerche (<i>Galerida cristata</i>) und Theklalerche (<i>G. theklae</i>). Bonner Zoologische Beiträge 14: 3-128 Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/17 Effects to birds	Bösenberg, K.	1969	Einige Gedanken zur Forschung auf dem Gebiet der angewandten Ornithologie und einige Ergänzungen zu den Untersuchungsergebnissen von W.F. Rjabow: „Die Nahrung der Feldlerche in der Kustanai-Steppe“ Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/18 Effects to birds	Collinge, W.E.	1927	The food of some British wild birds. York Non-GLP, published	N	-

Annex point / reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Added in August 2008 IIIA, 10.1/19 Effects to birds	Jeromin, K.	2002	Zur Ernährungsökologie der Feldlerche (<i>Alauda arvensis</i> L. 1758) in der Reproduktionsphase. PhD thesis. Christian-Albrechts-Universität, Kiel Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/20 Effects to birds	Green, R.E.	1978	Factors affecting the diet of farmland skylarks, <i>Alauda arvensis</i> . Journal of Applied Ecology 47: 913-928. Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/21 Effects to birds	Dunning	1993	Avian body masses. Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/22 Effects to birds	Glutz von Blotzheim, U.N., Bauer, K.M., Bezzel, W.	2001	Handbuch der Vögel Mitteleuropas. eBook, Aula-Verlag, Wiesbaden, and reference therein: G. CUENDET: Etude du comportement alimentaire de la Mouette rieuse et de son influence sur les peuplements lombriciens. These de doctorat, Université Lausanne, 1979 (Kurzfassung in Nos Oiseaux 35, 1979, 170–172). Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/23 Effects to birds	Snow, D., Perrins, C.	1998	The complete birds of the western palearctic (CD-ROM). OptiMedia Oxford University Press Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/24 Effects to birds	Colquhoun, M.K.	1951	The woodpigeon in Britain. London Non-GLP, published	N	-
Added in August 2008 IIIA, 10.1/25 Effects to birds	Ljunggren, L.	1968	Seasonal studies of woodpigeon populations. Viltrevy 5: 436-495. Non-GLP, published	N	-
added in August 2008 IIIA, 10.1/26 Effects to birds	Murton, R.K., Westwood, N.J., Isaacson, A.J.	1964	The feeding habits of the Wood Pigeons <i>Columba palumbus</i> , Stock Dove <i>C. oenas</i> and Turtle Dove <i>Streptopelia turtur</i> . Ibis 106:174-188. Non-GLP, published	N	-
added in August 2008 IIIA, 10.1/27 Effects to birds	Bettman, H.	1965	Rosenkohl als Nahrung der Ringeltaube in einem niederrheinischen Gemüsebauggebiet. Z. Jagdwissenschaften: 136-144. Non-GLP, published	N	-
added in August 2008 IIIA, 10.1/28 Effects to birds	Bettmann, H.	1966	Untersuchungen der Kropfinhalte von Ringeltauben. Zeitschrift für Jagdwissenschaften, 12, 97-125. Non-GLP, published	N	-

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
added in August 2008 IIIA, 10.1/29 Effects to birds	Schnock, G., Seutin, E.	1970	Le ramier (<i>Columba palumbus</i> L.) dans la région occidentale du Condroz. 1. Régime alimentaire en fonction des potentialités et du développement phénologique de son habitat au cours de l'année 1967. Bulletin des Recherches Agronomiques de Gembloux, 5 (3-4), 647-667. Non-GLP, published	N	-
added in August 2008 IIIA, 10.1/30 Effects to birds	Schnock, G., Seutin, E.,	1973	Contribution à l'étude écologique de l'alimentation du Pigeon ramier (<i>Columba palumbus</i>) en Belgique. <i>E Aves</i> 182-192. Non-GLP, published	N	-
added in August 2008 IIIA, 10.1/31 Effects to birds	Seutin E., Schnock, G.	1971	Le ramier (<i>Columba palumbus</i> L.) dans la région occidentale du Condroz. 2. Caractérisation du cycle alimentaire annuel. Bulletin des Recherches Agronomiques de Gembloux, 6 (3-4), 585-596. Non-GLP, published	N	-
added in August 2008 IIIA, 10.1/32 Effects to birds	Haynes, P.J., Inglis, I.R., Isaacson, T.J., Fryday, S.L.	2003	Woodpigeon <i>Columba palumbus</i> movements in eastern England: Woodpigeons range over greater areas during winter than summer with winter dispersion greatest in the first two winters following fledging. <i>Bird Study</i> (2003) 50(1): 33-38 Non-GLP, published	N	-
added in August 2008 IIIA, 10.1.3 Acceptance of bait, granules or treated seeds by birds	Teunissen, M.	2004	Avoidance of Japanese quail from seed scattered on granules containing Oncol8.6G. NOTOX, The Netherlands, report 383153 GLP, unpublished Otsuka File No: T-600	Y	OTS
added in August 2008 IIIA, 10.1.4 Effects of secondary poisoning (birds)	Partington, K.	1997a	Study to evaluate the palatability to blackbirds (<i>Turdus merula</i>) of earthworms exposed to Oncol10G Agrisearch UK, Ltd., England, report AW/3337/OT GLP, unpublished Otsuka File No: T-449	Y	OTS
added in August 2008 IIIA, 10.3/01 Effects to mammals	Fletcher, M.R., Hunter, K., Barnett, E.A., Sharp, E.A.	1999	Pesticide poisoning of animals 1998: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
<i>added in August 2008</i> IIIA, 10.3/02 Effects to mammals	Barnett E.A., Hunter K., Fletcher M.R., Sharp E.A.	2000	Pesticide poisoning of animals 1999: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>added in August 2008</i> IIIA, 10.3/03 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Sharp E.A.	2001	Pesticide poisoning of animals 2000: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>added in August 2008</i> IIIA, 10.3/04 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Sharp E.A.	2002	Pesticide poisoning of animals 2001: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>added in August 2008</i> IIIA, 10.3/05 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Sharp E.A.	2003	Pesticide poisoning of animals 2002: Investigations of suspected incidents in the United Kingdom Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>added in August 2008</i> IIIA, 10.3/06 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Sharp E.A.	2004	Pesticide poisoning of animals 2003: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>added in August 2008</i> IIIA, 10.3/07 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Sharp E.A.	2005	Pesticide poisoning of animals 2004: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
<i>added in August 2008</i> IIIA, 10.3/08 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Sharp E.A.	2006	Pesticide poisoning of animals 2005: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-

Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
added in August 2008 IIIA, 10.3/09 Effects to mammals	Barnett E.A., Fletcher M.R., Hunter K., Taylor M.J., Sharp E.A.	2007	Pesticide poisoning of animals 2006: investigations of suspected incidents in the United Kingdom. Central Science Laboratory, Sand Hutton, York, UK and Scottish Agricultural Science Agency, East Craigs, Edinburgh, UK Non-GLP, published	N	-
added in August 2008 IIIA, 10.3/10 Effects on mammals	Nufarm	2005	Oncol sales in the UK Non-GLP, unpublished	N	-
added in August 2008 IIIA, 10.3/11 Effects to mammals	Niethammer, J., Pegel, M.	2003	<i>Lepus europaeus</i> Pallas 1778 – Feldhase. In Krapp, F. Hasentiere – Lagomorpha in Handbuch der Säugetiere Europas Niethammer, J. (Hrsg.): - Akad. Verl.-Ges., Wiesbaden. Non-GLP, published	N	-
added in August 2008 IIIA, 10.3/12 Effects to mammals	Zörner, H.	1990	Feldhase (<i>Lepus europaeus</i> Pallas). In Stubbe, M. (Hrsg.): Buch der Hege, Band 1 Haarwild, Deutsche Landwirtschaftsverlag, Berlin: 285 - 323. Non-GLP, published	N	-
added in August 2008 IIIA, 10.3/13 Effects to mammals	Homolka, M.	1987	Problems associated with investigations into the diet of the European hare. Folia Zoologica 36: 193-202. Non-GLP, published	N	-
added in August 2008 IIIA, 10.3/14 Effects to mammals	Brüll, U.	1973	Wildfutterpflanzengesellschaften und Futterwert der vom Feldhasen (<i>Lepus europaeus</i> Pallas) genutzten Pflanzen. Diss. Fachber. Biologie, Univ. Hamburg. Non-GLP, published	N	-
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added in August 2008 IIIA, 10.3/17 Effects to mammals	Chapuis, J.	1990	Comparison of the diets of two sympatric lagomorphs, <i>Lepus europaeus</i> (Pallas) and <i>Oryctolagus cuniculus</i> (L.) in an agroecosystem of the Ile-de-France. <i>Zeitschrift für Säugetierkunde</i> , 55, 176 Non-GLP, published	N	-
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added in August 2008 IIIA, 10.8/01	Thorpe A.P.	2000	An evaluation of the efficacy of Oncol 10G and Oncol 20CS for the control of cabbage root fly in vegetable brassicas. O.A.T. Project No. : 624-99-WHY-CRF Whyte Agrochemicals Project No. : WHY/99/039	Y	OTS
added in August 2008 IIIA, 10.8/02	Carr D.E.	2003	An evaluation of the efficacy of Oncol 10G and 20EC for the control of cabbage root fly in cauliflower and cabbage. OAT Trial Series : 959/01/NUF/CRF Nufarm Protocol No. : NWA 01/025	Y	OTS
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Annex point reference number	Author(s)	Year	Title Source (where different from Company) Company Report No. GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
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added in August 2008 IIIA, 10.08/11	Partridge M.A.E.	1999	An assessment of the efficacy of Oncol 10G for the control of potato cyst nematode. Oxford Plant Sciences LTd. Project No. OPS/00770/WHY	Y	OTS

APPENDIX 1 :

NOTOX REPORT

BENFURACARB

STATEMENT ON ACCEPTANCE OF GRANULES BY BIRDS

EFSA OPEN POINT 11 / Annex III 10.1.3

Author

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Date

October 19, 2007

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Laboratory Project Identification

NOTOX Project 486760
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INTRODUCTION

In the EFSA Scientific Report [1] on benfuracarb the following was stated on page 37: “A study on the acceptance of granules by birds (relevant for all representative uses; data requirement identified in the DAR; study was submitted in April 2005; refer to point 5.1).”

An expert statement and study report [2] have been submitted to the RMS in April 2005. An updated risk assessment, following the updated risk assessment scheme by EPPO [3] is presented below.

EXPERT STATEMENT ON acceptance of granules by birds

In the Guidance document on risk assessment for birds and mammals under Council Directive 91/414/EC (SANCO/4145/2000 – final, 25 September 2002), it is stated under point 4.2 (Exposure routes and exposure estimates in case of granules), that suitable guidance to quantify exposure to granules with an anorganic base is found in the assessment scheme of the EPPO (EPPO 2002) [4].

The risk assessment presented in the DAR [5] concluded that for a bird weighing 15 g, the intake of 54, 41 and 24 granules, respectively, would suffice to achieve the LD50, LC50 and NOEC. It was then stated that according to the EPPO scheme, further risk assessment on granular formulations is necessary when only one or a few granules would be sufficient to achieve a lethal dose. This conclusion was based on the draft version of the assessment scheme [4]. In 2003, the assessment scheme of the EPPO was finalized (EPPO 2003. [3]). In the final version of the assessment scheme, it is stated that the one seed/one granule criterion can be considered as a precautionary warning system for potential high-risk applications for birds and mammals. In addition, a full risk assessment should be performed. The final EPPO assessment scheme [3] is followed below.

The first step in the risk assessment scheme is the assessment according to the one-granule criterion. In this initial assessment of potential high risk, the amount of active substance in one granule is compared to the LD50 (exposure toxicity ratio, ETR). If the resulting ETR is >1, the application should be classified as a potential high-risk application for birds. Subsequently, in all cases the second step in the scheme is a risk assessment for granular formulations conducted for the specific exposure scenarios of intentional and accidental ingestion of granules.

I One granule criterion (initial assessment of potential high risk)

The one granule criterion is based on the average concentration (amount) in one granule. In the DAR, the concentration in one granule (G_{loading}) was stated to be 0.0055 mg a.s./granule. Further, the diameter of the granules is assumed to be 0.25-0.71 mm.

Since the endpoint in the toxicity test (LD50) is expressed as mg a.s./kg bw, the one-granule dose (OGD) should be adjusted to a body weight of 1 kg. This is achieved by multiplication of the G_{loading} with a short-cut value: $\text{OGD} = \text{short-cut value} \times G_{\text{loading}}$. For granules <3.5 mm, the short-cut value is 40. The resulting OGD value is 0.220 mg a.s./kg bw.

The one-granule dose should then be compared to the fifth percentile of the toxicity distribution (LD50^{5th percentile}) to calculate the exposure toxicity ratio (ETR). Since toxicity tests are only available for 2 species, the method of Luttik and Aldenberg (1997) is used to estimate the fifth percentile from the available data, by applying the extrapolation factors especially derived for small samples to the geometric mean of the species tested. For short-term toxicity, the LD₅₀ values from the acute toxicity studies with birds are used (values taken from the DAR [5], section B.9.1.1). The fifth percentile toxicity value is calculated as

$$5th \text{ percentile toxicity value} = \frac{10^{(\text{mean log toxicity value})}}{\text{extrapolation factor}}$$

Where the extrapolation factor depends on the number of species for which a toxicity endpoint is available. According to EPPO, the more conservative method should be used to calculate the 5th percentile toxicity values, i.e. using extrapolation factors for one-sided left confidence limits (rather than median estimates, which is only to be used in cases where the available toxicity endpoints were derived from a test with a sensitive species). Based on LD50 values of 19.8 and 39.9 mg a.s./kg bw and an extrapolation factor of 19.6, the 5th percentile toxicity value is 1.43 mg a.s./kg bw.

The exposure toxicity ratio value (ETR) for the consumption of one granule, calculated as $\text{OGD}/\text{LD50 } 5^{\text{th}} \text{ percentile}$, is shown in the table below. The $\text{ETR}_{1 \text{ granule}}$ is <1, and hence, there is no indication that the application under consideration is of high-risk to birds.

Table 1 Calculated exposure toxicity ratios for the one granule criterion for small birds (bw 25 g)

Granule diameter (mm)	OGD (mg a.s./kg bw)	LD50 5 th percentile (mg a.s./kg bw)	ETR _{rwc}
0.25 - 0.71	0.220	1.43	0.15

II Risk assessment for granular formulations

According to the risk assessment scheme, if it is uncertain whether ingestion is predominantly accidental or intentional, both routes should be examined. For intentional ingestion, it should be then decided if granules are mistaken for food or grit. Since benfuracarb granules are not based on an organic carrier having a nutritional value, mistaking granules for food is not considered relevant. In this case therefore, exposure as a result of accidental ingestion needs to be considered. In addition, intake as grit should also be assessed. Below, the accidental ingestion of granules is considered, followed by an assessment of the intake of grit.

Accidental ingestion of granules (as part of soil ingestion)

For the accidental ingestion of granules, the reasonable worst-case daily dry soil dose for a 25 g bird is calculated. For the short-term and medium-term, the daily dry soil dose (DDSD_{rwc}; rwc referring to reasonable worst-case) is calculated as DDSD_{rwc} = short-cut value x application rate, where application rate is expressed in kg a.s./ha and DDSD_{rwc} is expressed in mg a.s./kg bw/day. The short-cut values are taken from EPPO. For the long-term, the DDSD_{rwc} is calculated as DDSD_{rwc} = short-cut value x application rate x f_{TWA}, where f_{TWA} is the time weighted average factor for residue decline, derived from the DT₅₀ in soil (DT₅₀ in soil 0.44 day, mean value without correction for moisture, taken from [6]) as f_{TWA} = (1-e^{-kt})/kt, where k = ln2/DT₅₀, and t is the averaging time (taken to be the time of standard long-term risk assessment: 21 days).

The short-cut values used and the resulting DDSD_{rwc} values are shown in the table below.

Table 2 Calculated reasonable worst-case daily dry soil doses (DDSD_{rwc}) for small birds (bw 25 g) resulting from accidental ingestion of granules

Scenario	Short-cut value	f _{TWA}	Application rate (kg a.s./ha)	DDSD _{rwc} (mg a.s./kg bw/day)
Short-term	0.473	-	1	0.47
Medium-term	0.095	-	1	0.10
Long-term	0.095	0.031	1	0.003

For the accidental intake of granules, the 5th percentile of the LD₅₀, LC₅₀ and NOEC values should be calculated for short-term, medium-term and long-term exposure, respectively. Since toxicity tests are only available for 1 or 2 species, the method of Luttk and Aldenberg (1997) is used to estimate the fifth percentile from the available data, by applying the extrapolation factors especially derived for small samples to the geometric mean of the species tested. For short-term, medium-term and long-term toxicity, the LD₅₀ values from the acute toxicity studies with birds, the LC₅₀ values for birds and the NOEC value from the chronic study with birds are used, respectively. All values are taken from the DAR (see also [7]).

The fifth percentile toxicity value is calculated as

$$5^{\text{th}} \text{ percentile toxicity value} = \frac{10^{(\text{mean log toxicity value})}}{\text{extrapolation factor}}$$

Where the extrapolation factor depends on the number of species for which a toxicity endpoint is available. According to EPPO, the more conservative method should be used to calculate the 5th percentile toxicity values, i.e. using extrapolation factors for one-sided left confidence limits (rather than median estimates, which is only to be used in cases where the available toxicity endpoints were derived from a test with a sensitive species). Toxicity endpoints (taken from the DAR of benfuracarb, July 2004), extrapolation factors and resulting fifth percentile toxicity values are shown in the table below.

Table 3 Toxicity endpoints, extrapolation factors and resulting 5th percentile toxicity values to be used for the assessment of the risk due to accidental ingestion of granules

Scenario	Toxicity endpoint (mg a.s./kg bw)	Extrapolation factor	5 th percentile toxicity value (mg a.s./kg bw)
Short-term	LD ₅₀ : 19.8 and 39.9	19.6	1.4

Medium-term	LC ₅₀ : 15 and 179	19.6	2.6
Long-term	NOEC: 8.93	32.9	0.27

The resulting exposure toxicity ratio (ETR) values, calculated as $DDSD_{rwc}/5^{th}$ percentile toxicity value, are shown in the table below. According to EPPO, when ETR is ≤ 1 , the risk is low. Since all ETRs are < 1 , the risk for small birds as a result of accidental ingestion of granules is low.

Table 4 Calculated exposure toxicity ratios for accidental ingestion of granules for small birds (bw 25 g)

Scenario	$DDSD_{rwc}$ (mg a.s./kg bw/day)	5 th percentile toxicity value (mg a.s./kg bw)	ETR_{rwc}
Short-term	0.47	1.4	0.3
Medium-term	0.10	2.6	0.04
Long-term	0.003	0.27	0.01

Intentional ingestion of granules (as part of grit ingestion)

For the intentional ingestion of granules, the reasonable worst-case daily granule dose (expressed in mg/kg bw/day) is calculated for a representative bird. Based on the size of the granules (0.25-0.71 mm), the risk assessment is based on a small bird. For short-term and medium-term exposure, the daily granule dose is calculated as $DGD_{rwc} = DGI_{rwc} * (G_{surface} / (SP_{surface} + G_{surface})) * G_{loading}$. For the long-term, the daily granule dose is calculated as $DGD_{rwc} = DGI_{rwc} * (G_{surface} / (SP_{surface} + G_{surface})) * (G_{loading} * TWA_{factor \text{ for a.s.}})$. In these calculations, DGI is daily grit intake, $G_{surface}$ is the number of granules at soil surface (calculated from the actual dose of 1 kg a.s./ha), $SP_{surface}$ is the number of soil particles at the soil surface in the same size classes as the granules per m² (15200, default value), and $G_{loading}$ is the amount of active substance in one granule (0.0055 mg a.s./granule). The daily grit intake is taken from table 9 of the EPPO scheme and is 651 for small birds (reasonable worst-case (RWC) scenario). A TWA_{factor} can be used if data are available for the active substance in granules. No data are available on the degradation rate of benfuracarb in granules. However, for the aspect of accidental ingestion of granules (see above), the f_{TWA} was derived from the DT50 in soil (0.44 day, mean value without correction for moisture, taken from [6] and a 21-day averaging time). This f_{TWA} (0.031) is taken to be the TWA_{factor} in the current assessment.

The daily granule doses should then be compared to the appropriate toxicity values. These toxicity values are the same as used for the accidental ingestion of granules. If ETR values are ≤ 1 , the granular formulation is classified as low risk for short-term, medium-term and/or long-term exposure. If ETR values are > 1 , the risk assessment needs to be refined. The table below summarises the DGI, $G_{surface}$, TWA_{factor} , DGD, 5th percentile toxicity and resulting ETR values for the short-, medium- and long-term exposure.

Table 5 Calculated exposure toxicity ratios for intentional ingestion of granules for small birds as part of grit ingestion

Scenario	DGI _{rwc} (granules/kg bw/day)	G _{surface} (granules/m ²)	TWA _{factor}	DGD _{rwc} (mg a.s./kg bw/day)	5 th percentile toxicity value (mg a.s./kg bw)	ETR _{rwc}
Short-term	651	18182	-	1.95	1.4	1.4
Medium-term	651	18182	-	1.95	2.6	0.7
Long-term	651	18182	0.031	0.06	0.27	0.2

The ETR value for short-term ingestion of granules is above 1, and the risk assessment needs to be refined. According to the assessment scheme, the DGI should now be based on the most likely case (MLC) instead of on the reasonable worst case (RWC). In effect, this implies the use of a lower DGI (386 granules/kg bw/day). For medium-term exposure, the G_{surface} may be adapted to allow for granules lost from the soil surface (through disintegration or by being covered with soil during rainfall, or by wind erosion) and a TWA_{factor} may be used. No data are available on the fraction of granules lost from the soil surface. The refined risk assessment for short-term exposure based on the MLC scenario is shown in the table below.

Table 6 Calculated exposure toxicity ratios for intentional ingestion of granules for small birds as part of grit ingestion, MLC scenario

Scenario	DGI _{mlc} (granules/kg bw/day)	G _{surface} (granules/m ²)	TWA _{factor}	DGD _{mlc} (mg a.s./kg bw/day)	5 th percentile toxicity value (mg a.s./kg bw)	ETR _{mlc}
Short-term	386	182	-	1.16	1.4	0.8

The refined ETR value is <1 for short-term exposure, indicating low risk due to intentional ingestion as part of grit ingestion.

Furthermore, considering the mode of application (furrow application), only a small fraction of the granules will be remain on the soil surface following application. This information is not incorporated in the risk assessment scheme of Eppo, yielding an unrealistically high estimation of the DGI. Taking the low fraction of granules present on the soil surface, the ETR values for short-term, medium-term and long-term exposure will be even lower than calculated in the above assessment. The risk due to intentional ingestion as part of grit ingestion is considered to be low.

Conclusion

Based on the risk assessment performed according to the Eppo assessment scheme [4], the risk to birds as a result of uptake of granules is low.

Supplementary data

An acceptance study of Japanese quail to Oncol 8.6G has been submitted (Teunissen, M.S., 2004) [2]. In this study, two replicate groups of Japanese quail weighing 249-317 g were exposed for 24 hours to seed and quail mash spread out on the floor of the test cabin on top of a layer of granules with a granule density of 18750/m². The latter value corresponds with the density of the incorporated granules after application of Oncol 8.6G according to GAP (12 kg product/ha). This granule density is an estimated factor of 100 higher than the density of the granules present on the soil surface (in the risk assessment scenario of USES 2.0 it is estimated that 1% of the applied granules remain on the surface after incorporation). Hence the exposure situation of the study represents a worst case scenario for the field situation. Control birds (1 replicate) were exposed to seed and quail mash only. The 24-hour exposure period was followed by a four-day post-treatment observation period (total test duration five days).

No mortality occurred during the study. One treated bird showed clinical signs up to 2 hours after the start of exposure (ventro-lateral recumbency, shaking of head, fluttering of wings, floundering), which might have been caused by the test article.

The observations performed during the first two hours of exposure suggest that no avoidance behaviour occurred (about equal numbers of observations of eating seeds in both treated replicates and in the control). In the two exposed replicates, the total granule weight at the end of exposure was about 0.3 g lower than the initial weight of 1.2 g.

The results of the acceptance study confirm the outcome of the risk assessment for acute exposure to granules, as it is clearly demonstrated that no mortality occurs in a worst case exposure situation (100 times expected granule density offered on a cage floor instead of natural soil, birds deprived of food 15-20 hours prior to exposure).

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SUBMITTED STUDIES in the re-application procedure

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APPENDIX 2 :

NOTOX REPORT

BENFURACARB

STATEMENT ON LONGTERM RISK ASSESSMENT FOR MAMMALS FROM UPTAKE OF GRANULES

EFSA OPEN POINT 15 / Annex IIIA 10.3

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INTRODUCTION

In the EFSA Scientific Report [1] on benfuracarb the following was stated on page 38: “Long-term risk assessment for mammals from uptake of granules (relevant for all representative uses; data requirement identified in DAR; new risk assessment submitted in August 2005; refer to point 5.1).”

A risk assessment has been submitted to the RMS in August 2005. As a consequence of new data for the DT50 of benfuracarb in soil, an updated risk assessment is presented below.

*EXPERT STATEMENT ON LONGTERM RISK ASSESSMENT FOR MAMMALS FROM UPTAKE OF GRANULES***Long term risk for mammals from ingestion of granules**

A risk assessment is performed according to the guidance provided in the revised EPPO Environmental risk assessment scheme for plant protection products of 2003, points 45-47 [2]. The DAR states that granules are not attractive to mammals (no grit consumption), and the granule does not resemble a natural food source (e.g. insect or seed grain). Therefore accidental exposure to contaminated soil is the only relevant route to be taken into consideration.

The reasonable worst case Daily Soil Dose (DDSD_{rwc}) for a 25 g mammal is calculated as DDSD_{rwc} (mg/kg bw/day) = short-cut value * application rate in kg a.s./ha * TWA factor (f_{TWA}). For benfuracarb (DT50 in soil 0.44 day, mean value without correction for moisture, taken from [3]) the f_{TWA} factor is 0.031 (21-day averaging time). For an application of 1 kg a.s./ha the DDSD_{rwc} is equal to 0.00070 mg/kg bw/day.

For the accidental intake of granules, the 5th percentile of the NOED values should be calculated for long-term exposure. Since a toxicity test is only available for 1 species, the method of Luttik and Aldenberg (1997) is used to estimate the fifth percentile from the available data, by applying the extrapolation factors especially derived for small samples to the geometric mean of the species tested.

The fifth percentile toxicity value is calculated as:

$$5th \text{ percentile toxicity value} = \frac{10^{(mean \log \text{ toxicity value})}}{\text{extrapolation factor}}$$

Where the extrapolation factor depends on the number of species for which a toxicity endpoint is available, and differs between birds and mammals. According to EPPO, the more conservative method should be used to calculate the 5th percentile toxicity values, i.e. using extrapolation factors for one-sided left confidence limits (rather than median estimates, which is only to be used in cases where the available toxicity endpoints were derived from a test with a sensitive species). The ecological NOAEL is 1.2 mg a.s./kg bw/day. Based on an extrapolation factor of 14.9, the 5th percentile toxicity value for long-term exposure (NOED) is 0.081 mg a.s./kg bw.

The resulting exposure toxicity ratio (ETR), calculated as DDSD_{rwc}/5th percentile NOED, is 0.009. According to EPPO, when ETR is ≤1, the risk is low. Therefore, the risk for small mammals as a result of accidental ingestion of granules is low.

Conclusion

The long-term risk to mammals from the ingestion of granules contaminated with benfuracarb is low (ETR_{rwc} <1).

Short- and medium-term risk for mammals from ingestion of granules

The risk assessment for short- and medium-term exposure to granules may be performed according to the same calculations as for long-term exposure. Based on an LD50 of 205 mg/kg bw and an LC50 of 2 mg/kg bw, the 5th percentile toxicity values for short- and medium-term exposure are 14 and 0.13 mg/kg bw, respectively. Short-cut values are respectively 0.113 and 0.023. The ETR values for short-term and medium-term exposure are 0.008 and 0.2, respectively. Hence, the short-term and medium-term risk due to ingestion of granules is low.

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SUBMITTED STUDIES in the re-application procedure

- [3] Willems H.P.L. (2007). Benfuracarb, PEC_{GW} calculations for benfuracarb, carbofuran, 3-OH-carbofuran, 3-keto-carbofuran and carbofuran-phenol. Statement on EFSA Open point 10 / Annex IIIA 9.2.1. NOTOX Project 486759.