TABLE OF CONTENTS

	Document	**File Name**
00	Cover page	00 lenacil cover
01	All comments received on the DAR	01 lenacil all comments
02	Reporting table all sections	02 lenacil rep table rev 1-1
03	All reports from PRAPeR Expert Meetings	03 lenacil all reports.
04	**Evaluation table**	**04 lenacil eval table rev 2-1**

1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 1 Open points: ***11*** Points for clarification: ***3*** Data gaps: ***0***			Section 1 Open points: ***1*** Data gaps: ***5***
1.1	Point of clarification for the applicant: Applicant to provide information on the level of [redacted] of [redacted] See reporting table 1(2)	The trade name of the additive [redacted]. According to published information by the producer (See enclosed << [redacted] product info.pdf>>, the degree of [redacted] is indicated by the first two digits in the trade name. In conclusion [redacted] contains [redacted] moles of [redacted]	RMS considers the provided clarification to be sufficient. The information on degree of [redacted] of the additive has been included in the updated Vol.4 (C) (dated March 2009).	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
	Open point: 1.1 The expression of the content of impurity 9 in the five batch to be discussed in a meeting of experts See reporting table 1(11)	Impurity 9 was determined as total [redacted] In the study report the corresponding [redacted]$_4$ content has been calculated (The calculation factor is 4.29) and this value has been used in the calculation based on the information from the synthesis process and the earlier 5-batch analysis where [redacted] has been analysed for instead of [redacted]	The mentioned results for [redacted] content from an earlier 5-batch analysis were not provided to the RMS, but this is considered irrelevant.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		8.3. results [redacted] UCL GmbH, Köln page 27/99		
	Open point: 1.2 To be discussed in a meeting of experts whether the 5-batch analysis study (Wittig, 2000) sufficiently covers the analytical profile of lenacil technical. See reporting table 1(12)	The notifier is of the opinion that the 5-batch analysis study does cover the analytical profile of lenacil technical sufficiently. A full screening was done by UCL and each peak has been identified at the time. As the manufacturing process was not changed at [redacted] UCL was able to use previous experience on possible impurities and information from former 5 batch analysis.	Indeed, a limited number of impurities was sought for in the 5-batch analysis study by Wittig (2000). Looking back to the study report, it is noted that two peaks observed in the provided sample chromatogram were not identified. As the identity is unknown, estimating the concentration level is hard; However, comparing their response at wavelengths 200 nm, 270 nm and 285 nm with that of the impurities sought for, it is considered unlikely that these unknown compounds were present at significant levels in the technical material analysed.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.3 The acceptability of the water measurement by „loss on drying' to be discussed in a meeting of experts. See reporting table 1(14)	Water content is measured constantly during quality control at Schirm via Karl Fisher Titration. Results from 1999 – 2009 can be provided upon request. The water content for lenacil technical ranges between [redacted] The mean water content measured by "loss on drying" in the five batch	The quality control data referred to by the applicant were not provided to the RMS.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		analysis study is [redacted] and should therefore be acceptable.		
	New data gap 1.1 identified at PRAPeR 66 meeting: The material quantified under "loss on drying" should be quantified by specific methods			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open: The material quantified under "loss on drying" should be quantified by specific methods
	Open point: 1.4 The necessity to request the „accelerated' storage stability testing of the preparation if a shelf life study is available to be (re-)discussed in a meeting of experts. See reporting table 1(21)	It should be noted that both Croplife Monograph 17 (GIFAP) and CIPAC MT46 clearly indicate that the 54°C stability test is an accelerated test which may be used as a temporary indicator of shelf life stability. If a full 2 year shelf life study has been presented, then accelerated data is redundant and therefore not necessary.	RMS: no additional comment	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 1.2 identified at PRAPeR 66 meeting: Accelerated storage stability test of the preparation is required.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open: Accelerated storage stability test of the preparation is required.
	Open point: 1.5 The acceptability of the	The notifier requests that this issue is addressed at member state level	RMS: The overall results for suspensibility	PRAPeR 66 (21 – 24 April 2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	suspensibility study to be discussed in a meeting of experts See reporting table 1(22)	during the re-registration of Venzar 80 WP. Evidence of satisfactory importance and homogeneity of the diluted spray solution in the form of efficacy data will be submitted in the biological assessment dossier to member state authorities.	(before and after storage) were considered to be unsatisfying, based on the laboratory tests. Further information is to be requested at Member State level.	Open point fulfilled.
	New data gap 1.3 identified at PRAPeR 66 meeting: A sprayability test is required.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open: A sprayability test is required
1.2	Point of clarification for the applicant: Applicant to provide information demonstrating acceptable performance of the preparation under field conditions See reporting table 1(25)	The notifier requests that this issue is addressed at member state level during the re-registration of Venzar 80 WP. Evidence of satisfactory importance and homogeneity of the diluted spray solution in the form of efficacy data will be submitted in the biological assessment dossier to member state authorities.	See open point 1.5	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
1.3	Point of clarification for the applicant: Applicant to clarify the unit used in table B.3.5.1.1-1 No. 3 under material/bag See reporting table 1(28)	“my” was used for the unit “micrometers”: 3. HDPE film, 20 micrometers, needled.	RMS: The point has been sufficiently clarified by the applicant.	PRAPeR 66 (21 – 24 April 2009): Point of clarification addressed.
	Open point: 1.6	This method was used in the previous	RMS agrees with applicant.	PRAPeR 66 (21 – 24 April 2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	The acceptability of the linearity determination of method (Hansen, 1998 – Report No. AMR 3747-96) to be discussed in a meeting of experts See reporting table 1(29)	5-batch analysis report that is provided for reference only and there should be no need to further discuss its acceptability. The HPLC-UV method used in the batch analysis study Wittig (2000) is suitable for the determination of lenacil content in the technical material.		Open point fulfilled.
	Open point: 1.7 The acceptability of the ICP-OES method (Wittig, 2000 – Report No. PR00/015) to be discussed in a meeting of experts See reporting table 1(30)		Linearity and accuracy data were not provided for the ICP-OES method. Following waiver was received from the applicant: *"ICP-OES is a well established technique for inorganic analysis and is generally accepted as being linear and acceptably accurate for all purposes."* RMS can agree that full validation data should have been provided for this method.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.8 The necessity to provide further data to demonstrate the applicability of the multi-residue method to be discussed in a meeting of experts. See reporting table 1(35)		The validation data provided in the study by Tillkes (1998) do not fully comply with the requirements of SANCO/825/00. RMS therefore considered the study as being not acceptable, whereas EFSA is of the opinion that it does sufficiently address the demonstration of the applicability of DFG S19, even with the poor validation data set.	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.
	Open point: 1.9 The acceptability of method	The notifier agrees with the RMS comments in the reporting table.	RMS considers the method to be acceptable as primary method in the range 0.05 to 0.5 mg/kg. Sufficient	PRAPeR 66 (21 – 24 April 2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Brodsky and Zietz as primary method should be discussed in a meeting of experts See reporting table 1(38)		replicates were done at each of the fortification levels.	Open point fulfilled.
	Open point: 1.10 The necessity to require a confirmatory method for determination of residues in water to be discussed in a meeting of experts See reporting table 1(39)		Before the DAR was finalised, the RMS asked this question to the applicant, who provided the following answer: *"[…] Identity is primarily confirmed by comparison of retention times against standard solutions of lenacil. This is supported by the comparison of UV spectra, which has been reported in a GLP study so presentation of the raw data should not be required. HPLC/DAD is an inherently self-confirmatory technique."*	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled. New data gap proposed, see below.
	New data gap 1.4 identified at PRAPeR 66 meeting: A confirmatory method for determination of residues in water.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open: A confirmatory method for determination of residues in water
	Open point: 1.11 The acceptability of the air method with the validated LOQ to be discussed in a		Indeed, the validated LOQ of the method is below the relevant concentration C, which was estimated following the guidelines described in	PRAPeR 66 (21 – 24 April 2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	meeting of experts See reporting table 1(42)		SANCO/825/00 rev.7. However, it should be noted that the difference between validated LOQ and concentration C is quite small. In addition, lenacil is a very slightly volatile compound (see B.2.1.5) and furthermore, it should be kept in mind that there is already a safety factor of 100 included in the AOEL and an additional safety factor of 10 for the calculation of concentration C. Therefore, the request for further data may not be necessary in this case.	New data gap proposed, see below.
	New data gap 1.5 identified at PRAPeR 66 meeting: An air method with a LOQ of at least 48 □g/m^3.is required.			PRAPeR 66 (21 – 24 April 2009): Data gap open. Written procedure: Data gap still open: An air method with a LOQ of at least 48 □g/m^3.is required
	New open point 1.12: RMS to amend the list of end points according to the discussions during the PRAPeR 66 meeting		**RMS (May 2009):** List of end points has been amended accordingly.	PRAPeR 66 (21 – 24 April 2009): Open point open. Written procedure: Open point fulfilled.

2. Mammalian toxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 2 Open points: ***6*** Points for clarification: ***1*** Data gaps: ***0***			Section 2 Open points: ***1***
	Open point: 2.1 Oral absorption to be discussed at an expert's meeting. See reporting table 2(1)	Notifier agrees with RMS position set out in reporting table. The use of an oral absorption value of greater than 80% has been justified by RMS. Further discussion of this point is presented in the attached position paper. See: <<Lenacil toxicology position paper_TSGE 30Mar09.doc>>	**04.2009:** The oral absorption is usually calculated based on the results obtained after application of a single low dose. The absorption of a compound is largely determined by the capacity to cross semi permeable membranes and depends strongly from its physic chemical properties, concentration at the site of contact, dissolution of the substance, gastric empting rate and intestinal motility. In the repeat study, the same low dose as in the single dose study was used but administered 7x with a time interval of 24h. Therefore, RMS considers that repeated dose study is well adapted for estimation of oral absorption. After a single oral low dose of lenacil, oral absorption= 63% (females) and 82% (males) increasing to 85-89% after repeated low dose. Females excrete more unchanged parent compound after a single low dose, an effect disappearing after repeated dosing. This could suggest that lenacil induces its own metabolism and therefore bioavailability.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. A value of at least 80% was agreed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			When the mean value of the different oral absorption (see table B.6.1-4) is calculated, a value of about 80% is obtained. If bile excretion is added to urinary excretion, after single low dose administration, an oral absorption value of 64-73% of the dose is obtained. The latter approach was not followed as bile and urinary excretion were not measured in the same study.	
	Open point: 2.2 The NOAEL of 15.5 mg/kg bw/d from the 90-day mouse toxicity study to be discussed by the experts. See reporting table 2(9)	Derivation of the appropriate AOEL is discussed in attached position paper. Notifier agrees with DE: the 100 ppm dose level is an NOEL rather than NOAEL and a higher value should be investigated for setting the AOEL. See discussion in attached position paper and addendum produced by RMS.	**04.2009:** At the tested doses, it is probable that oral absorption of lenacil is low as suggested in the ADME part of the DAR, where at doses of 1000 mg/kg bw (= 5000 ppm) oral absorption is strongly reduced. Therefore, the lack of dose response starting at 1000 ppm onwards results from a low oral absorption at high dose with as a consequence a plateau in the toxic effects.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. Agreed NOAEL is 1000 ppm corresponding to 157 mg-kg bw-d
	Open point: 2.3 Carcinogenic properties and proposal for classification and labelling for carcinogenicity (R40) to be discussed in an experts' meeting. See reporting table 2(13)	Notifier agrees with RMS, Proposal to classify with R40 cannot be justified from available data. Further discussions of the mammary adenocarcinoma, thyroid adenoma and mouse lung tumour incidence are set out in the attached position paper to demonstrate the absence of any treatment related increase in tumour incidence. In the absence of any new data, the incidence of these findings are not considered	**04.2009:** Allocation of R40 was not proposed as RMS considered that : (i) The incidence of malignant mammary adenocarcinoma was outside the historical control data of the laboratory but within the data of [redacted] Han Wistar rats in 2003 and therefore considered **questionable**. (ii) Thyroid adenoma are not a basis for classification: the adenoma are within historical control data.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. R40 agreed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		indicative of human carcinogenic potential.	(iii) Lung tumors in male mice: Incidences of adenoma and adenocarcinoma, taken separately, were not statistically increased. There was no statistical significance with the Fisher exact test at p=0.05 for any dose group. There was no decrease in alveolar tumor latency; most tumors were observed in mice killed at terminal sacrifice. There was no increase in focal hyperplasia of type II alveolar cells. There was no shift in tumor cell anaplasia.	
	Open point: 2.4 Proposal for classification and labelling with R64 based on reduction in body weight gain in offspring during lactation to be discussed in an expert's meeting. See reporting table 2(13)	Notifier agrees with DE: the proposed classification with R64 is not supported since bodyweight effects in offspring were only apparent at very high doses, were not accompanied by other developmental effects and only occurred at parentally toxic doses. This point is further clarified in the attached position paper.	**04.2009:** Allocation of R64: we agree that the effects are confined to a very high dose but classification is hazard- and not risk-based. Parental toxicity was not evident in the 2 generation studies. However, as proposed in the DAR this point should be discussed in the PRAPeR meeting.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. R64 not agreed.
2.1	Point of clarification for the applicant: Applicant to submit laboratory control data including all details (dates, strain, number of animals, etc) for liver	This has been requested from the Contract Laboratories and will be submitted as soon as possible.	**04.2009:** This information could be helpful for further discussion.	PRAPeR 69 (4 – 8 May 2009) Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	and lung tumours in mice and for mammary gland tumours in rats. See reporting table 2(18)			
	Open point: 2.5 The setting of references values to be confirmed in an experts' meeting See reporting table 2(28)	A revised table of endpoints for short term and long term toxicity studies has been presented in the attached position paper to take account of the adaptive nature of liver effects. The implication of taking these effects into account in deriving the AOEL/ADI is discussed in the position paper and a revised value reached that takes account MS comments in the reporting table.	**04.2009:** RMS agrees with the company that Lenacil increases metabolic workload leading to adaptation of liver (increased weight, centrilobular hypertrophy…); however, enzyme induction was never measured. Therefore, RMS cannot exclude another mechanism for the observed liver effects.	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. Experts agreed: ADI = 0.12 mg/g/kg bw/d AOEL = 0.4 mg/kg bw/d ARfD – not required
	Open point 2.6 Operator, worker and bystander exposure to be confirmed at a meeting of experts. See reporting table 2(38)	Revised exposure calculations have been prepared by the RMS. The notifier would like to point out that the version of UK POEM used by the RMS has been superseded by a 2007 version of the UK model. Calculations using UK POEM 2007 are presented by the Notifier in the attached position paper: << Lenacil tox position paper_TSGE 24Mar09.doc>> Calculations using UK POEM 2007 model demonstrate that exposure is below the AOEL for operators wearing gloves during mixing/loading	**04.2009:** It is correct that new generic values were introduced into the original „merged' UK-POEM and BBA model. RMS used the version with the original German generic value (75th %ile) for dust inhalation during mixing and loading, i.e. 0.659 mg/kg a.s. handled, while in the new version, the value is reduced to 0.21 mg/kg a.s. handled. This explains the different results in the UK model. However, as the German model predicts an acceptable exposure (30-40% of the proposed AOEL), the evaluation remained unaltered. In the addendum, it was also demonstrated that the worker and the bystander exposure was	PRAPeR 69 (4 – 8 May 2009) Open point fulfilled. New open point proposed, see below

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		and application. The Notifier has no other comments on the revised calculations presented by the RMS.	below the proposed AOEL.	
	New open point 2.7 identified at PRAPeR 69 meeting: RMS to provide an Addendum to the DAR with revised operator, worker and bystander exposure to be recalculated taking into account agreed on input parameters and the agreed on AOEL of 0.4 mg/kg bw/d.			PRAPeR 69 (4 – 8 May 2009) Open point open. Written procedure (June 2009) Open point fulfilled. An Addendum 2 to the DAR (May 2009) has been submitted.
	Message from PRAPeR 70 to PRAPeR 69: 1/3 of the identified total residue in sugar beet leaves (0.01 -0.02 mg/kg) was 7-OH-lenacil (IN-KC943) and its conjugates. Should 7-OH-lenacil (IN-KC943) be regarded as less, equally or more			PRAPeR 69 (4 – 8 May 2009) The experts agreed that the metabolite is covered by the toxicological studies of the parent compound, and if it is included in the residues definition the same trigger values can be applied.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	toxic than parent lenacil?			

3. Residues

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	Section 3 Open points: ***7*** Points for clarification: ***1*** Data gaps: ***2***			Section 3 Data gaps: ***1***
	Data gap: 3.1 Frozen storage stability data covering the 26 months to be submitted if the trials can be considered as acceptable. See reporting table 3(1)	Samples from the 2001, 2002 and 2005 trials (4 North EU, 3 South EU) were stored for 1 to 7 months and are covered by the existing storage stability study. In all these trials residues in roots were <LOQ. Therefore, sufficient data are available to support the MRL proposal in sugar beet. Three additional trials from 1995 (North EU) were submitted with samples stored for 26 months. These were submitted as supporting data and are not required to set the MRL. Therefore additional storage data are not required.	**04.2009:** RMS agrees that the residue trials referenced F-95-001-RES and characterized by a frozen storage period of 26 months are supporting data and were not used to set the MRL since these trials were not performed at the critical growth stage of application (BBCH 31). No additional frozen storage stability data are required.	PRAPeR 70 (5 – 8 May 2009) Data gap obsolete.
	Open point: 3.1 Experts meeting to discuss if metabolism studies on livestock are required. See reporting table 3(6)	In 7 trials covering North and South EU residues in sugar beet roots were <0.02 mg/kg and residues in sugar beet tops were <0.02 to 0.04 mg/kg. (In 5 trials residues in tops were <0.02 mg/kg.) Therefore, dietary intake for all livestock is less than 0.1 mg/kg total diet as received (the EU trigger value according to Working Document 7030/VI/95 rev 3 and Commission Directive 96/68/EC) and consequently	**04.2009:** a) The way the residue dietary burden has to be estimated for animals was considered during the PRAPeR Expert Meeting 65. It was reminded that the intake by animals should always be taken into account on a dry matter basis and not "as received" as stated in the guideline 7031/VI/95 rev. 4. The calculation on the dry matter basis is the lonely way to	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. The majority of experts agreed a ruminant livestock metabolism study should not be required.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		metabolism studies in livestock are not required. The calculations presented in the DAR are based on a dry weight basis which is not consistent with Working Document 7030/VI/95 rev 3 and Commission Directive 96/68/EC. Copies of the calculations in the DAR which now include intake on a fresh weight basis are submitted. See: <<Lenacil livestock intake calculations_27Mar09.doc>>	obtain comparable figures and the trigger value of "0.1 mg/kg total diet" has to be understood "on the dry matter basis". b) Although the trigger value is exceeded, this case is border line since the feed intake was calculated using the residue values of 0.04 and 0.03 mg/kg on sugar beet tops with leaves generated by trials performed at BBCH GS 37, 38. Based on the available residue trials, there is a non-residue situation in the roots and a very low residue situation in the leaves with tops. Lenacil is not fat-soluble. RMS is of the opinion that a metabolism study on ruminants is not required. A metabolism study on pigs is therefore also not required.	
	Open point: 3.2 Meeting of experts to discuss the residue definition in plant matrices. See reporting table 3(8)	The notifier agrees with the comments made by the RMS in the reporting table. Lenacil is metabolised in both plants and mammals via hydroxylation of the pyrimidine ring. The resulting metabolites are therefore structurally the same and any toxicity will be apparent in the available toxicology studies. There are no metabolites that are unique to plants and the residue	**04.2009:** a) RMS refers to the detailed metabolism study presented in the Addendum to the DAR-April 2009. The metabolite IN-KC961 was not recovered in the sugar beet leaves as it is explained in the DAR – Table B.7.1.1-1: HPLC analyses showed a peak that matched the retention time of IN-KQ961 (hydroxylated Lenacil on C2), indicating the presence of this metabolite. Later	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. For root crops the relevant residue for risk assessment and monitoring purposes should be lenacil alone.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		definition as parent only is considered valid.	results indicated that IN-KQ961 showed a similar retention time to that of IN-KC 943-glucoside and the peak corresponding to IN-KQ961 could be IN-KC943-glucoside or a mixture of the 2. Therefore, the peak was isolated for further β-glucosidase hydrolysis and this peak matched the retention time of IN-KC943, indicating the existence of IN-KC943 glucose conjugate before hydrolysis with no detectable amount of the metabolite IN-KQ961. This metabolite should not be included in the residue definition both for monitoring and risk assessment. b) The metabolites IN-KC943 and IN-KQ961 were generated by hydroxylation of the parent compound on the C5 cycle of the molecule. This is a step of detoxification in plants. Those metabolites are structurally similar to the metabolites recovered in the rat. In rat metabolism, hydroxylation on C5 and C6 cycles is the main step of degradation of the parent Lenacil. IN-KC943 and IN-KQ961 can therefore be considered as covered by the available toxicological dossier. These metabolites are as toxic as the parent or less toxic. In the frame of the representative use on sugar beet only, the exhaustion of	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			the ADI is very low (max. 0.11 % of the ADI), the DOR both for monitoring and risk assessment can be established as the parent compound alone.	
	Open point: 3.3 Meeting of experts to discuss acceptability of the residue trials carried out in Northern Europe. See reporting table 3(11)	Samples from the 2001, 2002 and 2005 trials (4 North EU, 3 South EU) were stored for 1 to 7 months and are covered by the existing storage stability study. In all these trials residues in roots were <LOQ. Therefore, sufficient data are available to support the MRL proposal in sugar beet.	**04.2009:** RMS agrees not to accept the trials referenced F-95-001-RES for MRL setting. So, the actual valid database is presented as follows: *North*: -Roots:4x<0.02 mg/kg -Leaves:<0.02-<0.02-<0.02-0.04 mg/kg *South*: -Roots:3x<0.02 mg/kg -Leaves:<0.02-<0.02-0.03 mg/kg These trials are covered by acceptable storage stability data.	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. Though application was at a later stage than BBCH 31 the 4 trials conducted in Germany (BBCH 37) can be used to support the notified use in the North.
	Data gap: 3.2 Further trials covering SE necessary to complete the residue database. (Meeting of experts to discuss the number of trials necessary). See reporting table 3(12)	According to the guidelines (7525/VI/95 rev 8) when residues are expected to be <LOQ and this is confirmed in 2 trials, further trials are not required. Lenacil is used early in the season and residues in the sugar beet roots are not expected. This has been confirmed in 7 trials over three seasons (4 North and 3 South, all supported by adequate storage stability data) in which residues in sugar beet roots were <0.02 mg/kg in all trials. These trials are sufficient to propose a MRL for sugar beet roots.	**04.2009:** To clarify the situation: -In the guideline 7029/VI/95 rev.6, it is stated that the number of residue trials can be reduced if it can be justified that the residue levels in plants will be lower than the Limit of Quantification (LoQ). -In the guideline 7525/VI/95-rev.8, it is stated in section 2.6 that when residues are foreseen to be under the LoQ and at least 2 residue trials confirm this then no further trials are normally necessary.	PRAPeR 70 (5 – 8 May 2009) Data gap closed. Taking into account the overall data set from North and South the available trials are sufficient to support the notified use in the South.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
		In the same 7 trials residues in sugar beet tops were <0.02 to 0.04 mg/kg. (In 5 trials residues in sugar beet tops were <0.02 mg/kg.) Therefore, additional trials are not required.	In that specific case, a low residue situation is encountered since residue levels of 0.03 and 0.04 mg/kg were recovered in sugar beet tops and leaves. These residue values were generated from trials performed at BBCH GS 37-39. It is very unlikely that further data both for Northern and Southern Europe will change the residue levels recovered both in the roots and in the leaves. RMS proposes not to require additional residue trials for N and S Europe.	
3.1	Point for clarification: Spray concentration does not agree with application rate and water volumes for use pattern provided in Table B.7.4-1. Notifier to clarify. See reporting table 3(13)	The spray concentration range in the GAP table is correct. The rate/ha and spray volume are independent. The maximum rate is 0.~~25~~ 5kg as/ha, which at the minimum spray volume of 200 L/ha is 0.25 kg as/hL. The minimum rate is 0.125 kg as/ha which at the maximum spray volume of 400 L/ha is 0.03125 kg as/hL.	**04.2009:** RMS notes the comment.	PRAPeR 70 (5 – 8 May 2009) Point of clarification addressed.
	Open point: 3.4 RMS to consider presenting relevant validation data for method Hamburger R., 2002 in an addendum to the DAR. See reporting table 3(14)	The notifier agrees that the relevant validation data should be presented as proposed.	**04.2009:** The validation data of the analytical methods used to generate the residue trials were reported in the Addendum to the DAR-April 2009.	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled. All methods used to generate residue trial results that were considered in the assessment are sufficiently validated.

<table>
<tr><th>No.</th><th>Column A
Conclusions of the EFSA Evaluation Meeting</th><th>Column B
Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion</th><th>Column C
Rapporteur Member State comments on main data submitter / applicant comments</th><th>Column D
Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting</th></tr>
<tr><td></td><td>Open point: 3.5
Meeting of experts to discuss if methods used in residue trials (Tillkes, 1998; Mende 2002; Hamburger, 2002; Witte, 2006) comply with guidance document SANCO/3029/99 concerning methods of analysis in support of pre-registration requirements and therefore are suitable to support the respective residue trials.

See reporting table 3(14)</td><td></td><td><u>04.2009</u>:
The validation data of the analytical methods used to generate the residue trials were reported in the Addendum to the DAR-April 2009.</td><td><u>PRAPeR 70 (5 – 8 May 2009)</u>

Open point fulfilled.
All methods used to generate residue trial results that were considered in the assessment are sufficiently validated.</td></tr>
<tr><td></td><td>Open point: 3.6
Meeting of experts to discuss if further information or studies concerning rotational/succeeding crops are required.

See reporting table 3(22)</td><td>The notifier agrees with the comments made by the RMS in the reporting table.</td><td><u>04.2009</u>:
a) Succeeding crops should not be planted or drilled until at least 4 months have elapsed after application and ploughing and cultivation to a depth of at least 15 cm should be carried out. When Venzar 80 WP is applied and crop failure occurs for any reason during this period only sugar beet, red beet, or spinach should be drilled or planted. No further application of Venzar 80 WP should be made for at least 4 months.
b)
<table>
<tr><th></th><th>DT_{50} (Lab)</th><th>DT_{50} (Field)</th><th>DT_{90} (Field)</th></tr>
<tr><td>Lenaci</td><td>11-18</td><td>18-28</td><td>61-91</td></tr>
</table></td><td><u>PRAPeR 70 (5 – 8 May 2009)</u>

Open point fulfilled.

New data gap proposed, see below.</td></tr>
</table>

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
			<table><tr><td>**I**</td><td></td><td></td><td></td></tr><tr><td>**IN-KF 313**</td><td>3-20</td><td></td><td></td></tr><tr><td>**IN-KE 121**</td><td>4-11</td><td></td><td></td></tr></table> The DT_{50}/DT_{90} values: 88/291 days from a fourth study (Spain) were discounted as there was no rainfall after application and no irrigation was applied. These conditions would not apply to sugar beets that require regular rainfall or irrigation for development. Based on these DT_{50}/DT_{90} values, no further information on rotational crops is required.	
	New data gap 3.3 identified at PRAPeR 70 meeting: A rotational crop metabolism study is necessary to address residues in rotational crops.			PRAPeR 70 (5 – 8 May 2009) Data gap open. Written procedure: Data gap remains open.
	Open point: 3.7 Meeting of experts to discuss the requirement of a re-entry period and/or the prohibition of the feeding of sugar beet tops after thinning and crop	The notifier agrees with the comments made by the RMS in the reporting table.	**04.2009:** No re-entry period was proposed since Lenacil is intended to be used on sugar beet. Livestock are not supposed to be grazed on such an area. Thinning out the sugar beet crop is not	PRAPeR 70 (5 – 8 May 2009) Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the Evaluation Meeting
	failure taking into account the practices in different countries. See reporting table 3(25)		relevant anymore nowadays (seeds selection). It is not expected that sugar beet leaves after the crop failure (30 days) will be fed to livestock.	

4. Environmental fate and behaviour

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Section 4 Open points: ***21*** Points for clarification: ***5*** Data gaps: ***0***			Section 4 Open points: ***3*** Data gaps: ***4***
	Open point: 4.1 RMS to clarify which DT_{50} values for IN-KE121 are the proper values for Sheringham and Wick soils and if necessary, to normalize these values to FOCUS reference conditions in an addendum. Note: the „k' values of these DT_{50} values are reported in Table B.8.1.2.1-13 originating from the report of Shaw (2004). See reporting table 4(5)	Only correction of the observed DT_{50} values for the Sheringham and Wick soils is necessary. The remainder of Table B8.1.2.1-16 is correct. Further normalisation of the DT_{50} values for IN-KE121 is not necessary.	See below	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
4.1	Point of clarification for the applicant: Regarding the studies by Theis (2003), Girkin (2003), Berg (1994a) and Berg (1994b): a) correctly classify the soils b) appropriately	The requested information is provided in the attached position paper for environmental fate.	The information has been included in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	normalize the soils to soil moisture (e.g without normalization, where the soils were wet enough) and to temperature where necessary c) calculate the geometric mean values of the normalized DT_{50} values from the studies by Theis (2003) and Girkin (2003) d) calculate the geometric mean values of the normalized DT_{50} values considering all studies e) calculate the mean values of the kinetic formation fractions of the metabolites Before the normalization procedure and derivation of the mean values it should be considered that f) DT_{50} values for IN-KE121 for Sheringham and Wick soils might be corrected based on the open point for the comment 4(5) (rounding) g) DT_{50} and kinetic formation fraction for IN-KE121 from the Theis study should not be used			

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	h) DT_{50} and kinetic formation fraction for the metabolites derived from the Whimle soil should be used (currently missing from the LoEP) See reporting table 4(13)			
	Open point: 4.2 MS experts to agree on the DT50 and kinetic formation fractions for use in FOCUS simulations (PECsw & PECgw) for lenacil, IN-KF313 and IN-KE121. See reporting table 4(13)	It is considered that the data analysis provided by Shaw (2004) is sufficient and the values given for lenacil, IN-KE313 and IN-KE121 should be referred to as the definitive end-points.	The information has been added in the DAR	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.3 Experts to discuss the validity of the studies by Berg 1994a and 1994b and the possible use of the results in the risk assessment. RMS to provide scientifically relevant details of the studies by Berg (1994a and 1994b) (e.g. preparation and storage of the soils, microbial biomass) in an addendum which can facilitate the discussion of experts about	It should be noted that in the Berg (1994a) study the test item was applied using methylene chloride (0.25 mL) as the carrier solvent. The use of this solvent may have adversely affected soil microbial populations. Also addition of a water immiscible solvent to the soil may have affected the distribution of the test item resulting in „hot-spots' which could have affected the subsequent degradation rate.	The notifier indicated that the test item was applied using methylene chloride (0.25 mL) as the carrier solvent. The use of this solvent may have adversely affected soil microbial populations. Also addition of a water immiscible solvent to the soil may have affected the distribution of the test item resulting in „hot-spots' which could have affected the subsequent degradation rate. There are no detailed information on the biomass evolution. The soils were taken from field sites and storted moist under refrigeration at	PRAPeR 67 (20 -24 April.2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	the validity of these studies. See reporting table 4(14)		4°C for less than 90 days. The graphs showing the evolution of the as and metabolites show that metabolite formation and mineralisatioan were very limited in this study. Bound residue formation is the main process of this study.	
	New open point 4.22: RMS to update PEC groundwater and surface water calculations for IN-KF313.			PRAPeR 67 (20 -24 April.2009): Open point open. Written procedure (June 2009): Fulfilled by EFSA for surface water. Changed to data gap for groundwater
	Open point: 4.4 RMS to provide information on the used kinetic model and the assessment of the goodness of fit for the field dissipation study in an addendum. Note: in the study description FOMC kinetic model is referred, however the ratio between the reported DT_{50} and DT_{90} values indicate SFO kinetics for all the 4 experiments. In the LoEP	The field study data are evaluated in the report by Shaw (2004) using first order kinetics. Goodness of fit data is adequately presented in the report and is reproduced in Table B 8.1.3.1-2.	Sufficient information is available in the report by Shaw (2004) and in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	SFO kinetics are indicated, however the DT_{50} and DT_{90} values are not the same. See reporting table 4(17)			
	Open point: 4.5 MS to discuss in a meeting of expert whether the field experiment in Spain is considered as representative to European conditions and the DT_{50} of 88 days (alternatively 52 days) should be used or not for PECsoil calculations for lenacil. MS to discuss moreover the used application intervals, and that the PECsoil for the metabolites should be recalculated using the maximum observed instead of the kinetic formation fractions. See reporting table 4(21)	The soil studied at the site in Spain indicates an extreme condition with respect to degradation. The data point is an outlier in the overall behaviour of lenacil in field soil, which was noted by the RMS. The risk assessment is based on maximum initial PEC values so there will be no impact if a different DT50 is used.	The RMS considers that the long DT50 that has been observed in the study performed in Spain can be explained by the negligible degradation on a very dry soil during the 3 first months after application. The RMS considers that this study cannot be used to derive a meaningful DT50 for PEC assessment. The risk assessment is based on maximum initial PEC values so there will be no impact if a different DT50 is used.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.6 MS to discuss whether any requirement of additional data for the degradation of lenacil and its metabolites in soil at higher pH is necessary.	The range of soils tested is considered adequate to determine the route and rate of degradation of lenacil and metabolites.	Point to be discussed in PRAPER meeting.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(27)			
	New open point 4.23: EFSA to indicate in the conclusion that pH range of the soils investigated for aerobic degradation rate is limited.			PRAPeR 67 (20 -24 April.2009): Open point open. Written procedure (June 2009): Open point fulfilled.
4.2	Point of clarification for the applicant: To provide a table of OM% and OC% content, the maximum water holding capacity and the actual wet content (used in the degradation studies) for the soils used in all Berg studies (list references). See reporting table 4(31)	Berg 1994a (AMR 2400-92) Lenacil Soil Degradation Sassafras OM% = 1.3 OC% = 0.75 (by calculation) MWHC = 12.1 Hillsdale OM% = 2.0 OC% = 1.16 (by calculation) MWHC = 17.5 Tama OM% = 2.3 OC% = 1.33 (by calculation) MWHC = 28.2 Study conducted at pF 2.5. Study initiated 28/8/1992 Berg 1994b (AMR 2545-92) IN-KF313 Soil Degradation	The information has been included in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		Sassafras OM% = 0.9 OC% = 0.52 (by calculation) MWHC = 8.5 Hillsdale OM% = 1.0 OC% = 0.58 (by calculation) MWHC = 8.2 Tama OM% = 2.4 OC% = 1.39 (by calculation) MWHC = 23.5 Study conducted at pF 2.5. Study initiated 17/11/1993 Berg 1996 (AMR 2948-94) IN-KF313 Adsorption/Desorption Sassafras OM% = 0.9 OC% = 0.52 (by calculation) MWHC = 8.5 Hillsdale OM% = 1.0 OC% = 0.58 (by calculation) MWHC = 8.2 Tama OM% = 2.4 OC% = 1.39 (by calculation) MWHC = 23.5 Study initiated 23/5/1994		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		The soils used were taken from the same location and in all probability were the same batch. Reduction in OM content between 28/8/1992 and 17/11/1993 would appear to be consistent with storage of the soil. The same characterisation results were used for the adsorption/desorption study suggesting that the same batch of soil was tested.		
4.3	Point of clarification to the applicant: Applicant to clearly clarify that the exact identity or structures of the metabolites M14.0 and M15.0 are not available (however their structure are similar to IN-KE121) and confirm that the metabolite IN-KE121 was identified to be 3-cyclohexyl-6,7-dihydro-7-1H-cyclo pentapyrimidine-2,4,5(3H)-trione. Clearly indicate moreover, where the position of metabolite IN-KE121 is in the degradation pathway in soil. See reporting table 4(32)	Identity of M14/M15 as IN-KE121 in the study by Theis (2003) was indicated by MS analysis but the assignment was not definitive. Conclusion described M14/M15 as oxo-lenacil. Study by Girkin gives a better understanding of the metabolite profile in soil. 3-cyclohexyl-6,7-dihydro-7-1H-cyclo pentapyrimidine-2,4,5(3H)-trione is the chemical name for IN-KF313. IN-KF313 (5-oxo-lenacil) results from oxidation of the cyclopentapyrimidine ring moiety. IN-KE121 (7-oxo-lenacil) results from oxidation of the cyclohexyl ring moiety. Both processes can occur simulataneously. Further degradation probably occurs by opening of the pyrimidine ring to produce a number of unidentified polar fragments prior to	The information has been included in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		mineralisation.		
	Open point: 4.7 RMS to remove the DT_{50} of IN-KE121 for the Speyer soil from the LoEP. The PEC values for the metabolite IN-KE121 without using this DT_{50} or the formation fraction calculated from the Theis study might need to be recalculated. See reporting table 4(32)	From the known degradation profile it is reasonable to conclude that M15 is equivalent to IN-KE121 and the data from the Speyer soil may be used.	From the known degradation profile it is reasonable to conclude that M15 is equivalent to IN-KE121 and the data from the Speyer soil may be used. An assessment of the metabolites that are present in the environment has been performed in the toxicological chapter.	PRAPeR 67 (20 -24 April.2009): Open point becomes obsolete, the Speyer soil DT50 value should be retained.
	Open point: 4.8 MS to discuss in a meeting of experts whether to address the leaching potential of M15.0 is necessary. See reporting table 4(32)	M15 is considered to be equivalent to IN-KE121 and the leaching potential of this metabolite has been addressed.	According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study, assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
4.4	Point of clarification for the applicant: to clarify whether Polar B, Met.B, category „Polars' or „other polars' from the studies by Berg (1994a) and Girkin, R. (2003) contain any common transformation products.	It is not possible to conclude whether the named fractions contain common products. The fractions in question are areas of unresolved radioactivity eluting at T_0 by HPLC or remaining at the origin by TLC. The indication is that the material is highly polar. Inspection of the structure of lenacil and its known metabolites suggests that the polar material must result from a significant breakdown of the lenacil	The RMS considers that the study of Berg (1994a) is not acceptable and cannot be used in the risk assessment. In this study no degradation has been observed for at least 14 days According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study,	PRAPeR 67 (20 -24 April.2009): Data gap proposed instead, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	See reporting table 4(36)	molecule. A large number of fragments are possible but none will be significant as a percent of applied.	assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	
	New data gap 4.1 identified at the PRAPeR 67 meeting: Notifier to provide further characterisation of „Polar B' and/or „polars' from the Girkin study or new incubations with comparable soil types having a proper material balance and characterisation of the radio-activity.			PRAPeR 67 (20 -24 April.2009): Data gap open.
	Open point: 4.9 Experts to discuss whether further consideration of Polar B and „Polars' from the study by Girkin, R., 2003 and category „Other polars' and the Met.B from the study by Berg (1994a) is needed. See reporting table 4(36)	See above comment.	See above comment.	PRAPeR 67 (20 -24 April.2009): Open point closed.
	Open point: 4.10 RMS to include the statistical and visual assessment of the fit of the parent compounds	Exisiting statistical assessment presented in the report by Shaw (2004) is sufficient. Further recalculation is not considered necessary.	Sufficient information is available in the report by Shaw (2004) and in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	and metabolites of the kinetic analysis for each experiment, where the formation fractions and degradation rates of the metabolites were calculated in an addendum. See reporting table 4(40)			Written procedure (June 2009): Open point remains open.
	Open point: 4.11 RMS to include the DT_{50} values from the Whimle soils in the LoEP. The PEC values using these DT_{50} values and the pertaining to formation fractions might need to be recalculated. See reporting table 4(41)	Whimple soil omitted because the statistical fit was poor in the analysis performed by Shaw (2004). Inclusion of this soil will give a lower mean DT50 for the metabolites and hence a less conservative risk assessment.	The Whimple soil has been added in the DAR	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.12 RMS to include information about the preliminary test to determine the adsorption of the test substance on the surface of the test vessels and its results. See reporting table 4(46)	Recoveries were quantitative in preliminary tests indicating no adsorption to the test vessels.	Recoveries were quantitative in preliminary tests indicating no adsorption to the test vessels.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.13 In relation of the adsorption/desorption study of the metabolite IN-KF313	Additional sorption data are available from the lysimeter study which shows no movement of lenacil or its significant metabolites. Further data	According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study,	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	(Berg, D. S., 1996c), MS to discuss in a meeting of experts: a) similarity of Sassafras and Hillsdale soils b) narrow range of the pH of the used soils c) dependence of the adsorption to any soil parameter (pH, CEC, clay) d) to use the arithmetic mean or the (any) worst case K_{Foc} value for PEC calculations, and/or e) the need of additional adsorption data See reporting table 4(47)	are not considered necessary.	assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	New open point proposed, see below. New data gap proposed, see below.
	New open point 4.24: RMS to redo the groundwater PEC calculations and amend the LoEP to only represent the lowest Koc input value and subsequent results also taking into account the new geomean DT50soil of 41 days for IN-KF313, and redo the PEC surface water and sediment calculations for IN-KF313 using the lowest Koc		New PEC gw calculations have already been performed in preparation of the PRAPER meetings with worst case Koc of 79. It is obvious from the toxicological dossier that these metabolites are not relevant. The RMS considers therefore that recalculation of PECgw is not useful at this stage.	PRAPeR 67 (20 -24 April.2009): Open point open. Written procedure (June 2009): Fulfilled by EFSA for surface water. Changed to data gap for groundwater Same as for new Open point 4.22. LoEP was amended by EFSA.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	value of 79 L/kg and the new geomean DT50soil of 41 days for IN-KF313. For 1/n see open point 4.14.		The risk assessment for aquatic organisms is driven by the active substance. The TERsw for the metabolites (clearly less toxic than the a.s.) are far above the annex VI triggers. The RMS considers that the recalculation of PECsw is not useful at this stage.	
	New data gap 4.2 identified at the PRAPeR 67 meeting: A soil batch adsorption study in one soil for IN-KF313 under environmentally relevant alkaline conditions is missing.			PRAPeR 67 (20 -24 April.2009): Data gap open.
	Open point: 4.14 MS experts to agree on the K_{Foc} and 1/n values for use in FOCUS simulations for lenacil, IN-KF313 and IN-KE121. See reporting table 4(47)	Exisiting adsorption data in conjunction with the short DT_{50} and lysimeter information are sufficient to determine a low risk from leaching. Additional modelling with PEARL to confirm this point is provided in the attached position paper for environmental fate. Further studies to calculate additional adsorption data for lenacil and metabolites is not considered necessary.	According to the RMS, sufficient information on the leaching potential of the metabolites is available: detailed information in the lysimeter study, assessment of the toxicological relevance, detailed PECgw calculations for the a.s. and 2 main metabolites) metabolites.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.15 MS to discuss in a meeting of experts whether there is a	The addendum to the lysimeter study (Schnöder, 2004) contains a thorough assessment of the identity of polar metabolites and is considered	The addendum to the lysimeter study (Schnöder, 2004) has been included in the DAR.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	need for further information for the unidentified lysimeter metabolites M1, M2 and M3 for the EU level assessment. See reporting table 4(50)	sufficient to conclude they are of no concern.		New data gap proposed, see below.
	New data gap 4.3 identified at the PRAPeR 67 meeting: Notifier to provide further (details of) characterisation of M1, M2, and M3 found in the lysimeter study.			PRAPeR 67 (20 -24 April.2009): Data gap open.
	Open point: 4.16 RMS to check the classification of the soils used in the adsorption/desorption studies and change the names of the soils with the soil types based on the USDA classification system in the relevant boxes of the LoEP. See reporting table 4(51)	Soils characterised in the study by Girkin (2002) used the UK/BBA classification scheme and the results should be reported as such. USDA classification is not possible from the data available for these soils.	Soils characterised in the study by Girkin (2002) used the UK/BBA classification scheme and the results should be reported as such. USDA classification is not possible from the data available for these soils.	PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
4.5	Point of clarification for the applicant: to clarify whether is it correct that the Elmton soil in the study by Kane, T., 2004 had	The value of 263.1 g/kg is correct as shown in the original study report.	Addressed	PRAPeR 67 (20 -24 April.2009): Point of clarification addressed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	a $CaCO_3$ content of 263.1 g/kg. See reporting table 4(53)			
	Open point: 4.17 RMS to amend the LoEP taking into consideration all the inconsistency identified in the reporting table. RMS to highlight all the changes in the LoEP with a colour (yellow is already proposed by the RMS for changes in February 2009) as part of the track changes procedure. See reporting table 4(55)	No further comment.	The information has been included in the listing of endpoints.	PRAPeR 67 (20 -24 April.2009): Open point still open. Written procedure (June 2009): Fulfilled by EFSA Open point fulfilled.
	Open point: 4.18 MS to discuss in a meeting of experts whether additional PECsw and PECsed calculation is needed or not with the option of DT50 of 1000 days for the sediment phase and geomean DT50 of the total system for the water phase. See reporting table 4(62)	Using the default value of 1000 days for the water phase will give worst-case values for PECsw compared to PECsed. The ecotox risk from the use of lenacil is associated with aquatic plants and therefore a worst-case assessment has already been conducted. Revision of the PEC values is not considered necessary.		PRAPeR 67 (20 -24 April.2009): Open point fulfilled.
	Open point: 4.19 RMS to indicate in the LoEP	A value of 0.03 cm^{-1} was used for the surface water calculations only.	The washoff factor of 0.03 cm^{-1} has been added in the listing of endpoints	PRAPeR 67 (20 -24 April.2009):

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	the washoff factor used in the FOCUS calculations. See reporting table 4(67)			Open point open. Written procedure (June 2009): Has not been added for surface water but added for groundwater. Open point still open Written procedure (July 2009): EFSA has cancelled from the box of groundwater and has added to the box of surface water based on the information given in Column B and the relevant points of the discussion table. Open point fulfilled.
	Open point: 4.20 RMS to clarify that the crop washoff factor was used only for SW calculations or for the GW calculations as well and that whether the crop half-life was or was not changed for the modelling in an addendum. See reporting table 4(67)	A value of 0.03 cm^{-1} was used for the surface water calculations only. This represents a change from the default value of 0.05 cm^{-1}, however it is not expected to make a significant change to the resulting PEC values.	The washoff factor of 0.03 cm^{-1} has been added in the listing of endpoints	PRAPeR 67 (20 -24 April.2009): Open point still open with regard to the crop half-life value. Written procedure (June 2009): Open point still open
	Open point: 4.21 The studies by Berg (Berg, D. S. 1994a and Berg, D. S. 1994b) should be removed	The studies in question should be removed.	The change has been done in the updated chapter B.8.	PRAPeR 67 (20 -24 April.2009): Open point open.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	from the list of references relied on depending on the discussions on the validity of these studies during the peer review. See reporting table 4(68)			Written procedure (June 2009): Done not in line with PRAPeR 67 Open point still open

5. Ecotoxicology

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	Section 5 Open points: ***7*** Points for clarification: ***0*** Data gaps: ***0***			Section 5 Open points: ***3*** Data gaps: ***2***
	Open Point: 5.1 B.9.2.12, Effects on primary productivity and macrophyte biomass in field-based microcosms, (Jenkins, 2005). Several uncertainties (is not clear where the study was conducted, results of statistical analysis are not presented, the study was performed with a single application) can be observed in the outdoor microcosm study. Furthermore, some MS did not agree with the NOEAEC = 22.1 µg a.s./L, proposed by the RMS considering that at this endpoint it was noted that there were effects on *Elodea canadensis* and Charophyta.	Notifier has submitted a proposal for the endpoint and an appropriate assessment factor to be applied to take account of uncertainty (see accompanying position paper <<Lenacil mesocosm position paper_TSGE 30Mar09.doc>>).	**RMS (April 2009):** The report of the microcosm study (Jenkins C. A., 2005) has been revised, taking into account the comments raised in the reporting table. Some essential raw data have been added to the study summary in the updated DAR. An overall NOEAEC = 22.1 µg a.s./L was established. A NOEC of 22.1 µg a.s./L or higher has been identified for periphyton, phytoplankton, zooplankton and 10 out of 12 macrophyte species. A NOEAEC of 22.1 µg a.s./L has been determined for *Eleodea Canadensis*. Charophyta was the only macrophyte species with a NOEC < 0.4 µg a.s./L. RMS considers that setting the NOEAEC at 5.81 or 0.4 µg a.s./L is not appropriate since the functioning of the mesocosm is not impaired at 22.1 µg a.s./L. The position paper of the notifier is presented in an addendum. The RMS agrees with the conclusions of the notifier; the endpoint NOEAEC of 22.1	PRAPeR 68 (4 – 8 May 2009) Open point fulfilled. New data gap proposed, see below. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	The endpoint for the microcosm study (Jenkins, 2005) as well as the assessment factor to be applied should be discussed by the MS experts in a meeting. See reporting table 5(7)		µg a.s./L is maintained and a safety factor of 5 in stead of 3 can be applied (nominal and measured exposure, inter-species sensitivity, multiple applications).	
	New data gap 5.1 identified at PRAPeR 68 meeting: The relative sensitivity of Charophyta should be determined.			PRAPeR 68 (4 – 8 May 2009) Data gap open Written procedure June 2009 Data gap still open
	New open point 5.8 identified at PRAPeR 68 meeting: RMS to update LoE: Perform first tier risk assessment for fish and daphnids. Delete first tier TERs for algae and macrophytes (because these indicate low risk, which may be confusing for the risk managers). State with a footnote that the first tier endpoints are not protective enough for algae and		**RMS (May 2009):** The List of Endpoints is corrected accordingly.	PRAPeR 68 (4 – 8 May 2009) Open point open Written procedure June 2009 Open point closed

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	macrophytes. Remove the metabolites from the section „ecotoxicologically relevant compounds'.			
	Open point: 5.2 B.9.2 Effects on aquatic organisms, B.9.2.8 Effects on algae. The study by Douglas M.T. and Handley J.W., 1988 is regarded as not acceptable and should only be used as additional information. The endpoints of this study should be deleted from the list of endpoint by the RMS. See reporting table 5(9)	The issue concerning the validity of the Douglas & Handley/ *S. capricornutum* study hangs on the absence of any analytical confirmation that exposure concentrations were a) achieved and b) satisfactorily maintained for the duration of the exposure. Although other algal studies and the *Lemna* study performed with the technical a.s. provide a weight of evidence that suggests lenacil concentrations will have remained at close-to-initial levels for at least 72 h (covering 2 of the 3 reported endpoints), it is not possible to make any convincing claim as to whether or not condition a) is likely to have been satisfied.	**RMS (April 2009):** The RMS confirms that the E_rC_{50} is calculated for the period 24-48 hours. No further explanation is given in the study why it was calculated as such and not for the period 0-72 hours. The endpoints are in close agreement with the study of Flatman D., 2003c and are not deleted from the List of Endpoints. **RMS (May 2009):** The List of Endpoints and the List of Studies relied on are corrected accordingly.	PRAPeR 68 (4 – 8 May 2009) Open point open. RMS to delete the study by Douglas M.T. and Handley J.W., 1988 from the LoE and the list of studies relied on. Written procedure June 2009 Open point closed
	Open point: 5.3 B.9.2.8, effects on algae, *Navicula pelliculosa* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the	This issue is an artefact of the way the information has been presented in the summary and the inappropriate and misleading use of the term "nominal". In this study lenacil dissolved in DMF was dispersed in a primary stock at 10 mg a.s./L algal medium: a loading that exceeded the aqueous solubility of the test substance, but nevertheless	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. The mean measured lenacil concentrations represent 98 – 104 % of t_0 measured concentrations at mean measured concentrations of 11, 22, 47, 105, 219 and 468 µg a.s./L,	PRAPeR 68 (4 – 8 May 2009) Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003b" study. See reporting table 5(25)	afforded the opportunity to maximise dissolution in the aqueous medium over the course of 22 h stirring, followed by 2 h settlement. The portion of the stock preparation transferred to the algal test was taken from mid-water, post-settlement, to confine exposure to the test substance dissolved in the test medium. The degree of dissolution achieved under these conditions is shown in APPENDIX 2 (p. 25) of the study report: at t_0 the top-dose medium comprising 100% primary stock contained only 476.1 µg a.s./L, *i.e*. just 4.76% of the unachievable "nominal" 10 mg/L. Other t_0 measured concentrations are similarly low, since all the other tested concentrations were derived by serial dilution of the primary medium. It is essential to note that no "nominal" target exposure concentrations were set in this study. Report APPENDIX 2 shows that the lenacil concentrations measured after 72 h are close to the t_0 values; in media inoculated with algae the 72 h measured lenacil concentrations represent 102%, 107%, 99%, 95% and 97% of the corresponding t_0 concentrations of 10.57, 21.24, 46.95, 107.5, 221.6 and 476.1 µg a.s./L, respectively.	respectively. The results are based on mean measured concentrations. More details are presented in the updated DAR.	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		The notifier therefore proposes that it would be more meaningful to express mean measured concentrations in terms of measured t_0 concentrations rather than spurious, notional "nominal" values. The former demonstrates clearly that the achieved exposure concentrations were adequately maintained for the duration of the algal study, whereas the latter is misleading and capable of being misinterpreted as an indication that substantial lenacil degradation occurred. Doubts about the validity/acceptability of the study are not justified. The mean measured lenacil concentrations represent 104%, 104%, 100%, 98%, 99% and 98% of t_0 measured concentrations at mean measured 11, 22, 47, 105, 219 and 468 µg a.s./L, respectively.		
	Open point: 5.4 B.9.2.8, effects on algae, *Selenastrum capricornutum* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the nominal the validity of the	As above, this issue is an artefact of the way the information has been presented in the summary and the inappropriate and misleading use of the term "nominal". Lenacil dissolved in DMF was dispersed in a primary stock at 10 mg a.s./L algal medium: a loading that exceeded the aqueous solubility of the test substance, but nevertheless afforded the opportunity	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. The mean measured lenacil concentrations represent 86 – 103 % of t_0 measured concentrations at mean measured concentrations of 0.41, 0.79, 1.5, 3.4, 8.1, 17 and 36 µg a.s./L, respectively. The results are based on mean	PRAPeR 68 (4 – 8 May 2009) Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003c" study. See reporting table 5(26)	to maximise dissolution in the aqueous medium over the course of overnight stirring, followed by 10 min settlement. The portion of the stock preparation transferred to the algal test was taken from mid-water, post-settlement, to confine exposure to the test substance dissolved in the test medium. The degree of dissolution achieved under these conditions is shown in APPENDIX 3 (p. 24) of the study report: at t_0 the top-dose medium comprising a 1.0% dilution of the primary stock contained only 34.88 µg a.s./L, *i.e.* just 34.88% dissolution was achieved in the primary stock at the unachievable "nominal" 10 mg/L. Other t_0 measured concentrations are similarly low, since all the other tested concentrations were derived by serial dilution of the primary medium. It is essential to note that no "nominal" target exposure concentrations were set in this study. Report APPENDIX 3 shows that the lenacil concentrations measured after 96 h are close to the t_0 values; in media inoculated with algae the 96 h measured lenacil concentrations represent 97%, 82%, 103%, 89%, 98%, 103% and 109% of the corresponding t_0 concentrations of 0.4127, 0.8678, 1.453, 3.962, 8.234,	measured concentrations. More details are presented in the updated DAR.	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		16.52 and 34.88 µg a.s./L, respectively. The notifier therefore proposes that it would be more meaningful to express mean measured concentrations in terms of measured t_0 concentrations rather than spurious, notional "nominal" values. The former demonstrates clearly that the achieved exposure concentrations were adequately maintained for the duration of the algal study, whereas the latter is misleading and capable of being misinterpreted as an indication that substantial lenacil degradation occurred. Doubts about the validity/acceptability of the study are not justified. Expressed in terms of t_0 measured concentrations, the mean measured lenacil concentrations represent 99%, 91%, 103%, 86%, 98%, 103% and 103% at mean measured 0.41, 0.79, 1.5, 3.4, 8.1, 17 and 36 µg a.s./L, respectively.		
	Open point: 5.5 B.9.2.10, effects on aquatic plants, *Lemna* study. According to guidance SANCO/3268/2001 if the measured concentrations are very low compared to the	As above, this issue is an artefact of the way the information has been presented in the summary and the inappropriate and misleading use of the term "nominal". In this study lenacil dissolved in DMF was dispersed in a primary stock at	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. The mean measured lenacil concentrations represent 96 – 102 % of t_0 measured concentrations at mean measured concentrations of 3.7, 8.8,	PRAPeR 68 (4 – 8 May 2009) Open point closed.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	nominal the validity of the test might be questionable. MS to discuss in an expert meeting the acceptability of Flatman D., 2003d" study. See reporting table 5(27)	10 mg a.s./L *Lemna* medium: a loading that exceeded the aqueous solubility of the test substance, but nevertheless afforded the opportunity to maximise dissolution in the aqueous medium by stirring, followed by 10 min settlement. The portion of the stock preparation transferred to the algal test was taken from mid-water, post-settlement, to confine exposure to the test substance dissolved in the test medium. The degree of dissolution achieved under these conditions is shown in APPENDIX 6 (pp. 25&26) of the study report: at t_0 (fresh media at each renewal during the semi-static exposure) the top-dose medium comprising a 1.8% dilution of the saturated primary stock contained 67.44, 69.85 and 73.29 µg a.s./L (mean = 70.19 µg a.s./L). Therefore, just 38.99% dissolution was achieved in the primary stock at the unachievable "nominal" 10 mg/L. Other t_0 measured concentrations are similarly low, since all the other tested concentrations were derived by serial dilution of the primary medium. It is essential to note that no "nominal" target exposure concentrations were set in this study. Report APPENDIX 6 shows that the	15, 24 and 71 µg a.s./L, respectively. The results are based on mean measured concentrations. More details are presented in the updated DAR.	

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		lenacil concentrations measured in expired media on Days 2, 5 and 7 are close to the corresponding t_0 values for the Days 0, 2 and 5 fresh media, respectively. Thus the measured lenacil concentrations in Day 2 expired samples represent 108%, 94%, 101%, 105% and 108% of the corresponding Day 0 fresh concentrations of 3.508, 8.431, 15.22, 23.73 and 67.44 µg a.s./L, respectively. Similarly, the measured lenacil concentrations in Day 5 expired samples represent 108%, 94%, 101%, 105% and 108% of the corresponding Day 2 fresh concentrations of 3.392, 8.916, 15.64, 23.11 and 69.85 µg a.s./L, respectively, and measured lenacil concentrations in Day 7 expired samples represent 110%, 92%, 95%, 99% and 105% of the corresponding Day 5 fresh concentrations of 3.391, 9.831, 15.93, 23.96 and 73.29 µg a.s./L, respectively. The notifier therefore proposes that it would be more meaningful to express overall mean measured concentrations (all data for fresh and expired media) in terms of mean measured t_0 concentrations in freshly prepared media (Days 0, 2 and 5 combined) rather than spurious,		

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
		notional "nominal" values. Mean measured t_0 concentrations in freshly prepared media are not presented in the report, but have been calculated for this purpose (in ascending order) as 3.610, 9.059, 15.60, 23.60 and 70.19 µg a.s./L. The proposed comparison demonstrates clearly that the achieved exposure concentrations were adequately maintained for the duration of the *Lemna* study, whereas the current alternative is misleading and capable of being misinterpreted as an indication that substantial lenacil degradation occurred. Doubts about the validity/acceptability of the study are not justified. Expressed in terms of mean measured t_0 concentrations in freshly prepared media, the mean measured lenacil concentrations represent 102%, 97%, 96%, 102% and 101% at overall mean measured 3.7, 8.8, 15, 24 and 71 µg a.s./L, respectively.		
	Open point: 5.6 Vol. 3, B.9.2.11, acute toxicity of the preparation, *Selenastrum capricornutum* study. The validity of the study	The question mark over the validity of the Venzar 80% WP/ *S. capricornutum* study hangs on the absence of any analytical confirmation that exposure concentrations were a) achieved and b) satisfactorily maintained for the duration of the exposure. Although	**RMS (April 2009):** Please refer to the explanation of the notifier in the column B. Three studies with *Pseudokirchneriella subcapitata* were conducted (Flatman D., 2003c; Douglas M.T. and Handley J.W., 1988; Douglas M.T. and Halls	PRAPeR 68 (4 – 8 May 2009) Open point fulfilled. New open point proposed, see below.

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	should be discussed by the experts in a PRAPeR meeting. See reporting table 5(28)	other algal studies and the *Lemna* study with the technical a.s. provide a weight of evidence that suggests lenacil concentrations will have remained at close-to-initial levels for at least 72 h (covering the reported E_bC_{50} and E_rC_{50} endpoints), it is not possible to make any convincing claim as to whether or not condition a) is likely to have been satisfied. EFSA have suggested elsewhere (reporting table 5(28)) that a "new, valid study could be useful to address potential highest sensitivity of algae to the formulation with respect to the active ingredient." Alternatively, the notifier is able to offer data from a more recent study of the effects of Venzar 500 SC (lenacil a.s.) on the same algal species and this could be offered to avoid having to perform a new study with Venzar 80% WP. Venzar 500 SC may be considered to be a suitable surrogate for Venzar 80% WP.	R.W.S, 1993), leading to similar endpoints. Moreover, a microcosm study (Jenkins C.A., 2005) is available. The effects of lenacil on algae are investigated. The endpoint is acceptable and therefore not deleted from the List of Endpoints.	New data gap proposed, see below.
	New open point 5.9 identified at PRAPeR 68 meeting: RMS to delete the endpoint from the acute toxicity study with the preparation on *Selenastrum capricornutum*.		**RMS (May 2009):** The List of Endpoints and the List of Studies relied on are corrected accordingly.	PRAPeR 68 (4 – 8 May 2009) Open point open. Written procedure June 2009 Open point closed

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	New data gap 5.1 identified at PRAPeR 68 meeting: notifier to submit the study with the Venzar 500 SC formulation on *Selenastrum capricornutum.*			PRAPeR 68 (4 – 8 May 2009) Data gap open. Written procedure June 2009 After the peer review EFSA noted a data gap to derive a valid endpoint for the most sensitive algae identified in the outdoor microcosm field study, taking in to account multiple applications. Given this data gap the study with the Venzar 500 SC formulation on *Selenastrum capricornutum* could be considered superfluous. Data gap closed See new data gap below
	New data gap 5.2 identified by EFSA after the peer review. EFSA noted a data gap to derive a valid endpoint for the most sensitive algae identified in the outdoor microcosm field study, taking in to account multiple applications.			Written procedure June 2009 New data gap
	Open point: 5.7 B.9.2.12, aquatic organisms,		**RMS (April 2009):** As indicated in the DAR, only 4	PRAPeR 68 (4 – 8 May 2009)

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations PRAPeR Expert Meeting / Conclusions of the evaluation group
	microcosm and mesocosm study (Taylor S.A., 2004). The acceptability of the (Taylor S.A. 2004) should be discussed in an experts meeting. See reporting table 5(29)		macrophyte species were tested in a laboratory microcosm test. Since an outdoor, more elaborated microcosm study (Jenkins C.A., 2005) is available, RMS decided to base the risk assessment on the last one. RMS would welcome discussion in the expert meeting.	Open point fulfilled.