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Conclusion on the peer review of captan

CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance captan

(Question No EFSA-Q-2009-604)

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SUMMARY

Captan is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Italy being the designated rapporteur Member State submitted the DAR on captan in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 20 October 2003. Following a quality check on the DAR, the peer review was initiated on 21 June 2004 by dispatching the DAR for consultation of the Member States and the two applicants Makhteshim Chemical Works Ltd and Arysta Life Science SAS (formerly Tomen France). Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting in 14 December 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in April and May 2005.

A discussion of the outcome of the consultation of experts took place with representatives from the Member States on 6 April 2006 leading to the conclusions.

The outcome of experts' consultation was re-discussed within a series of scientific meetings in the section of mammalian toxicology and residues with Member States experts in November 2007 and April 2008. The conclusion has been amended accordingly and the changed reference values are laid

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

down in this report. This updated conclusion replaces the previous version, which was finalised on 24 April 2006 (EFSA Scientific Report (2006) 71 refers).

The conclusion was reached on the basis of the evaluation of the representative uses as fungicide as proposed by the applicant which comprises foliar spraying to control a broad range of fungi in pome fruit, tomatoes and peaches at application rate up 2.4 kg (pome fruit), 1.8 kg (tomatoes) and 2.5 kg (peaches) captan per hectare. Captan can be used only as fungicide.
The representative formulated products for the evaluation were "Merpan 80 WDG", registered in some Member State of the EU and "Malvin WG", registered under different trade names in Belgium, the Netherlands and the UK. Both formulations are coded as water dispersible granule (WG).

No adequate analytical methods are available to monitor all the compounds given in the residue definitions for food. For the environmental compartment water no enforcement method is needed for the determination of captan, due to the fact that the DT_{90} values are less than 3 days. In case of soil the DT_{90} values are only partly (3.6 d) above the 3 day trigger value given in SANCO/825/00. However, analytical methods are available for the determination of captan and THPI in soil and water. For the other matrices (air and blood) no adequate method is available to monitor all compounds given in the respective residue definition.
A multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least limited quality control measurements of the plant protection products are possible.

Captan is rapidly and extensively absorbed and metabolised. Captan is of low toxicity by the oral and dermal routes but it is toxic via inhalation (classification R23 ‘Toxic by Inhalation’ proposed). It is not irritating to the skin but severely irritating to eyes, thus classification as R41 ‘Risk of serious damage to eyes’ is proposed. It is a skin sensitiser (proposal for R43 ‘May cause sensitisation by skin contact’). Overall, captan did not show any genotoxic potential but was found to cause duodenal tumours in mice. A clear threshold for duodenal tumours in mice was established. The classification category 3, R 40 is proposed by the majority of the MSs. Captan is not teratogenic or embryotoxic by itself but can affect the embryonic development by inducing specific alterations in maternal gastro-intestinal physiology. The Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure Level (AOEL) are 0.1 mg/kg bw/day, with a safety factor of 100; the Acute Reference Dose (ARfD) is 0.3 mg/kg bw. The ADI and the ARfD is applicable to the general population. Operator exposure estimates (German model) accounts for 56 to 91% (hand held and tractor mounted application) of the AOEL when PPE is worn. The exposure of bystanders is approximately 25% of the AOEL. Both modelling and field exposure data indicate that the exposure of workers involved with the handling of crops treated with is below the AOEL for re-entry at 14 days.

The metabolism of captan in plants has been adequately elucidated. Captan forms the major part of residue and only one metabolite, THPI has been identified as contributing in a significant way to the toxicological burden. The levels of THPI are drastically increased in case of processing of treated commodities involving a heating step. However the information on the behaviour of captan under processing conditions should be further investigated by degradation studies under representative hydrolytic conditions.

Although argumentation has been presented tending to demonstrate that THPI is of lower toxicity than the parent compound, the available data are not sufficient to firmly conclude on its toxicological non relevance. Therefore the residue definition in plant commodities should be the sum of captan and THPI.

Supervised residue trials have been conducted allowing to determine the needed MRLs for the representative uses and to conduct acute and chronic dietary exposure assessments. Residues of captan and of its metabolite THPI are not expected in succeeding crops. In accordance with the proposed mode of application in representative uses, MRLs should be established at 10 mg/kg for apples, pears, peaches and nectarines. However, at this level, residues present an acute risk for the safety of the consumer. Only the use on tomatoes for which an MRL of 2 mg/kg may be proposed leads to consumer intakes below the trigger toxicological levels of acceptable exposure.

The animal metabolism of captan is extensive, and no captan as such is present in animal commodities. Only structurally related metabolites were identified in edible animal tissues: THPI, 3-OH THPI and 5-OH THPI. These metabolites should be included in the residue definition for animal products. Metabolism studies suggest that these metabolites should not be present above usual Limits of Quantification of monitoring analysis, but existing feeding studies should be evaluated to confirm that expectation.

In soil under aerobic conditions captan exhibits very low to low persistence, breaking down to the major metabolites 1,2,3,6-tetrahydrophthalimide (THPI, max. 66% applied radioactivity (AR) at 7 days) and tetrahydrophthalimic acid (THPAM, max. 17%AR at 14 days), which exhibited low to moderate persistence. Significant mineralisation of the trichloromethyl, and carbonyl portions of the molecule occurred accounting for 81-91%AR, with unextracted radioactivity accounting for 7-14%AR. Photolysis at the soil surface was not a significant mechanism for degradation. The published literature indicated captan would be expected to exhibit high to medium soil mobility. Laboratory batch adsorption studies indicated THPI exhibited very high soil mobility. No pattern between adsorption and soil pH was apparent for these two compounds. THPAM exhibited very high to high soil mobility with its adsorption being pH dependant (highest mobility at high soil pH) in the available batch soil adsorption studies. For the applied for representative uses FOCUS groundwater modelling indicates contamination of vulnerable groundwater at concentrations> 0.1µg/L (the parametric drinking water limit) is not expected for parent captan. However annual average concentrations of THPI and THPAM leaving the top 1m soil layer are predicted to be up to ca. 2.7 and 5.9µg/L respectively while for some scenarios values are still below the trigger 0.1 µg/L. Groundwater non relevance assessments for these two metabolites were therefore triggered. However their contribution to the global exposure of the consumer to residues of captan and its metabolites is very limited.

In natural surface waters captan exhibits very low persistence. It breaks down to form the major metabolites THPI in water (max. 51%AR) and sediment (max 41%AR), THPAM (max. 26%AR) in water only and tetrahydrophthalic acid (THPAI, max. 11.3%AR) in sediment only. A conservative estimate of the degradation rate of these metabolites indicates they exhibit moderate persistence. Mineralisation to CO_2 of the cyclohexene label accounted for ca. 50%AR at 90 days whilst unextracted sediment residues accounted for 23-29%AR. Aqueous photolysis was not a significant mechanism for degradation. Should captan be included in Annex 1, Member States would need to address the drainage and runoff routes of entry to surface water for the soil metabolites THPI and THPAM in national assessments, as these routes of entry to surface water have not been adequately addressed for these soil metabolites in the available, peer reviewed EU level assessment.

The acute and short term risk to birds and the acute risk to mammals from uptake of contaminated food items is low. A high long-term risk is indicated in the first tier risk assessment for insectivorous birds for all representative uses and for herbivorous mammals for the representative uses in pome fruit and peaches/nectarines. The expert meeting on ecotoxicology rejected some of the refinement steps suggested in the refined risk assessment presented in the addendum of January 2005. Hence, the risk to insectivorous birds is not sufficiently addressed on the basis of the peer reviewed data. Some indication was provided that no grass/weeds are available as a potential food source for herbivorous mammals in southern European countries. Therefore it is suggested that the risk to herbivorous mammals should be assessed at Member State level. The first tier risk assessment resulted in a low acute risk to birds and mammals from uptake of contaminated drinking water for all representative uses. A high short-term risk to birds was indicated for the representative uses in pome fruit (South EU) and peaches/nectarines and a high long-term risk to birds and mammals was indicated for all representative uses. The risk to the aquatic environment is high and risk mitigation measures such as no spray buffer zones of 5 m, 15 m and 20 m are required for the representative uses in tomatoes, pome fruit (North EU), pome fruit (South EU) and peaches/nectarines. The acute risk to earthworms was assessed as low for all representative uses. The long-term risk to earthworms based on laboratory studies could lead to a potential underestimation of the risk to earthworms under dry soil conditions. It is proposed that the long-term risk to earthworms is assessed at Member State level taking into account the particular soil conditions in the respective Member State.
The risk to bees, other non-target arthropods, other soil non-target organisms, soil non-target micro-organisms and biological methods of sewage treatment is considered to be low for all representative uses.

Key words: captan, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Captan is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Italy as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Italy submitted the report of its initial evaluation of the dossier on captan, hereafter referred to as the draft assessment report, to the EFSA on 20 October 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 21 June 2004 to the Member States and TSGE co-ordinating the common dossier of the two main applicants Makhteshim Chemical Works Ltd and Arysta Life Science SAS (formerly Tomen France) as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 14 December 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the EPCO-Team at the Federal Office for Consumer Protection and Food Safety (BVL) in Braunschweig, Germany, in April and May 2005. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 6 April 2006 leading to the conclusions.

The outcome of experts' consultation was re-discussed within a series of scientific meetings in the section of mammalian toxicology and residues with Member States experts in November 2007 and April 2008. The conclusion has been amended accordingly and the changed reference values are laid down in this report. This updated conclusion replaces the previous version, which was finalised on 24 April 2006 (EFSA Scientific Report (2006) 71 refers).

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-3 of 17 January 2005)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 7 March 2006)

Given the importance of the draft assessment report including its addendum (compiled version of January 2006 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Captan is the ISO common name for *N*-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide (IUPAC). The name does not identify the configuration but the *cis*-isomer is strongly favoured thermodynamically, so the *trans*-isomer is not detectable in practice.

Captan belongs to the class of phthalimide fungicides such as captafol and folpet. Captan acts as a multi-site inhibitor. However, the precise nature of the site of action is still unclear.

The representative formulated products for the evaluation were "Merpan 80 WDG", registered in some Member State of the EU and "Malvin WG", registered under different trade names in Belgium, the Netherlands and the UK. Both formulations are coded as water dispersible granule (WG).

The evaluated representative uses as a fungicide as proposed by the applicant, which comprises foliar spraying to control a broad range of fungi in pome fruit, tomatoes and peaches at application rates of up 2.4 kg (pome fruit), 1.8 kg (tomatoes) and 2.5 kg (peaches) captan per hectare. Captan can be used only as fungicide.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of captan as manufactured should not be less than 910 g/kg for the Arysta source and 930 g/kg for the Makhteshim source, which is higher than the minimum purity given in the FAO specification 40/TC/S (1990) of 880 g/kg. The higher values relate to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity. The *cis*-isomer is strongly favoured thermodynamically, so the *trans*-isomer is not detectable in practice.

It should be noted that from an analytical point of view the two sources cannot be regarded as equivalent. For the moment, based on the available data, it cannot be concluded whether or not the technical materials can be regarded as equivalent from a toxicological and ecotoxicological point of view. In addition, maximum levels for the three impurities (i.e. perchloromethylmercaptan[3], folpet and carbon tetrachloride), which have to be regarded as relevant impurities cannot be set for the moment. However, according to the FAO specification the maximum content in the technical material should not be higher than 10 g/kg for perchloromethylmercaptan (FAO 183/TC/S).
The rapporteur Member State is after the evaluation of the recently received EPA assessment of the opinion that the technical materials can be regarded as equivalent. Furthermore, taken the new proposed specification (received by the RMS, February 2006) into account, the rapporteur Member State proposed maximum levels for the relevant impurities. However, this assessment was neither presented in an addendum nor peer reviewed nor discussed in meetings of experts.

Therefore, for the moment the specifications for the technical materials as a whole should be regarded as provisional, since data to confirm the identity of some impurities revealed by chemical analysis are still missing to address the requirement of the Directive on the specificity of the method(s). In addition, clarification is required, with respect to one impurity (R016907) in the Makhteshim source, to confirm the proposed maximum levels in the technical material.
It should be noted that no analytical methods are available for the determination of the relevant impurities in the representative formulations. It was not possible to get an agreed general statement on this issue. However, it was agreed at the expert meeting not to ask for respective analytical methods in this certain case. According to a later discussion at the EPCO 30 meeting (July 2005), where the discussion was continued, analytical methods for the determination in the formulation must be provided to demonstrate that relevant impurities in the technical material are not increasing in the formulation upon storage.

[3] Perchloromethylmercaptan: PMM; trichloromethane sulphenyl chloride

Beside this, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of captan or the respective formulations. However, it should be noted that the provided data with respect to the composition of the formulations used in some studies is insufficient to assess their comparability.
Moreover, Member States may wish to consider for "Malvin WG" whether it is necessary for a phrase like "Agitation must be used during mixing and loading and until spraying complete" to be added to the label.
In addition, it should be noted that one MS has some concerns with respect to the acceptability (insufficient validation data) of the analytical methods used for the batch analyses.

At the moment no FAO specification exits for a WG formulation.

The content of captan in the representative formulations "Merpan 80 WDG" and "Malvin WG" is 800 g/kg (pure).

The main data regarding the identity of captan and its physical and chemical properties are given in appendix 1.

Although some data gaps have been identified with respect to the specification of the technical material, it seems that sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least limited quality control measurements of the plant protection products are possible.

Regarding analytical methods for monitoring purposes the situation is as follows:
Analytical methods are available to determine residues of captan in food of plant origin. For the determination of THPI[4] one method (recently submitted) is available and assessed by the rapporteur Member State in the addendum to volume 3 (B.2, B.5), but the applicability of the method for the determination of THPI has to be confirmed by the outstanding independent laboratory validation (ILV). Furthermore, it should be noted that the validation data for THPI as given in the addendum to Volume 3, B.5 were not accepted by the expert meeting, as the method was only validated for tomato ketchup as a manufactured product and "washing water", so validation data are not available for an appropriate unprocessed matrix (of high water content, as given in SANCO/825/00). In addition a confirmatory method is missing.
In case of food of animal origin a method is required since MRLs are proposed, but no method(s) is/are available for the determination of 3-OH-THPI[5] and 5-OH-THPI[6].
For the environmental compartment water an enforcement method is not needed for the determination of captan as the water DT_{90} values are less than 3 days. In the case of soil the DT_{90} values are only partly above the 3 day trigger value (3.6 d) given in SANCO/825/00. However, analytical methods

[4] THPI: Tetrahydrophthalimde; 3a,4,7,7a-tetrahydroisoindole-1,3-dione
[5] 3-OH-THPI: 3-Hydroxy-tetrahydrophthalimide; 4-Hydroxy-3a,4,7,7a-tetrahydroisoindole-1,3-dione
[6] 5-OH-THPI: 5-Hydroxy-tetrahydrophthalimide; 5-Hydroxy-3a,4,5,7a-tetrahydroisoindole-1,3-dione

are available for the determination of captan and THPI in soil and water. An analytical method for the determination of captan in air is not available (the position paper from the applicant to address this data requirement was not accepted by the expert meeting).
An analytical method for the determination of blood is required to cover the requirement of Directive 96/46/EC for substance is classified as toxic (Annex point 4.2.5). An analytical method for the determination of captan was recently (February, 2006) submitted to the rapporteur Member State. Due to the fact captan metabolises rapidly, it seems that captan is not an appropriate target analyte. Whether or not one or more of the metabolites are suitable as target analyte, is still under discussion.

The analytical methodology employs is GC with EC, PN or MS detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.

The discussions in the expert meeting (EPCO 25, May 2005) on identity, physical and chemical properties and analytical methods included the specification of the technical material, physical, chemical and technical properties of captan and the formulations as well as the analytical methods.

Recently submitted studies, regarding the analytical method for the determination of impurity R290234 in the technical material and the determination of THPI in food of plant origin were neither peer reviewed by other MS nor discussed in an EPCO expert meeting. These studies were assessed by the rapporteur Member State. The evaluation of the rapporteur Member State is given in the addendum to the DAR (Annex B.2, B.5).

2. Mammalian toxicology

Captan was discussed at EPCO experts' meeting for mammalian toxicology (EPCO 23) in May 2005, and at 2 PRAPeR expert meetings (PRAPeR 39 and 44) in 2007 and 2008.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Captan is rapidly absorbed (around 80%) and excreted following oral administration to rats. A significant amount of radioactivity is excreted in expired air following administration of the [^{14}C]trichloromethyl labelled form only. Biotransformation of captan occurs in the gastrointestinal tract. At low doses a high it is extensively metabolised, whilst at higher doses captan is incompletely metabolised and a proportion is excreted unchanged. Captan undergoes metabolic cleavage of the nitrogen-sulphur bond, which probably occurs rapidly. There is no evidence for accumulation. Main metabolites in rodents are 4,5-cyclohexene-1,2-dicarboximide (THPI), 3-hydroxy-4,5-cyclohexene-1,2-dicarboximide (3OH-THPI), 5-hydroxy-4,5-cyclohexene-1,2-dicarboximide (5OH-THPI), 4,5-epoxy-1,2-dicarboximide (THPI-epoxide), 4,5-dihydroxy-1,2-dicarboximide (4,5-diOH THPI), 1-amido-2-carboxy-4,5-cyclohexene (THPAM) and 6-hydroxy-1-amido-2-carboxy-4,5-cyclohexene (3-OH THP-amic acid).

2.2. ACUTE TOXICITY

Captan is of low toxicity by the oral and dermal routes (LD_{50} > 2000 mg/kg bw). The acute LC_{50} is 0.67 mg/L, therefore the classification **R23 'Toxic by inhalation'** is proposed. Captan is not irritating to the skin but severely irritating to eyes, thus classification as **R41 'Risk of serious damage to eyes'** is proposed. It is a skin sensitiser (proposal for **R43 'May cause sensitisation by skin contact'**).
Since captan is to be classified as toxic and it is rapidly metabolised, rapporteur Member State was asked to identify a marker for captan residue(s) in body fluids or blood as well as an analytical method for the determination, according to Directive 96/46/EC.

2.3. SHORT TERM TOXICITY

In short-term studies, the relevant NOEL is 300 mg/kg bw/day from a 1-year study in dogs (emesis, inappetence and marked weight loss, mainly due to the taste and physical nature of the test substance). A 90-day oral study in rat is not available. The experts discussed the need of performing such a study and agreed that the outcome was not likely to affect endpoints used in risk assessment. Therefore the study was not required.
The NOEL of 0.60 µg/L from a 90-day inhalation study proposed in the DAR was agreed on by the experts. In a 21-day dermal toxicity study in the rabbit, decreased body weight, body weight gain and food consumption were observed in animals in the 1000 mg/kg bw/day dose group. Dermal application in rats produced skin irritation which was pronounced at higher dose levels and which was reversible when dosing was discontinued.

2.4. GENOTOXICITY

The acceptability of genotoxicity studies was discussed during the meeting. Many of the studies were old and performed with purities (ranging from 91.2% to 99.9%) higher than the technical material. Two of the submitted studies were considered reliable (94% and 91% purity). They both gave negative results. Overall, captan did not show a genotoxic potential.

2.5. LONG TERM TOXICITY

Chronic dietary administration of captan to rats was associated with reduced body weight gains at dietary intakes equivalent to 98 mg/kg bw/day and above. Two studies were performed in the rat. In one study, increases in mean absolute and relative liver and kidney weights were observed at the 18 month sacrifice at 250 mg/kg bw/day in males, together with to significant hepatocellular hypertrophy. Organ weight changes were not recorded in the second study. Captan did not show carcinogenic potential in the rat. The NOAEL following two year dietary administration was 25 mg/kg bw/day.
In the mouse, captan was found to be carcinogenic in the duodenum leading to the production of duodenal tumours at 122.8 mg/kg bw/day and above. The NOAEL was 61 and 70 mg/kg bw/day in males and females, respectively.
There is evidence supporting a non-genotoxic mechanism of oncogenicity in the mouse, associated with the irritant nature of captan. Studies showed no evidence of covalent binding of captan with

DNA and the lack of nuclear aberrations in duodenal crypt cells. This is supported by the fact that there is a threshold for duodenal tumours in mice: there is a clear NOAEL for tumours at 60.9 mg/kg bw/day for males.

The proposed mechanism for duodenal tumour induction in the mouse is that at high doses, captan degradation in the duodenum results in the formation of the irritant thiophosgene, leading to villus cell damage and irritation and as a result there is enhanced cell replication. This in turn leads to crypt cell hyperplasia, adenoma and ultimately carcinoma. In conclusion, there is a large body of evidence that the oncogenic effect manifested in the mouse duodenum results from a non-genotoxic mechanism for which a NOAEL has been established. The classification **category 3, R 40** was proposed and agreed by the majority of the experts.

2.6. REPRODUCTIVE TOXICITY

Captan does not adversely affect fertility at doses up to 500 mg/kg bw/day; offspring NOAEL is 12.5 mg/kg bw/day and parental NOAEL 25 mg/kg bw/day in the rat.

Captan was associated with increased incidence of malformations in the rabbit at 100 mg/kg bw/day and skeletal abnormalities at 30 mg/kg bw/day. The rapporteur Member State hypothesize that they might be secondarily produced by specific maternotoxic effects at the level of intestinal mucosae, due to an imbalance of nutrient absorption resulting in abnormal amount of nutrients acting as morphogens. It can be concluded that captan is not teratogenic or embryotoxic by itself but can affect the embryonic development by inducing specific alterations in maternal gastro-intestinal physiology.

The embryo/foetal and maternal NOAEL is 10 mg/kg bw/day rabbit. In the rat, the embryo/foetal NOAEL is 90 mg/kg bw/day and the maternal NOAEL is 18 mg/kg bw/day.

EFSA note that a discussion on a **possible classification for developmental effects might be needed.** This is due to the similarities in toxicity between captan and folpet and for folpet the possible proposal for classification of R63 was discussed during the experts´ meeting based on similar effects as seen during captan exposure (a R63? will be highlighted for folpet). It should also be kept in mind that the level of folpet as an impurity in captan needs to be confirmed (see section 1).

EFSA notes: The ARfD set by JMPR is 0.3 mg/kg bw, (JMPR 2004), based on the results from the rabbit study discussed at the experts meeting. In the JMPR conclusion, it is stated that the maternal NOAEL and the embryofetal toxicity is 10 mg/kg bw/day. The embryofetal NOAEL is based on increased skeletal variations at 30 mg/kg bw/day. The ARfD is based on the NOAEL of 30 mg/kg bw/day where increased incidences of early and late intra-uterine deaths were observed, as were increased incidences of several malformations observed at 100 mg/kg bw/day. Two other studies are discussed with maternal NOAELs in the same range whereas the developmental NOAELs are somewhat higher. The JMPR stated that it was not possible to conclude on the mode of action for the developmental effects.

2.7. NEUROTOXICITY

Studies to evaluate the delayed neurotoxicity of captan have not been conducted as captan is not a substance of similar or related structure to those capable of inducing delayed neurotoxicity.

2.8. FURTHER STUDIES

Metabolites:

The acute toxicity of THPI is low LD_{50} > 10 000 mg/kg bw (study from 1955, not according to current guidelines), present in the addendum from July 2005, thus not pr reviewed. It was not mutagenic in the *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA102 or the *E. coli* strain WP2 uvrA in the presence or absence of metabolic activation. In a study from 1968 (not according to current guidelines) summarised in the addendum from July 2005 thus not peer reviewed, it was shown that THPI at a dose of 75 mg/kg bw/day was not teratogenic or embryotoxic in rabbits. The experts agreed that the reference values for captan would apply also for THPI.

THPAM is an animal metabolite. It is not genotoxic. In the experts´ meeting, it was agreed that the ADI for captan would apply also for THPAM.

3 OH-THPI and 5 OH-THPI (animal metabolites) show up in low amounts. They are hydrophilic. The experts agreed that the reference values for captan would apply also for these two metabolites.

EFSA note: The rapporteur Member State submitted an argumentation on the toxicological properties of THPI and the hydroxy metabolites after the experts meeting thus not peer reviewed (addendum July, 2005, section B.7). Based on structure it might be assumed that they are probably of less toxicity than captan and as for the consumer risk assessment in the lack of specific reference values it can be assumed, as a worst case scenario, that the reference values agreed for captan cover the metabolites as well. However, as THPI and THPAM are found in the ground water (according to modelling) above 0.1 µg/L and even above the trigger of 0.75 µg/L and captan is proposed to be classified as toxic (R23) and carcinogenic (R40) further toxicological data are needed according to the guidance of the relevance of metabolites in groundwater (SANCO/221/2000 –rev 10). Thus the following new data gaps are set; to provide information:

- addressing the carcinogenic potential of THPI
- on the acute toxicity of THPAM
- addressing the carcinogenic potential of THPAM

There is no toxicological information on THPI epoxide available.

During the PRAPeR meeting 44 the toxicological profile of metabolites THPI, 3OH-THPI and 5OH-THPI was re-discussed, based on the availability of new toxicological studies.
The experts agreed that the results of the existing studies demonstrated less toxicity of the metabolites compared with captan. Also mechanistic data indicated that THPI and 3- and 5-OH THPI do not have the potential to induce critical effects (carcinogenic, reproductive toxicity effects).
As it was not possible to set specific reference values, the ones of captan could be used for risk assessment, if needed.

2.9. MEDICAL DATA

No epidemiological evidence of carcinogenicity in humans specifically related to captan exposure. Some cases related to of acute injury/illness in humans but no cases were reported of poisoning.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

ADI, ARfD and AOEL

The ADI, ARfD and AOEL reference values were discussed during the experts´ meeting. It was agreed that the most representative study was the rabbit developmental study with the maternal NOAEL of 10 mg/kg bw/day based on marked reduced bodyweight and that it should be used for deriving all reference values. **The resulting ADI, ARfD and AOEL values are 0.1 mg/kg bw/day with the safety factor of 100 applied.** This is in line with values proposed by the RMS initially in the DAR. It should be noted that the ARfD applies for the general population.
EFSA notes: The ARfD set by JMPR is 0.3 mg/kg bw, (JMPR 2004), based on a the results from the same rabbit study (see 2.6). In the evaluation meeting discussing the draft conclusion, the rapporteur Member State indicated to support the ARfD value agreed upon by JMPR.

During PRAPeR 39 the experts re-discussed the ARfD of captan: the meeting established an ARfD of 0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw per day for increased incidences of intra-uterine deaths and malformations at 100 mg/kg bw per day in the study in rabbits and a safety factor of 100 (previous value: 0.1 mg/kg bw)

2.11. DERMAL ABSORPTION

Dermal absorption value of 3% from a comparative *in vivo*/*in vitro* study with human and rat skin proposed by the rapporteur Member State was discussed. From the *in vivo* rat study a value of 10% was derived but, due to the poor quality of the *in vitro* study with human skin, no reduction could be applied. Therefore, the value of 10% for both Merpan 80 WDG and Malvin WG formulation was agreed on.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Captan is intended to be used in orchards and field crop tomatoes, at the maximum application rates of 2.5 and 1.8 kg a.s./ha, respectively.
Exposure of the operators has been assessed by the rapporteur Member State only with the German model and a field study was submitted and analysed. The recalculated estimated operator exposure according to the revised dermal absorption value of 10% is shown in the table below (presented in the addendum October, 2005 not peer reviewed).

Model	No PPE	With PPE:
German		
Tractor mounted sprayer (orchard)	393%	56%
Tractor mounted field crop sprayer	212%	91%
Hand held knapsack sprayer	166%	86%

The results with the German Model calculations, refined with the new dermal absorption value agreed on during the meeting, demonstrate that for the different spray application techniques and different crops, 166 to 393% of the AOEL is accounted for by exposure when spray operators wear no protective clothing. When protective equipment is worn (gloves during mixing/loading and application for applications to tomato using tractor-mounted sprayer and hand-held knapsack sprayer; gloves during mixing/loading and gloves and protective garment/sturdy footwear during application to orchard crops using tractor mounted airblast sprayer) estimated exposure accounts for 56 to 91% of the AOEL.

A field study was submitted carried out with a WP and thus exposure during mixing/loading is not relevant to a WG formulation such as 'Merpan' 80 WDG/ 'Malvin WG'. Due to the larger size and granular nature of the particles comprising 'Merpan' 80 WDG/ 'Malvin WG' there is likely to be less adhesion to clothing or skin and less inhalation exposure with this type of WG formulation compared to a WP, and so the operator exposure study will tend to over-predict exposure for a WG formulation.

Furthermore, in the operator exposure study the operators wore what are described in the report as 'overalls' but a full description of the overalls is not given in the report and their nature (i.e. whether they were chemical proof overalls) cannot be verified.

Worker

Amended calculations of worker exposure are presented below in comparison with an AOEL of 0.1 mg/kg bw/day using a dermal absorption value of 10%. The recalculated values are presented in the Addendum October, 2005 thus not peer reviewed.

Workers could enter crops such as pome fruit, peaches/nectarines or tomatoes that had been treated with 'Merpan' 80 WDG and 'Malvin' WG soon after application to harvest the crop or to carry out maintenance pruning.

Two estimates of worker exposure to captan for workers harvesting peaches/nectarines with and without additional protective clothing (gloves) using the German Model were submitted in the Addendum, not peer reviewed. The first one assumes re-entry of workers 7 days after application, the second one at 14 days. 'Dislodgeable residues of captan on peach foliage are derived from a study in California.

The maximum systemic exposure of workers to captan in the worst-case calculation in the absence of protective gloves is 0.71 mg/kg bw/day which is above the AOEL. This assumes that all of the foliar

residues measured in the peach foliage 14 days after application will be dislodgeable. The exposure of workers harvesting peaches with protective gloves was 35.5% of the AOEL.
With a harvest interval of 14 days exposure for workers with uncovered arms and legs was 75% of the AOEL.
According to results of a worker field study, exposure 7 days after application (equivalent to the PHI) is 107% of the proposed AOEL, while is only 75% of the AOEL with a harvest interval of 14 days exposure.
In conclusion, both modelling and field exposure data indicate that the exposure of workers involved with the handling of crops treated with 'Merpan' 80 WDG/'Malvin' WDG is slightly higher than the AOEL 7 days after application, while exposure is below the AOEL for re-entry at 14 days.

Bystander
The exposure of bystanders following the use of 'Merpan' 80 WDG and 'Malvin' WG is approximately 25% of the AOEL.

3. Residues

Captan was discussed at EPCO experts' meeting for residues (EPCO 24) in May 2005 and at 2 PRAPeR expert meetings (PRAPeR 40 and 45) in 2007 and 2008.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of captan in plants was investigated on lettuce, tomatoes and apples. Studies in lettuce and tomatoes were not considered as entirely valid with regard to the representative uses as the plant parts were harvested only 3 hours after the application of the substance. However, due to the labelling position they provided useful information on the fate of the trichloromethylthio side chain, demonstrating the rapid degradation of the thiophosgene produced after cleavage of the N-S bond into CO2, later incorporated into natural plant components.
In studies on apples the sampling of the residual products was carried out 20 days after treatment and provided reliable information. Captan was the dominant compound of the residue in these conditions (50-70 % of the Total Radioactive Residue). Several metabolites were identified, among which THPI (1,2,3,6-tetrahydrophthalimide) was the most important (reaching 10-15% of the captan levels). Other identified metabolites present at low levels were captan epoxide (N-(trichloromethylthio)-4,5-epoxyhexahydrophthalimide), THPI epoxide (7-oxabicyclol(2.2.1)-heptane-2,3-dicarboximide) and THPAM (*cis/trans*-6-carbamoyl-3-cyclohexene-1 carboxylic acid). This metabolic pattern suggests that the metabolic pathway of captan in plants proceeds through cleavage of the N-S link, epoxidation and ring opening. 16-30 % of the extracted material in the apple metabolism study could not be identified and consisted in polar compounds remaining at the origin of the TLC plates. Using the results of the tomato and lettuce metabolism studies, it was postulated that these not identified extracted residues consisted of several products most likely being conjugates of captan metabolites.

The residue definition was extensively discussed in particular during the expert meeting (EPCO 24), considering in particular the extensive formation of THPI in processed commodities produced with a heating step. It was the view of the expert meeting that THPI should be included in the residue definition for risk assessment and for monitoring. This was opposed to the opinion of the RMS which considered that, despite the high level of THPI in processed commodities, the residue definition could be restricted to captan only, given that in the view of the RMS arguments were available for considering THPI significantly less toxic than captan.
This residue definition was discussed in an additional peer review exercise after the Annex I listing of Captan. The residue definition was confirmed by PRAPeR meetings 44 (mammalian toxicology,08-11/4/2008) and 45 (residues,10-11/4/2008).

A sufficient number of supervised residue trials have been submitted in accordance with the representative uses supported by the manufacturer. In these trials, captan and its metabolite THPI were analysed. These trials are reported in the addendum produced by the EFSA, with expression of their results according to the residue definition proposed by the expert meeting. THPI, expressed as captan, was in all crops present at lower or similar levels to captan (30 to 40 % of the captan levels in the case of pome fruits, peaches and nectarines and equal to the captan levels in the case of tomatoes).
For pome fruits, 10 valid trials have been identified for the Northern region of EU and 7 for the Southern region. The Highest Residue (HR) was found in the Southern region (9.6 mg/kg) and this value was found to be an outlier under application of the Dixon Q-test. However as no obvious indication was present demonstrating a practical problem related to this trial (the initial deposit was similar to other trials) it was decided to keep that value as relevant. The Supervised Trial Median Residues (STMR) were 1.8 and 3.1 mg/kg for the Northern and Southern regions respectively.
In tomatoes 8 valid trials were available with HR and STMR at 1.5 and 0.57 mg/kg respectively.
In peaches and nectarines, the dispersion of the results was small and the HR and STMR were 9.4 and 5.0 mg/kg respectively.
These results of field trials can be considered as reliable on the basis of storage stability studies demonstrating that captan and its metabolite THPI are stable for at least 9 months in plant substrates, when stored entire or coarsely ground at – 20°C. On macerated commodities, experimental data indicated progressive hydrolysis of captan into THPI during deep freeze storage, due to the contact of the substance with plant juice and enzymes.
The effect of processing on the nature of residues was not investigated following the usually required hydrolysis studies at high temperature simulating pasteurisation, baking, brewing and sterilisation. The applicant argued that the available hydrolysis studies conducted at room temperature were sufficient to conclude to the transformation of captan into THPI under processing conditions. However the expert meeting was of the opinion that the required hydrolysis studies conducted in extreme conditions should be carried out in order to identify eventual unpredictable breakdown or reaction products to enable a robust risk assessment for the safety of the consumer.

Studies have been submitted on the influence of industrial processing and household preparation on the residue level in processed commodities from apples and tomatoes. In these studies captan and THPI were analysed in raw and transformed products.
Transfer factors could be derived for the sum of captan and its metabolite THPI. In all processed products intended for human consumption undergoing a heating step (apple pasteurised juice and puree, tomato juice, ketchup and puree as well as canned tomatoes) no residue of captan was present. Obviously captan is extensively degraded under practical conditions of processing. A corresponding increase of the THPI level after processing was observed. The concentration of the sum of captan and THPI is weakly affected, with transfer factors for the sum of captan and THPI ranging from 0.5 to 1.6, depending on the commodity.
No processing studies were submitted for peaches and nectarines. Although similar results are expected, these studies are currently conducted and final reports should be submitted when available.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A rotational crop study is available. Total Radioactive Residues in edible plant parts of wheat, lettuce and beets planted 34 days after application on bare soil of captan at a realistic dose were below 0.05 mg/kg. Identification of the metabolic pattern in immature crops indicated that captan was not present and only very low amounts of THPI were detected. Field trials are not required and it is not necessary to propose MRLs for succeeding crops, nor plant-back restriction after the use of captan.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The metabolism of captan has been investigated in lactating goats and laying hens. The substance is extensively metabolised in both animals and was not found in any edible tissue. No sign of accumulation is present. The metabolite pattern is rather similar to that observed in plants, with additional metabolites in animal tissues, consisting in hydroxylated forms of THPI (3-OH THPI (*cis/trans*-3-hydroxy-1,2,6-trihydrophthalimide), 5-OH THPI (*cis/trans*-5-hydroxy-1,2,6-trihydrophthalimide), and 4,5-diOH HHPI (4,5-dihydroxyhexahydrophthalimide)). 3-OH THPI and THPI were clearly the dominant compounds in the edible tissues of lactating goats and laying hens, respectively. The expert meeting was of the opinion that a common residue definition should be established for all animal commodities and proposed the sum of THPI, 3-OH THPI, 5-OH THPI expressed as captan, for both risk assessment and monitoring.

This residue definition was discussed in an additional peer review exercise after the Annex I listing of Captan. The residue definition was confirmed by PRAPeR meetings 44 (mammalian toxicology,08-11/2008) and 45 (residues,10-11/4/2008).
As for plant commodities, this is in contrast with the proposal of the rapporteur Member State, which suggested establishing a default residue definition consisting in parent compound only for animal commodities, and supporting this proposal by the fact that arguments had been provided that the metabolites observed in the animal tissues were of significantly lower toxicity than captan.
As far as feedingstuffs are concerned, apple pomace is the only feed item to be considered as potential source of exposure of livestock resulting from the representative uses supported by the

applicant. The transfer factor from apples to wet pomace for the sum of captan and its metabolite THPI has been estimated to be 2.

Taking into account the level of incorporation of apple pomace in animal diet according to nutrition practices of ruminants, it has been calculated that the highest exposure to residues likely to occur, resulting from the use of captan was 0.35 and 0.10 mg/kg bw/d, for beef and diary cattle respectively, these figures representing the sum of captan and THPI, expressed as captan equivalents. On the basis of the information derived from the available metabolism studies, it is reasonable to expect that residues of THPI, 3-OH THPI and 5-OH THPI will not exceed 0.05 mg/kg in animal commodities. To confirm this expectation and to set MRLs on an appropriate scientific basis, feeding studies at realistic level of exposure need to be carried out. A feeding study on lactating goats has been assessed by the RMS in an addendum provided in July 2005, after the expert meeting. RMS reported low but measurable residue levels of THPI and 3-OH THPI in milk and tissues, but these results were not peer-reviewed.

3.3. CONSUMER RISK ASSESSMENT

Assessments of the chronic and acute exposures of consumers have been conducted on the basis of the residue definition (sum of captan and THPI expressed as captan) proposed by the expert meeting (EPCO 24). All the underlying data allowing these assessments can be found in the addendum prepared by the EFSA.

Chronic exposure.

The chronic dietary exposure assessment has been carried out according to the WHO guidelines for calculating Theoretical Maximum Daily Intakes (TMDI) and International (National) Estimated Daily intakes (I(N)EDI). Two consumption patterns were considered: the WHO European typical diet for adult consumers and the national diets of UK for infants, toddlers, child and adult populations, which take into consideration high individual consumption levels (at the 97.5th percentile of the distribution of consumptions in the respective populations).

For TMDI calculations, residues in pome fruits, peaches, nectarines and tomatoes were assumed to be at the level of the respective MRLs proposed on the basis of the supervised residue trials. No exposure resulting from the consumption of animal commodities was considered as available data are not sufficient to fix MRLs. However, on the basis of the metabolism data it is expected that animal commodities do not contribute significantly to the total intake. These calculations indicated an exceedence of the ADI for infants and toddlers in UK with high individual consumption of commodities supported as representative uses.

Therefore I(N)EDI calculations were carried out for these particular populations in order to get a better estimate of the actual exposure to residues, using the STMR (Supervised Trials Median Residue levels) rather than the MRLs. No processing factor was applied as it was shown that processing had no significant effect on the total amount of captan and THPI. This resulted in calculations well below the ADI (the estimated exposures were 40 and 70 % of the ADI for infants and toddlers respectively.

In groundwater the level of 0.1 µg /L is expected to be exceeded by the metabolites THPI and THPAM. As indicated under point 2.8, the ADI of captan should apply to these metabolites. Therefore, an exposure assessment through consumption of drinking water was performed after the expert meeting by EFSA. This assessment is based on the default assumptions for water consumption laid down in the WHO Guidelines of drinking water quality and on the highest predicted values from FOCUS modelling for the use on apples at the intended application rate, in order to reflect the worst case.
For the considered consumer subgroups of infants, toddlers and adults the estimated intakes of THPI and THPAM together, expressed as captan, from drinking water are 0.00238 mg/kg bw/day, 0.00159 mg/kg bw/day and 0.00053 mg/kg bw/day, respectively corresponding to *ca* 2%, 2% and 1% of the ADI of captan, respectively. Therefore, it can be considered that the exposure to captan degradation products through consumption of drinking water does not represent a significant increase of the toxicological burden resulting from the consumption of plant commodities.

Acute exposure.
The acute exposure to residues of captan and THPI has been assessed according to the WHO model for estimates of short term intakes. Large portion consumption data for adults, toddlers and infants in UK were used. Calculations were carried out considering residues in treated commodities at the level of the respective MRLs as well as high unit to unit variability (7). These calculations showed potential exposures largely in excess of the ARfD (NESTI calculations amounted for 500 to 1000 % of the ARfD) for infants and toddlers in the case of apple, pears, peaches and nectarines. Only for tomatoes, the potential acute exposure is below (but close to) the ARfD.

The acute reference dose was discussed in an additional peer review exercise after the Annex I listing. In PRAPeR meeting 39 (mammalian toxicology,08-11/4/2008) the ARfD was changed from 0.1 mg/kg bw to 0.3 mg/kg bw. So this changes the percentage of the ARfD as follows. NESTI calculations accounted for 115 to 327 % of the ARfD) for infants and toddlers in the case of apple, pears, peaches and nectarines. So still only for tomatoes, the potential acute exposure is below the ARfD.

In conclusion a potential for acute risk for the health of the consumer has been demonstrated for apples, pears, peaches and nectarines.

3.4. PROPOSED MRLS

Based on the results of supervised residue trials, MRLs of 10 mg/kg would be needed for apples, pears, peaches and nectarines, while the use on tomatoes would require 2 mg/kg.
No MRL is proposed at this stage for animal commodities, given that the late assessment provided by the RMS in the July 2005 addendum of feeding studies allowing determining the appropriate level was not peer-reviewed.

4. Environmental fate and behaviour

Captan was discussed at the EPCO experts' meeting for environmental fate and behaviour (EPCO 21) in April 2005.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

In laboratory soil degradation studies carried out under aerobic conditions on 2 different viable sandy loam soils (25°C and 75-80% of 1/3 bar soil moisture content for 2 of the soils) the only significant sinks for the trichloromethyl radiolabel were CO_2 (81-91% applied radioactivity (AR) at 28-30 days, study end) and residues not extracted by ethyl acetate or water (13.3-14.3%AR at study end). Low levels (0.6-1.1%AR) of thiocarbonic acid were also detected in soil extracts between days 7 and 28. Member Stateexperts discussed the potential for the formation of the gas thiophosgene from this labelled moiety. The volatile traps contained only low levels of radioactivity (maximum 0.21%AR). The applicant proposed that this radioactivity in the volatile traps was likely to be thiocarbonic acid, based on the identified radioactivity in soil extracts. The experts considered this was likely, but noted it could not be excluded that thiophosgene was present at trace levels in the volatile trap. They therefore concluded that thiophosgene might possibly be released to the air as a result of the soil metabolism of captan, but that if this occurs, it would only be present in trace amounts.

In a laboratory soil degradation study carried out under aerobic conditions on a third viable sandy loam soil, (pH 6.8, incubation conditions not reported) dosed with carbonyl radiolabelled captan, CO_2 accounted for 91%AR and radioactivity not extracted by acidified ethyl acetate and water 7.6 %AR at 122 days. The metabolites 1,2,3,6-tetrahydrophthalimide (THPI, max. 66%AR at 7 days) and tetrahydrophthalimic acid (THPAM, max. 17%AR at 14 days) were formed. The minor metabolite tetrahydrophthalic acid (THPAI, max. 3.2%AR at 14 days) was also identified.

Evidence from sterilised soil experiments and sterile aqueous hydrolysis studies (see section 4.2.1) demonstrate that initial degradation of parent captan occurs by chemical hydrolysis and does not require microbial enzyme activity.

Under anaerobic conditions in a microbially active soil in laboratory studies, the metabolite 2-cyano-cyclohex-4-ene carboxylic acid (THCY) that was not formed under aerobic conditions was identified (max 21%AR after 112 days). Data indicated that any THCY formed under anaerobic conditions was readily degraded when aerobic conditions returned (DT_{98} 7 days). For the representative uses applied for regarding Annex 1 listing (spring / summer applications to Pome fruit, stone fruit and tomatoes) periods of anaerobic conditions would be unlikely. The experts from the Member States agreed that in relation to these uses, further consideration of the fate and behaviour of this anaerobic metabolite (for example a leaching assessment) was not required, but that the information on the route of degradation under anaerobic conditions from the studies was reliable, so these results have been included in the list of endpoints (see appendix 1).

The results from laboratory soil photolysis experiments indicate photolysis at the soil surface will not be a significant process in the natural environment. In the US EPA guideline laboratory photolysis study carried out with cyclohexene labelled captan, that utilised air dried soil, the soil metabolite THCY was measured at > 10%AR (10.2-15%AR) in the irradiated and or dark control samples at day 1and day 4 (but not days 2, 3 or 5) after treatment. The EPCO meeting proposed that the applicant should assess this metabolite further with regard to its occurrence under field conditions and possible leaching to groundwater. The EFSA considered that that this was not necessary as THCY has been shown to be readily degraded in aerobic soil with more usual soil moisture conditions and was only formed in dry soil (or under prolonged anaerobic conditions as discussed above). As leaching is only a concern when soils are above field capacity and THCY is unlikely to be present in soil in significant amounts for the notified uses under these soil moisture conditions in aerobic soils, leaching to groundwater of THCY is considered by the EFSA to be very unlikely. Information from the applicant relating to these issues and THCY was provided by the applicant and summarised in the addendum to the DAR dated October 2005. This information has not been peer reviewed.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

See the addendum to the DAR dated January 2005 for full details of the soil DT_{50} discussed below.

In the three aerobic laboratory degradation studies discussed at section 4.1.1 above, single first order non linear regression soil DT_{50} for Captan were 0.44, 0.6 and 1.09 days. (After normalising to 20°C and -10kPa soil moisture content following FOCUS recommendations and assuming the study for which the experimental conditions were not reported was carried out at 25°C and 75% of 1/3 bar soil moisture content (US EPA guideline conditions) these values were essentially the same at 0.45, 0.63 and 1.09 days). Using the carbonyl labelled study where captan was dosed, described at section 4.1.1 above and the results from aerobic laboratory (20°C 40% maximum water holding capacity (MWHC)) studies on a further 3 soils where THPI or THPAM were dosed, single first order non linear regression soil DT_{50} were 5.9–14.4 days and 6–11.1 days[7] respectively (soil pH range 6.0-7.1). (After normalising to 20°C and -10kPa soil moisture content following FOCUS recommendations the arithmetic mean values subsequently used as FOCUS modelling input were 9.05 days and 7.8 days respectively).

The experts from Member States discussed the potential for pH dependence of the rate of soil degradation of captan and its metabolites. The conclusion was that considering all the available data parent captan degrades very rapidly under all pH and biotic/abiotic conditions. Whilst sterile aqueous hydrolysis study results (see section 4.2.1) indicated that THPI was degraded faster under very alkali conditions and THPAM faster under very acidic conditions, this trend of degradation rate with soil pH was not observed in the studies with biologically active soils (soil pH range 6.0-7.1). Therefore it

[7] Contrary to what is outlined in the report of the EPCO meeting of experts (open point 4.3) the EFSA considers there is no evidence that the THPAM degradation rate in these studies was correlated with soil pH.

was agreed it was appropriate to use mean DT_{50} values as input to leaching modelling (with the exception of parent captan, where the longest value was selected, as results were only available from experiments on 3 soils).

In field dissipation studies carried out in the USA (6 different sites) but climatic conditions considered by Member State experts to be representative of European conditions at 5 of these sites, single first order non linear regression soil DT_{50} for captan were estimated to be 0.33-7.04 days. These values for the decline phase of measured THPI concentrations from the sampling time point with the maximum measured concentration (0-28 days) were 2.6-33.9 days. The experts from Member States agreed it was appropriate to use the longest field DT_{50} value for use in the calculation of PEC soil.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

It was not possible to measure the adsorption potential of captan in guideline batch adsorption studies or column leaching studies due to the rapid hydrolysis of captan that occurs (even under sterile conditions). Member State experts agreed it could be appropriate to use an arithmetic mean K_{oc} value of 97 mL/g (range 29-198 mL/g, 6 values) in leaching assessments based on values reported in the open literature (This excludes the values in the Wauchope *et al.* review reference that upon further investigation were personal communications and did not originate from peer reviewed journals). The EFSA would wish to point out that this value of 97 mL/g has considerable uncertainty and that the cited references have still not been critically assessed. It is unclear to EFSA how these literature values were derived and how reliable they are. They appear to be, (based on the limited information summarised in the addendum to the DAR dated January 2005) derived from TLC experiments or estimations based on octanol water partition coefficient, water solubility or molecular connectivity models. However even though this value of 97 mL/g is very uncertain, the EFSA agrees with the conclusion of the experts from the Member States that the very rapid degradation of captan in soil means that this, much higher level of uncertainty than usual can be accepted in sorption estimates as the very rapid degradation of captan (by chemical hydrolysis) will mitigate the potential leaching of captan to deeper soil layers.

The adsorption of the soil metabolite THPI was reliably measured in guideline batch adsorption studies on 5 soils[8]. The K_{foc} for THPI were 5.7-11mL/g (arithmetic mean 8.1 mL/g) 1/n 0.83-1 (arithmetic mean 0.91).

The adsorption of the soil metabolite THPAM was reliably measured in guideline batch adsorption studies on 6 soils. The K_{foc} for THPAM measured were 4.5-100mL/g, 1/n 0.99-1.26. Adsorption was pH dependant with the lowest adsorption being related to soils of highest pH. In the addendum to the DAR dated January 2005 a relationship between soil pH and adsorption as derived by the applicant

[8] In section B.8.2.1 of the addendum to the DAR dated January 2005 it is clarified that the results for the ‘Kenny Hill’ soil have been excluded.

was presented: K_doc=(-25.611*pH)+212.05). This empirical correlation based on the results from the available experiments on 6 soils had a correlation coefficient (r^2) of 0.757. The related Freundlich exponents also appeared to have a pattern with pH. The applicant proposed that for situations where soil pH was <6, a 1/n value of 0.99 (mean of 3 values where pH was<6) should be used. Where pH was >6 but <7.5, a 1/n value of 1.09 (mean of the complete dataset) was proposed. Where pH was >7.5, a 1/n value of 1.19 (mean of 3 values where pH was> 7.5) was proposed. Member State experts considered this proposal and considered it an acceptable approach. The values derived using this approach pertinent to the soil pH at each FOCUS groundwater scenario are provided in the list of endpoints (appendix 1 of this conclusion). The EFSA also agrees that the approach outlined is reasonable. (Whilst it would have been preferable and more consistent for the relationship to have been derived using the adsorption results expressed as K_{foc} and not K_{doc}, as Freunlich slope 1/n values were used in the leaching modelling assessment, the approach used is considered conservative as K_{foc} values were generally higher or comparable relative to the calculated K_{doc} values).

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

In sterile aqueous buffer solutions at pH 5, 7 and 9 at 25°C captan was rapidly hydrolysed. At pH 7 single first order DT_{50} were 2.6-4.9 hours. At pH 9 breakdown was faster (single first order DT_{50} were 4-8 minutes). At pH 5 breakdown was slightly slower (single first order DT_{50} were 11-19 hours). The identified major (>10%AR) hydrolysis breakdown products identified were THPI, S-(tetrahydrophthalimido) thiocarbonate (THPC), sodium carbonate (alkaline pH) and CO_2 (acidic and neutral pH). In addition 2 further major breakdown products were resolved by chromatography but not identified. The applicant postulated these breakdown products that were derived from the trichloromethyl radiolabel were: sodium thiocarbonate and sodium-(tetrahydrothalimido) thiocarbonate.

In a laboratory aqueous photolysis study carried out at pH 5 dosed with captan as test substance degradation rates were comparable in illuminated samples to that in the dark control.

No ready biodegradability study is available. The experts from Member States agreed that it was not essential for this study to be provided, but in the absence of the results from a study captan must be considered for classification purposes as 'not readily biodegradable'.

In a guideline laboratory aerobic sediment water study on 2 natural systems (20°C, pH 8.1 with 12.5%oc sediment or pH 7.8 with 3.1%oc sediment) dosed with cyclohexene labelled captan, as would be expected from the hydrolysis studies parent captan disappeared very rapidly. At the first sampling time immediately after application parent captan in the water phase accounted for only 5.6%AR in the higher pH (8.1) system and 61%AR in the pH 7.8 system. The DT_{90} for captan in the whole systems was < 1 day. The major metabolites THPAM (max. 26%AR in water at 7 days), THPI (max. 51%AR in water at 7 days and max 41%AR in sediment at 1 day) and THPAI (max. 11.3%AR in sediment at 30 days) were identified. These metabolites were further degraded. At study end (90 days) CO_2 accounted for 49-52%AR. Radioactivity in sediment not extracted by acidified ethyl acetate and a reflux with acidified acetonitrile accounted for 23-29%AR at 90 days. The metabolite THPC formed in significant amounts under sterile pH 9 conditions was not formed in these biologically active alkaline sediment water systems. Member State experts concluded that, under field conditions in natural water systems, THPC was unlikely to be present in significant amounts.

The single first order DT_{90} for parent captan in these systems were < 24 hours. For THPI in just the pH 8.1, 12.5%oc sediment system a single first order DT_{50} of 4.8 days was estimated. For the pH 7.8, 3.1%oc sediment system for THPI and THPAI and both systems for THPM a conservative estimate of a single first order DT_{50} of 17.8 days was made. (The calculation to derive this value used the observation that there were no detectable levels of metabolites in either system by 59 days. 59 days was then assumed to be a conservative DT_{90}. When a first order pattern of decline is assumed a DT_{50} of 17.8 days is derived from this DT_{90}).

Data indicated THPI was stable to aqueous photolysis and did not hydrolyse under sterile neutral and acidic conditions. However under sterile alkali conditions (pH9, 25°C) relatively rapid hydrolysis occurred (single first order DT_{50} 3 days). For THPAM the converse pattern was apparent. It did not hydrolyse under sterile neutral and alkali conditions. However under sterile acidic conditions (pH4, 25°C) relatively rapid hydrolysis occurred (single first order DT_{50} 4 days).

PEC in surface water and sediment have been calculated from the spray drift route of entry to a static 30cm water body overlying 5cm of sediment assumed to have a wet weight bulk density of 1.3g/mL, using the agreed approach outlined in the aquatic guidance document SANCO/3268/2001 1 October 2001. Because of the rapid degradation of parent captan in soil and subsequently water, it was considered that the drainage and runoff routes of entry would result in negligible surface water exposure from parent captan. However assessments of these routes of entry are necessary for the major soil metabolites THPI and THPAM. The drainage route of entry has not been addressed in the available peer reviewed EU level exposure assessment. Whilst a calculation for runoff for the major soil metabolites was presented in the DAR, the assumptions used in these calculations have not been agreed at the EU level and may not cover all runoff situations in all Member States. Note calculations using step 1 and 2 FOCUS surface water approaches that include an input to surface water from drainage and runoff were provided for the 2 major soil metabolites and have been summarised in the addendum to the DAR dated October 2005 (though detail of the application rates and for step 2 crop interception assumptions used, that were stated as being pertinent to pome fruit use in Northern Europe, were not reported in the addendum). These calculations have not been peer reviewed and agreed at the EU level. Therefore, the runoff and drainage routes of entry to surface water for the soil metabolites THPI and THPAM should be considered in national assessments made by Member States should captan be included in Annex 1.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

FOCUSPELMO 3.3.2 was used to simulate the potential leaching of captan and its major soil metabolites THPI and THPAM from the top 1m soil horizon for the applied for representative uses on tomatoes, peaches/nectarines in Southern Europe and Apples in Southern and Northern Europe for the FOCUS groundwater scenarios. This modelling was summarised at section B.8.6 of the addendum to the DAR dated January 2005. The pattern of use simulated is considered to encompass the representative uses applied for, for Annex 1 listing. The simulations carried out utilised appropriate chemical substance input parameters with the exception of adsorption data for captan and THPI where the Member State experts / EFSA considered lower values (97 as opposed to 200mL/g for Captan and, 8.1 as opposed to 9.3mL/g for THPI, see section 4.1.3) should have been used. However due to the very rapid soil degradation of captan and the application patterns being supported, these differences in adsorption input parameters would not change the proportion of scenarios where the model calculated annual average concentrations in leachate leaving the top 1m for these two compounds in the simulations, were above the regulatory triggers of 0.1, 0.75 and 10µg/L. For captan all scenarios had simulated annual average concentrations of <0.001µg/L. For THPI and THPAM model calculated annual average concentrations in leachate leaving the top 1m soil horizons for the worst case scenario / crop combination (Chateaudun / apples) were in the assessment range prescribed by the guidance SANCO/221/2000-rev.10 dated 25 February 2003[9] of 0.75-10µg/L (up to *ca.* 2.7µg/L for THPI and *ca.* 5.9µg/L for THPAM). For other representative uses / scenarios, some scenarios gave PECgw values <0.1 µg/L for both THPI and THPAM. These were: south EU pome fruit (Porto), peaches/nectarines (Porto, Sevilla, Thiva), tomatoes (Porto, Sevilla, Thiva).

4.3. FATE AND BEHAVIOUR IN AIR

Measured volatilisation from soil under controlled indoor conditions was negligible. Captan has a vapour pressure of 4.2×10^{-4} Pa at 20° C and a Henry law constant of 2×10^{-4} Pa m^3 mol^{-1}. Volatilization from soil and aqueous systems / soil water would therefore be expected to be negligible. Air concentrations would therefore be expected to be low. Based on the Atkinson method, the half life for oxidative photochemical degradation of captan in the upper atmosphere was estimated to be 1.5h (12 h photoperiod). This atmospheric half life indicates that for any small proportion of the applied captan that did volatilise, the potential for long range transport through the atmosphere should be negligible. It was concluded that the metabolism of captan in soil would only be expected to produce the volatile breakdown product thiophosgene in trace amounts (see section 4.1.1.).

5. Ecotoxicology

Captan was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 22) in April 2005.

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC

The risk assessment for ecotoxicology is based on the assumption that the technical material is equivalent.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk assessment for birds and mammals presented in the DAR was conducted according to EPPO 1992 (Hoerger and Kenaga, 1982). The relevant trigger values were breached for the long-term risk to mammals. The rapporteur Member State asked the applicant for a risk assessment according to SANCO/4145/2000.

The new risk assessment was summarized in the addendum of January 2005 and discussed at the EPCO experts´ meeting. The acute TER values for birds and mammals exceeded the Annex VI trigger of 10 for all representative uses except for herbivorous mammals for the use in pome fruit in South EU and peaches/nectarines and for herbivorous birds in tomatoes. The TER values of > 9.9, >9 and > 9.3 are not far below the trigger of 10 and are based on LC_{50} values which were above the highest tested dose. Therefore the expert meeting agreed that the acute risk posed to birds and mammals is low for all representative uses. The short-term TER value of > 6.6 for herbivorous birds was below the Annex VI trigger of 10 for the use in tomatoes. It was agreed in the expert meeting that tomato foliage is not attractive as a food source for birds and therefore the short-term risk to herbivorous birds is considered to be low. The long-term TER values were below the Annex VI trigger for insectivorous birds for all representative uses, for herbivorous birds in tomatoes and for herbivorous mammals in pome fruit (South EU), peaches/nectarines and tomatoes. To refine the long-term risk to insectivorous birds the applicant proposed to use a RUD (residue per unit dose) value of 5.1 and a PT (proportion of time spent foraging in the treated area) value of 0.61. The meeting agreed to the PT refinement for the representative uses in pome fruits and peaches/nectarines based on data on blue tits (*Parus caeruleus*) in orchards. The RUD of 5.1 was rejected since this would imply that blue tits feed solely on large insects. The TERs based only on PT refinement would not meet the Annex VI trigger of 5 suggesting a high long-term risk to insectivorous birds for the representative uses in pome fruit (North and South EU), peaches/nectarines and tomatoes. An open point was set for the rapporteur Member State at the expert meeting to recalculate the long-term TER values with the default RUD value. The long-term TER calculation and a refined risk assessment was submitted by the applicant and summarised in the addendum of October 2005. The first tier long-term TER values were calculated as 3.2, 1.7, 1.6, 1.4 for the representative uses in pome fruits North EU, pome fruits South EU, peaches and tomatoes. The new refined risk assessment was based on yellow wagtail (*Motacilla flava*) for the use in tomatoes and great tit (*Parus major*) for the use in orchards. Refinements of FIR (Food intake rate), PD (Proportion of food type in the diet) and PT were suggested to refine the long-term risk to insectivorous birds. The resulting TER values were in the range of 7.09 to 10.6 indicating a potential low risk to insectivorous birds. However, the refined risk assessment presented in the addendum of October 2005 is not peer reviewed and some of the refinement steps are questionable. A deposition factor for ground dwelling insects is not applicable since interception is already taken into account in the RUD values for insects. It is not clear if the PT of 0.61 for blue tits (*Parus caeruleus*) is also applicable for great tit (*Parus major*).

The long-term risk assessment for mammals is based on the NOEC of 250 mg captan/kg bw/d from a 3 generation reproduction study with rats. Effects on pup body weight were observed at this dose. The experts in the EPCO meeting agreed that the next lower dose of 100 mg captan/kg bw/d should be used for the risk assessment. Based on the NOEC of 100 mg a.s./kg bw/d the long term TER trigger value of 5 would not be met for all representative uses. The TER for medium herbivorous mammals in tomatoes would be 4.24. Taking into consideration that tomato foliage is not a preferred food source; the risk to herbivorous mammals is expected to be low. The expert's meeting agreed that the PT refinement for the use in orchards needs to be supported with further data/information. The residues in foliage were calculated for a 21 day period. If the f(twa) value is correctly calculated for the minimum spray interval of 7 days the TER values would be even more markedly below the Annex VI trigger. Some information was provided by MS experts from Greece and Spain that weeds are managed and that the orchards are free from grass during most of the time giving some indication that voles are not exposed due to a lack of food. Therefore it is suggested that the risk to herbivorous mammals is assessed at Member State level taking into account the presence of potential food for herbivorous mammals.

The rapporteur Member State is still of the opinion that the original NOEC of 250 is appropriate for the risk assessment assuming that the effects on pub weight are due to reduced food uptake in the parental generation. The opinion of the PPR panel[10] (Panel on Plant Health, Plant Protection Products and their Residues) on the ecotoxicological relevance of effects observed in toxicological tests could be taken into account at Member State level to evaluate the endpoint used for the risk assessment.

The plant metabolites THPI and THPAM found in lettuce, tomato and apples were also found in metabolism studies with rats and hens after dosing with the active substance. Therefore it is assumed that the risk to birds and mammals from THPI and THPAM is covered by the risk assessment for captan.

No risk assessment for the uptake of contaminated drinking water was available. It is not clear whether exposure via this exposure route can be excluded for the representative uses. Therefore EFSA provided a risk assessment for the uptake of contaminated drinking water (according to SANCO/4145/2000) in an addendum. The acute TER values for birds and mammals exceeded the relevant Annex VI trigger values. The short-term TER values for birds were below the Annex VI trigger of 10 for the use in pome fruit (South EU), peaches/nectarines and tomatoes. The short-term risk for birds from uptake of contaminated drinking water is considered to be low for the representative use in tomatoes because the TER value of > 9.89 is very close to the Annex VI trigger and based on a NOEC from a study where no effects were observed at the highest tested dose. The long-term TER values for birds and mammals were below the Annex VI trigger value of 5.

[10] Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the choice of endpoints to assess the long term risk to mammals. The EFSA Journal (2006) 344, 1-22
http://www.efsa.europa.eu/science/ppr/ppr_opinions/1437/ppr_op_ej344_noec_mammals_en1.pdf

A refined risk assessment for the uptake of contaminated drinking water is required for the intended uses in pome fruit (South EU) and in peaches/nectarines to address the short-term risk to birds and the long-term risk to mammals. For the representative uses in pome fruit (North EU) and in tomatoes a refined risk assessment is required to address the high long-term risk posed to birds and mammals.

Overall it is concluded that the acute and short term risk to birds and the acute risk to mammals from uptake of contaminated food items is low. A high long-term risk is indicated for insectivorous birds for all representative uses and for herbivorous mammals for the representative uses in pome fruits and peaches/nectarines if grass/weeds are present as a potential food source. The first tier risk assessment resulted in a low acute risk to birds and mammals from uptake of contaminated drinking water for all representative uses. A high short-term risk to birds was indicated for the representative uses in pome fruit (South EU) and peaches/nectarines and a high long-term risk to birds and mammals was indicated for all representative uses.

5.2. RISK TO AQUATIC ORGANISMS

A new aquatic risk assessment was presented by the rapporteur Member State in the addendum of January 2005. Fish were the most sensitive group of tested organisms. The results from studies conducted under static/semistatic test conditions were used for the risk assessment. The endpoints from flow through tests would have led to an overestimation of the risk because of the rapid degradation of captan in the water-sediment system (DT_{90} whole system < 24 h). A prolonged toxicity study under semistatic conditions (renewal of test medium every 2-3 days) with rainbow trout (*Oncorhynchus mykiss*) (28 d) and the formulation Merpan 83 WP resulted in a LC_{50} of >199 µg a.s./L. Since the test result was in the range of the LC_{50} values for rainbow trout from static acute studies with technical captan (186 – 215 µg a.s./L) it was concluded that repeated pulsed exposure, which is expected from the representative uses, does not lead to build up of effects. The initial PECsw from entry via spray drift were used for the TER calculations.

The first tier TER values for fish were below the Annex VI trigger for all representative uses and a higher tier risk assessment was required.

Acute tests under static conditions with technical captan were available for six fish species. The LC_{50} values ranged from 98 (*Salmo trutta*) to 492 µg a.s./L (*Cyprinus carpio*). Differences in species sensitivity were considered to be sufficiently addressed and the acute TER trigger was lowered by the full order of magnitude from 100 to 10. The opinion of the PPR opinion[11] on the possibility of lowering the uncertainty factor if additional species were tested should be taken into account at Member State level.

The TER values for fish, based on the acute toxicity to brown trout (*Salmo trutta*) and initial PECsw, exceeded the revised trigger of 10 if no spray buffer zones of 5 m (tomatoes), 15 m (pome fruit North EU), 20 m (pome fruit South EU) and 20 m (peaches/nectarines) are applied. The opinion of the PPR

[11] Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested. The EFSA Journal (2005), 301, 1-45. http://www.efsa.europa.eu/science/ppr/ppr_opinions/1332/ppr_op_ej301_aquatic_ecotox_en1.pdf

panel (Panel on Plant health, plant protection products and their residues) on the reduction of safety factors in the aquatic risk assessment is expected to become available soon and can be taken into account at Member State level.

In addition, a probabilistic risk assessment was presented in the addendum to address the acute toxicity to fish. The expert meeting agreed in principle to the suggested risk assessment but no agreement was reached on the safety factor which should be applied to the HC_5 based on LC_{50} data.

The need for a fish early life stage study was discussed during the meeting. The meeting agreed to the proposal of the rapporteur Member State that no early life stage study is required because the DT_{50} of the substance is much less than the minimum spray interval, the acute/chronic toxicity ratio is close to 1 and the risk from repeated exposure was covered by the 28 d prolonged toxicity study under semi-static conditions with rainbow trout.

In order to assess the risk to fish from multiple applications the meeting set an open point for the rapporteur Member State to calculate the long–term TERs on the basis of the initial PECsw and the endpoint from the 28 d prolonged toxicity study with rainbow trout. No effects on fish weight, length or mortality were observed in the 28 d study with rainbow trout up to the highest tested dose of 199.2 µg a.s./L. The 28 d NOEC of 199 µg a.s./L for rainbow trout is higher than the acute LC_{50} for brown trout suggesting that the long-term risk to fish is covered by the acute risk assessment. Rainbow trout was less sensitive to captan compared to brown trout in the acute toxicity tests. But if it is assumed that the acute/chronic toxicity ratio for brown trout is close to 1 as observed for rainbow trout it can be concluded that the long-term risk to fish is covered by the acute risk assessment based on the LC_{50} for brown trout. New long-term TER calculations were submitted by the applicant and presented in the addendum of October 2005. Based on the NOEC of 199 µg a.s./L and initial PECsw values the TER values exceed the Annex VI trigger of 10 if no spray buffer zones of 10 m (pome fruits North EU), 15 m (pome fruits South EU) and 15 m (peaches/nectarines) are applied. The long-term TER trigger for tomatoes of 10 is met for the use in tomatoes.

The acute TER values for *Daphnia magna* exceeded the Annex VI trigger of 100 indicating a low risk to aquatic invertebrates for the use in tomatoes. No spray buffer zones of up to 10 m are required to achieve TER values above the relevant Annex VI trigger of 100 for the representative uses in pome fruit and peaches/nectarines. The TER calculations were based on the endpoint from a study with the formulation Merpan 80 WDG. The test result after 24 h was used instead of the 48 h value since the test medium was replaced after 24 h. The 24 h EC_{50} reflects the toxicity to daphnids after a single exposure peak while the 48 h EC_{50} would take into consideration a second exposure peak within a period of time much shorter than the suggested minimum spray interval of 7 days. Because of the rapid degradation in the water-sediment system it was considered appropriate by the rapporteur Member State to use the 24 h EC_{50} of 5.2 mg a.s./L following a single exposure peak for the acute risk assessment.

No risk assessment was conducted to address the long-term risk to aquatic invertebrates. Since the representative uses include multiple applications of up to 12 times for pome fruit (South EU) a long-term risk assessment for aquatic invertebrates is considered necessary. The endpoint from the 21 d daphnia reproduction study under semi-static test conditions (NOEC = 0.56 mg a.s./L) could be used for the long-term risk assessment. The semi-static test design reflects the expected exposure from multiple exposure peaks. The time between test medium renewal was 2-3 days and therefore the exposure regime was worst case compared to the expected exposure in the field with a minimum spray interval of 7 days. The NOEC of 0.56 mg a.s./L is higher than the endpoint used for the acute risk assessment for fish (LC_{50} = 0.098 mg/L). The aquatic risk assessment is driven by the acute risk assessment for fish, based on initial PECsw and a revised TER trigger value of 10, hence it is concluded that the long-term risk to aquatic invertebrates is covered by the risk assessment for fish.

The risk to algae was assessed as low for the representative uses in tomato and pome fruit (North EU). Based on the EbC_{50} of 1.18 mg a.s./L for the formulation Malvin 83 WP the Annex VI trigger of 10 was exceeded if a no spray buffer zone of 5 m was applied in the TER calculations for the representative uses in pome fruit (South EU) and peaches/nectarines.

The two major metabolites in the water phase THPI and THPAM were markedly less acutely toxic to fish (by about 2 orders of magnitude), daphnids and algae compared to captan. The peak PECsw were calculated as 33.23 µg THPI/L and 18.79 µg THPAM/L for a single application and as 72.35 µg THPI/L and 40.89 µg THPAM/L after multiple applications to peaches/nectarines. The resulting TER values were far above the Annex VI trigger of 100 suggesting a low acute risk to aquatic organisms from all representative uses. No data on the chronic toxicity of THPI and THPAM were available. However, the long-term risk of the metabolite THPI to fish and aquatic invertebrates is considered to be covered by the semi-static long-term tests with captan since THPI is formed rapidly by hydrolysis. Other than stated in the DAR and in the addendum of January 2005, the metabolite THPAM is not formed by hydrolysis and it is unlikely that it was present in the long-term toxicity tests with captan. Taking into account that the metabolite THPAM is of markedly lower acute toxicity to aquatic organisms compared to captan, it is considered an assessment of the long-term risk to aquatic organisms from THPAM is not required.

The acute risk to aquatic organisms from THPI and THPAM entering surface water via runoff was assessed as low by the rapporteur Member State. However the assumptions used in the calculation for runoff PECsw have not been agreed at the EU level and may not cover all runoff situations in all Member States. Therefore the risk from THPI and THPAM to aquatic organisms from entry via runoff should be considered in national assessments made by Member States.

In the EPCO expert meeting it was discussed whether the metabolite THPAI which occurred in one of the water sediment systems in amounts of > 10% needs to be further addressed in the risk assessment. The meeting decided that the potential risk from this metabolite is low because of its transient nature and low levels of formation in the other water-sediment systems.
The risk of bioaccumulation is considered as low because captan degrades rapidly in the aquatic environment and the BCF value was below the Annex VI trigger of 1000 for readily degradable substances. The rapporteur Member State estimated the water solubility of THPI and THPAM as 42778 and 53720 mg/L (calculated with EPIWIN v. 3.10 based on molecular structure). The very

high water solubility gives an indication that the bioaccumulation potential is low for both metabolites.

Overall it is concluded that the risk to the aquatic environment is high for all representative uses and risk mitigation measures such as no spray buffer zones of up to 20 m are required.

5.3. RISK TO BEES

Tests on the acute oral and contact toxicity to bees were conducted with technical captan and the formulations Merpan 83 WP and a WP formulation containing only 50% captan. No mortality was observed in the tests with technical captan up to the highest tested concentrations of 100 µg captan/bee (oral exposure) and 200 µg captan/bee (contact exposure). The risk assessment was based on the results of Merpan 83 WP for Merpan 80 WDG since the two formulations were regarded as comparable. The risk assessment for the formulation Malvin WG were based on the results of technical captan assuming that the formulation is not more toxic than the technical captan. The HQ values for the maximum application rate of 2500 g captan/ha in peaches/nectarines resulted in HQ values in the range of 12 – 25 indicating a low risk to bees from all representative uses.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Tests with 7 different arthropod species including *Aphidius rhopalosiphi* and *Typhlodromus pyri* were performed. The risk to *T. pyri* was assessed as low for all representative uses based on the first tier HQ calculations and the available field studies. 100 % mortality was observed in a glass plate test with *A. rhopalosiphi* at a dose rate of 0.6 kg a.s./ha indicating a high potential risk. No effects exceeding the ESCORT 2 trigger value of 50 % mortality were observed in extended laboratory studies with *A. rhopalosiphi* and *Coccinella septempunctata* at the highest tested dose of 6.25 kg a.s./ha suggesting a low risk to non-target arthropods. The dose of 6.25 kg a.s./ha was chosen to represent the use in peaches/nectarines of 4 applications of 2.5 kg a.s./ha with a multiple application factor (MAF) of 2.7. The application rates in the first tier tests with the other arthropod species were to low to address the risk posed from the representative uses. It was discussed during the EPCO expert meeting whether further higher tier testing with arthropod species is required since the ESCORT 2 guidance document suggests to test two additional species if the in field and the off field HQ trigger of 2 is exceeded.

The EPCO experts agreed that no further species needs to be tested since *A. rhopalosiphi* was identified as the most sensitive species out of 7 and no effects of > 50 % were observed in the extended laboratory tests at a dose of 6.25 kg a.s./ha which was considered to be high enough to cover also the risk from the other representative uses.

5.5. RISK TO EARTHWORMS

Acute toxicity studies were conducted with technical captan and the formulation Merpan 83 WP. Effects on reproduction of earthworms were examined with Merpan 80 WDG and Malvin 80 WDG. Because the log K_{ow} of captan is >2 the endpoints were divided by 2 in order to account for the high content of organic matter (>10 %) in the artificial soil of the test systems. The first tier risk assessment resulted in a low acute risk for earthworms. The lowest long-term endpoint was observed for the formulation Malvin 80 WDG. The long-term TER values calculated with the corrected NOEC of 5.8 mg a.s./kg for Malvin 80 WDG resulted in TER values of 5.78, 3.2, 4.28 and 3.09 for the representative uses in pome fruit (North EU), pome fruit (South EU), tomatoes and peaches/nectarines, respectively. The applicant argued that captan degraded rapidly in the moistened soil of the test systems (a mean DT_{50} < 1d was observed in laboratory studies) and that earthworms would have been exposed in the long-term studies mainly to the metabolites THPI and THPAM. The two metabolites don't have a strong affinity to organic matter and hence the organic matter content in the test systems is considered unlikely to have had a significant influence on the test results. If the correction factor of 2 is not applied the resulting long-term TERs would be 11.6, 6.4, 8.6 and 6.18 for the representative uses in pome fruit (North EU), pome fruit (South EU), tomatoes and peaches/nectarines, indicating a low long-term risk to earthworms.

The risk assessment for earthworms was discussed in the EPCO expert meeting. It was agreed that it is likely that captan degraded rapidly in the test system and that the earthworms were mainly exposed to the metabolites. However, the meeting noted that the DT_{50} of captan under field conditions can be significantly longer than under laboratory conditions. DT_{50} values of up to 7 days were observed in 5 field degradation studies. The experts in the meeting raised concern that the risk assessment based on the long-term studies could underestimate the risk in the field. Under drier field conditions the degradation of captan is expected to be significantly slower than under the laboratory test conditions which would lead to a higher long-term exposure of earthworms to captan. Therefore it is concluded that the long-term risk to earthworms is low under field conditions where captan degrades rapidly. No conclusion can be drawn for the long-term risk to earthworms for the representative uses under more dry soil conditions. Member States with soils where captan degrades not as rapidly as in the test systems should assess the potential long-term risk to earthworms.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

The field DT_{90} of captan is < 100 days, therefore no risk assessment for soil non-target organisms is required.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

Captan was applied as a 80 % WP formulation at dose rates of 1.5 kg a.s./ha and 15.2 kg a.s./ha. No effects of > 25 % on soil respiration or nitrification were observed at the highest dose which is about 6 times higher than the highest application rate for the representative uses. A statement on the comparability of the 80 % WP formulation to the lead formulations was accepted during the EPCO meeting. The risk to soil micro-organisms is considered to be low for all representative uses.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

A data requirement was set in the evaluation meeting to address the risk to other non-target fauna and flora since no data/information on the risk to other non-target organisms was available.

A study on herbicidal effects of captan was submitted by the applicant and summarised in the addendum of October 2005. No phytotoxic effects were observed in a test with 10 different crop plants (including both monocotyledon and dicotyledon plant species) at dose rates of 5.4 to 9 kg a.s./ha indicating a low risk to non-target organisms. The addendum of October 2005 is not peer reviewed.

5.9. Risk to biological methods of sewage treatment

No test with sewage sludge and captan were performed. It was discussed during the EPCO expert meeting whether a study with sewage sludge needs to be performed. It was agreed that no study is required and that the risk to biological methods of sewage treatment is expected to be low because of the very rapid degradation of captan in the water-sediment system.

6. Residue definitions

Soil

Definitions for risk assessment: captan, THPI[12], THPAM[13]

Definitions for monitoring: captan

Water

Ground water

Definitions for exposure assessment: captan, THPI, THPAM

Definitions for monitoring: identified mammalian toxicological data gaps need to be closed before a residue definition can be proposed.

Surface water

Definitions for risk assessment: water: captan, THPI, THPAM

sediment: THPI, THPAI[14]

Definitions for monitoring: identified mammalian toxicological data gaps need to be closed before a residue definition can be proposed.

Air

Definitions for risk assessment: captan

Definitions for monitoring: captan

Food of plant origin

Definitions for risk assessment: sum of captan and THPI, expressed as captan

Definitions for monitoring: sum of captan and THPI, expressed as captan

[12] THPI: 1,2,3,6-tetrahydrophthalimide

[13] THPAM: tetrahydrophthalamic acid or *cis/trans*-6-carbamoyl-3-cyclohexene-1 carboxylic acid

[14] THPAI: tetrahydrophthalic acid

Food of animal origin

Definitions for risk assessment: sum of THPI, 3-OH THPI and 5-OH THPI expressed as captan

Definitions for monitoring: sum of THPI, 3-OH THPI and 5-OH THPI expressed as captan

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
captan	Very low to low persistence ($DT_{50\ lab}$ = 0.45-1.09 d, 20°C, -10kPa soil moisture, $DT_{50\ field}$ = 0.33-7.04 d)	The acute risk of captan to earthworms is low (acute TERs ranged from 138.1 to 258.9), the extend of the long-term risk to earthworms under dry soil conditions is uncertain, the risk to soil micro-organisms is low
THPI	Low to moderate persistence ($DT_{50\ lab}$ = 5.9-14.4 d, 20°C, 40% MWHC)	No toxicity tests were conducted with the metabolite and soil dwelling organisms. Due to rapid degradation of captan it was considered likely that the metabolite was present in the studies with captan and the risk from THPI to earthworms and soil micro-organisms is considered to be covered by the tests with captan. Hence the risk of THPI to earthworms and soil micro organisms is considered to be low.
THPAM	Low to moderate persistence ($DT_{50\ lab}$ = 6-11.1 d, 20°C, 40% MWHC)	No toxicity tests were conducted with the metabolite and soil dwelling organisms. Due to rapid degradation of captan it was considered likely that the metabolite was present in the studies with captan and that the risk from THPAM to earthworms and soil micro-organisms is considered to be covered by the tests with captan. Hence the risk of THPAM to earthworms and soil micro organisms is considered to be low.

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 μg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter) Apples (worst case application pattern for leaching)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
captan	No reliable data, literature estimates indicate high to medium mobility	No	Yes	Yes	Yes
THPI	Very high mobility (K_{foc} = 5.7-11L/kg)	5 northern scenarios and Piacenza 1.3-2.7μg/L 3 remaining southern scenarios < 0.1μg/L	No	LD_{50}> 10 000 mg/kg bw not mutagenic short term NOAEL 75 mg/kg bw/day, not embryotoxic Mechanistic studies indicate no potential of carcinogenic and reproductive effects	The toxicity and the risk to aquatic organisms are lower than for captan
THPAM	Very high to high mobility (K_{foc} = 4.5-100L/kg) pH dependant highest mobility at high soil pH	5 northern scenarios and Piacenza 0.9-5.9μg/L Sevilla and Thiva 0.1&0.2 μg/L Porto< 0.1μg/L	No	No acute toxicity studies or studies on carcinogenetic potential are available. Not genotoxic	The toxicity and the risk to aquatic organisms are lower than for captan.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
captan	See point 5.2.
THPI	The toxicity and the risk to aquatic organisms are lower than for captan
THPAM	The toxicity and the risk to aquatic organisms are lower than for captan.
THPAI	No toxicity data are available. The potential risk from this metabolite is considered to be low because of its transient nature and low levels of formation in the water-sediment systems.

Air

Compound (name and/or code)	Toxicology
captan	Toxic via inhalation; LC_{50} 0.67 µg/L

LIST OF STUDIES TO BE GENERATED,-STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Data to confirm the identity of certain impurities revealed by chemical analysis must be provided to address the requirement of the Directive on the specificity of the method(s) (relevant for both applicants, date of submission unknown, data gap identified at the expert meeting, refer to chapter 1).
- Clarification with respect to the proposed maximum levels for impurity R016907 in the technical material specification (relevant for the Makhteshim source, data gap identified at the expert meeting and confirmed by the rapporteur Member State in addendum to Volume 4, October 2005; rapporteur Member State has received recently (February 2006) an new study (updated specification), but has not evaluated it; refer to chapter 1).
- Spectra for the relevant impurities perchlorometylmercaptan (PMM) and folpet (in case of PMM relevant for both applicants, in case of folpet relevant for Arysta, date of submission unknown, data gap identified at the expert meeting, refer to chapter 1).
- Applicants to provide the compositions for the preparations "captan 80 WDG" and "Merpan 83 WP" to be able to confirm that these preparations (used in certain tests) are identical to the respective representative ones (date of submission unknown, provided clarifications were not accepted at the expert meeting; refer to chapter 1).
- An analytical method for the determination of impurity R290236 in the technical material (relevant for the Makhteshim source, data gap identified at the expert meeting; method submitted to the rapporteur Member State and assessed in addendum to Volume 4, October 2005, but neither peer-reviewed by other MS nor discussed in an expert meeting; refer to chapter 1).
- A validated analytical method including an ILV for the determination of THPI in food of plant origin (matrices with high water content) according to Directive 96/46/EC (data gap identified at the expert meeting, method (without ILV) submitted to the rapporteur Member State and assessed in addendum to Volume 3, B.5, October 2005, but neither peer-reviewed by other MS nor discussed in an expert meeting; rapporteur Member State has received recently (February 2006) a new ILV, but has not evaluated it; refer to chapter 1).
- A validated analytical method including an ILV for the determination of 3-OH-THPI and 5-OH-THPI in food of animal origin according to Directive 96/46/EC (data gap identified in the DAR and agreed at the expert meeting; rapporteur Member State has received recently (February 2006) a study, but has not evaluated it; refer to chapter 1).
- An analytical method for the determination of captan in air (data gap identified in the DAR and confirmed by the expert meeting, the submitted position paper was not accepted by the expert meeting; rapporteur Member State has received recently (February 2006) a study, but has not evaluated it; refer to chapter 1).
- An analytical method for the determination of residues of captan in blood and animal tissues to cover the requirement of Directive 96/46/EC for substance classified as very toxic (Annex point 4.2.5) (data requirement identified by the expert meeting, May 2005 and by the EFSA after the

expert meeting; rapporteur Member State has received recently (February 2006) a new study, but has not evaluated it; refer to chapter 1).

- Information addressing the carcinogenic potential of the metabolite THPI found in ground water modelling above the trigger 0.75 µg/L (data requirement identified by EFSA after the expert meeting; refer to chapter 2).
- An acute toxicity study of the metabolite THPAM found in ground water modelling above the trigger 0.75 µg/L (data requirement identified by EFSA after the expert meeting; submission date unknown; refer to chapter 2).
- Information addressing the carcinogenic potential of the metabolite THPAM found in ground water modelling above the trigger 0.75 µg/L (data requirement identified by EFSA after the expert meeting; submission date unknown; refer to chapter 2).
- Studies on the effect of processing on the nature of residues in representative hydrolytic conditions (simulating pasteurisation, baking, brewing, boiling and sterilisation) (relevant for all representative uses; studies ongoing, submission date unknown; refer to point 3.1.1).
- Processing studies for peaches and nectarines (balance study and 3 follow-up studies) (relevant for representative uses on peaches and nectarines); studies ongoing, submission expected in March 2006; refer to point 3.1.1).
- Feeding study in lactating ruminant in order to establish MRLs for captan metabolites (THPI, 3-OH THPI and 5-OH THPI) (relevant for representative uses in pome fruits; data gap identified by EFSA as a consequence of the residue definitions established in the EPCO expert meeting; study available and reported by the RMS in the addendum of July 2005 but not peer-reviewed; refer to point 3.2).
- Argumentation regarding the assessment of the potential occurrence of the metabolite THCY in soil under field conditions and its potential leaching to groundwater (data were submitted to the rapporteur Member State and summarised; refer to point 4.1.1).
- Step 1 and 2 FOCUS surface water calculations (data were submitted to the rapporteur Member State and have been summarised; refer to point 4.2.1).
- A refined risk assessment is required to address the long-term risk to birds and mammals from uptake of contaminated food items (relevant for all representative uses; data gap identified in the EPCO expert meeting in April 2005; submitted in October 2005, refer to point 5.1).
- A refined risk assessment is required to address the short-term risk birds in pome fruit (South EU) and peaches/nectarines and the long-term risk to birds and mammals from uptake of contaminated drinking water (data gap identified by EFSA, not peer reviewed; submission date unknown; refer to point 5.1).
- Data to address the risk to other non-target organisms (relevant for all representative uses; data gap identified in the EPCO expert meeting in April 2005; study submitted in October 2005, refer to point 5.8).

Conclusions and Recommendations

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as fungicide as proposed by the applicant which comprises foliar spraying to control a broad range of fungi in pome fruit, tomatoes and peaches at application rate up 2.4 kg (pome fruit), 1.8 kg (tomatoes) and 2.5 kg (peaches) captan per hectare. Captan can be used only as fungicide.

The representative formulated products for the evaluation were "Merpan 80 WDG", registered in some Member State of the EU and "Malvin WG", registered under different trade names in Belgium, the Netherlands and the UK. Both formulations are coded as water dispersible granule (WG).

No adequate analytical methods are available to monitor all the compounds given in the residue definitions for food. For the environmental compartment water no enforcement method is needed for the determination of captan due to the fact that the DT_{90} values are less than 3 days. In case of soil the DT_{90} values are only partly (3.6 d) above the 3 day trigger value given in SANCO/825/00. However, analytical methods are available for the determination of captan and THPI in soil and water. For the other matrices (air and blood) no adequate method is available to monitor all compounds given in the respective residue definition.

A multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that at least limited quality control measurements of the plant protection products are possible.

Captan is of low toxicity by the oral and dermal routes but it is toxic via inhalation (classification **R23 'Toxic by Inhalation'** proposed). It is not irritating to the skin but severely irritating to eyes, thus classification as **R41 'Risk of serious damage to eyes'** is proposed. It is a skin sensitiser (proposal for **R43 'May cause sensitisation by skin contact'**). Overall, captan did not show any genotoxic potential but was found to cause duodenal tumours in mice, therefore the classification **category 3, R 40** is proposed by the majority of the experts. A clear NOAEL of 60.9 mg/kg bw/day for duodenal tumours in mice can be established. Captan is not teratogenic or embryotoxic by itself but can affect the embryonic development by inducing specific alterations in maternal gastro-intestinal physiology. The Acceptable Daily Intake (ADI) and the Acceptable Operator Exposure Level (AOEL) are 0.1 mg/kg bw/day, the Acute Reference Dose (ARfD) is 0.3 mg/kg bw, with an assessment factor of 100. Operator exposure estimates (German model) accounts for 56 to 91% (hand held and tractor mounted application) of the AOEL when PPE is worn. The exposure of bystanders is approximately 25% of the AOEL. Both modelling and field exposure data indicate that the exposure of workers involved with the handling of crops treated with is below the AOEL for re-entry at 14 days.

The metabolism of captan in plants has been adequately elucidated. Captan forms the major part of residue and only one metabolite, THPI has been identified as contributing in a significant way to the toxicological burden. The levels of THPI are drastically increased in case of processing of treated commodities involving a heating step. However the information on the behaviour of captan under processing conditions should be further investigated by degradation studies under representative hydrolytic conditions.

Although argumentation has been presented tending to demonstrate that THPI is of lower toxicity than the parent compound, the available data are not sufficient to firmly conclude on its toxicological non relevance. Therefore the residue definition in plant commodities should be the sum of captan and THPI.

Supervised residue trials have been conducted allowing to determine the needed MRLs for the representative uses and to conduct acute and chronic dietary exposure assessments. Residues of captan and of its metabolite THPI are not expected in succeeding crops. In accordance with the proposed mode of application in representative uses, MRLs should be established at 10 mg/kg for apples, pears, peaches and nectarines. However, at this level, residues present an acute risk for the safety of the consumer. Only the use on tomatoes for which an MRL of 2 mg/kg may be proposed leads to consumer intakes below the trigger toxicological levels of acceptable exposure.

The animal metabolism of captan is extensive, and no captan as such can be present in animal commodities. Only metabolites were identified in edible animal tissues: THPI, 3-OH THPI and 5-OH THPI. These metabolites should be included in the residue definition for animal products. Metabolism studies suggest that these metabolites should not be present above usual Limits Of Quantification of monitoring analysis, but existing feeding studies should be evaluated to confirm that expectation.

Sufficient satisfactory information on the fate and behaviour of captan in environmental matrices is available to complete an appropriate EU level environmental exposure assessment. For the applied for intended uses, FOCUS groundwater modelling indicates contamination of vulnerable groundwater at concentrations > 0.1µg/L (the parametric drinking water limit) is not expected for parent captan. However annual average leachate concentrations of the major soil metabolites THPI and THPAM leaving the top 1m soil layer were predicted by FOCUS groundwater modelling to be up to ca. 2.7 and 5.9µg/L respectively for the applied for representative use on Pome fruit. Groundwater non relevance assessments were therefore triggered for these metabolites. However their contribution to the global exposure of the consumer to residues of captan and its metabolites is very limited. For other applied for representative uses, some scenarios gave PECgw values <0.1 µg/L for both THPI and THPAM. These were: South EU pome fruit (Porto), peaches/nectarines (Porto, Sevilla, Thiva), tomatoes (Porto, Sevilla, Thiva). For the applied for representative uses, Member States need to address the drainage and runoff routes of entry to surface water for the soil metabolites THPI and THPAM in their national assessments if captan is included in Annex 1, as these routes of entry to surface water have not been assessed (drainage) or adequately assessed (runoff) for these soil metabolites in the available peer reviewed EU level assessment.

A high long-term risk is indicated for insectivorous birds for all representative uses and for herbivorous mammals for the representative uses in pome fruits and peaches/nectarines. Some indication was provided that no grass/weeds are available as a potential food source for herbivorous mammals in southern European countries. Therefore it is suggested that the risk to herbivorous mammals should be assessed at Member State level. The first tier risk assessment resulted in a low acute risk to birds and mammals from uptake of contaminated drinking water for all representative uses. A high short-term risk to birds was indicated for the representative uses in pome fruit (South EU) and peaches/nectarines and a high long-term risk to birds and mammals was indicated for all representative uses. Risk mitigation measures such as no spray buffer zones of 5 m, 15 m and 20 m are required for the representative uses in tomatoes, pome fruit (North EU), pome fruit (South EU) and peaches/nectarines.

The acute risk to earthworms was assessed as low for all representative uses. The long-term risk to earthworms based on laboratory studies could lead to a potential underestimation of the risk to earthworms for dry soil conditions. It is proposed that Member States should assess the potential long-term risk for their particular soil conditions. The risk to bees, other non-target arthropods, other soil non-target organisms, soil non-target micro-organisms and biological methods of sewage treatment is considered to be low for all representative uses.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- MS may wish to consider for "Malwin WG" whether it is necessary for a phrase like "Agitation must be used during mixing and loading and until spraying complete" to be added to the label (refer to chapter 1).
- The use of PPE (gloves during mixing/loading and application for applications to tomato using tractor-mounted sprayer and hand-held knapsack sprayer; gloves during mixing/loading and gloves and protective garment/sturdy footwear during application to orchard crops using tractor mounted airblast sprayer) has to be considered in order to reach exposure levels below the AOEL.
- Risk mitigation measures such as no spray buffer zones of 5 m (tomatoes), 15 m (pome fruit North EU) and 20 m (pome fruit South EU and peaches/nectarines) are required (refer to point 5.2).

Critical areas of concern

- At the moment no specification for the technical material can be given (refer to chapter 1 and to the list of studies to be generated,-still ongoing or available but not peer reviewed).
- For food of plant origin, no validated analytical methods for monitoring purposes are available (refer to chapter 1 and to the list of studies to be generated,–still ongoing or available but not peer reviewed).
- Captan is toxic by inhalation, severely irritating to eyes (R41 ‘Risk of serious damage to eyes’), it is a skin sensitiser (R43 ‘May cause sensitisation by skin contact’) and carcinogenic in mice (category 3, R 40).

- Toxicological data lacks in relation to studies on acute toxicity and assessment of the carcinogenic potential for the metabolite THPAM which is above the trigger 0.75 μg/L in ground water (according to modelling for some crop scenario combinations).
- An acute dietary risk has been identified, particularly for infant and toddlers, in case of consumption of treated apples, pears, peaches and nectarines.
- Based on the risk assessment according to SANCO 4145/2000 and on the peer reviewed data to refine the risk assessment a high long-term risk to birds and mammals cannot be excluded for all representative uses.
- A high risk to the aquatic environment was identified for all representative uses requiring risk mitigation measures such as no spray buffer zones of up to 20 m.

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

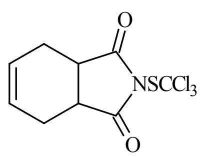
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Captan
Function (e.g. fungicide)	Fungicide

Rapporteur Member State	Italy
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide
Chemical name (CA) ‡	3a, 4, 7, 7a-tetrahydro-2-[(trichloromethylthio)]-1*H*-isoindole-1,3(2H)-dione
CIPAC No ‡	40
CAS No ‡	133-06-02
EEC No (EINECS or ELINCS) ‡	613-044-00-6
FAO Specification ‡ (including year of publication)	910 g/kg ± 30 g/kg (FAO Specification 40/TC/S 1990) Perchloromethylmercaptan (R005406) maximum level of 10 g/kg; loss on drying, maximum level 15.0 g/kg.
Minimum purity of the active substance as manufactured ‡ (g/kg)	930 g/kg (Makhteshim) 910 g/kg (Arysta) ratio *cis/trans* isomers: 100:0
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	*under discussion*
Molecular formula ‡	$C_9H_8Cl_3NO_2S$
Molecular mass ‡	300.59
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	173 – 175 °C (99.2% purity) 172 °C (99.8% purity)
Boiling point (state purity) ‡	Not determinable – The test substance decomposes below the boiling point
Temperature of decomposition	Decomposition on melting starting at 173 °C (98.9% purity)
Appearance (state purity) ‡	Cream solid (90.3% purity) White solid (99.8% purity)
Relative density (state purity) ‡	1.65 (99.2% purity) 1.71 at 20 °C (99.8% purity)
Surface tension	72.4 mN m^{-1} at 20 °C (90.3% purity)
Vapour pressure (in Pa, state temperature) ‡	4.2 x 10^{-6} Pa (20 °C) (99.8% purity) 2.01 x 10^{-4} Pa (50 °C) (98.95% purity)
Henry's law constant (Pa m^3 mol^{-1}) ‡	3 x 10^{-4} Pa.m^3.mol^{-1} using purified water data 3 x 10^{-4} Pa.m^3.mol^{-1} using pH 5 buffered water data 2 x 10^{-4} Pa.m^3.mol^{-1} using pH 7 buffered water data (at 20 °C)
Solubility in water ‡ (g/L or mg/L, state temperature)	4.9 mg/L in purified water (20 °C) 4.8 mg/L at pH 5 (20 °C); 5.2 mg/L at pH 7 (20 °C); 3.77 mg/L (25 °C); 2.67 mg/L (15 °C)
Solubility in organic solvents ‡ (in g/L or mg/L, state temperature)	Hexane 0.04 g/kg (20 °C) *n*-octanol 1 g/kg (20 °C) methanol 4 g/kg (20 °C) xylenes 9 g/kg (20 °C) ethyl acetate 25 g/kg (20 °C) acetonitrile 31 g/kg (20 °C) acetone 38 g/kg (20 °C) 1,2-dichloroethane 41 g/kg (20 °C)
Partition co-efficient (log POW) ‡ (state pH and temperature)	2.5 at 20 °C (pH 5) 2.57 at 25 °C (pH 7)
Hydrolytic stability (DT_{50}) ‡ (state pH and temperature)	12.11 hours (pH 4; 25 °C) 1.66 hours (pH 4; 40 °C) 2.61 hours (pH 7; 25 °C) 0.51 hours (pH 7; 40 °C) too fast to measure (pH 9; 25 °C and 40 °C)

Dissociation constant ‡	Captan does not dissociate at the pH ranges encountered in aqueous solution.
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	The molar extinction coefficient ε (L.mol-1.cm-1): 4 at 290 nm, 325 at 247.2 nm and 303 at 237.3 nm (acetonitrile); 312 at 243 nm (purified water:methanol 1:1 v/v); 330 at 243 nm (aqueous hydrochloric acid: methanol 1:1) 12.6 and 195 at 343 and 286 nm (aqueous sodium hydroxide: methanol 1:1)
Photostability (DT_{50}) ‡ (aqueous, sunlight, state pH)	Photolysis either does not occur or is very slow relative to hydrolysis.
Quantum yield of direct phototransformation in water at λ > 290 nm ‡	Due to the rapid chemical hydrolysis of captan the quantum yield is impossible to measure experimentally.
Flammability ‡	Not classified as flammable (purity 90.3%).
Explosive properties ‡	No data submitted – Justification given Captan does not contain functional groups known to confer or enhance explosivity. Therefore it is expected to be non-explosive.

Summary of representative uses evaluated*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Pome fruit	North EU	'Merpan' 80 WDG / 'Malvin' WG	F	Scab and *Nectria*	WG	800 g/kg	Airblast foliar spray; upwards/ sideways	From BBCH 53 / April	9 - 10	7 d	0.125	1000	1.25	14	[1] [2]
	South EU	'Merpan' 80 WDG / 'Malvin' WG	F	Scab and *Nectria*	WG	800 g/kg	Airblast foliar spray; upwards/ sideways	From BBCH 69 / April	9 + 3 [a]	7 d	0.125 0.24	1000 1000	1.25 2.4	14	[1] [2]
Tomatoes	South EU	'Merpan' 80 WDG / 'Malvin' WG	F	Various diseases	WG	800 g/kg	Foliar spray; down-wards	From BBCH 60 to 87	4	7 d	0.15	1200	1.8	14	[2]
Peaches/ nectarines	South EU	'Merpan' 80 WDG / 'Malvin' WG	F	Various diseases	WG	800 g/kg	Airblast foliar spray; upwards/ sideways	From BBCH 69: petal fall	4	7 d	0.25	1000	2.5	7	[1] [2]

[a] Nine applications at 1.25 kg a.s./ha (scab control) followed by three applications at 2.4 kg a.s/ha (*Nectria* control).

[1] An acute dietary risk for the consumer has been identified in section 3
[2] The risk assessment has revealed a risk/data gap in section 5.

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical a.s. (principle of method)	Captan technical material is dissolved in acetonitrile and analysed by HPLC with diode array ultraviolet (UV) detection. HPLC analysis is reverse-phase with acetonitrile/water mobile phase (detector wavelength 220 nm). Further impurities are analysed by dilution of the technical material in dichloromethane and determined by capillary GC with thermal conductivity detection (TCD). In addition, there are existing CIPAC methods (40/TC/M 3/- and 40/TC/M 4/-) for captan in technical material.
Impurities in technical a.s. (principle of method)	Reverse phase HPLC with UV-DAD detection as described for captan technical material. Capillary GC with flame ionisation detection (FID). packed- column GC/TCD. packed-column GC/FID. gravimetry Karl Fischer titration
Plant protection product (principle of method)	Merpan 80 WDG: samples are dissolved in acetonitrile acidified with phosphoric acid. Determination is by reverse phase high performance liquid chromatography (RP-HPLC) with ultraviolet (UV) detection. Nucleosil ODS column with an acetonitrile/water/phosphoric acid mobile phase and a detector wavelength of 210 nm. Malvin 92 WG: samples are treated with dichloro-methane containing2,4-dinitro-acetanilide as internal standard. Determination is by normal phase HPLC with UV detection at 254 nm; mobile phase dichloromethane:ethanol 999:1.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	1. Residues of captan are extracted by blending the crop samples in acetone. The filtered extract is diluted with water and residues are extracted into dichloromethane by liquid-liquid partition. Extracts are purified using an activated carbon-silica gel column. Determination of captan is by gas chromatography (GC) with electron capture detection. LOQ = 0.01 mg/kg.

	2. Residues of captan are extracted by blending the crop samples in the presence of sodium sulphate, ethyl acetate and ortho-phosphoric acid. The filtered extract is washed with phosphoric acid solution, evaporated to dryness and reconstituted in dichloromethane. Purification and analyte separation is achieved by use of a combination of nuchar/activated silica gel column, GPC and silica gel column. Determination is by packed-column GC with electrolytic conductivity detection (operating in the halogen mode) or electron capture detection. LOQ = from 0.02 to 0.05 mg/kg. 3. Captan and THPI are extracted from tomato processed fractions and purified according the protocol above described (point 2). Determination is by capillary GC/ECD for captan and capillary GC/NPD for THPI. LOQ = 0.02 mg/kg for captan and THPI
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Residues of captan are extracted by blending the samples with acetone and ortho-phosphoric acid. The acetone in the filtered extract is removed by evaporation and the sample is purified by passage through a chromatography column containing sodium sulphate and Extrelut. The extracts are purified by gel permeation chromatography. For muscle and liver samples, an addition clean-up using a silica gel solid phase extraction cartridge is necessary. Determination of captan is by capillary GC with electron capture detection. The LOQ is 0.005 mg/kg for milk, 0.02 mg/kg for kidney and fat and 0.03 mg/kg for liver and muscle.
Soil (principle of method and LOQ)	1. Extraction of captan and THPI from soil is by blending with acetone and acidic methanol. Captan and THPI residues are separated by selective partitioning (captan into hexane and THPI into dichloromethane). The captan extract is purified by florisil column chromatography and clean-up of the THPI extract is by liquid-liquid partition at pH 11. Determination of captan is by packed-column GC with electron capture detection and determination of THPI is by packed or capillary GC with nitrogen-phosphorus detection. LOQ = 0.02 mg/kg for captan and THPI.

	2. A second confirmatory method is presented based on shaking soil with aqueous acetonitrile, clean up by activated carbon solid phase extraction and determination by GC/MS. LOQ is 0.02 mg/kg for both compounds.
Water (principle of method and LOQ)	Not required (DT_{90} in water less than 3 days)
Air (principle of method and LOQ)	Residues of captan are extracted from air by passage through an XAD-2 sorbent tube for six hours at a flow rate of 2 L/min (total volume 0.72 m3). Captan residues are eluted from the sorbent with acetone using a mechanical shaker. Determination is by capillary GC with electron capture detection. LOQ = 0.06 µg/m_3 *Validation required – Open point*
Body fluids and tissues (principle of method and LOQ)	*No specific methods are available for human body fluids and tissues. Open point.*

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None

Appendix 1.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Absorbed rapidly in rats following oral administration (81%). High dose levels (500 mg/kg bw) incompletely absorbed.
Distribution ‡	Widely distributed following initial absorption, but tissue residues negligible because of rapid excretion.
Potential for accumulation ‡	Very low.
Rate and extent of excretion ‡	Rapid excretion via urine and faeces.
Metabolism in animals ‡	Metabolic cleavage of the nitrogen-sulphur bond.
Toxicologically significant compounds ‡ (animals, plants and environment)	Captan

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2,000 mg/kg bw (rat, mouse)	
Rat LD_{50} dermal ‡	> 2,000 mg/kg bw (rat, rabbit)	
Rat LC_{50} inhalation ‡	0.67 mg/L	**T; R23**
Skin irritation ‡	Not irritating.	
Eye irritation ‡	Severely irritating	**R41**
Skin sensitization ‡ (test method used and result)	Sensiter (Magnusson and Kligman)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Minor effects (emesis) in dog following oral administration, responses to taste and physical nature of test substance rather than toxicological effects. Treatment-related effects in rabbit following dermal exposure were decreased body weight, body weight gain and food consumption. Treatment-related effects in rat following inhalation exposure were confined to the respiratory tract and consistent with exposure to an irritant particulate.
Lowest relevant oral NOAEL / NOEL ‡	60 mg/kg bw/day (90 day, dog)
Lowest relevant dermal NOAEL / NOEL ‡	110 mg/kg bw/day (21-day rabbit)
Lowest relevant inhalation NOAEL / NOEL ‡	0.60 µg/L (90-day rat)

Genotoxicity ‡ (Annex IIA, point 5.4)

…………………………………………………………	Genotoxic *in vitro*, diminished/offset by metabolic activation, glutathione or cysteine. Not genotoxic *in vivo*.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Reduced weight gain at intakes of 98 mg/kg bw/day and above. At 250 mg/kg bw/day, increased liver weight and associated hepatocellular hypertrophy (rat).
Lowest relevant NOAEL / NOEL ‡	25 mg/kg bw/day
Carcinogenicity ‡	Not carcinogenic in rat. Carcinogenic (duodenal tumours) in mice, non-genotoxic mechanism, clear NOAEL established (61 and 70 mg/kg bw/day in male and females, respectively). **Cat 3, R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Reduced weight of offspring. No effect on fertility or general reproductive performance.
Lowest relevant reproductive NOAEL / NOEL ‡	500 mg/kg bw/day (reproductive effects) 25 mg/kg bw/day (parental toxicity) 12.5 mg/kg bw/day (offspring toxicity)
Developmental target / critical effect ‡	Foetotoxicity at high doses
Lowest relevant developmental NOAEL / NOEL ‡	Embryofetal and maternal: 10 mg/kg bw/day (rabbit) Embryofetal: 90 mg/kg bw/day (rat) Maternal: 18 mg/kg bw/day (rat) **R63?**

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

…………………………………………………………	No studies conducted. Captan is not a substance of similar or related structure to those capable of inducing delayed neurotoxicity.

Other toxicological studies ‡ (Annex IIA, point 5.8)

Metabolites	THPI: Acute oral LD_{50} > 10 000 mg/kg bw THPI was negative in the Ames test, and not embryotoxic or teratogenic in a rabbit embryotoxicity study. Mechanistic data show no potential for carcinogenic and reproductive effects. THPAM: Found in rat metabolism studies No genotoxicological potential 3-OH-THPI and 5-OH-THPI: No toxicological studies performed Found in rat metabolism studies THPI epoxide: No toxicological studies performed
Mechanistic studies	Studies were carried out to investigate the role of covalent binding of captan to DNA and the role of hyperplasia in the gastrointestinal tract in the mechanism of oncogenicity of captan in the mouse.

Medical data ‡ (Annex IIA, point 5.9)

....	No epidemiological evidence of carcinogenicity in humans. Few cases of acute injury/illness in humans. No cases were reported of human poisoning.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.1 mg/kg bw/day	teratogenicity study in rabbits	100
AOEL ‡	0.1 mg/kg bw/day	teratogenicity study in rabbits	100
ARfD ‡	0.3 mg/kg bw/day	teratogenicity study in rabbits	100

Dermal absorption (Annex IIIA, point 7.3)

Merpan 80 WDG and or Malvin WG	10% based on an *in vivo* study.

Acceptable exposure scenarios (including method of calculation)

Operator	Exposure below the AOEL when operators wear protective clothing (German model) for all proposed uses (% of AOEL). without PPE with PPE Tractor mounted Drawn airblast 393% 56% Filed crop sprayer 212% 91% Hand held 166% 86%
Workers	Exposure above the AOEL after 7 days from the application (115% German model and data on dislodgeable residues 107% field study) Exposure below the AOEL after 14 days from the application (35.5% German model 75% field study)
Bystanders	Exposure accounts for 25% of the AOEL (estimate based on drift data).

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	T; Toxic R 23 Toxic by inhalation R 40 Limited evidence of carcinogenic effect R 41 Risk of serious damage to eyes R 43 May cause sensitisation by skin contact R 63? Possible risk of harm to the unborn child

Appendix 1.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruits (tomato, apple) Leafy crops (lettuce)
Rotational crops	Wheat, lettuce, sugar beet
Plant residue definition for monitoring	Sum of captan and THPI expressed as captan
Plant residue definition for risk assessment	Sum of captan and THPI expressed as captan
Conversion factor (monitoring to risk assessment)	-

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Goat, hen
Animal residue definition for monitoring	Sum of THPI, 3-OH THPI and 5-OH THPI expressed as Captan
Animal residue definition for risk assessment	Sum of THPI, 3-OH THPI and 5-OH THPI expressed as Captan
Conversion factor (monitoring to risk assessment)	-
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

....	Residues in wheat grain, lettuce plants and beet roots and tops harvested at the normal harvest time from crops planted 34 days after application of a worst-case treatment were less than 0.02 mg captan equivalents/kg and no captan was detected in the crops. Residues of captan are not expected in crops grown in normal rotation after crops treated with captan according to the proposed GAPs.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

....	Captan and THPI are stable for at least 9 months in plant substrates, when stored entire or coarsely ground at -20°C. Progressive degradation of captan to THPI in macerated commodities during deep freeze storage.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes, expected intakes for beef and diary cattle are 0.35 and 0.10 mg captan eq/kg bw/d respectively	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Metabolism studies not fully conclusive on that point	Not relevant	Not relevant
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle Liver Kidney Fat	Feeding study required and available but not peer-reviewed.	Study not required	Study not required
Milk			
Eggs		Study not required	

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP Sum of captan and THPI expressed as captan (mg/kg) (a)	Recommendation/comments	MRL	STMR (b)
Apples, pears	Northern	0.81, 1.3, 1.4, 1.48, 1.48, 2.16, 2.88, 3.24, 3.36, 4.18	Residue levels were not related to formulation type Values for apples and pears are considered together. Trials relevant to the critical GAP are those conducted in Northern EU crops in which captan was applied at 1.245 to 1.494 kg a.s./ha.	10 mg/kg	1.86 mg/kg
	Southern	1.50, 1.55, 2.44, 3.1, 3.72, 6.0, 9.6	Residue levels were not related to formulation type. Values for apples and pears are considered together. Trials relevant to the critical GAP are those conducted in Southern EU crops in which captan was applied at 2.3 to 2.9 kg a.s./ha with a PHI of 14 days.	10 mg/kg	3.1 mg/kg
Tomatoes	Southern	0.23, 0.26, 0.41, 0.43, 0.70, 0.82, 1.05, 1.52	No effect of formulation type on residue levels. The relevant trials to support the existing MRL are those in which captan was applied at 1.35 to 2.25 kg a.s./ha with a PHI of 13 to 15 days.	2 mg/kg	0.57 mg/kg
Peaches, nectarines	Southern	2.82, 3.10, 3.62, 4.54, 5.5, 6.48, 6.92, 9.44	No effect of formulation type on residue levels. Values for peaches and nectarines are considered together.	10 mg/kg	5.02 mg/kg

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.1 mg/kg bw/day
TMDI (European Diet) (% ADI)	13% of the ADI
TMDI (% ADI) according to national (to be specified) diets	40, 50, 230 and 120% of the ADI for adults, children, toddlers and infants respectively according to British diet. 44% of the ADI for children according to German diet
NEDI (% ADI)	70 and 40% of the ADI for toddlers and infants respectively according to British diet
Factors included in NEDI	STMRs from supervised residue trials
Contribution of metabolites present in ground water to the ADI exhaustion (WHO guidelines for drinking water quality)	1%, 2% and 2% for adults, children and infants respectively, for the highest ground water concentrations of THPI and THPAM predicted by FOCUS modelling
ARfD	0.3 mg/kg bw
NESTI (% ARfD) according to national (to be specified) large portion consumption data	According to British large portion consumption data for apples, pears, peaches and tomatoes: 50, 54, 41 and 7% of the ARfD respectively for adults; 327, 241, 115, and 32% of the ARfD respectively for infants; 240, 255, 183 and 27% of the ARfD respectively for toddlers
Factors included in IESTI and NESTI	Variability factor of 7 for all commodities examined, MRL instead of HR

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Apple: fruit to pasteurised juice	9	0.9	Not calculated
Apple: fruit to puree	13	0.8	Not calculated
Apple: fruit to wet pomace	6	2	Not calculated
Tomato: fruit to puree	4	1.2	Not calculated
Tomato: fruit to juice	4	0.5	Not calculated
Tomato: fruit to canned fruit	2	0.5	Not calculated
Tomato: fruit to ketchup	4	1.6	Not calculated

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Apples, pears, peaches and nectarines	10 mg/kg
Tomatoes	2 mg/kg
Animal products	Feeding studies in lactating goats not peer-reviewed

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	trichloromethyl- C^{14}: 80.8-90.8%AR after 28-30 days; carbonyl-C^{14}: 91.5%AR after 122 days
Non-extractable residues after 100 days ‡	trichloromethyl- C^{14};14%AR after 30 days carbonyl-C^{14}: 7.6%AR after 122 days
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	THPI[15] max 66%AR after 7 days, THPAM[16] max 16.8%AR after 14 days

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	Captan DT_{90} <7 days Major metabolites: THPI (46.4%AR after 7 days, 11.3%AR after 256 days) THPAM (34.4%AR after 256 days) THCY[17] (ca 17%AR from 7 - 256 days) THPAI (21.6%AR after 256 days) Soil extracts containing THCY incubated in soil under aerobic conditions: >97% of applied THCY degraded within 7 days.
Soil photolysis ‡	Relatively minor route in the overall soil degradation process. Captan was rapidly degraded on an air dried soil surface under both illuminated and dark conditions, i.e. no significant effect of light. In both light exposed and dark control samples two major (i.e. >10% AR) degradation products were observed, THPI (max 51.0%AR after 4 days) and THCY (max 15.3%AR after 4 days).

[15] 1,2,3,6-tetrahydrophthalimide
[16] tetrahydrophthalamic acid or *cis/trans*-6-carbamoyl-3-cyclohexene-1 carboxylic acid
[17] 2-cyano-cyclohex-4-ene carboxylic acid

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Single first order non linear regression
Laboratory studies ‡ (range or median, with n value, with r^2 value)	<u>Captan</u> DT_{50lab} (25°C, aerobic): 0.44-1.09 days (r^2 0.87-1.00, n=3) DT_{90lab} (25°C, aerobic): 1.46-3.62 days <u>THPI</u> DT_{50lab} (20°C, aerobic): 5.87-14.37 days (r^2 0.98-1.00, n=4) DT_{90lab} (20°C, aerobic): 19.50-47.74 days <u>THPAM</u> DT_{50lab} (20°C, aerobic): 6.00- 11.08 days (r^2 0.98-0.99, n=4) DT_{90lab} (20°C, aerobic): 19.93-36.77 days DT_{50} for FOCUSgw modeling (normalised to 20°C and -10kPa)– Captan longest value 1.09 days THPI arithmetic mean 9.05 days THPAM arithmetic mean 7.8 days
	degradation in the saturated zone ‡: Data not submitted, not required
Field studies ‡ (state location, range or median with n value)	5 US field study sites considered representative of EU conditions <u>Captan</u> $DT_{50field}$: 0.33-7.04 days (r^2 0.91-1.00, mean 3.82, n=5) $DT_{90field}$: not specified <u>THPI</u> $DT_{50field}$: 2.63-33.94 days (r^2 0.87-1.00, mean 12.27, n=5) $DT_{90field}$: not specified
Soil accumulation and plateau concentration ‡	Captan and metabolites are not expected to accumulate in soil

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ K_d ‡	K_{OC} Captan: not measurable due to rapid hydrolysis. Values calculated and reported in literature are considered uncertain: K_{OC} = 97 mL/g mean of literature K_{OC} values. THPI: K_{fOC} = 5.7-11mL/g. (mean 8.1mL/g), 1/n 0.83-1, mean 0.91, n=5) THPAM: K_{dOC} = 74 mL/g (pH 4.7), 71 mL/g (pH 5), 110 mL/g (pH 5.7), 3.8 mL/g (pH 7.7), 6.5 mL/g (pH 7.9) and 5.6 mL/g (8.1) Linear regression for K_{OC} of THPAM with pH of soil: K_{dOC} = (-25.611*pH) + 212.05 K_{fOC} = 74mL/g, 1/n=1 (pH 4.7), 68mL/g, 1/n=0.99 (pH 5), 100mL/g, 1/n=0.99 (pH 5.7) 4.5mL/g, 1/n=1.14 (pH 7.7), 8.5mL/g, 1/n=1.16 (pH 7.9) and 7.6mL/g 1/n=1.26 (8.1) FOCUS scenario specific values: Chateaudun: Koc=7.2mL/g, 1/n=1.19 Hamburg: Koc=48.1mL/g, 1/n=1.09 Jokioinen: Koc=53.3mL/g, 1/n=1.09 Kremsmunster: Koc=14.8mL/g, 1/n=1.19 Okehampton: Koc=63.5mL/g, 1/n=0.99 Piacenza: Koc=32.8mL/g, 1/n=1.09 Porto: Koc=86.6mL/g, 1/n=0.99 Sevilla: Koc=25.1mL/g, 1/n=1.09 Thiva: Koc=14.8mL/g, 1/n=1.19
pH dependence ‡ (yes / no) (if yes type of dependence)	Captan & THPI no THPAM more readily adsorbed at lower pH.

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data available, not required
Aged residues leaching ‡	Captan aged in soil unlikely to significantly leach through soil THPI: "Very high potential mobility in soil". In sand soil: up to 15% found in the leachate THPAM: "High potential mobility in soil". In sand soil: up to 3% found in the leachate
Lysimeter/ field leaching studies ‡	Not submitted, not required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	First order kinetics assumed : captan DT_{50} 7.04 days (highest value from field studies); THPI formed at 66%AR of captan, DT_{50} of 21.1 days (highest FOCUS normalised lab value adjusted to 15°C) MW correction 0.5 THPAM formed at 16.8%AR of captan, DT_{50} of 16.3 days (highest FOCUS normalised lab value of 11.07 days adjusted to 15°C) MW correction 0.56,even incorporation over 5cm soil bulk density 1.5g/cm^3.
Application rate	Pome fruit Northern Europe: 10 x 1.25 kg a.s./ha Pome fruit Southern Europe: 9 x 1.25 kg a.s./ha + 3 x 2.4 kg a.s./ha Nectarines/Peaches: 4 x 2.5 kg a.s./ha Tomatoes: 4 x 1.8 kg a.s./ha 70% crop interception applied in calculating PEC values. 7 day application intervals.

Pome fruit Northern Europe - Captan

PEC$_{(s)}$ Captan (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.500	-	1.003	-
Short term 24h	-	-	0.909	0.956
2d	-	-	0.824	0.911
4d	-	-	-	-
Long term 7d	-	-	0.503	0.725
28d	-	-	0.064	0.723
50d	-	-	0.007	0.708
100d	-	-	0.000	0.505

Pome fruit Southern Europe - captan

$PEC_{(s)}$ **Captan** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.960	-	0.960	-
Short term 24h	-	-	1.641	1.726
2d	-	-	1.487	1.645
4d	-	-	-	-
Long term 7d	-	-	0.909	1.309
28d	-	-	0.115	1.081
50d	-	-	0.013	0.925
100d	-	-	0.000	0.731

Nectarines/Peaches Southern Europe - captan

$PEC_{(s)}$ **Captan** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.000	-	1.880	-
Short term 24h	-	-	1.704	1.792
2d	-	-	1.544	1.708
4d	-	-	-	-
Long term 7d	-	-	0.944	1.360
28d	-	-	0.119	1.111
50d	-	-	0.014	0.792
100d	-	-	0.000	0.407

Tomatoes Southern Europe - captan

$PEC_{(s)}$ **captan** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.720		1.354	-
Short term 24h	-	-	1.227	1.290
2d	-	-	1.112	1.230
4d	-	-	-	-

$PEC_{(s)}$ **captan** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d	-	-	0.680	0.979
28d	-	-	0.086	0.799
50d	-	-	0.010	0.570
100d	-	-	0.000	0.293

Metabolites

Pome fruit Northern Europe - THPI

$PEC_{(s)}$ **THPI** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.166	-	0.727	-
Short term 24h	-	-	0.703	0.715
2d	-	-	0.681	0.681
4d	-	-	-	-
Long term 7d	-	-	0.577	0.649
28d	-	-	0.290	0.616
50d	-	-	0.141	0.571
100d	-	-	0.027	0.442

Pome fruit Northern Europe - THPAM

$PEC_{(s)}$ **THPAM** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.047	-	0.174	-
Short term 24h	-	-	0.167	0.171
2d	-	-	0.160	0.167
4d	-	-	-	-
Long term 7d	-	-	0.129	0.151
28d	-	-	0.053	0.145
50d	-	-	0.021	0.135
100d	-	-	0.002	0.103

Pome fruit Southern Europe - THPI

$PEC_{(s)}$ **THPI** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.319	-	1.127	-
Short term 24h	-	-	1.091	1.109
2d	-	-	1.055	1.091
4d	-	-	-	-
Long term 7d	-	-	0.896	1.007
28d	-	-	0.449	0.875
50d	-	-	0.218	0.764
100d	-	-	0.042	0.615

Pome fruit Southern Europe - THPAM

$PEC_{(s)}$ **THPAM** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.091	-	0.278	-
Short term 24h	-	-	0.267	0.272
2d	-	-	0.256	0.267
4d	-	-	-	-
Long term 7d	-	-	0.207	0.241
28d	-	-	0.085	0.206
50d	-	-	0.033	0.179
100d	-	-	0.004	0.143

Nectarines/Peaches Southern Europe - THPI

$PEC_{(s)}$ **THPI** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.332	-	0.972	-
Short term 24h	-	-	0.940	0.956
2d	-	-	0.910	0.941
4d	-	-	-	-

PEC$_{(s)}$ **THPI** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d	-	-	0.772	0.868
28d	-	-	0.387	0.706
50d	-	-	0.188	0.585
100d	-	-	0.036	0.382

Nectarines/Peaches Southern Europe - THPAM

PEC$_{(s)}$ **THPAM** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.095	-	0.256	-
Short term 24h	-	-	0.245	0.250
2d	-	-	0.235	0.245
4d	-	-	-	-
Long term 7d	-	-	0.190	0.221
28d	-	-	0.078	0.179
50d	-	-	0.030	0.143
100d	-	-	0.004	0.087

Tomatoes Southern Europe - THPI

PEC$_{(s)}$ **THPI** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.239	-	0.700	-
Short term 24h	-	-	0.677	0.688
2d	-	-	0.655	0.677
4d	-	-	-	-
Long term 7d	-	-	0.556	0.625
28d	-	-	0.279	0.508
50d	-	-	0.135	0.421
100d	-	-	0.026	0.275

Tomatoes Southern Europe - THPAM

PEC$_{(s)}$ **THPAM** (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.068	-	0.184	-
Short term 24h	-	-	0.176	0.180
2d	-	-	0.169	0.176
4d	-	-	-	-
Long term 7d	-	-	0.137	0.159
28d	-	-	0.056	0.129
50d	-	-	0.022	0.103
100d	-	-	0.003	0.063

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	Captan 11 - 18.8 hours (pH 5, 25°C) 2.6 - 4.9 hours (pH 7, 25°C) 3.6 - 8.3 minutes (pH 9, 25°C) Major water metabolites: THPI 62%AR max formation (at pH 5; 15.1%AR at pH9); THPC 46.6%AR max formation (at pH9; 4.6%AR at pH5). THPC: Max first order DT_{50} 15.73 minutes (at pH 9 25°C) Major soil metabolites: THPI and THPAM THPI (pseudo first order DT_{50}) >1 year (pH 4 25°C) 150 days (pH 7 25°C) 3 days (pH 9 25°C) THPAM (pseudo first order DT_{50}) 4 days (pH 4 25°C) 360 days (pH 7 25°C) >1 year (pH 9 25°C)
Photolytic degradation of active substance and relevant metabolites ‡	The rate of degradation in illuminated samples was comparable to that in dark controls (pH 5 experiment)
Readily biodegradable (yes/no)	No data from a ready biodegradeability test available. In the absence of data considered ‘not readily biodegradeable’

Degradation in water/sediment	
- DT_{50} water ‡	-
- DT_{90} water ‡	-
- DT_{50} whole system ‡	Captan: < 24 hours THPI :4.8 days (calculable in one system only) THPI and THPAM: 17.8 days (based on no metabolites detectable in either system by 59 days; taking 59 days as a worst case first order DT_{90} value for all metabolites and calculating corresponding DT_{50} value).
- DT_{90} whole system ‡	Captan: < 24 hours
Mineralization	48.9 to 52.5 %AR after 90 days.
Non-extractable residues	23.5 to 29.2%AR after 90 days.
Distribution in water / sediment systems (active substance) ‡	Captan declined rapidly to <0.1% AR after 1 day.
Distribution in water / sediment systems (metabolites) ‡	Major metabolites: THPI up to 50.7%AR in water phase; 41.2% in sediment. THPAM up to 25.6%AR in water. THPAI[18] up to 11.3%AR in sediment.

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	Assuming spray drift to a water body of 30 cm depth. Spray drift values according to Rautmann (2001) for spray drift from 3 m for late applications to top fruit. PEC values for single application (90^{th}-percentile spray drift value) of captan, only (as DT_{90} < 1 day); multiple applications (77^{th}-percentile spray drift values) for THPI (7 day intervals) and for THPAM (7 day intervals). THPI formed to 50.7%AR of drifted captan in water phase (DT_{50} 17.8 days). MW correction 0.5 THPAM formed to 25.6% of drifted captan in water phase (DT_{50} 17.8 days). MW correction 0.56

[18] Tetrahydrophthalic acid

Application rate	Single (Nectarines/peaches Southern Europe): 2.5 kg a.s./ha (Pome fruit Northern Europe): 1.25 kg a.s./ha Multiple (Nectarines/peaches Southern Europe): 4 x 2.5 kg a.s./ha (Pome fruit Southern Europe): 9 x 1.25 kg a.s./ha + 3 x 2.4 kg a.s./ha
Main routes of entry	Spray drift. Other routes of exposure determined not to be relevant for parent captan.

Nectarines/Peaches Southern Europe - captan

$PEC_{(sw)}$ Captan (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	131.08	-	-	-

Pome fruit Northern Europe - captan

$PEC_{(sw)}$ Captan (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	65.54	-	-	-

Captan PEC_i for spray drift from application to top fruit crops

Dist. (m)	Late season Drift (%)	Pome fruit		Peaches, nectarines
		1.25 kg a.s./ha PEC_i (µg a.s./L)	2.4 kg a.s./ha PEC_i (µg a.s./L)	2.5 kg a.s./ha PEC_i (µg a.s./L)
3	15.73	65.54	125.84	131.08
5	8.41	35.04	67.28	70.08
10	3.60	15.00	28.80	30.00
15	1.81	7.54	14.48	15.08
20	1.09	4.54	8.72	9.08
30	0.54	2.25	4.32	4.50
40	0.32	1.33	2.56	2.67
50	0.22	0.92	1.76	1.83

Captan PEC_i for spray drift from application to tomatoes

Distance (m)	Drift (%)	Tomatoes
		1.8 kg a.s./ha; PEC_i (µg a.s./L)
1	2.77	16.62
5	0.57	3.42
10	0.29	1.74
15	0.20	1.20
20	0.15	0.90
30	0.10	0.60
40	0.07	0.42
50	0.06	0.36

Metabolites

Nectarines/Peaches Southern Europe - THPI

$PEC_{(sw)}$ **THPI** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	65.09	-
Short term 24h	-	-	62.61	-
2d	-	-	60.22	-
4d	-	-	55.70	-
Long term 7d	-	-	49.56	-
14d	-	-	37.74	-
21d	-	-	28.73	-
28d	-	-	21.88	-
42d	-	-	12.68	-

Nectarines/Peaches Southern Europe - THPAM

$PEC_{(sw)}$ **THPAM** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	36.78	-
Short term 24h	-	-	35.38	-
2d	-	-	34.03	-
4d	-	-	31.48	-

PEC$_{(sw)}$ **THPAM** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d	-	-	28.01	-
14d	-	-	21.33	-
21d	-	-	16.24	-
28d	-	-	12.36	-
42d	-	-	7.17	-

Pome fruit Southern Europe - THPI

PEC$_{(sw)}$ **THPI** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	72.35	-
Short term 24h	-	-	69.59	-
2d	-	-	66.93	-
4d	-	-	61.92	-
Long term 7d	-	-	55.09	-
14d	-	-	41.95	-
21d	-	-	31.94	-
28d	-	-	24.32	-
42d	-	-	14.10	-

Pome fruit Southern Europe - THPAM

PEC$_{(sw)}$ **THPAM** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	40.89	-
Short term 24h	-	-	39.33	-
2d	-	-	37.82	-
4d	-	-	34.99	-
Long term 7d	-	-	31.13	-
14d	-	-	23.70	-
21d	-	-	18.05	-
28d	-	-	13.74	-
42d	-	-	7.97	-

Pome fruit Northern Europe - THPI

PEC$_{(sw)}$ **THPI** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	45.81	-
Short term 24h	-	-	44.06	-
2d	-	-	42.38	-
4d	-	-	39.20	-
Long term 7d	-	-	34.88	-
14d	-	-	26.56	-
21d	-	-	20.22	-
28d	-	-	15.40	-
42d	-	-	8.93	-

Pome fruit Northern Europe - THPAM

PEC$_{(sw)}$ **THPAM** (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	25.89	-
Short term 24h	-	-	24.90	-
2d	-	-	23.95	-
4d	-	-	22.15	-
Long term 7d	-	-	19.71	-
14d	-	-	15.01	-
21d	-	-	11.43	-
28d	-	-	8.70	-
42d	-	-	5.04	-

PEC$_{(sw)}$ (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	65.09	-
Short term 24h	-	-	62.61	-
2d	-	-	60.22	-
4d	-	-	55.70	-

$PEC_{(sw)}$ (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d	-	-	49.56	-
14d	-	-	37.74	-
21d	-	-	28.73	-
28d	-	-	21.88	-
42d	-	-	12.68	-

PEC (sediment)

Method of calculation	Assuming spray drift to a water body of 30 cm depth with 5 cm of sediment (density 1.3 g/cm^3). Spray drift values according to Rautmann (2001) for spray drift from 3 m for late applications to top fruit.. 77th-percentile spray drift values with 7 day intervals. Captan and THPAM not relevant for sediment compartment. THPI formed 41.2%AR in sediment (DT_{50} 4.8 days). THPAI formed 11.3%AR in sediment (DT_{50} 17.8 days)
Application rate	(Nectarines/peaches): 4 x 2.5 kg a.s./ha (Pome fruit Southern Europe): 9 x 1.25 kg a.s./ha + 3 x 2.4 kg a.s./ha (Pome fruit Northern Europe): 10 x 1.25 kg a.s./ha
Route of entry:	Spray drift.

Nectarines/Peaches Southern Europe - THPI

$PEC_{(sed)}$ **THPI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	135.51	-
Short term 24h	-	-	117.29	126.40
2d	-	-	101.52	117.90
4d	-	-	76.05	103.12

PEC$_{(sed)}$ **THPI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d	-	-	49.32	85.42
14d	-	-	17.95	84.09
21d	-	-	6.53	81.20
28d	-	-	2.38	74.73
42d	-	-	0.31	56.89

Nectarines/Peaches Southern Europe - THPAI

PEC$_{(sed)}$ **THPAI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	75.38	-
Short term 24h	-	-	72.50	73.94
2d	-	-	69.73	72.52
4d	-	-	64.50	69.81
Long term 7d	-	-	57.39	65.98
14d	-	-	43.70	60.75
21d	-	-	33.27	54.42
28d	-	-	25.33	46.75
42d	-	-	14.69	45.91

Pome fruit Southern Europe - THPI

PEC$_{(sed)}$ **THPI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	129.36	-
Short term 24h	-	-	111.96	120.66
2d	-	-	96.91	112.55
4d	-	-	72.60	98.43
Long term 7d	-	-	47.07	81.54
14d	-	-	17.13	79.86
21d	-	-	6.23	76.21
28d	-	-	2.27	68.02
42d	-	-	0.30	59.83

Pome fruit Southern Europe - THPAI

PEC$_{(sed)}$ **THPAI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	83.78	-
Short term 24h	-	-	80.58	82.18
2d	-	-	77.51	80.61
4d	-	-	71.70	77.59
Long term 7d	-	-	63.79	73.34
14d	-	-	48.57	69.89
21d	-	-	36.98	65.71
28d	-	-	28.16	63.24
42d	-	-	16.33	57.08

Pome fruit Northern Europe - THPI

PEC$_{(sed)}$ **THPI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	68.96	-
Short term 24h	-	-	59.69	64.33
2d	-	-	51.66	60.00
4d	-	-	39.20	52.48
Long term 7d	-	-	25.10	43.47
14d	-	-	9.13	43.47
21d	-	-	3.32	43.47
28d	-	-	1.21	43.46
42d	-	-	0.16	43.40

Pome fruit Northern Europe - THPAI

PEC$_{(sed)}$ **THPAI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	53.05	-
Short term 24h	-	-	51.02	52.04
2d	-	-	49.07	51.04
4d	-	-	45.40	49.13

PEC$_{(sed)}$ **THPAI** (µg / kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term 7d	-	-	40.39	46.44
14d	-	-	30.75	45.93
21d	-	-	23.42	45.31
28d	-	-	17.83	44.57
42d	-	-	10.34	42.54

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS PELMO (v3.3.2)
Application rate [Key to scenarios: C: Châteaudun H: Hamburg J: Jokioinen K: Kremsmünster N: Okehampton O: Porto P: Piacenza S: Sevilla T: Thiva]	Simulations were conducted with applications to peaches/nectarines (4 scenarios P, O, S, T), application rate of 4 x 2.5 kg a.s./ha in southern EU and to tomatoes (5 scenarios C, P, O, S, T), application of 4 x 1.8 kg a.s./ha and southern EU pome fruit (apples) usages (4 scenarios P, O, S, T) at 9 x 1.25 plus 3 x 2.4 a.s./ha (however, PELMO could not accommodate 12 applications each year. The last five applications were combined into three), and for northern EU pome fruit (apples) usages (5 scenarios C, H, J, K, N) at 10 x 1.25 a.s./ha. Application intervals 7 days. Crop interception 70%. Substance parameters: Captan: K_{OC}: 200 g/mL, 1/n: 0.9, DT_{50}:1.10 days THPI: K_{OC}: 9.34 g/mL, 1/n: 0.91, DT_{50}:9.05 days THPAM: mean K_{OC} value could not be used because of pH dependent adsorption; pH profile for each scenario was matched to an appropriate K_{OC} and Freundlich exponent value, DT_{50}: 7.80 d.

PEC$_{(gw)}$

Maximum concentration	Not an output provided by the FOCUS groundwater modeling shells, not required.
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Captan: <0.001 µg/L in all scenarios. THPI and THPAM: **Tomatoes:** THPI: 0.000 to 0.459 µg/L, <0.1 µg/L in 3 (O, S, T) of 5 scenarios. THPAM: 0.000 to 0.721 µg/L, <0.1 µg/L in 3 (O, S, T) of 5 scenarios. **Nectarines/Peaches:** THPI: 0.010 to 0.963 µg/L, <0.1 µg/L in 3 (O, S, T) of 4 scenarios. THPAM: 0.001 to 1.246 µg/L, <0.1 µg/L in 3 (O, S, T) of 4 scenarios. **Pome fruit Southern Europe:** THPI: 0.022 to 2.081 µg/L, <0.1 µg/L in 3 (O, S, T) of 4 scenarios. THPAM: 0.002 to 2.645 µg/L, <0.1 µg/L in 1 (O) of 4 scenarios. **Pome fruit Northern Europe:** THPI: 1.260 to 2.294 µg/L, <0.1 µg/L in 0 of 5 scenarios. THPAM: 0.901 to 5.566 µg/L, <0.1 µg/L in 0 of 5 scenarios.

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Not measured, not required
Quantum yield of direct phototransformation	Direct aqueous photolysis negligible, so quantum yield could not be determined
Photochemical oxidative degradation in air ‡	Half-life for captan due to reaction with hydroxyl radicals (average conc over a 12-hour day) calculated to be 1.465 hours. Half-life for captan due to reaction with ozone (average conc over a 12-hour day) calculated to be 1.375 hours . Therefore, the photochemical oxidative half-life of captan in air was predicted to be < 1.5 hours.
Volatilization ‡	Negligible.

PEC (air)

Method of calculation	Expert judgement based on volatility

PEC$_{(a)}$

Maximum concentration	Negligible

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	**For risk assessment** Soil: captan, THPI & THPAM groundwater: captan, THPI & THPAM surfacewater: captan, THPI & THPAM sediment: THPI & THPAI Air: captan **For monitoring** Soil: captan Water: cannot be proposed, *data gaps identified* Air: captan

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	In a total of 336 samples collected in the Netherlands (1996 and 1997), captan was detected only once (at 0.08 µg/L) above the LOQ of 0.05 µg/L.
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	R53 May cause long-term adverse effects in the aquatic environment

Appendix 1.6: Effects on non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals ‡	LD_{50} > 2,000 mg/kg bw (rat, mouse; captan) LD_{50} > 2,000 mg/kg bw (rat; 'Merpan' 80 WDG)
Reproductive toxicity to mammals ‡	NOAEL 100 mg/kg bw/day (reproduction), equivalent to 3075 ppm (mean) in diet
Acute toxicity to birds ‡	LD_{50} > 2,000 mg/kg bw (quail, mallard).
Dietary toxicity to birds ‡	LC_{50} > 5,200 ppm in diet (quail, mallard). Calculated daily dose: quail: >800 mg/kg bw/day mallard: >1040 mg/kg bw/day
Reproductive toxicity to birds ‡	NOEC 1,000 ppm in diet (quail, mallard; highest concentration tested). Calculated daily dose: quail: 83.2 mg/kg bw/day mallard: 74.4 mg/kg bw/day

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
2.5	peaches/ nectarines	small bird; consumption of insects	acute oral	Tier 1: > 14.8	10
2.5	peaches/ nectarines	small bird; consumption of insects	short-term dietary	Tier 1: > 10.6	10
2.5	peaches/ nectarines	small bird; consumption of insects	long-term dietary	Tier 1: 1.0	5
2.5	peaches/ nectarines	small mammal; consumption of grass[b]	acute oral	Tier 1: > 9.0[c]	10

[a] The lowest TER values are shown based on the risk assessment.
[b] Foliar interception by trees adjusted to 75% as trees in full leaf at time of application.
[c] As captan is of low acute toxicity (LD50 >2000 mg/kg bw) there is a low risk.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests ‡				
Fish (rainbow trout)	captan	96 –hour (static)	LC50	186 µg captan/L
Fish (brown trout*)	captan	96 –hour (static)	LC50	98 µg captan/L
Fish (rainbow trout)	THPI	96 –hour (static)	LC50	>12000 µg/L
Fish (rainbow trout)	THPAM	96 –hour (static)	LC50	>12000 µg/L
Fish (rainbow trout)	'Merpan' 83 WP	28-day (semi-static)	NOEC	199.2 µg captan/L
Invertebrates *(Daphnia magna)*	'Merpan' 80 WDG	24-hour (semi-static)	EC_{50}	5200 µg captan/L
Invertebrates *(Daphnia magna)*	83% WP formulation of captan	24-hour (static)	EC_{50}	3400 µg captan/L
Invertebrates *(Daphnia magna)*	THPI	48-hour	EC_{50}	>120000 µg/L
Invertebrates *(Daphnia magna)*	THPAM	48-hour	EC_{50}	220000 µg/L
Invertebrates *(Daphnia magna)*	captan	21-day (semi-static)	NOEC	560 µg captan/L
Algae *(Selenastrum capricornutum)*	captan	96-hour (static)	E_bC_{50}	1600 µg captan/L
Algae *(Selenastrum capricornutum)*	83% WP formulation of captan	72-hour (static)	E_bC_{50}	1180 µg captan/L
Algae *(Selenastrum capricornutum)*	THPI	96-hour	E_bC_{50}	>180000 µg/L
Algae *(Selenastrum capricornutum)*	THPAM	72-hour	E_bC_{50}	33000 µg/L

* Six species of fish were tested. Brown trout was the most sensitive species tested, and this LC50 should be used in the higher tier risk assessment. Uncertainty regarding interspecies variation in sensitivity has been reduced. Hence, a TER trigger of 10 should be used.

Microcosm or mesocosm tests
No data submitted

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
1.25	pome fruit	brown trout	acute	15 m	13.0	10[a]
2.4	pome fruit	brown trout	acute	20 m	11.2	10[a]
2.5	peaches/ nectarines	brown trout	acute	20 m	10.8	10[a]
1.8	tomatoes	brown trout	acute	5 m	28.7	10[a]

[a] Modified on the basis of a higher tier risk assessment (IIIA, 11.2).

Bioconcentration

Bioconcentration factor (BCF) ‡	140 (whole fish).
Annex VI Trigger:for the bioconcentration factor	1,000 (for a readily degradable compound such as captan).
Clearance time (CT_{50}) (CT_{90})	1 to 3 days (whole fish) Not determined
Level of residues (%) in organisms after the 14 day depuration phase	< 16%; < 5% (all tissues)

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity ‡	LD_{50} > 100 µg captan/bee (captan tech.) LD_{50} > 169.3 µg captan/bee ('Merpan' 80 WDG)
Acute contact toxicity ‡	LC_{50} > 200 µg captan/bee (captan tech.) LC_{50} > 200 µg captan/bee ('Merpan' 80 WDG)

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
2.5	peaches/nectarines	oral	< 25.0	50
2.5	peaches/nectarines	contact	< 12.5	50

Field or semi-field tests Not required.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species (exposed life stage)	Captan (kg/ha)	Test and test substance	Results	Conclusion
Laboratory tests ‡				
*Typhlodromus pyri** (protonymphs)	1.49	laboratory, residues on glass. 83% WP	*mortality:* 1.49 kg/ha: 7.2% control: 17.4% *eggs/female*: 1.49 kg/ha: 2.0 control: 2.0 *hatch rate:* 1.49 kg/ha: 0.68 control: 0.82	Effects less than ESCORT 2 trigger (50%)
*Aphidius rhopalosiphi** (adults)	0.60	laboratory, residues on glass. 83% WP	*mortality:* 0.6 kg/ha: 100% control: 13.7%	Effect greater than ESCORT 2 trigger (50%)
*Chrysoperla carnea** (larvae)	0.56	laboratory, residues on glass. 83% WP	*mortality:* control: 7% 0.56 kg/ha: 7% *fertile eggs/female:* control: 1037 0.56 kg/ha: 1089	Effects less than ESCORT 2 trigger (50%)
	0.20	laboratory, residues on glass. 83% WP	*mortality:* control: 20% 0.2 kg/ha: 23% *eggs/female:* control: 418 0.2 kg/ha: 461	Effects less than ESCORT 2 trigger (50%)
Pardosa spec. (adults and subadults)	0.75	laboratory, spiders and sand treated. 83% WP	*mortality:* control: 0% 0.75 kg/ha: 0% food consumption not affected	Effects less than ESCORT 2 trigger (50%)
*Orius insidiosus** (nymphs)	1.49	laboratory, residues on glass 83% WP	*mortality:* control: 15.9% 1.49 kg/ha: 8% *eggs/female:* control: 12.2 1.49 kg/ha: 11.8 *hatch rate:* control: 0.96 1.49 kg/ha: 0.94	Effects less than ESCORT 2 trigger (50%)

Species (exposed life stage)	Captan (kg/ha)	Test and test substance	Results	Conclusion
Pterostichus melanarius (adults)	3.6	laboratory, residues on soil. 50% WP	*mortality:* 0% no effect on feeding behaviour	Effects less than ESCORT 2 trigger (50%)
Trybliographa rapae (adults)	3.6	laboratory, residues on glass. 50% WP	*mortality:* control: 17% 3.6 kg/ha: 28% *parasitism:* control: 18% 3.6 kg/ha: 12%	Effects less than ESCORT 2 trigger (50%)

*ESCORT 2 recommended test species.

Species (exposed life stage)	Captan (kg/ha)	Test and test substance	Results	Conclusion
Extended laboratory tests ‡				
*Aphidius rhopalosiphi** (adults)	0.0042 to 1.868	extended laboratory, residues on apple leaves. 83% WP	*mortality:* control: 5% 1.868 kg/ha: 12% *parasitism mummies/female:* control: 9.4 1.868 kg/ha: 5.9	LR_{50} > 1.868, no significant effects on survival or reproduction (i.e. less than ESCORT 2 trigger (50%))
*Aphidius rhopalosiphi** (adults)	3.42 and 6.75	extended laboratory, residues on bean leaves. 80% WDG	*corrected mort.:* 3.42 kg/ha: 0% 6.75 kg/ha: 13% *Reduction in parasitisation:* 3.42 kg/ha: 49% 6.75 kg/ha: 22%	No significant effect at 6.75 kg/ha. Effects less than ESCORT 2 trigger (50%)
*Coccinella septempunctata** (larvae)	0.45 – 6.75	extended laboratory, residues on bean leaves (fresh residues, and 14 day aged residues). 80% WDG	Fresh residues: *corrected mort:* 0.45 kg/ha: 0% 1.89 kg/ha: 9% 3.42 kg/ha: 32% 6.75 kg/ha: 44% *Fertile eggs/female/day:* control: 3.7 0.45 kg/ha: 4.8 1.89 kg/ha: 7.0 3.42 kg/ha: 7.9 6.75 kg/ha: 15.7	Effects on survival less than ESCORT 2 trigger (50%) for fresh residues at 6.75 kg/ha. No negative difference in reproduction compared with control.

*ESCORT 2 recommended test species.

Laboratory studies show *A. rhopalosiphi* to be the most sensitive species tested. When this species (and also

Coccinella septempunctata) is tested in an extended laboratory test at 6.75 kg a.s./ha, a low risk is indicated for the proposed uses (effects less than trigger of 50%).

Field or semi-field tests
In two field trials in apples (10 applications of 1.8 kg captan/ha) there were no significant effects of an 83% WP formulation of captan on *Typhlodromus pyri* populations. Effects of 'Merpan' 80 WDG were limited. In two field trials with vines (8 applications of 0.75 to 3.3 kg captan/ha) there were no significant effects on *T. pyri* populations.

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	14-day LC_{50} >519.3 mg captan/kg (technical) ($LC50_{corrected}$ >259.7 mg captan/kg) 14-day LC_{50} 839 mg captan/kg (83% WP) ($LC50_{corrected}$ 419.5 mg captan/kg)
Reproductive toxicity ‡	NOEL: 11.25 kg a.s./ha ('Merpan' 80 WDG) NOEC: 12.18 mg a.s./kg soil $NOEC_{corrected}$: 6.09 mg a.s./kg soil NOEL: 8.70 kg a.s./ha ('Malvin' WG) NOEC: 11.60 mg a.s./kg soil $NOEC_{corrected}$: 5.80 mg a.s./kg soil

('corrected' values derived by dividing endpoint by 2, for substances with logPow >2, in accordance with EPPO earthworm scheme 2002.)

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Crop use and max. number of applications	timescale	Toxicity endpoint (mg a.s./kg soil)	Maximum PEC*	TER	Annex VI Trigger
North EU pome fruit (10 applns)	acute	>259.7	1.003	258.9	10
	long term	5.80	1.003	5.78	5
South EU pome fruit (12 applns)	acute	>259.7	1.811	143.4	10
	long term	5.80	1.811	3.20	5
	long term	11.60**	1.811	6.4	5
Tomatoes (4 applns)	acute	>259.7	1.354	191.8	10
	long term	5.80	1.354	4.28	5
	long term	11.60**	1.354	8.6	5
peaches/nectarines (4 applns)	acute	>259.7	1.880	138.1	10
	long term	5.80	1.880	3.09	5
	long term	11.60**	1.880	6.18	5

*PECsoil directly after the final application.
**Following initial degradation of captan, likely exposure in reproduction studies was mainly to soil metabolites.

These have low affinity for organic matter. Hence, EPPO correction factor of 2 is not needed for the NOEC from the reproduction study. Therefore, low risk indicated for the proposed uses.

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	No significant effects (< 25% deviation from untreated control)
Carbon mineralization ‡	No significant effects (< 25% deviation from untreated control)

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N;	Harmful
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median

LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year