## CONCLUSION ON PESTICIDE PEER REVIEW

# Conclusion on the peer review of the pesticide risk assessment of the active substance fenoxycarb[1]

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**SUMMARY**

Fenoxycarb is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002[3] , as amended by Commission Regulation (EC) No 1095/2007[4] . In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the Netherlands being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of fenoxycarb in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of fenoxycarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Syngenta Crop Protection AG made a resubmission application for the inclusion of fenoxycarb in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, The Netherlands being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 10 December 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 11 December 2009. The DAR was also distributed to Member States for comments in view of the fact that the original peer review had been terminated following the applicant's notification of withdrawal of support. The EFSA collated and forwarded all comments received to the Commission on 25 January 2010,

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of ecotoxicology and mammalian toxicology and deliver its conclusions on fenoxycarb.

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[1] On request from the European Commission, Question No EFSA-Q-2010-00136 issued on 13 September 2010.

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[3] OJ L224, 21.08.2002, p.25

[4] OJ L 246, 21.9.2007, p. 19

[5] OJ L 333, 11.12.2008, p0.11

[6] OJ L 15, 18.01.2008, p.5

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fenoxycarb EFSA Journal 2010;8(12):1779. [75 pp.]. doi:10.2903/j.efsa.2010.1779. Available online: www.efsa.europa.eu/efsajournal.htm

 

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fenoxycarb as an insecticide on apples and pears as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No areas of concern were identified in the area of physical-chemical properties. One data gap was identified for attrition characteristics of the granule formulation before and after 2 years storage.

No data gaps or areas of concern were identified in the area of mammalian toxicology.

The consumer risk assessment for the representative use of fenoxycarb in apples and pears has been addressed by the available data and no areas of concern were identified.

The data available in the area of environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the EU level for the representative uses.

A high risk was identified for aquatic organisms based on higher tier level assessment for all the representative uses which was considered a critical area of concern. A data gap was identified for to further address the risk to aquatic invertebrates taking into account the mode of action of fenoxycarb and the most sensitive growth stages. A data gap was identified to further address the effects on bee brood and mitigation measures to protect bees (i.e. SPe8) were recommended. A high risk was identified for the in-crop and off-crop risk to non-target arthropods and a data gap was set for all the representative uses. A critical area of concern was identified. A low risk was assessed for birds and mammals, soil non-target macro and micro-organisms, terrestrial non-target plants and biological methods for sewage treatments.

**KEY WORDS**

fenoxycarb, peer review, risk assessment, pesticide, insecticide

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## BACKGROUND

### Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

### Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Fenoxycarb is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, the Netherlands which was received by the EFSA on 4 June 2007 (Netherlands, 2007)

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of fenoxycarb in Annex I to Council Directive 91/414/EEC.

### Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of fenoxycarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Syngenta Crop Protection AG made a resubmission application for the inclusion of fenoxycarb in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18, the Netherlands being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Netherlands, 2009). The Additional Report was received by the EFSA on 10 December 2009.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 11 December 2009. The DAR was also distributed to Member States for comments in view of the fact that it had not previously been distributed for consultation. In addition, the EFSA conducted a public consultation on the Additional Report and the DAR. The EFSA collated and forwarded all comments received to the Commission on 25 January 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table.

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 333, 11.12.2008, p.11

The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response was evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 23 February 2010 the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on fenoxycarb within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 24 February 2010 the applicant wasalso invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and ecotoxicology and that further information should be requested from the applicant in the area of ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as an insecticide on apples and pears, as proposed by the applicant A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2010) comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 24 February 2010
- the Evaluation Table (09 September 2010)
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of August 2010, Netherlands 2010) containing all individually submitted addenda) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fenoxycarb is the ISO common name for ethyl 2-(4-phenoxyphenoxy)ethylcarbamate (IUPAC).

The representative formulated product for the evaluation was 'Insegar 25 WG' a water dispersible granule (WG) containing 250 g/kg of fenoxycarb.

The representative uses evaluated comprise outdoor foliar spraying to control insect pests on apples and pears. Full details of the GAP can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

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

The minimum purity of the active substance as manufactured is 970 g/kg. Toluene was considered as a relevant impurity but, based on its hazards and the level proposed in the technical specification, does not give rise to significant toxicological concern.

The main data regarding the identity of fenoxycarb and its physical and chemical properties are given in Appendix A.

Data were not available on the attrition characteristics of the granule before and after two years storage and a data gap has been identified.

The residue definition for all matrices is fenoxycarb. For plant matrices the multi-method DFG S19 is available as well as single HPLC-UV methods. For products of animal origin a HPLC-UV method is available. All environmental matrices can be analysed by LC-MS/MS methods. A method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

### 2. Mammalian toxicity

Fenoxycarb was discussed in the PRAPeR 79 expert meeting in July 2010. The batches used in the toxicological studies were considered representative of the technical specification. Toluene is a relevant impurity in the technical specification, but not of concern at the proposed level.

Of low acute toxicity upon oral, dermal or inhalation exposure, fenoxycarb is neither a skin or eye irritant nor a skin sensitiser. In short-term toxicity studies, the target organs were the liver (in all species), the thyroid and the kidney (in rats). The relevant NOAEL for the rat is 9.7 mg/kg bw/day based on the 13-week study, whereas only a LOAEL was identified for the dog (25 mg/kg bw/day in the 1-year study) and for the mouse (100 mg/kg bw/day in a 13-week study with limitations).

No potential for genotoxicity *in vivo* or *in vitro* was demonstrated in the available studies. In the long-term study with rats, the relevant NOAEL is 8.1 mg/kg bw/day based on liver findings (increased weight, hypertrophy and focal necrosis and fibrosis). In the first long-term study with mice (from 1995), the NOAEL was set at 5.3 mg/kg bw/d based on the increased incidences of lung and liver tumours. In the second long term study with mice (from 1987), a LOAEL of 5.3 mg/kg bw/day was identified based on higher incidences of alveolar/bronchiolar tumours in the lungs of males of all treated groups. Based on mechanistic studies, it was demonstrated that the liver tumours were due to peroxisome proliferation induced by fenoxycarb, a mechanism for which humans are less sensitive, and therefore were not relevant for humans. However, the experts could not conclude that the lung tumours observed in male mice are not relevant to humans, and the classification as **Carc. Cat.3, R40** *Limited evidence of a carcinogenic effect* was proposed. As metabolic differences were shown in the production of metabolites potentially related to tumour induction, it was nevertheless agreed that humans could be considered less sensitive to tumour formation than mice.

In the rat multigeneration study, the NOAEL for the reproductive parameters is 119 mg/kg bw/day, whereas the parental and offspring NOAEL is 13 mg/kg bw/day based on an increased liver weight. In the rat developmental study, no adverse effects were observed in foetuses and the maternal NOAEL was 50 mg/kg bw/d. From the two rabbit developmental studies presented, the maternal NOAEL was 100 mg/kg bw/day, and the developmental NOAEL was 200 mg/kg bw/day based on an increased incidence of spina bifida at 300 mg/kg bw/day, above historical control data. Based on this finding, the majority of the experts agreed to propose classification as **Repr. Cat. 3 R63** *Possible risk of harm to the unborn child*.

With regard to neurotoxicity, fenoxycarb is unlikely to have any significant effect on cholinesterase, and no clinical signs indicative of neurotoxicity were observed in the available repeated dose studies.

For the derivation of the **Acceptable Daily Intake** (ADI), the experts agreed to use the LOAEL of the second long-term mouse study. For the safety factor, while mouse to human extrapolation can be reduced by a factor of 3 based on the mechanistic studies, the use of a LOAEL does imply the use of a higher safety factor, resulting in an overall safety factor of 100 and an ADI of 0.053 mg/kg bw/day. The agreed **Acceptable Operator Exposure Level** (AOEL) is 0.1 mg/kg bw/day based on the 13-week rat study and with the use of a safety factor of 100. The agreed **Acute Reference Dose** (ARfD) is 2.0 mg/kg bw/day based on the rabbit developmental studies and the use of a safety factor of 100.

The ARfD is provides a margin of safety of 150 with regard to the dose level where spina bifida (triggering R63) are observed in the rabbit developmental studies.

For the dermal absorption, the experts agreed on the values of 0.2% for the concentrate and 28% for the spray dilution. The exposure assessment was performed for mechanical upward spraying on pome fruits. For operators and re-entry workers, the exposure levels are below the AOEL without the use of personal protective equipment. For bystanders, the estimated exposure is also below the AOEL.

## 3. Residues

Metabolism of fenoxycarb was investigated in oranges and apples. A study in Bermuda grass is available as supportive information. The major component of the residue in oranges was fenoxycarb, representing between 60% and 80% of the TRR at harvest. In apples, at a comparable PHI as in oranges, fenoxycarb represented 44% of the TRR; at a later PHI only 8% of the TRR were present as parent. Very similar metabolites were identified in both oranges and apples. Metabolism of fenoxycarb in the fruits proceeded mainly by reactions such as ring hydroxylation, cleavage of the ether linkages and loss of the side chain, followed by further hydroxylation and conjugation steps. Although fenoxycarb is eventually extensively metabolised in fruit and metabolisation seemed to occur faster in apple than in oranges, fenoxycarb will be the major component of the residue in fruit upon treatment according to the representative uses for apple and pear. Therefore, the residue definition for post-registration monitoring and for risk assessment is proposed as fenoxycarb only.
Crop rotation is not relevant in the cultivation of apple and pear; however an available confined crop rotational study indicated there was no significant uptake into rotational crops.
Metabolism studies with fenoxycarb were submitted in goat and in hen. In livestock, fenoxycarb is rapidly metabolised by oxidation and dealkylation followed by conjugate formation. Residues were assessed in ruminant matrices only since fruit pomace is not relevant in chicken and pig diet. With the exception of kidney fenoxycarb was recovered in all edible ruminant products, with the highest percentage in the fat (22% of the TRR). The metabolite CGA294850 and its glucuronide and sulphate conjugates were by far the major residues in ruminant matrices (up to 66% of the TRR). However, based on the goat metabolism data and the cow feeding study with analysis for fenoxycarb and CGA294850, residues of fenoxycarb and CGA294850 are expected to be less than 0.01 mg/kg in animal tissues with the exception of fat where fenoxycarb was present up to 0.02 mg/kg at the relevant dose level. Hence, for the representative uses a definition of residues in food of animal origin should be fenoxycarb for risk assessment and monitoring, and a MRL of 0.02 mg/kg in ruminant fat is proposed.

A sufficient number of residue trials are available in apple in Northern Europe and Southern Europe. By extrapolation of data from apple to pear an MRL of 0.5 mg/kg fenoxycarb for apple and pear could be proposed. The residue trials are supported by validated analytical methods and acceptable freezer storage stability data for fenoxycarb residues.
Fenoxycarb was shown to be stable under conditions simulating industrial and houshold processing. Based on a processing study in apple, processing factors could be established for apple juice, puree, wet and and dry pomace.
A consumer risk assessment with the proposed MRLs, using EFSA PRIMo rev. 2.0 indicated the chronic intake (TMDI) was 12% of the ADI for the most critical consumer group. The highest short term intake (IESTI) was less than 3% of the ARfD for the most critical consumer group.

## 4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, fenoxycarb exhibits very low to moderate persistence forming no major (>10% applied radioactivity (AR)) or minor non-transient (>5% AR at least 2 consecutive sampling times[11]) soil metabolites that trigger further assessment. Mineralisation of both phenyl ring radiolabels to carbon dioxide accounted for 24-32% AR after 88-91 days. The formation of unextractable residues (not extracted using acetonitrile:water followed by Soxhlet with acetonitrile or either basified methanol or methanol water followed by aqueous sodium hydroxide) from these phenyl ring radiolabels accounted for 53 – 63 % AR after 88-91 days. In an anaerobic dark laboratory soil incubation and a laboratory soil photolysis study, the behaviour of fenoxycarb was comparable to that observed in the aerobic incubations. Fenoxycarb exhibited slight to low mobility in soil. In satisfactory field dissipation studies carried out at 3 sites, (in the USA (California), Spain and Southern France, spray application to the bare soil surface in June or August, subsequently sown grass emerged except in California where plots were maintained bare) fenoxycarb exhibited low persistence.
In laboratory incubations in dark aerobic natural sediment water systems, fenoxycarb exhibited low persistence, forming no major metabolites. The unextractable sediment fraction (not extracted using acetonitrile followed by acetonitrile:water, then aqueous neutral and acid extraction at 80ºC) of the phenoxy ring radiolabel, accounted for 50 – 52 % AR at study end (119 days). Mineralisation of this radiolabel accounted for 36-40 % AR at the end of the study. The rate of decline of fenoxycarb in laboratory sterile aqueous photolysis experiments was either faster or comparable to that which occurred in the aerobic sediment water incubations (short light path lengths with light energy equated to summer sunlight at 40ºN). Under these photolysis conditions the major metabolites CGA-294847 (max. 17% AR at study end), 30 days and phenol (max. 18 % AR at 22 days) were produced.
The necessary surface water exposure assessments (Predicted Environmental Concentrations (PEC)) in were carried out for the metabolites CGA-294847 and phenol, using a FOCUS (FOCUS, 2001) step 1 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). For the active substance fenoxycarb, appropriate step 2 (FOCUS, 2001), step 3 and step 4 calculations PEC in surface water and sediment were available[12]. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with just no-spray drift buffer zones of up to 30 m being implemented. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations.
The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the models PEARL 3.3.3 and PELMO 3.3.2[13] for parent fenoxycarb. The potential for groundwater exposure from the representative uses assessed by fenoxycarb above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

[11] The importance of this is for groundwater exposure assessment of metabolites as discussed in European Commission (2003)
[12] Step 3 and 4 simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[13] Simulations complied with EFSA, 2004 recomendations and correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

## 5. Ecotoxicology

The risk to birds and mammals via dietary exposure and from consumption of contaminated water was assessed as low at first tier following the Guidance Document (European Commission, 2002). For long-term risk assessment for birds residue data from the PPR-panel opinion (EFSA, 2008) were taken into account.

Fenoxycarb was very toxic to aquatic organisms. The lowest endpoint was observed in the chronic toxicity study with *Daphnia magna* and the active substance (NOEC of 1.6 ng a.s./L). Based on this data, a high risk was identified at FOCUS step 3. The risk was subsequently refined with FOCUS step 4 calculations including mitigation measures and the higher tier endpoint from an outdoor microcosm study. However, the higher tier endpoint was questioned because several deficiencies in study were identified during the PRAPeR expert meeting. The geographic and climatic conditions were not comparable with the conditions in Europe because the study was conducted in Texas. The dosing scheme applied was considered not sufficient to cover all the representative uses. The presence of bluegill sunfish was considered to be a factor which could potentially reduce the statistical power of the study and, as a consequence, the reliability of a derived NOEC. In addtition, since fenoxycarb is an insect growth regulator, it was questioned whether the relevant life stages were considered in the study, even if the RMS confirmed that the most sensitive species and univoltine insects were included. Therefore, due to all these uncertainties, the consensus was reached to reject the microcosm study. The TERs, calculated on the basis of FOCUS step 4 including no-spray buffer zone up to 30m and first-tier endpoints, were still below the trigger for aquatic invertebrates (chronic risk) and sediment-dwelling organisms. A data gap was identified to address the risk to aquatic invertebrates and sediment-dwelling organisms taking into account the mode of action of fenoxycarb and the most sensitive growth stages. Overall, since a high risk was identified for aquatic organisms for all the representative uses, a critical area of concern was proposed. The potential for endocrine disruptor effects to fish was discussed during the PRAPeR expert meeting. It was noted that there was no evidence of endocrine effects in the mammalian toxicology assessment and potential risk to fish would be covered by the risk assessment for aquatic invertebrates. The risk to aquatic organisms from the photolysis metabolite CGA-294847 was assessed as low. In the DAR the risk from the other photolysis metabolite phenol was considered addressed by the microcosm study As the microcosm study was not accepted, therefore the data gap remains to address the risk from the photolysis metabolite phenol.

The available study on bee brood was considered not sufficient to address the risk because it was conducted with an application rate lower than the representative uses and with only one application. Therefore, the risk assessment for bee brood could not be finalised and a data gap to further address the effects on bee brood was identified. Due to the mode of action of fenoxycarb, mitigation measures (i.e SPe8) should be taken into account at Member State level to protect bees

The first tier risk assessment for non-target arthropods indicated a high risk to in-crop and off-crop species. *Coccinella septempunctata* was the most sensitive species in extended laboratory tests and semi-field studies. To demonstrate the potential for recovery and recolonisation, the applicant conducted a population simulation modelling with Coccinella and Lepidoptera. Geographic Information System (GIS) analysis was also provided to demonstrate the presence of recolonisation areas around orchards in Europe and the potential exposure of these areas, in support of the population modelling. However, the entire approach was questioned during the PRAPeR expert meeting. The population modelling was rejected because the parameterisation was not supported by substantial and reliable data. For example an inappropriate DT50 value was used (i.e derived from a study where residues on leaves were washed off, and the residues observed were not in accordance with duration of residual toxicity in other studies); for Lepidoptera, the endpoint used was a geometric mean of LD50 values of other Lepidopteran species than the meadow brown, resulting in further uncertainty (large variation in endpoints). In addition, the literature data used to derive some parameters could not be considered during the peer review and there was no indication of the degree of validation of the

modelling. The assumption of a distance of 20m between the treated field and the potential areas for recolonisation was considered too large. It was not described to what extent the outcome covered the uncertainty for the biodiversity of the off-crop area and the experts were concerned that the most sensitive species in the off-crop area were not represented in the population modelling studies. Overall, besides these uncertainties and concerns, the potential recovery was not definitely demonstrated and the application of additional mitigation measures such as drift reduction nozzles and in-field no spray buffer zones would be needed. Therefore, the experts agreed that the simulations and their outcomes could not be used in the refined risk assessment. Although the GIS analysis was considered relevant to show potential in-crop recovery, geographically. However, an analysis of the off-crop recovery was lacking. The resolution of the data source (i.e.CORINE[14] 2000 land cover database) was considered too low to properly represent the edge-of-field situations. The buffer zone applied from the orchard areas to the recovery/recolonisation areas (i.e.20-500 m) was also considered too large, without any validation at field level. Therefore, overall it was agreed that the GIS approach could not be used in the risk assessment. A data gap was identified to further address the in- and off-crop risk to non-target arthropodsfor all representative uses .

A low risk was assessed for soil not target macro and micro-organisms, terrestrial non-target plants and biological methods for sewage treatments.

[14] *Coordinated Information on the European Environment.*

## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

### 6.1. Soil

| Compound (name and/or code) | Persistence | Ecotoxicology |
|---|---|---|
| fenoxycarb | very low to moderate persistence<br><br>Biphasic $DT_{50}$ 0.75-2.91 days (DT90 4.9-66 days 20-25ºC 25-40% maximum water holding capacity and pF 2-2.5 soil moisture)<br><br>Field dissipation studies Single first order $DT_{50}$ 4.1-8.9 days. | The risk was assessed as low for soil living organisms. |

### 6.2. 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) | Pesticidal activity | Toxicological relevance | Ecotoxicological activity |
|---|---|---|---|---|---|
| fenoxycarb | low to slight mobility<br><br>KFoc 1251-2599mL/g | No | yes | yes | yes |

### 6.3. Surface water and sediment

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| fenoxycarb | Very toxic to aquatic organisms. The lowest endpoint was observed in the chronic toxicity study with *Daphnia magna* and the active substance (NOEC of 1.6 ng a.s./L). the risk was assessed as high. |
| CGA 294847 | Risk to aquatic organisms was assessed as low |
| phenol | Data gap to address the risk to aquatic organisms. |

### 6.4. Air

| Compound (name and/or code) | Toxicology |
|---|---|
| fenoxycarb | Low toxicity by inhalation ($LC_{50}$ in rats > 4.4 mg/L air) |

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

- Attrition of the granule before and after two years storage (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- The risk to aquatic invertebrates and sediment-dwelling organisms needs to be further addressed taking into account the mode of action and the most sensitive growth stages (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- The risk to aquatic organisms from the photolysis metabolite phenol needs to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- The effects on bee brood need to be further addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5) o.k.
- The in- and off-crop risk to non-target arthropods need to be further addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

## PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Mitigation measures to protect bees (i.e. SPe8) were recommended.

## ISSUES THAT COULD NOT BE FINALISED

- The risk assessment for bee brood was not finalised and a data gap was identified to further address the effects.

## CRITICAL AREAS OF CONCERN

- Based on a higher tier level assessment a high risk to aquatic organisms was identified.
- Based on a higher tier level assessment a high in-crop and off-crop risk to non-target athropods was identified.

## REFERENCES

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EFSA (2007). Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default *Q*10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32

EFSA (2004). Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models comparability and the consistency of this risk assessment of groundwater contamination. The EFSA Journal (2004) 93, 1-20

European Commission, 2001. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO Doc 7525/VI/95-rev.7. pp.1-31.

[15] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

# APPENDICES

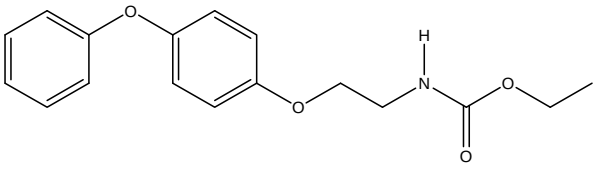
## APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

### Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

**Identity, Physical and Chemical Properties, Details of Uses, Further Information**

| | |
|---|---|
| Active substance (ISO Common Name) | Fenoxycarb |
| Function (*e.g.* fungicide) | Insecticide |
| Rapporteur Member State | The Netherlands |

**Identity** (Annex IIA, point 1)

| | |
|---|---|
| Chemical name (IUPAC) | ethyl 2-(4-phenoxyphenoxy)ethylcarbamate |
| Chemical name (CA) | ethyl N-[2-(4-phenoxyphenoxy)ethyl]carbamate |
| CIPAC No | 425 |
| CAS No | 72490-01-8 (old); 79127-80-3 (new) |
| EEC No (EINECS or ELINCS) | 276-696-7 |
| FAO Specification (including year of publication) | Not available |
| Minimum purity of the active substance as manufactured (g/kg) | 970 g/kg |
| Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg) | Toluene max. 1 g/kg |
| Molecular formula | $C_{17}H_{19}NO_4$ |
| Molecular mass | 301.4 |
| Structural formula |  |

**Physical-chemical properties (**Annex IIA, point 2**)**

| | |
|---|---|
| Melting point (state purity) | 53.6°C (99.2%) |
| Boiling point (state purity) | 100.4°C at reduced pressure; 65 mPa (99.2%) |
| Temperature of decomposition (state purity) | decomposition in air started at about 248°C (99.2%) |
| Appearance (state purity) | Pure material: white flakes (99.5%) |

| | |
|---|---|
| | Technical material: colourless to white solidified melt (97.6%) |
| Vapour pressure (state temperature, state purity) | 8.670x10-7 Pa at 25°C (99.2%) |
| Henry's law constant | 3.3x10-5 Pa.m3.mol-1 |
| Solubility in water (state temperature, state purity and pH) | 7.9 mg/L at 25°C (99.2%)<br>Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range |
| Solubility in organic solvents (state temperature, state purity) | Solubility at 25°C (97.6%)<br>acetone >500<br>dichloromethane >500<br>ethyl acetate >500<br>methanol >500<br>toluene >500 g/L.<br>hexane 4.6 g/L<br>octanol 110 g/L |
| Surface tension (state concentration and temperature, state purity) | 56.7 to 57.6 mN/m; filtrates of 10.0 g/L suspensions at 20° C (97.6%) |
| Partition co-efficient (state temperature, pH and purity) | Log Po/w = 4.07 at 25°C (99.2%)<br>Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range |
| Dissociation constant (state purity) | no dissociation constant in the pH range from 1 to 10 (purified) |

| | |
|---|---|
| UV/VIS absorption (max.) incl. ε (state purity, pH) | methanol solution: 13.831 mg/L<br>λmax (nm); ε (L.mol-1.cm-1)<br>228 15219<br>278 2453<br>300 745<br><br>acidic (9% 1N HCl) methanol solution: 13.831 mg/L<br>λmax (nm); ε (L.mol-1.cm-1)<br>228 15062<br>278 2357<br>300 643<br><br>basic (9% 1N NaOH) methanol solution: 13.831 mg/L<br>λmax (nm); ε (L.mol-1.cm-1)<br>228 14879<br>278 2374<br>300 664<br><br>(99.5%)<br>No absorption maximum between 310 and 750 nm. |
| Flammability (state purity) | flammability (A.10): not highly flammable (97.6%)<br>auto-flammability (A.16): no self-ignition between room temperature and the melting point (about 56°C) (97.6%) |
| Explosive properties (state purity) | not explosive (97.6%) |
| Oxidising properties (state purity) | not oxidizing (97.6%) |

**Classification and proposed labelling** (Annex IIA, point 10)

| | RMS/peer review proposal |
|---|---|
| Active substance | none |

**Summary of representative uses evaluated (fenoxycarb)***

| 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 (l) | | | PHI (days) (m) | Remarks: |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of as (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 | | |
| Apples and pears | North EU | INSEGAR 25 WG | F | Lepidoptera, Tortricidae | WG | 250 g/kg | Spray | *) | 2 | 10 | Max. 0.015 | Min. 1000 | 0.150 | 21 | *) April – June Dependant on pest pressure. No application during flowering. (I), (2) |
| Apples and pears | South EU | INSEGAR 25 WG | F | Lepidoptera, Tortricidae | WG | 250 g/kg | Spray | *) | 2 | 21 | Max. 0.015 | Min. 1500 | 0.225 | 21 | *) April – June Dependant on pest pressure. No application during flowering. (I), (2) |

(1) Based on the data available the risk to aquatic organisms and non-target arthropods (in-crop and off-crop) was assessed as high.
(2) The risk assessment for bee brood could not be finalised.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

## Chapter 2.2 Methods of Analysis

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

| | |
|---|---|
| Technical as (analytical technique) | Dissolution in acetonitrile followed by reversed phase HPLC-UV analysis. |
| Impurities in technical as (analytical technique) | Dissolution in solvent followed by HPLC-UV analysis |
| Plant protection product (analytical technique) | Dissolution in acetonitrile:water followed by reversed phase HPLC-UV analysis. |

**Analytical methods for residues** (Annex IIA, point 4.2)

**Residue definitions for monitoring purposes**

| | | |
|---|---|---|
| Food of plant origin | | Fenoxycarb |
| Food of animal origin | | Fenoxycarb |
| Soil | | Fenoxycarb |
| Water | surface | Fenoxycarb |
| | drinking/ground | Fenoxycarb |
| Air | | Fenoxycarb |

**Monitoring/Enforcement methods**

| | |
|---|---|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Multi-residue method DFG S19:<br>GC-MS 0.02 mg/kg (fenoxycarb in apples) (ILV + conf. method available)<br>Single Method REM 169.02:<br>HPLC-UV 0.02 mg/kg (fenoxycarb in apples) (ILV + conf. method available)<br>Single method AG-622A:<br>HPLC-UV 0.01 mg/kg (fenoxycarb in apples) (ILV + conf. method available) |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Single Method AG-608:<br>HPLC-UV 0.01 mg/kg (fenoxycarb in liver, fat, muscle, milk) (ILV + conf. method available) |
| Soil (analytical technique and LOQ) | Method RAM 406/01:<br>LC-MS/MS 0.01 mg/kg (fenoxycarb) |
| Water (analytical technique and LOQ) | Method RAM 408/01:<br>LC-MS/MS 0.1 µg/L (fenoxycarb)<br>matrix: surface, ground and drinking water |
| Air (analytical technique and LOQ) | Method: RAM 409/01<br>LC-MS/MS 2.8 µg/m³ |
| Body fluids and tissues (analytical technique and LOQ) | Fenoxycarb is not classified as a toxic substance. Therefore, no method in body fluids and tissues is required. |

## Chapter 2.3 Impact on Human and Animal Health

### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

| | |
|---|---|
| Rate and extent of oral absorption | Based on the comparison between oral and IV administration:<br>complete, based on urinary (14-23%), faeces (assumed biliary) (73-81%) excretion within 168h |
| Distribution | Highest residues in fat, liver and kidneys at 168 h (< 0.01% AR). |
| Potential for accumulation | No evidence for accumulation. |
| Rate and extent of excretion | Rapid and extensive within 72 h: mainly via faeces (73-81%), also via urine (16-22%). |
| Metabolism in animals | Extensively metabolised, mainly by conjugation |
| Toxicologically relevant compounds (animals and plants) | Fenoxycarb |
| Toxicologically relevant compounds (environment) | Fenoxycarb |

### Acute toxicity (Annex IIA, point 5.2)

| | | |
|---|---|---|
| Rat $LD_{50}$ oral | > 10000 mg/kg bw | |
| Rat $LD_{50}$ dermal | > 2000 mg/kg bw | |
| Rat $LC_{50}$ inhalation | > 4.4 mg/L air /4h (nose only) | |
| Skin irritation | Non-irritant | |
| Eye irritation | Non-irritant | |
| Skin sensitisation | Non-sensitiser (M & K) | |

### Short term toxicity (Annex IIA, point 5.3)

| | | |
|---|---|---|
| Target / critical effect | Liver (weight and hypertrophy) in rats, dogs, mice<br>Thyroid (weight and hypertrophy) and kidneys (weight) in rats | |
| Relevant oral NOAEL | 9.7 mg/kg bw/d (13-wk rat)<br>LOAEL 25 mg/kg bw/d (1-yr dog)<br>LOAEL 100 mg/kg bw/d (13-wk mouse) | |
| Relevant dermal NOAEL | 200 mg/kg bw/d (4-wk rat) | |
| Relevant inhalation NOAEL | 99 $mg/m^3$ (4-wk rat) | |

### Genotoxicity (Annex IIA, point 5.4)

| | |
|---|---|
| Fenoxycarb has no genotoxic potential | |

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

| | | |
|---|---|---|
| Target/critical effect | Liver: increased weight, hypertrophy, focal necrosis and fibrosis (rat, mouse)<br>Lung: alveolar/bronchiolar tumours (mouse) | |
| Relevant NOAEL | 8.1 mg/kg bw/d (2-yr rat)<br>5.3 mg/kg bw/d (18-mo mouse) NOAEL (mouse study 1); LOAEL (mouse study 2) | |
| Carcinogenicity | Tumours in liver and lungs (liver tumours not relevant for human risk assessment; attributed to peroxisome proliferation). | **Carc cat.3 R40** |

**Reproductive toxicity (Annex IIA, point 5.6)**

**Reproduction toxicity**

| | | |
|---|---|---|
| Reproduction target / critical effect | Parental and offspring: increased liver weight<br>Reproductive: no adverse effects | |
| Relevant parental NOAEL | 13 mg/kg bw/d | |
| Relevant reproductive NOAEL | 119 mg/kg bw/d | |
| Relevant offspring NOAEL | 13 mg/kg bw/d | |

**Developmental toxicity**

| | | |
|---|---|---|
| Developmental target / critical effect | Maternal: clinical signs (rat), decreased body weight gain (rabbit)<br>Developmental: no developmental or irreversible structural effects (rat); increased incidence of spina bifida (rabbit) | **Repr Cat.3 R63** |
| Relevant maternal NOAEL | 50 mg/kg bw/d (rat)<br>100 mg/kg bw/d (rabbit) | |
| Relevant developmental NOAEL | 500 mg/kg bw/d (rat)<br>200 mg/kg bw/d (rabbit) | |

**Neurotoxicity (Annex IIA, point 5.7)**

| | | |
|---|---|---|
| Acute neurotoxicity | No data available – not required | |
| Repeated neurotoxicity | No data available – no concern from other studies. No additional data required | |
| Delayed neurotoxicity | No data available – not required | |

**Other toxicological studies (Annex IIA, point 5.8)**

| | |
|---|---|
| Mechanism studies | No inhibition of plasma cholinesterase in rats after a single oral dose of fenoxycarb.<br>In a 14-day oral study with mice, fenoxycarb showed to be a strong inducer of hepatic metabolising enzymes and can be classified as a peroxisome proliferator.<br>In a 14-day oral study with mice fenoxycarb had no inducing properties on pulmonary xenobiotic metabolising enzymes.<br>In a repeated dose study with mice, cell proliferation was noted in liver (PCNA labelling) at 500 and 2000 mg/kg food, but not in lung.<br>The oxidative metabolisme fo fenoxycarb was studied *in vitro* using liver and lung microsomes. Lung microsome from mouse, rat, marmoset and man did not metabolise fenoxycarb. Liver microsomes did metabolise fenoxycarb. Mice showed the highest formation rate of metabolites possibly related to tumour formation as ethyl carbamate (urethane) or hydroquinone (benzoquinone).<br>*In vitro* formation of urethane by (mouse and human) liver microsomes was confirmed by GC-MS. Human liver rmicrosomes were 11-173 fold slower than control mice and 22-253 fold slower than fenoxycarb pre-treated mouse liver microsomes.<br>In an *in vivo* study with mice, no indication was found for a genotoxic potential of fenoxycarb mediated by the formation of urethane-type DNA adducts after single oral exposure. |
| Studies performed on metabolites or impurities | No data available – not required. |

**Medical data (Annex IIA, point 5.9)**

| |
|---|
| No evidence of adverse effects to workers of manufacturing plants, agricultural workers and consumers. |

| **Summary (Annex IIA, point 5.10)** | Value | Study | Safety factor |
|---|---|---|---|
| ADI | 0.053 mg/kg bw/d | 18-mo, mouse | 100* |
| AOEL | 0.1 mg/kg bw/d | 13-wk, rat | 100 |
| ARfD | 2.0 mg/kg bw | Rabbit developmental | 100 |

* decreased by a factor of 3 based on mechanistic data, and increased by a factor of 3 based on the use of a LOAEL.

**Dermal absorption (Annex IIIA, point 7.3)**

| | |
|---|---|
| Formulation (Insegar 25 WG) | *In vivo* and *in vitro* studies:<br>High dose (612 µg/cm$^2$): 0.2%<br>Low dose (0.5 µg/cm$^2$): 28% |

**Exposure scenarios (Annex IIIA, point 7.2)**

| | |
|---|---|
| Operator | Use in pome fruit<br>Without PPE: 88% (UK-POEM), 84% (DE-model)<br>With PPE*: 62% (UK-POEM), 78% (DE-model). |
| Workers | 73% of AOEL without PPE (EUROPOEM II) |
| Bystanders | 32% of AOEL (EUROPOEM II) |

* PPE: gloves during mixing/loading and application

**Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)**

| | RMS/peer review proposal |
|---|---|
| Substance classified (fenoxycarb) | **Xn** "Harmful"<br>**R40** "Limited evidence of a carcinogenic effect"<br>**R63** "May cause harm to the unborn child" |

## Chapter 2.4 Residues

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

| | |
|---|---|
| Plant groups covered | Fruits (citrus, apple) (soil, leaf-paint, fruit-paint and spray applications)<br>supportive: Cereals (Bermuda grass) (spray application) |
| Rotational crops | Wheat, mustard, radish |
| Metabolism in rotational crops similar to metabolism in primary crops? | Low total residues in rotational crops. Triggers for metabolite identification were not exceeded. |
| Processed commodities | Conditions simulating baking, brewing and sterilisation |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Fenoxycarb residues are stable upon processing. |
| Plant residue definition for monitoring | Fenoxycarb (fruit crop category). |
| Plant residue definition for risk assessment | Fenoxycarb (fruit crop category). |
| Conversion factor (monitoring to risk assessment) | None. |

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

| | |
|---|---|
| Animals covered | Goat, hen. |
| Time needed to reach a plateau concentration in milk and eggs | milk: 2 and >5 days.<br>eggs: 8 days. |
| Animal residue definition for monitoring | Fenoxycarb |
| Animal residue definition for risk assessment | Fenoxycarb (for representative uses only; different uses with higher animal exposure may require reevaluation for inclusion of metabolites) |
| Conversion factor (monitoring to risk assessment) | None. |
| Metabolism in rat and ruminant similar (yes/no) | Yes. |
| Fat soluble residue: (yes/no) | Yes (LogPow >3; in livestock feeding studies fenoxycarb in fat was at the LOQ (0.01 mg/kg) at intake levels relevant to the representative use). |

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

| |
|---|
| No studies submitted and no studies required. |

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

| |
|---|
| Fenoxycarb is stable for up to 24 months in whole oranges, orange juice, dried orange pulp, whole apples and wet pomace during frozen storage (-20°C).<br>Fenoxycarb is stable for up to 22 months in beef muscle, beef liver, milk and eggs during frozen storage (-20°C). For fat, storage stability of parent is not shown (it is strongly suggested that the sum of fenoxycarb and GCA249850 is constant. However, CGA 249850 is not stable in muscle. |

**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, 0.787 mg/kg dw diet | no | no |
| Potential for accumulation (yes/no): | yes | - | - |
| Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no) | yes | - | - |
| | Feeding studies (cows: 1.1 mg/kg dm feed)<br>Residue levels in matrices : Mean (max) mg/kg | | |
| Muscle | <0.01 | - | - |
| Liver | <0.01 | - | - |
| Kidney | <0.01 | - | - |
| Fat | 0.01 (0.02) | - | - |
| Milk | <0.01 | | |
| Eggs | | - | |

**Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)**

| Crop | Northern or Mediterranean Region, field or glasshouse, and any other useful information | Trials results relevant to the representative uses | Recommendation/comments | MRL estimated from trials according to the representative use | HR | STMR |
|---|---|---|---|---|---|---|
| Apple | NE | 0.03<br>0.10<br>0.03<br>0.12<br>0.27<br>0.03<br>0.17<br>0.19 | - | 0.5 | 0.27 | 0.11 |
| Apple | SE | 0.16<br>0.17<br>0.06<br>0.32<br>0.17<br>0.16<br>0.26<br>0.06<br>0.26 | - | 0.5 | 0.32 | 0.17 |

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

| | |
|---|---|
| ADI | 0.053 mg/kg bw/d |
| TMDI (% ADI) according to EFSA PRIMo rev. 2a | 12% (DE child)<br>1.3% (WHO cluster diet B) |
| IEDI (WHO European Diet) (% ADI) | Not calculated. |
| NEDI (specify diet) (% ADI) | Not calculated. |
| Factors included in IEDI and NEDI | Not applicable |
| ARfD | 2.0 mg/kg bw |
| IESTI (% ARfD) | Apples 2.4 % (UK infants)<br>Pears 2.3% (DE child) |
| NESTI (% ARfD) according to national (to be specified) large portion consumption data | Not calculated |
| Factors included in IESTI and NESTI | MRL of 0.5 mg/kg. |

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

| Crop/ process/ processed product | Number of studies | Processing factors | | Amount transferred (%) (Optional) |
|---|---|---|---|---|
| | | Transfer factor | Yield factor | |
| Juice | 1 | 0.1 (0.1, 0.1) | na | |
| Puree | 1 | 0.73 (0.67, 0.72, 0.74, 0.79) | na | |
| Wet pomace | 1 | 3.55 (3.5-3.6) | na | |
| Dry pomace | 1 | 13.8 (11, 12, 14, 18) | na | |

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

| | |
|---|---|
| Proposed MRLs | apple, pear: 0.5 mg/kg fenoxycarb<br>ruminant fat: 0.02 mg/kg |

## Chapter 2.5 Fate and Behaviour in the Environment

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

| | |
|---|---|
| Mineralization after 100 days ‡ | 32% after 90 d, A-label fenoxycarb (n=1)<br>29% after 88 d, A-label fenoxycarb (n=1)<br>24% after 91 d, B-label fenoxycarb (n=1) |
| Non-extractable residues after 100 days ‡ | 63% after 90 d, A-label fenoxycarb (n=1)<br>53% after 88 d, A-label fenoxycarb (n=1)<br>58% after 91 d, B-label fenoxycarb (n=1) |
| Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum) | none |

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

Anaerobic degradation ‡

| | |
|---|---|
| Mineralization after 100 days | 25% after 90 d, A-label fenoxycarb (n=1) |
| Non-extractable residues after 100 days | 52% after 90 d, A-label fenoxycarb (n=1) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | none |

Soil photolysis ‡

| | |
|---|---|
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | None<br>The $DT_{50}$ of fenoxycarb in irradiated soil was not different from the dark control. |

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

Laboratory studies ‡

| Parent | Aerobic conditions - **persistence endpoints** | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type | X[1] | pH | t. °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d) | $DT_{50}$ (d) 20°C | $Chi^2$ | Method of calculation |
| Silt loam | | 7.3 | 20°C/40% MWHC | 0.75/5.10 | 0.75 | 0.633 | FOMC |
| Silt loam | | 7.3 | 20°C/25% MWHC | 2.03/13.1 | 2.03 | 2.17 | FOMC |
| geomean for silt loam 20 °C | | | | | 1.23 | | |
| Sandy loam (1) | | 7.7 | 25°C/75% pF2.5 | 0.40/66.5 | - | 11.9 | DFOP |
| Sandy loam (1) | | 7.8 | 25°C/75% pF2.5 | 2.91/29.0[2] | - | 18.0 | FOMC |
| Geomean for Sandy loam (1) | | | | 1.08/43.9 | | | |
| Sandy loam (2) (aged residue column leaching) | | 6.4 | 20°C/40%MWHC | 2.27/20.5 | 2.27 | 5.24 | FOMC |
| Silty clay loam | | 7.2 | 20°C/pF2 | 1.47/4.87 | 1.47 | 7.00 | SFO |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | ($H_2O$) | | | | | |
| Geometric mean/median/mean | | | | | Not calculated (not needed for exposure assessment) | | |

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
[2] average of 2 values derived from the same soil with equal incubation

| Parent | Aerobic conditions - **modelling endpoints**<br>Normalisation of DT50 values to FOCUS reference conditions was carried out using the Q10 of 2.58 and Walker equation coefficient of 0.7 | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type | X[1] | pH | t. °C / % MWHC | $DT_{50}$ (d) | $DT_{50}$ (d) 20°C pF2/10kPa | Chi[2] | Method of calculation |
| Silt loam | | 7.3 | 20°C/40% MWHC | 1.29 | 1.29 | 7.75 | SFO |
| Silt loam | | 7.3 | 20°C/25% MWHC | 2.70 | 2.01 | 13.2 | SFO |
| geomean for silt loam 20 °C | | | | | **1.61** | | |
| Sandy loam (1) | | 7.7 | 25°C/75% pF2.5 | 81.5* | 86.0 | 11.9 | DFOP |
| Sandy loam (1) | | 7.8 | 25°C/75% pF2.5 | 8.73 # [2] | 13.1 [2] | 18.0 | FOMC |
| Geomean for Sandy loam (1) | | | | | **33.6** | | |
| Sandy loam (2) (aged residue column leaching) | | 6.4 | 20°C/40%MWHC | 2.89 | 2.89 | 14.1 | SFO |
| Silty clay loam | | 7.2 ($H_2O$) | 20°C/pF2 | 1.47/4.87 | 1.47 | 7.00 | SFO |
| Geometric mean/median/mean | | | | | **3.89 **/-/-** | | |

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
[2] average of 2 values derived from the same soil with equal incubation
# - calculated from DegT90 / 3.32
* - calculated from ln2 / k2
** for exposure modeling, the notifier geomean value of 4.06 days is used.

Field studies ‡

| Parent | Aerobic conditions **(supplementary data, not required)** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | X[1] | pH | Depth (cm) | $DT_{50}$ (d) actual | $DT_{90}$(d) actual | St. ($r^2$) | $DT_{50}$ (d) Norm. | Method of calculation |
| sandy loam, bare | California | | 6.9 | 0-30 | 7.3 | 24.2 | ≥0.87 | - | SFO |
| sandy loam, grass | Spain | | 7.9 | 0-30 | 4.08 | 13.55 | 0.99 | - | SFO |
| loam, grass | France (south) | | 7.5 | 0-30 | 8.89 | 29.53 | 0.92 | - | SFO |
| Geometric mean/median/mean | | | | | | | | | |

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

| | |
|---|---|
| pH dependence (yes / no) (if yes type of dependence) ‡ | No |
| Soil accumulation and plateau concentration ‡ | No data. Not required. |

Laboratory studies ‡

| Parent | 10° C study- persistence endpoint **(supplementary data, not required)** | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type | X[1] | pH | t. °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d) | $DT_{50}$ (d) 20°C | Chi2 | Method of calculation |
| Silt loam (Gartenacker) | | 7.3 | 10°C/40% MWHC | 4.46/14.8 | - | 7.39 | SFO |
| Geometric mean/median/mean | | | | | - | | |

Laboratory studies ‡

| Parent | Anaerobic conditions **(supplementary data, not required)** | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil type | X[1] | pH | t. °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d) | $DT_{50}$ (d) 20°C | St. ($r^2$) | Method of calculation |
| Sandy loam | | 7.7 | 25°C/flooded | 0.25/365 | 0.37 | na | graphically |
| Geometric mean/median/mean | | | | | 0.37 | | |

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

**Soil adsorption/desorption (Annex IIA, point 7.1.2)**

| Parent ‡ | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH (water) | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfoc (mL/g) | 1/n |
| Clay | 1.8 | 6.6 | - | - | 46.7 | 2599 | 0.839 |
| Sand | 0.2 | 6.0 | - | - | 4.4 | 1883 | 0.910 |
| Sandy loam | 1.8 | 7.7 | - | - | 22.5 | 1251 | 0.867 |
| Silt loam | 1.0 | 6.7 | - | - | 16.2 | 1639 | 0.962 |
| Loam | 1.9 | 6.8 | - | - | 32.7 | 1710 | 0.873 |
| Arithmetic mean/median | | | | | 24.5/22.5 | 1816/1710 | 0.89/0.87 |
| pH dependence, Yes or No | | | No | | | | |

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

| | |
|---|---|
| Column leaching ‡ | Eluation (mm): 200-550 mm (n=12)<br>Time period (d): <1 d to 19 d (n=12) |
| | Leachate: ≤1.5 %AR (n=12)<br>Active substance was not detected in the leachate<br>>91 % total residues/radioactivity retained in top 12 cm |
| Aged residues leaching ‡ | Aged for (d): 2-14 d (n=2)<br>Time period (d): 2-4 d (n=2)<br>Eluation (mm): 196-508 mm (n=2) |
| | Analysis of soil residues post ageing (soil residues pre-leaching): 18.5-51 % active substance, 3-12 % other extractables.<br>Leachate: ≤1.0 % column applied radioactivity (n=2)<br>Active substance was not detected in the leachate<br>89.6 % total column applied radioactivity retained in top 6 cm (n=1) |
| Lysimeter/ field leaching studies ‡ | No study submitted. No data required. |

**PEC (soil) (Annex IIIA, point 9.1.3)**

| | |
|---|---|
| Parent<br>Method of calculation | *Northern and Southern Europe:*<br>$DT_{50}$ / $DT_{90}$ (d): 8.9 / 29.5 days<br>Kinetics: SFO<br>Absolute worst case from field studies. |
| Application data | Crop: apple/pear<br>Depth of soil layer: 5 cm.<br>Soil bulk density: 1.5 g/$cm^3$<br>% plant interception: 50%<br>Number of applications: 2<br>Interval (d): 10 d (NE), 21 d (SE)<br>Application rate(s): 150 (NE) and 225 (SE) g as/ha |

**Northern Europe**

| $PEC_{(s)}$ (mg/kg) | | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---|---|---|---|---|---|
| Initial | | x | | 0.146 | - |
| Short term | 24h | x | x | 0.135 | 0.140 |
| | 2d | x | x | 0.125 | 0.135 |
| | 4d | x | x | 0.107 | 0.125 |
| Long term | 7d | x | x | 0.085 | 0.112 |
| | 14d | x | x | 0.049 | 0.089 |
| | 21d | x | x | 0.028 | 0.072 |
| | 28d | x | x | 0.016 | 0.059 |
| | 50d | x | x | 0.003 | 0.037 |
| | 100d | x | x | 0.001 | 0.019 |
| Plateau concentration | | not applicable | | | |

**Southern Europe**

| $PEC_{(s)}$ (mg/kg) | | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---|---|---|---|---|---|
| Initial | | x | | 0.179 | |
| Short term | 24h | x | x | 0.166 | 0.172 |
| | 2d | x | x | 0.153 | 0.166 |
| | 4d | x | x | 0.131 | 0.154 |
| Long term | 7d | x | x | 0.104 | 0.138 |
| | 21d | x | x | 0.035 | 0.088 |
| | 28d | x | x | 0.020 | 0.073 |
| | 50d | x | x | 0.004 | 0.045 |
| | 100d | x | x | 0.000 | 0.023 |
| Plateau concentration | | not applicable | | | |

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

| | |
|---|---|
| Hydrolytic degradation of the active substance and metabolites > 10 % ‡ | pH 3: stable at 35°C and 50°C |
| | pH 5: stable at 25°C |
| | pH 7: stable at 25, 35 and 50°C |
| | pH 9: stable at 25, 35 and 50°C |
| | distilled water: stable at 35 and 50°C |
| Photolytic degradation of active substance and metabolites above 10 % ‡ | photolytic half-life was 4 h, 16.1 d and 29.4 d under study conditions (roughly equivalent to summer sunlight at 40ºN)<br>phenol (max 17.9% AR at 22 d)<br>CGA-294847 (max 16.9% AR at 30 d) |
| Quantum yield of direct phototransformation in water at Σ > 290 nm | $5.11 \cdot 10^{-2}$ |
| Readily biodegradable ‡ (yes/no) | Submitted study was not acceptable. Therefore considered not readily biodegradable. |

**Degradation in water / sediment**

| Parent | **Persistence endpoints**<br>Distribution (max in water 95.0% after 0 d. Max. sed 37.1% after 3 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed | t. °C | $DT_{50}$-$DT_{90}$ whole sys. | St. ($r^2$) Chi2 | $DT_{50}$-$DT_{90}$ water[1] | St. ($r^2$) Chi2 | $DT_{50}$- $DT_{90}$ sed[1] | St. ($r^2$) Chi2 | Method of calculation |
| River | 6.9 | 7.9 | 20 | 6.09-20.2 | 10.5 | 2.69-8.94 | 1.93 | 13.4-44.5 | 19.4* | SFO/SFO/SFO |
| Pond | 6.9 | 7.3 | 20 | 4.54- 15.1 | 14.7 | 1.35-4.47 | 2.23 | 10.0-33.4 | 26.8* | SFO/SFO/SFO |
| Geometric mean | | | | 5.26-17.5 | | 1.91-6.32 | | 11.6-38.6 | | |
| Median | | | | n.c. | | n.c. | | n.c. | | |
| Mean | | | | n.c. | | n.c. | | n.c. | | |

[1] half-lives for dissipation
* T0 values left out
n.c.: Not calculated

| Parent | **Modelling endpoints** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed | t. °C | $DT_{50}$ whole sys. | St. ($r^2$) Chi2 | $DT_{50}$ water | St. ($r^2$) | $DT_{50}$ sed | St. ($r^2$) | Method of calculation |
| River | 6.9 | 7.9 | 20 | 6.09 | 10.5 | 6.09 | - | 6.09 | - | SFO |
| Pond | 6.9 | 7.3 | 20 | 4.54 | 14.7 | 4.54 | - | 4.54 | - | SFO |
| Geometric mean | | | | 5.26 | | 5.26 | | 5.26 (STEP 1/ 2)<br>1000 (STEP | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | 3/ 4) | | |
| Median | | n.c. | | n.c. | | n.c. | | |
| Mean | | n.c. | | n.c. | | n.c. | | |

| Mineralization and non extractable residues | | | | | |
|---|---|---|---|---|---|
| Water / sediment system | pH water phase | pH sed | Mineralization x % after n d. (end of the study). | Non-extractable residues in sed. Max x % after n d | Non-extractable residues in sed. Max x % after n d (end of the study) |
| River | 6.9 | 7.9 | 40% after 119 d | max 56% after 29 d | 50% after 119 d |
| Pond | 6.9 | 7.3 | 36% after 119 d | max 55% after 14 d | 52% after 119 d |

**PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)**

| | |
|---|---|
| Parent<br>Parameters used in FOCUSsw step 1 and 2 | Version control no. of FOCUS calculator: vs 1.1<br>Molecular weight (g/mol): 301.4<br>Water solubility (mg/L): 7.9<br>$K_{OC}$ (L/kg): 1816<br>$DT_{50}$ soil (d): 3.46<br>$DT_{50}$ water/sediment system (d): 7.45<br>$DT_{50}$ water (d): 7.45 (system value used)<br>$DT_{50}$ sediment (d): 7.45 (system value used) |
| Parameters used in FOCUSsw step 3 (if performed) | MACRO in FOCUS vs 4; PRZ in FOCUS vs 1; TOXSWA in FOCUS vs 2.4.2<br>$DT_{50}$ water/sediment system (d): 5.26<br>$DT_{50}$ water (d): 5.26 (system value used)<br>$DT_{50}$ sediment (d): 1000<br>$DT_{50}$ soil (d): 4.06. *NB RMS calculated a geomean soil DT50 of 3.89 days. As notifier value is conservative, the use of 4.06 days is considered acceptable.*<br>normalisation of DT50 values to FOCUS reference conditions and subsequently the simulations were carried out using the Q10 of 2.58 and Walker equation coefficient of 0.7<br>$K_{OC}$ (L/kg): 1816<br>1/n: 0.89 |
| Application rate | *STEP 1 (worst-case conditions):*<br>Crop: pome/stone fruit/early application (SE)/late application (NE)<br>Number of applications: 2<br>Application rate(s): 150 (NE) and 225 g as/ha (SE)<br>*STEP 2 (worst-case conditions):*<br>Input as in STEP 1, additional input:<br>Interval (d): 10 (NE) and 21 (SE)<br>Crop interception: average crop cover (40%) (SE), full canopy (70%) (NE)<br>Application window: March-May (SE), June-Sep (NE)<br>NB For NE cGAP both single and multiple application was |

simulated in STEP 2.

*STEP 3 (worst-case conditions):*

Crop: pome/stone fruit/early application (NE and SE)

Number of applications: 2 (NE) and 2 (SE)

Application window: March-May (NE and SE)

*STEP 4 (worst-case conditions):*

As in STEP 3 with additional buffer zones, 25 m for NE GAP and 30 m for SE GAP

| FOCUS STEP 1 Scenario | Day after overall maximum | $PEC_{SW}$ (µg/L) | | $PEC_{SED}$ (µg/kg) | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| Apple, SE GAP | 0 h | 87.6381 | - | 796.1808 | - |

| FOCUS STEP 2 Scenario | Day after overall maximum | $PEC_{SW}$ (µg/L) | | $PEC_{SED}$ (µg/kg) | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| Apple, NE GAP Single application, 1x 150 g/ha | 0 h | 14.60 | | 85.30 | |
| | 24 h | 7.03 | 10.81 | 83.05 | 84.17 |
| | 2 d | 5.21 | 8.47 | 80.85 | 83.06 |
| | 4 d | 5.50 | 6.74 | 76.63 | 80.89 |
| | 7 d | 4.06 | 5.74 | 70.70 | 77.78 |
| | 14 d | 3.36 | 4.72 | 58.60 | 71.12 |
| | 21 d | 2.79 | 4.17 | 48.57 | 65.23 |
| | 28 d | 2.31 | 3.76 | 40.26 | 59.99 |
| | 42 d | 1.59 | 3.15 | 27.66 | 51.19 |

| FOCUS STEP 2 Scenario | Day after overall maximum | $PEC_{SW}$ (µg/L) | | $PEC_{SED}$ (µg/kg) | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| Apple, NE GAP Multiple application, 2x 150 g/ha | 0 h | 7.56 | - | 55.14 | - |
| | 24 h | 4.36 | 5.96 | 53.68 | 54.41 |
| | 2 d | 3.56 | 4.96 | 52.26 | 53.69 |
| | 4 d | 3.60 | 4.20 | 49.53 | 52.29 |
| | 7 d | 2.62 | 3.63 | 45.70 | 50.28 |
| | 14 d | 2.17 | 3.01 | 37.88 | 45.97 |
| | 21 d | 1.80 | 2.67 | 31.40 | 42.16 |
| | 28 d | 1.49 | 2.41 | 26.03 | 38.78 |
| | 42 d | 1.03 | 2.02 | 17.88 | 33.09 |

| FOCUS STEP 2 Scenario | Day after overall maximum | $PEC_{SW}$ (µg/L) | | $PEC_{SED}$ (µg/kg) | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| Apple, SE GAP Multiple application, 2x 225 g/ha | 0 h | 22.38 | - | 172.58 | - |
| | 24 h | 12.34 | 17.36 | 168.01 | 170.30 |
| | 2 d | 9.86 | 14.23 | 163.57 | 168.04 |
| | 4 d | 11.05 | 12.00 | 155.03 | 163.66 |
| | 7 d | 8.21 | 10.67 | 143.05 | 157.36 |
| | 14 d | 6.81 | 9.08 | 118.57 | 143.90 |
| | 21 d | 5.64 | 8.12 | 98.27 | 131.97 |
| | 28 d | 4.68 | 7.38 | 81.46 | 121.38 |
| | 42 d | 3.21 | 6.22 | 55.96 | 103.56 |

**STEP 3**

**NE GAP, 2x150 g a.s./ha, early application– single and multiple applications**

| Scenario | Time (d) | PECsw (µg/L) Single application | | PECsw (µg/L) Multiple applications | |
|---|---|---|---|---|---|
| | | **Actual** | **TWA** | **Actual** | **TWA** |
| D3 ditch NE GAP | 0 | 11.6 | - | 10.0 | - |
| | 1 | 4.70 | 8.61 | 4.40 | 7.55 |
| | 2 | 0.507 | 5.35 | 0.540 | 4.79 |
| | 4 | 0.061 | 2.76 | 0.064 | 2.48 |
| | 7 | 0.029 | 1.59 | 0.033 | 1.44 |
| | 14 | 0.010 | 0.804 | 0.012 | 0.729 |
| | 21 | 0.005 | 0.539 | 0.007 | 0.937 |
| | 28 | 0.003 | 0.405 | 0.005 | 0.710 |
| | 42 | 0.002 | 0.271 | 0.003 | 0.476 |
| | 50 | 0.002 | 0.228 | 0.002 | 0.400 |
| | 100 | 0.001 | 0.114 | 0.001 | 0.201 |
| D4 pond NE GAP | 0 | 0.706 | - | 0.985 | - |
| | 1 | 0.661 | 0.683 | 0.923 | 0.957 |
| | 2 | 0.622 | 0.662 | 0.884 | 0.932 |
| | 4 | 0.557 | 0.625 | 0.777 | 0.882 |
| | 7 | 0.481 | 0.579 | 0.633 | 0.805 |
| | 14 | 0.346 | 0.496 | 0.408 | 0.658 |
| | 21 | 0.225 | 0.425 | 0.274 | 0.600 |
| | 28 | 0.152 | 0.365 | 0.188 | 0.550 |
| | 42 | 0.075 | 0.279 | 0.081 | 0.442 |
| | 50 | 0.045 | 0.244 | 0.050 | 0.391 |
| | 100 | 0.004 | 0.130 | 0.005 | 0.210 |
| D4 stream NE GAP | 0 | 11.1 | - | 9.87 | - |
| | 1 | < 0.001 | 0.635 | < 0.001 | 0.795 |
| | 2 | < 0.001 | 0.317 | < 0.001 | 0.398 |
| | 4 | < 0.001 | 0.159 | < 0.001 | 0.199 |
| | 7 | < 0.001 | 0.091 | < 0.001 | 0.114 |
| | 14 | < 0.001 | 0.045 | < 0.001 | 0.096 |
| | 21 | < 0.001 | 0.030 | < 0.001 | 0.064 |
| | 28 | < 0.001 | 0.023 | < 0.001 | 0.048 |
| | 42 | < 0.001 | 0.015 | < 0.001 | 0.032 |
| | 50 | < 0.001 | 0.013 | < 0.001 | 0.027 |
| | 100 | < 0.001 | 0.006 | < 0.001 | 0.013 |
| D5 pond NE GAP | 0 | 0.706 | - | 0.876 | - |
| | 1 | 0.651 | 0.677 | 0.816 | 0.845 |
| | 2 | 0.604 | 0.652 | 0.764 | 0.817 |
| | 4 | 0.525 | 0.607 | 0.674 | 0.767 |
| | 7 | 0.435 | 0.552 | 0.567 | 0.703 |
| | 14 | 0.296 | 0.456 | 0.341 | 0.577 |
| | 21 | 0.208 | 0.387 | 0.205 | 0.500 |
| | 28 | 0.130 | 0.332 | 0.128 | 0.488 |
| | 42 | 0.052 | 0.250 | 0.054 | 0.397 |
| | 50 | 0.033 | 0.216 | 0.033 | 0.349 |
| | 100 | 0.003 | 0.114 | 0.004 | 0.187 |
| D5 stream NE GAP | 0 | 11.3 | - | 10.4 | - |
| | 1 | < 0.001 | 0.426 | < 0.001 | 0.697 |
| | 2 | < 0.001 | 0.213 | < 0.001 | 0.348 |
| | 4 | < 0.001 | 0.107 | < 0.001 | 0.174 |
| | 7 | < 0.001 | 0.061 | < 0.001 | 0.100 |

| Scenario | Time (d) | PECsw (µg/L) Single application | | PECsw (µg/L) Multiple applications | |
|---|---|---|---|---|---|
| | | **Actual** | **TWA** | **Actual** | **TWA** |
| | 14 | < 0.001 | 0.031 | < 0.001 | 0.050 |
| | 21 | < 0.001 | 0.020 | < 0.001 | 0.051 |
| | 28 | < 0.001 | 0.015 | < 0.001 | 0.038 |
| | 42 | < 0.001 | 0.010 | < 0.001 | 0.025 |
| | 50 | < 0.001 | 0.009 | < 0.001 | 0.021 |
| | 100 | < 0.001 | 0.004 | < 0.001 | 0.011 |
| R1 pond NE GAP | 0 | 0.706 | - | 0.857 | - |
| | 1 | 0.625 | 0.678 | 0.786 | 0.820 |
| | 2 | 0.605 | 0.653 | 0.723 | 0.786 |
| | 4 | 0.527 | 0.609 | 0.618 | 0.727 |
| | 7 | 0.421 | 0.550 | 0.497 | 0.653 |
| | 14 | 0.257 | 0.441 | 0.311 | 0.525 |
| | 21 | 0.164 | 0.363 | 0.202 | 0.486 |
| | 28 | 0.107 | 0.305 | 0.118 | 0.457 |
| | 42 | 0.043 | 0.228 | 0.044 | 0.369 |
| | 50 | 0.025 | 0.197 | 0.027 | 0.323 |
| | 100 | 0.002 | 0.103 | 0.003 | 0.171 |
| R1 stream NE GAP | 0 | 9.40 | - | 8.02 | - |
| | 1 | 0.001 | 1.62 | 0.001 | 1.38 |
| | 2 | 0.001 | 0.809 | 0.001 | 0.691 |
| | 4 | 0.001 | 0.405 | 0.001 | 0.346 |
| | 7 | < 0.001 | 0.232 | < 0.001 | 0.198 |
| | 14 | < 0.001 | 0.116 | < 0.001 | 0.175 |
| | 21 | < 0.001 | 0.077 | < 0.001 | 0.117 |
| | 28 | < 0.001 | 0.058 | < 0.001 | 0.089 |
| | 42 | < 0.001 | 0.039 | < 0.001 | 0.061 |
| | 50 | < 0.001 | 0.033 | < 0.001 | 0.051 |
| | 100 | < 0.001 | 0.017 | < 0.001 | 0.026 |
| R2 stream NE GAP | 0 | 12.5 | - | 10.6 | - |
| | 1 | 0.001 | 1.05 | 0.001 | 0.900 |
| | 2 | < 0.001 | 0.527 | < 0.001 | 0.450 |
| | 4 | < 0.001 | 0.264 | < 0.001 | 0.225 |
| | 7 | < 0.001 | 0.151 | < 0.001 | 0.129 |
| | 14 | < 0.001 | 0.076 | 0.056 | 0.066 |
| | 21 | < 0.001 | 0.050 | < 0.001 | 0.045 |
| | 28 | < 0.001 | 0.038 | < 0.001 | 0.065 |
| | 42 | < 0.001 | 0.025 | < 0.001 | 0.044 |
| | 50 | < 0.001 | 0.021 | < 0.001 | 0.037 |
| | 100 | < 0.001 | 0.011 | < 0.001 | 0.019 |
| R3 stream NE GAP | 0 | 13.2 | - | 11.4 | - |
| | 1 | 0.010 | 3.60 | 0.021 | 3.62 |
| | 2 | 0.007 | 1.80 | 0.009 | 1.81 |
| | 4 | 0.005 | 0.905 | 0.005 | 0.910 |
| | 7 | 0.003 | 0.519 | 0.003 | 0.522 |
| | 14 | 0.001 | 0.260 | 0.002 | 0.288 |
| | 21 | < 0.001 | 0.174 | 0.001 | 0.322 |
| | 28 | < 0.001 | 0.133 | < 0.001 | 0.255 |
| | 42 | < 0.001 | 0.089 | < 0.001 | 0.170 |
| | 50 | < 0.001 | 0.075 | < 0.001 | 0.143 |
| | 100 | < 0.001 | 0.037 | < 0.001 | 0.072 |
| R4 stream NE GAP | 0 | 9.40 | - | 8.03 | - |
| | 1 | 0.001 | 1.63 | 0.001 | 1.39 |
| | 2 | 0.001 | 0.814 | 0.001 | 0.695 |

| Scenario | Time (d) | PECsw (µg/L) Single application | | PECsw (µg/L) Multiple applications | |
|---|---|---|---|---|---|
| | | **Actual** | **TWA** | **Actual** | **TWA** |
| | 4 | 0.001 | 0.407 | 0.001 | 0.348 |
| | 7 | < 0.001 | 0.233 | < 0.001 | 0.199 |
| | 14 | < 0.001 | 0.117 | < 0.001 | 0.100 |
| | 21 | < 0.001 | 0.078 | < 0.001 | 0.133 |
| | 28 | < 0.001 | 0.058 | < 0.001 | 0.100 |
| | 42 | < 0.001 | 0.039 | < 0.001 | 0.067 |
| | 50 | < 0.001 | 0.033 | < 0.001 | 0.056 |
| | 100 | < 0.001 | 0.017 | < 0.001 | 0.028 |

**SE GAP, 2x225 g a.s./ha, early application– single and multiple applications**

| Scenario | Time (d) | PECsw (µg/L) Single application | | PECsw (µg/L) Multiple applications | |
|---|---|---|---|---|---|
| | | **Actual** | **TWA** | **Actual** | **TWA** |
| D3 ditch SE GAP | 0 | 17.4 | - | 15.0 | - |
| | 1 | 7.06 | 12.9 | 7.38 | 11.5 |
| | 2 | 0.766 | 8.03 | 1.20 | 7.63 |
| | 4 | 0.092 | 4.14 | 0.115 | 4.00 |
| | 7 | 0.043 | 2.39 | 0.054 | 2.32 |
| | 14 | 0.014 | 1.21 | 0.020 | 1.18 |
| | 21 | 0.007 | 0.808 | 0.011 | 0.789 |
| | 28 | 0.005 | 0.608 | 0.008 | 0.594 |
| | 42 | 0.003 | 0.406 | 0.004 | 0.740 |
| | 50 | 0.002 | 0.342 | 0.003 | 0.624 |
| | 100 | 0.001 | 0.172 | 0.002 | 0.314 |
| D4 pond SE GAP | 0 | 1.06 | - | 1.21 | - |
| | 1 | 0.992 | 1.02 | 1.11 | 1.16 |
| | 2 | 0.934 | 0.993 | 1.03 | 1.11 |
| | 4 | 0.837 | 0.938 | 0.891 | 1.03 |
| | 7 | 0.723 | 0.869 | 0.729 | 0.936 |
| | 14 | 0.521 | 0.746 | 0.478 | 0.765 |
| | 21 | 0.339 | 0.638 | 0.324 | 0.642 |
| | 28 | 0.229 | 0.549 | 0.197 | 0.636 |
| | 42 | 0.112 | 0.420 | 0.080 | 0.598 |
| | 50 | 0.068 | 0.367 | 0.052 | 0.545 |
| | 100 | 0.006 | 0.195 | 0.007 | 0.303 |
| D4 stream SE GAP | 0 | 16.7 | - | 14.4 | - |
| | 1 | < 0.001 | 0.952 | < 0.001 | 0.916 |
| | 2 | < 0.001 | 0.476 | < 0.001 | 0.458 |
| | 4 | < 0.001 | 0.238 | < 0.001 | 0.229 |
| | 7 | < 0.001 | 0.136 | < 0.001 | 0.131 |
| | 14 | < 0.001 | 0.068 | < 0.001 | 0.066 |
| | 21 | < 0.001 | 0.045 | < 0.001 | 0.044 |
| | 28 | < 0.001 | 0.034 | < 0.001 | 0.062 |
| | 42 | < 0.001 | 0.023 | < 0.001 | 0.041 |
| | 50 | < 0.001 | 0.019 | < 0.001 | 0.035 |
| | 100 | < 0.001 | 0.010 | < 0.001 | 0.017 |
| D5 pond SE GAP | 0 | 1.06 | - | 1.17 | - |
| | 1 | 0.977 | 1.02 | 1.06 | 1.11 |
| | 2 | 0.906 | 0.978 | 0.964 | 1.06 |
| | 4 | 0.788 | 0.911 | 0.806 | 0.971 |
| | 7 | 0.654 | 0.828 | 0.627 | 0.860 |
| | 14 | 0.446 | 0.685 | 0.365 | 0.672 |

| Scenario | Time (d) | PECsw (µg/L) Single application | | PECsw (µg/L) Multiple applications | |
|---|---|---|---|---|---|
| | | **Actual** | **TWA** | **Actual** | **TWA** |
| | 21 | 0.313 | 0.528 | 0.223 | 0.547 |
| | 28 | 0.195 | 0.500 | 0.141 | 0.566 |
| | 42 | 0.078 | 0.375 | 0.056 | 0.527 |
| | 50 | 0.049 | 0.325 | 0.035 | 0.474 |
| | 100 | 0.005 | 0.171 | 0.005 | 0.260 |
| D5 stream | 0 | 16.9 | - | 15.7 | - |
| SE GAP | 1 | < 0.001 | 0.640 | 0.001 | 1.14 |
| | 2 | < 0.001 | 0.320 | < 0.001 | 0.572 |
| | 4 | < 0.001 | 0.160 | < 0.001 | 0.286 |
| | 7 | < 0.001 | 0.092 | < 0.001 | 0.164 |
| | 14 | < 0.001 | 0.046 | < 0.001 | 0.082 |
| | 21 | < 0.001 | 0.031 | < 0.001 | 0.055 |
| | 28 | < 0.001 | 0.023 | < 0.001 | 0.060 |
| | 42 | < 0.001 | 0.015 | < 0.001 | 0.040 |
| | 50 | < 0.001 | 0.013 | < 0.001 | 0.034 |
| | 100 | < 0.001 | 0.006 | < 0.001 | 0.017 |
| R1 pond | 0 | 1.06 | - | 1.20 | - |
| SE GAP | 1 | 0.979 | 1.02 | 1.12 | 1.16 |
| | 2 | 0.908 | 0.979 | 1.04 | 1.12 |
| | 4 | 0.792 | 0.913 | 0.899 | 1.04 |
| | 7 | 0.633 | 0.826 | 0.722 | 0.942 |
| | 14 | 0.387 | 0.662 | 0.452 | 0.758 |
| | 21 | 0.246 | 0.545 | 0.293 | 0.628 |
| | 28 | 0.161 | 0.459 | 0.196 | 0.617 |
| | 42 | 0.065 | 0.342 | 0.078 | 0.568 |
| | 50 | 0.038 | 0.296 | 0.047 | 0.515 |
| | 100 | 0.004 | 0.154 | 0.005 | 0.286 |
| R1 stream | 0 | 14.1 | - | 12.0 | - |
| SE GAP | 1 | 0.002 | 2.43 | 0.002 | 2.07 |
| | 2 | 0.002 | 1.21 | 0.002 | 1.04 |
| | 4 | 0.001 | 0.607 | 0.001 | 0.519 |
| | 7 | < 0.001 | 0.347 | < 0.001 | 0.297 |
| | 14 | < 0.001 | 0.174 | < 0.001 | 0.148 |
| | 21 | < 0.001 | 0.116 | < 0.001 | 0.099 |
| | 28 | < 0.001 | 0.088 | < 0.001 | 0.148 |
| | 42 | < 0.001 | 0.059 | < 0.001 | 0.099 |
| | 50 | < 0.001 | 0.050 | < 0.001 | 0.084 |
| | 100 | < 0.001 | 0.025 | < 0.001 | 0.042 |
| R2 stream | 0 | 18.7 | - | 15.9 | - |
| SE GAP | 1 | 0.001 | 1.58 | 0.001 | 1.35 |
| | 2 | 0.001 | 0.791 | 0.001 | 0.676 |
| | 4 | < 0.001 | 0.396 | < 0.001 | 0.338 |
| | 7 | < 0.001 | 0.226 | < 0.001 | 0.193 |
| | 14 | < 0.001 | 0.113 | < 0.001 | 0.099 |
| | 21 | < 0.001 | 0.076 | < 0.001 | 0.068 |
| | 28 | < 0.001 | 0.057 | < 0.001 | 0.097 |
| | 42 | < 0.001 | 0.038 | < 0.001 | 0.066 |
| | 50 | < 0.001 | 0.032 | < 0.001 | 0.056 |
| | 100 | < 0.001 | 0.016 | < 0.001 | 0.028 |
| R3 stream | 0 | 19.9 | - | 17.0 | - |
| SE GAP | 1 | 0.016 | 5.40 | 0.031 | 5.43 |
| | 2 | 0.010 | 2.71 | 0.013 | 2.72 |
| | 4 | 0.007 | 1.36 | 0.008 | 1.39 |

| Scenario | Time (d) | PECsw (µg/L) Single application | | PECsw (µg/L) Multiple applications | |
|---|---|---|---|---|---|
| | | Actual | TWA | Actual | TWA |
| | 7 | 0.004 | 0.778 | 0.004 | 0.798 |
| | 14 | 0.001 | 0.390 | 0.001 | 0.401 |
| | 21 | 0.001 | 0.260 | 0.001 | 0.268 |
| | 28 | 0.001 | 0.200 | 0.001 | 0.366 |
| | 42 | < 0.001 | 0.133 | < 0.001 | 0.245 |
| | 50 | < 0.001 | 0.112 | < 0.001 | 0.206 |
| | 100 | < 0.001 | 0.056 | < 0.001 | 0.103 |
| R4 stream | 0 | 14.1 | - | 12.1 | - |
| SE GAP | 1 | 0.002 | 2.44 | 0.003 | 2.44 |
| | 2 | 0.002 | 1.22 | 0.002 | 1.22 |
| | 4 | 0.001 | 0.611 | 0.001 | 0.610 |
| | 7 | 0.001 | 0.350 | 0.001 | 0.349 |
| | 14 | < 0.001 | 0.175 | < 0.001 | 0.188 |
| | 21 | < 0.001 | 0.117 | < 0.001 | 0.126 |
| | 28 | < 0.001 | 0.088 | < 0.001 | 0.097 |
| | 42 | < 0.001 | 0.058 | < 0.001 | 0.108 |
| | 50 | < 0.001 | 0.049 | < 0.001 | 0.091 |
| | 100 | < 0.001 | 0.025 | < 0.001 | 0.049 |

**STEP 4 -global maximum values**

**NE GAP, 2x150 g a.s./ha, early application– single and multiple applications, 25 m crop-free buffer zone**

| Scenario | PECsw (µg/L) Single application | PECsw (µg/L) Multiple applications |
|---|---|---|
| D3 Ditch | 0.755 | 0.655 |
| D4 Pond | 0.095 | 0.121 |
| D4 Stream | 0.791 | 0.712 |
| D5 Pond | 0.095 | 0.107 |
| D5 Stream | 0.801 | 0.752 |
| R1 Pond | 0.095 | 0.105 |
| R1 Stream | 0.668 | 0.579 |
| R2 Stream | 0.885 | 0.767 |
| R3 Stream | 0.941 | 0.820 |
| R4 Stream | 0.668 | 0.579 |

**SE GAP, 2x225 g a.s./ha, early application– single and multiple applications, 30 m crop-free buffer zone**

| Scenario | PECsw (µg/L) Single application | PECsw (µg/L) Multiple applications |
|---|---|---|
| D3 Ditch | 0.734 | 0.608 |
| D4 Pond | 0.102 | 0.102 |
| D4 Stream | 0.770 | 0.644 |
| D5 Pond | 0.102 | 0.099 |
| D5 Stream | 0.779 | 0.702 |
| R1 Pond | 0.102 | 0.101 |
| R1 Stream | 0.650 | 0.537 |
| R2 Stream | 0.861 | 0.711 |
| R3 Stream | 0.915 | 0.760 |
| R4 Stream | 0.650 | 0.540 |

**PEC sediment**

**STEP 3 and 4 – global maximum values**

**NE GAP, 2x150 g a.s./ha, interval 10 days, early application– single and multiple applications, 25 m crop-free buffer zone**

| Scenario | STEP 3 PECsed (µg/kg) Single application | STEP 3 PECsed (µg/kg) Multiple application | STEP 4 (25 m) PECsed (µg/kg) Single application | STEP 4 (25 m) PECsed (µg/kg) Multiple application |
|---|---|---|---|---|
| D3 ditch | 6.65 | 7.84 | 0.453 | 0.556 |
| D4 pond | 2.52 | 3.99 | 0.373 | 0.543 |
| D4 stream | 0.456 | 0.737 | 0.033 | 0.056 |
| D5 pond | 2.28 | 3.743 | 0.337 | 0.509 |
| D5 stream | 0.298 | 0.592 | 0.021 | 0.044 |
| R1 pond | 2.13 | 3.42 | 0.316 | 0.466 |
| R1 stream | 1.18 | 1.12 | 0.085 | 0.097 |
| R2 stream | 0.765 | 0.831 | 0.055 | 0.195 |
| R3 stream | 2.56 | 3.26 | 0.185 | 0.460 |
| R4 stream | 1.19 | 1.33 | 0.085 | 0.101 |

**SE GAP, 2x225 g a.s./ha, interval 21 days, early application– single and multiple applications, 30 m crop-free buffer zone**

| Scenario | STEP 3 PECsed (µg/kg) Single application | STEP 3 PECsed (µg/kg) Multiple application | STEP 4 (30 m) PECsed (µg/kg) Single application | STEP 4 (30 m) PECsed (µg/kg) Multiple application |
|---|---|---|---|---|
| D3 ditch | 9.90 | 11.4 | 0.441 | 0.503 |
| D4 pond | 3.71 | 5.45 | 0.400 | 0.521 |
| D4 stream | 0.684 | 0.814 | 0.032 | 0.038 |
| D5 pond | 3.36 | 4.91 | 0.362 | 0.468 |
| D5 stream | 0.447 | 0.928 | 0.021 | 0.043 |
| R1 pond | 3.14 | 5.24 | 0.339 | 0.500 |
| R1 stream | 1.77 | 1.90 | 0.083 | 0.090 |
| R2 stream | 1.15 | 1.24 | 0.053 | 0.274 |
| R3 stream | 3.83 | 4.68 | 0.180 | 0.308 |
| R4 stream | 1.78 | 2.05 | 0.083 | 0.190 |

These values can be compared with a $NOEC_{Chironomus}$ of 2.8 µg/kg (recalculated based on NOEC of 0.75 µg/L and test characteristics, see addendum to the revised DAR, March 2010).

| | |
|---|---|
| Metabolites<br>Parameters used in FOCUSsw step 1 and 2 | Molecular weight: CGA294847 MW 225.2<br>CGA 294850 MW 317.34<br>Phenol MW 94<br>Soil or water metabolite: CGA294847 and phenol, photolysis in water; CGA 294850 water-sediment study<br>Maximum % observed<br>aqueous photolysis:<br>CGA294847: 16.9% and phenol: 17.9%<br>surface water: CGA 294850: 3.8 %<br>PECini calculated by using PECini parent from STEP 1 x maximum observed % x relative molecular weight |

| Crop[(A)] | CGA 294847 | CGA 294850 | Phenol |
|---|---|---|---|
| | PECsw (µg/L) | PECsw (µg/L) | PECsw (µg/L) |
| EU N | 5.7 | 1.8 | 2.5 |
| EU S | 11 | 3.5 | 4.9 |

(A) Apples and pears in EU N (Northern Europe) and EU S (Southern Europe)

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

| | |
|---|---|
| Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter ) | Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.<br>Model used: FOCUS-PEARL 3.3.3 and FOCUS-PELMO 3.3.2<br>Scenarios: All FOCUS scenarios<br>Crop: Apple<br>Geometric mean parent $DT_{50lab}$ 4.06 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). *NB RMS calculated a geomean soil DT50 of 3.89 days. As notifier value is conservative, the use of 4.06 days is considered acceptable.*<br>normalisation of DT50 values to FOCUS reference conditions and subsequently the simulations were carried out using the Q10 of 2.58 and Walker equation coefficient of 0.7<br>$K_{OC}$: parent, arithmetic mean 1816, $^1/_n$= 0.89. Metabolites: none |
| Application rate | Application rate: 150 (NE) and 225 g/ha (SE)<br>No. of applications: 2 (NE and SE)<br>Interval: 10 d (NE) and 21 d (SE)<br>Time of first application: Chateaudun & Piacenza 1st April; Hamburg, Kremsmunster 15th April; Porto, Sevilla, Thiva 15th March; Jokioinen 10th May; Okehampton 25th March. Selected to coincide with the leaf emergence date defined for each scenario, which respects 'before BBCH 59'<br>Crop interception: 50%, corresponding to before BBCH 59 |

**PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)**

| | Scenario | Parent (µg/L) |
|---|---|---|
| FOCUS-PEARL 3.3.3/FOCUS PELMO 3.3.2 Apple / **Northern EU GAP** | | |
| | Chateaudun | <0.001 |
| | Hamburg | <0.001 |
| | Jokioinen | <0.001 |
| | Kremsmunster | <0.001 |
| | Okehampton | <0.001 |
| | Piacenza | <0.001 |
| | Porto | <0.001 |
| | Sevilla | <0.001 |
| | Thiva | <0.001 |

| | Scenario | Parent (µg/L) |
|---|---|---|
| FOCUS-PEARL 3.3.3/FOCUS PELMO 3.3.2 Apple / **Southern EU GAP** | | |
| | Chateaudun | <0.001 |
| | Hamburg | <0.001 |
| | Jokioinen | <0.001 |
| | Kremsmunster | <0.001 |
| | Okehampton | <0.001 |
| | Piacenza | <0.001 |
| | Porto | <0.001 |
| | Sevilla | <0.001 |
| | Thiva | <0.001 |

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

| | |
|---|---|
| Direct photolysis in air ‡ | Not studied - no data requested |
| Quantum yield of direct phototransformation | Not studied - no data requested |
| Photochemical oxidative degradation in air ‡ | $DT_{50}$ of 3.2-4.9 hours derived by the Atkinson model. OH (12 h) concentration assumed = $9.7x10^5$ OH/$cm^3$ |
| Volatilisation ‡ | plant surface (BBA): 2.1% after 24 h (1 m/s) |
| | soil surface (BBA): 3.1-6.9% after 24 h (0.003 and 1m/s) |
| Metabolites | None |

**PEC (air)**

| | |
|---|---|
| Method of calculation | Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant, Atkinson calculation and laboratory volatility studies no residues in air are expected. |

**PEC(a)**

| | |
|---|---|
| Maximum concentration | No data provided - none requested |

**Residues requiring further assessment**

| | | |
|---|---|---|
| Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered. | Soil: | fenoxycarb |
| | Surface Water: | fenoxycarb, CGA 294847, phenol |
| | Sediment: | fenoxycarb |
| | Ground water: | fenoxycarb |
| | Air: | fenoxycarb |

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

| | |
|---|---|
| Soil (indicate location and type of study) | No data provided - none requested |
| Surface water (indicate location and type of study) | No data provided - none requested |
| Ground water (indicate location and type of study) | No data provided - none requested |
| Air (indicate location and type of study) | No data provided - none requested |

**Points pertinent to the classification and proposed labelling with regard to fate and behaviour data**

| |
|---|
| Not readily biodegradable (by default, submitted study was rejected). Candidate for R53. |

## Chapter 2.6 Ecotoxicology

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

| Species | Test substance | Time scale | End point (mg/kg bw/day) | End point (mg/kg feed) |
|---|---|---|---|---|
| Birds | | | | |
| Mallard duck | a.s. | Acute | LD50: >3000 | - |
| Bobwhite quail | a.s. | Acute | LD50: >7000 | - |
| Mallard duck | a.s. | Short-term | LC50: >5885 | LC50: >20000 |
| Bobwhite quail | a.s. | Short-term | LC50: 1356* | LC50: 10000 |
| Mallard duck | a.s. | Long-term | NOEC: 17.7 | NOEC: 160 |
| Bobwhite quail | a.s. | Long-term | NOEC: 35.9 | NOEC: 400 |
| Mammals | | | | |
| Rat | a.s. | Acute | LD50: >10000 | - |
| Rat | a.s. | Long-term | NOAEC: 40 | 600 |
| Additional higher tier studies ‡ | | | | |
| No data available – not required | | | | |

* based on the reported mean feed consumption and the mean body weight (days 0-5) of the two highest concentrations (5000 and 20000 ppm). Mean feed consumption: 3.3 g/bird/day; mean body weight: 24.3 g

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

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha (worst-case exposure)

| Indicator species/Category | Time scale | ETE | TER | Annex VI Trigger |
|---|---|---|---|---|
| Tier 1 (Birds) | | | | |
| Route: insects | Acute | 12 | >247 | 10 |
| Route: water | Acute | 0.024 | >1E+05 | 10 |
| Route: insects | Short-term | 6.8 | 200 | 10 |
| Route: insects | Long-term | 6.8 | **2.6** | 5 |
| Route: insects (higher tier)[1] | Long-term | 2.6 | 6.8 | 5 |
| Route: earthworms | Long-term | 0.23 | 78 | 5 |
| Route: fish | Long-term | 1.1 | 16 | 5 |
| Tier 1 (Mammals) | | | | |
| Route: short grass | Acute | 32 | >313 | 10 |
| Route: water | Acute | 0.014 | >7E+05 | 10 |
| Route: short grass | Long-term | 7.7 | 5.2 | 5 |
| Route: earthworms | Long-term | 0.28 | 143 | 5 |
| Route: fish | Long-term | 0.72 | 56 | 5 |

[1)] Based on a PPR-opinion by EFSA's PPR-panel published in June 2008 (Question No EFSA-Q-2006-064. *The EFSA Journal* (2008) 734:1-181).

Apples and pears, Northern Europe, 2 x 0.150 kg a.s./ha

| Indicator species/Category | Time scale | ETE | TER | Annex VI Trigger |
|---|---|---|---|---|
| Tier 1 (Birds) | | | | |
| Route: insects | Long-term | 4.5 | **3.9** | 5 |
| Route: insects (higher tier)[1] | Long-term | 2.2 | 8.1 | 5 |
| Tier 1 (Mammals) | | | | |
| Route: short grass | Long-term | 6.3 | 6.3 | 5 |

[1)] Based on a PPR-opinion by EFSA's PPR-panel published in June 2008 (Question No EFSA-Q-2006-064. *The EFSA Journal* (2008) 734:1-181).

**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 (Test type) | End point | Toxicity[1] (mg/L) |
|---|---|---|---|---|
| Laboratory tests | | | | |
| Fish | | | | |
| *Oncorhynchus mykiss* | a.s. | 96 hr (flow-through) | Mortality, $LC_{50}$ | 0.66 (mm) |
| | Preparation (A-8995 B) | 96 hr (static) | Mortality, $LC_{50}$ | 3.4 (initial, a.s.) |
| | CGA294847 | 96 hr (static) | Mortality, $LC_{50}$ | 100 (nom) |
| *Oncorhynchus mykiss* | a.s. | 96 d (flow-through) | ELS NOEC | 0.048 (mm) |
| *Salmo gairdneri* | a.s. | 74 d (flow-through) | ELS NOEC | <0.062 (mm) |
| *Lepomis macrochirus* | a.s. | 96 hr (flow-through) | Mortality, $LC_{50}$ | 0.74 (mm) |
| *Cyprinus carpio* | a.s. | 96 hr (flow-through) | Mortality, $LC_{50}$ | 1.5 (mm) |
| *Ictalurus punctatus* | a.s. | 96 hr (flow-through) | Mortality, $LC_{50}$ | 0.88 (mm) |
| *Cyprinodon variegatus* | a.s. | 96 hr (flow-through) | Mortality, $LC_{50}$ | 1.1 (mm) |
| Aquatic invertebrate | | | | |
| *Daphnia magna* | a.s. | 48 h (flow-through) | Mortality, $LC_{50}$ | 0.50 (mm) |
| | Preparation (A-8995 B) | 48 h (static) | Mortality, $LC_{50}$ | 1.5 (nom, a.s.) |
| | CGA294847 | 48 h (static) | Mortality, $LC_{50}$ | 61 (nom) |

| Group | Test substance | Time-scale (Test type) | End point | Toxicity[1] (mg/L) |
|---|---|---|---|---|
| | CGA294850 | 48 h (static) | Mortality, $LC_{50}$ | 8.5 (nom) |
| | a.s. | 21 d (flow-through) | Reproduction, NOEC | 1.6 **n**g/L (mm) |
| | a.s. | 21 d (flow-through) | Reproduction, NOEC | 0.0032 (initial)[2] |
| *Mysidopsis bahia* | a.s. | 96 h (flow-through) | Mortality, $LC_{50}$ | 0.35 (mm) |
| *Crassostrea virginica* | a.s. | 96 h (flow-through) | Mortality, $LC_{50}$ | 0.52 (mm) |
| Sediment dwelling organisms | | | | |
| *Chironomus riparius* | a.s. | 28 d (static) | NOEC | 0.75 µg/L (nom) or 2.8 µg/kg (nom) |
| Algae | | | | |
| *Pseudokirchneriella subcapitata* | a.s. | 72 h (static) | No data available –data required | |
| *Pseudokirchneriella subcapitata* | Preparation (A-8995 B) | 72 h (static) | Biomass: $E_bC_{50}$<br>Growth rate: $E_rC_{50}$ | 0.82 (mm, a.s.)[3]<br>1.4 (mm, a.s.)[3] |
| *Selenastrum capricornutum* | Preparation (A-8995 B) | 72 h (static) | Biomass: $E_bC_{50}$<br>Growth rate: $E_rC_{50}$ | 0.38 (initial, a.s.)<br>0.84 (initial, a.s.) |
| *Selenastrum capricornutum* | CGA294847 | 72 h (static) | Biomass: $E_bC_{50}$<br>Growth rate: $E_rC_{50}$ | 17.4 (nom)<br>67.8 (nom) |
| Higher plant | | | | |
| No data submitted – no data required | | | | |
| Microcosm or mesocosm tests: outdoor microcosm study submitted, but study not considered valid (fish added; 28 days interval between the two applications; climatic differences (Texas vs Europe); not clear if relevant life stages were included) | | | | |

[1] indicate whether based on nominal (nom) or mean measured concentrations (mm). In the case of preparations indicate whether end points are presented as units of preparation or a.s.
[2] Exposure concentrations were manipulated so as to gradually achieve a reduction of 50% in concentration after each ten-hour period throughout the duration of the study.
[3] Measured concentrations were 111-123% of nominal

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

**FOCUS Step1**

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha

| Test substance | Organism | Toxicity end point (µg/L) | Time scale | $PEC_i$ (µg/L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|
| a.s. | Fish | 660 | Acute | 87.6 | 7.5 | 100 |
| a.s. | Fish | 48 | Chronic | 87.6 | 0.55 | 10 |

| Test substance | Organism | Toxicity end point (µg/L) | Time scale | $PEC_i$ (µg/L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|
| a.s. | Aquatic invertebrates | 350 | Acute | 87.6 | 4.0 | 100 |
| a.s. | Aquatic invertebrates | 0.0016 | Chronic | 87.6 | 2E-05 | 10 |
| a.s. | Sediment-dwelling organisms | 0.75 | Chronic | 87.6 | 0.0086 | 10 |
| a.s. | Algae | 380 | Chronic | 87.6 | 4.3 | 10 |
| CGA294847 | Fish | 100000 | Acute | 11 | 8980 | 100 |
| CGA294847 | Aquatic invertebrates | 61000 | Acute | 11 | 5478 | 100 |
| CGA294847 | Algae | 17400 | Chronic | 11 | 1562 | 10 |
| CGA294850 | Aquatic invertebrates | 8500 | Acute | 3.5 | 2424 | 100 |

Apples and pears, Northern Europe, 2 x 0.150 kg a.s./ha

| Test substance | Organism | Toxicity end point (µg/L) | Time scale | $PEC_i$ (µg/L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|
| a.s. | Fish | 660 | Acute | 45.0 | 15 | 100 |
| a.s. | Fish | 48 | Chronic | 45.0 | 1.1 | 10 |
| a.s. | Aquatic invertebrates | 350 | Acute | 45.0 | 7.8 | 100 |
| a.s. | Aquatic invertebrates | 0.0016 | Chronic | 45.0 | 4E-05 | 10 |
| a.s. | Sediment-dwelling organisms | 0.75 | Chronic | 45.0 | 0.017 | 10 |
| a.s. | Algae | 380 | Chronic | 45.0 | 8.5 | 10 |

**FOCUS Step 2**

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha

| Test substance | N/S[1] | Organism[2] | Toxicity end point (µg/L) | Time scale | $PEC_{sw}$[3] (max., µg/L) | TER | Annex VI Trigger[4] |
|---|---|---|---|---|---|---|---|
| a.s. | S | Fish | 660 | Acute | 22.4 | 29 | 100 |
| a.s. | S | Fish | 48 | Chronic | 22.4 | 2.1 | 10 |
| a.s. | S | Aquatic invertebrates | 350 | Acute | 22.4 | 16 | 100 |
| a.s. | S | Aquatic invertebrates | 0.0016 | Chronic | 22.4 | 7E-05 | 10 |
| a.s. | S | Algae | 380 | Chronic | 22.4 | 17 | 10 |
| a.s. | S | Sediment-dwelling organisms[5] | 0.75 | Chronic | 22.4 | 0.033 | 10 |

Apples and pears, Northern Europe, 1 x 0.150 kg a.s./ha (single early application as worst case)

| Test substance | N/S[1] | Organism[2] | Toxicity end point (µg/L) | Time scale | $PEC_{sw}$[3] (max., µg/L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|---|

| Test substance | N/S[1] | Organism[2] | Toxicity end point (µg/L) | Time scale | $PEC_{sw}$[3] (max., µg/L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|---|
| a.s. | N | Fish | 660 | Acute | 14.6 | 45 | 100 |
| a.s. | N | Fish | 48 | Chronic | 14.6 | 3.3 | 10 |
| a.s. | N | Aquatic invertebrates | 350 | Acute | 14.6 | 24 | 100 |
| a.s. | N | Aquatic invertebrates | 0.0016 | Chronic | 14.6 | 1.1E-04 | 10 |
| a.s. | N | Algae | 380 | Chronic | 14.6 | 26 | 10 |
| a.s. | N | Sediment-dwelling organisms | 0.75 | Chronic | 14.6 | 0.051 | 10 |

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.

**Refined aquatic risk assessment using higher tier FOCUS modelling.**

**FOCUS Step 3**

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | Ditch | Fish | Acute | 660 | 17.4 | **38** | 100 |
| a.s. | D4 | Pond | Fish | Acute | 660 | 1.21 | 545 | 100 |
| a.s. | D4 | Stream | Fish | Acute | 660 | 16.7 | **40** | 100 |
| a.s. | D5 | Pond | Fish | Acute | 660 | 1.17 | 564 | 100 |
| a.s. | D5 | Stream | Fish | Acute | 660 | 16.9 | **39** | 100 |
| a.s. | R1 | Pond | Fish | Acute | 660 | 1.2 | 550 | 100 |
| a.s. | R1 | Stream | Fish | Acute | 660 | 14.1 | **47** | 100 |
| a.s. | R2 | Stream | Fish | Acute | 660 | 18.7 | **35** | 100 |
| a.s. | R3 | Stream | Fish | Acute | 660 | 19.9 | **33** | 100 |
| a.s. | R4 | Stream | Fish | Acute | 660 | 14.1 | **47** | 100 |
| Preparation[5] | D3 | Ditch | Fish | Acute | 3400 | 17.4 | 195 | 100 |
| Preparation[5] | D4 | Pond | Fish | Acute | 3400 | 1.21 | 2810 | 100 |
| Preparation[5] | D4 | Stream | Fish | Acute | 3400 | 16.7 | 204 | 100 |
| Preparation[5] | D5 | Pond | Fish | Acute | 3400 | 1.17 | 2906 | 100 |
| Preparation[5] | D5 | Stream | Fish | Acute | 3400 | 16.9 | 201 | 100 |
| Preparation[5] | R1 | Pond | Fish | Acute | 3400 | 1.2 | 2833 | 100 |
| Preparation[5] | R1 | Stream | Fish | Acute | 3400 | 14.1 | 241 | 100 |
| Preparation[5] | R2 | Stream | Fish | Acute | 3400 | 18.7 | 182 | 100 |
| Preparation[5] | R3 | Stream | Fish | Acute | 3400 | 19.9 | 171 | 100 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| Preparation[5] | R4 | Stream | Fish | Acute | 3400 | 14.1 | 241 | 100 |
| a.s. | D3 | Ditch | Fish | Chronic | 48 | 17.4 | **2.8** | 10 |
| a.s. | D4 | Pond | Fish | Chronic | 48 | 1.21 | 40 | **10** |
| a.s. | D4 | Stream | Fish | Chronic | 48 | 16.7 | **2.9** | 10 |
| a.s. | D5 | Pond | Fish | Chronic | 48 | 1.17 | 41 | 10 |
| a.s. | D5 | Stream | Fish | Chronic | 48 | 16.9 | **2.8** | 10 |
| a.s. | R1 | Pond | Fish | Chronic | 48 | 1.2 | 40 | 10 |
| a.s. | R1 | Stream | Fish | Chronic | 48 | 14.1 | **3.4** | 10 |
| a.s. | R2 | Stream | Fish | Chronic | 48 | 18.7 | **2.6** | 10 |
| a.s. | R3 | Stream | Fish | Chronic | 48 | 19.9 | **2.4** | 10 |
| a.s. | R4 | Stream | Fish | Chronic | 48 | 14.1 | **3.4** | 10 |

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether $PEC_{sw}$, or $PEC_{sed}$ and whether maximum or twa values used
[5] A-8995 B

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger[5] |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | Ditch | Invertebrate | Acute | 350 | 17.4 | 20 | 100 |
| a.s. | D4 | Pond | Invertebrate | Acute | 350 | 1.21 | 289 | 100 |
| a.s. | D4 | Stream | Invertebrate | Acute | 350 | 16.7 | **21** | 100 |
| a.s. | D5 | Pond | Invertebrate | Acute | 350 | 1.17 | 299 | 100 |
| a.s. | D5 | Stream | Invertebrate | Acute | 350 | 16.9 | **21** | 100 |
| a.s. | R1 | Pond | Invertebrate | Acute | 350 | 1.2 | 292 | 100 |
| a.s. | R1 | Stream | Invertebrate | Acute | 350 | 14.1 | **25** | 100 |
| a.s. | R2 | Stream | Invertebrate | Acute | 350 | 18.7 | **19** | 100 |
| a.s. | R3 | Stream | Invertebrate | Acute | 350 | 19.9 | **18** | 100 |
| a.s. | R4 | Stream | Invertebrate | Acute | 350 | 14.1 | **25** | 100 |
| Preparation[5] | D3 | Ditch | Invertebrate | Acute | 1500 | 17.4 | 86.2 | 100 |
| Preparation[5] | D4 | Pond | Invertebrate | Acute | 1500 | 1.21 | 1240 | 100 |
| Preparation[5] | D4 | Stream | Invertebrate | Acute | 1500 | 16.7 | **90** | 100 |
| Preparation[5] | D5 | Pond | Invertebrate | Acute | 1500 | 1.17 | 1282 | 100 |
| Preparation[5] | D5 | Stream | Invertebrate | Acute | 1500 | 16.9 | **89** | 100 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger[5] |
|---|---|---|---|---|---|---|---|---|
| Preparation[5] | R1 | Pond | Invertebrate | Acute | 1500 | 1.2 | 1250 | 100 |
| Preparation[5] | R1 | Stream | Invertebrate | Acute | 1500 | 14.1 | 106 | 100 |
| Preparation[5] | R2 | Stream | Invertebrate | Acute | 1500 | 18.7 | **80** | 100 |
| Preparation[5] | R3 | Stream | Invertebrate | Acute | 1500 | 19.9 | **75** | 100 |
| Preparation[5] | R4 | Stream | Invertebrate | Acute | 1500 | 14.1 | 106 | 100 |
| a.s. | D3 | Ditch | Invertebrate | Chronic | 0.0016 | 17.4 | **0.00009** | 10 |
| a.s. | D4 | Pond | Invertebrate | Chronic | 0.0016 | 1.21 | **0.0013** | 10 |
| a.s. | D4 | Stream | Invertebrate | Chronic | 0.0016 | 16.7 | **0.0001** | 10 |
| a.s. | D5 | Pond | Invertebrate | Chronic | 0.0016 | 1.17 | **0.0014** | 10 |
| a.s. | D5 | Stream | Invertebrate | Chronic | 0.0016 | 16.9 | **0.00009** | 10 |
| a.s. | R1 | Pond | Invertebrate | Chronic | 0.0016 | 1.2 | **0.0013** | 10 |
| a.s. | R1 | Stream | Invertebrate | Chronic | 0.0016 | 14.1 | **0.00011** | 10 |
| a.s. | R2 | Stream | Invertebrate | Chronic | 0.0016 | 18.7 | **0.00009** | 10 |
| a.s. | R3 | Stream | Invertebrate | Chronic | 0.0016 | 19.9 | **0.00008** | 10 |
| a.s. | R4 | Stream | Invertebrate | Chronic | 0.0016 | 14.1 | **0.00011** | 10 |

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether $PEC_{sw}$, or $PEC_{sed}$ and whether maximum or twa values used
[5] A-8995 B

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | Ditch | Sediment-dwelling organisms | Chronic | 0.75 | 17.4 | **0.04** | 10 |
| a.s. | D4 | Pond | Sediment-dwelling organisms | Chronic | 0.75 | 1.21 | **0.41** | 10 |
| a.s. | D4 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 16.7 | **0.045** | 10 |
| a.s. | D5 | Pond | Sediment-dwelling organisms | Chronic | 0.75 | 1.17 | **0.64** | 10 |
| a.s. | D5 | Stream | Sediment-dwelling | Chronic | 0.75 | 16.9 | **0.044** | 10 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| | | | organisms | | | | | |
| a.s. | R1 | Pond | Sediment-dwelling organisms | Chronic | 0.75 | 1.2 | **0.63** | 10 |
| a.s. | R1 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 14.1 | **0.053** | 10 |
| a.s. | R2 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 18.7 | **0.040** | 10 |
| a.s. | R3 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 19.9 | **0.038** | 10 |
| a.s. | R4 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 14.1 | **0.053** | 10 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/kg) | $PEC_{sed}$ (max., µg/kg)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | ditch | Sediment-dwelling organisms | Chronic | 2.8 | 11.4 | **0.25** | 10 |
| a.s. | D4 | Pond | Sediment-dwelling organisms | Chronic | 2.8 | 5.45 | **0.51** | 10 |
| a.s. | D4 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 0.814 | **3.4** | 10 |
| a.s. | D5 | Pond | Sediment-dwelling organisms | Chronic | 2.8 | 4.91 | **0.57** | 10 |
| a.s. | D5 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 0.928 | **3.017** | 10 |
| a.s. | R1 | pond | Sediment-dwelling organisms | Chronic | 2.8 | 5.24 | **0.53** | 10 |
| a.s. | R1 | stream | Sediment-dwelling organisms | Chronic | 2.8 | 1.9 | **1.47** | 10 |
| a.s. | R2 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 1.24 | **2.26** | 10 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/kg) | $PEC_{sed}$ (max., µg/kg)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | R3 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 4.68 | **0.60** | 10 |
| a.s. | R4 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 2.05 | **1.37** | 10 |

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether $PEC_{sw}$, or $PEC_{sed}$ and whether maximum or twa values used

Apples and pears, Northern Europe, 1 x 0.150 kg a.s./ha (single early application as worst case)

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | Ditch | Fish | Acute | 660 | 11.6 | **57** | 100 |
| a.s. | D4 | Pond | Fish | Acute | 660 | 0.99 | 667 | 100 |
| a.s. | D4 | Stream | Fish | Acute | 660 | 11.1 | **59** | 100 |
| a.s. | D5 | Pond | Fish | Acute | 660 | 0.88 | 750 | 100 |
| a.s. | D5 | Stream | Fish | Acute | 660 | 11.3 | **58** | 100 |
| a.s. | R1 | Pond | Fish | Acute | 660 | 0.86 | 767 | 100 |
| a.s. | R1 | Stream | Fish | Acute | 660 | 9.4 | **70** | 100 |
| a.s. | R2 | Stream | Fish | Acute | 660 | 12.5 | **53** | 100 |
| a.s. | R3 | Stream | Fish | Acute | 660 | 13.2 | **50** | 100 |
| a.s. | R4 | Stream | Fish | Acute | 660 | 9.4 | **70** | 100 |
| Preparation[5] | D3 | Ditch | Fish | Acute | 3400 | 11.6 | 293 | 100 |
| Preparation[5] | D4 | Pond | Fish | Acute | 3400 | 0.99 | 3434 | 100 |
| Preparation[5] | D4 | Stream | Fish | Acute | 3400 | 11.1 | 306 | 100 |
| Preparation[5] | D5 | Pond | Fish | Acute | 3400 | 0.88 | 3864 | 100 |
| Preparation[5] | D5 | Stream | Fish | Acute | 3400 | 11.3 | 301 | 100 |
| Preparation[5] | R1 | Pond | Fish | Acute | 3400 | 0.86 | 3953 | 100 |
| Preparation[5] | R1 | Stream | Fish | Acute | 3400 | 9.4 | 362 | 100 |
| Preparation[5] | R2 | Stream | Fish | Acute | 3400 | 12.5 | 272 | 100 |
| Preparation[5] | R3 | Stream | Fish | Acute | 3400 | 13.2 | 257 | 100 |
| Preparation[5] | R4 | Stream | Fish | Acute | 3400 | 9.4 | 362 | 100 |
| a.s. | D3 | Ditch | Fish | Chronic | 48 | 11.6 | **4.1** | 10 |
| a.s. | D4 | Pond | Fish | Chronic | 48 | 0.99 | 48 | 10 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D4 | Stream | Fish | Chronic | 48 | 11.1 | **4.3** | 10 |
| a.s. | D5 | Pond | Fish | Chronic | 48 | 0.88 | 55 | 10 |
| a.s. | D5 | Stream | Fish | Chronic | 48 | 11.3 | **4.2** | 10 |
| a.s. | R1 | Pond | Fish | Chronic | 48 | 0.86 | 56 | 10 |
| a.s. | R1 | Stream | Fish | Chronic | 48 | 9.4 | **5.1** | 10 |
| a.s. | R2 | Stream | Fish | Chronic | 48 | 12.5 | **3.8** | 10 |
| a.s. | R3 | Stream | Fish | Chronic | 48 | 13.2 | **3.6** | 10 |
| a.s. | R4 | Stream | Fish | Chronic | 48 | 9.4 | **5.1** | 10 |

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether $PEC_{sw}$, or $PEC_{sed}$ and whether maximum or twa values used
[5] A-8995 B

Apples and pears, Northern Europe, 1 x 0.150 kg a.s./ha (single early application as worst case)

| Test substance | Scenario | Water body type | Test organism | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L) | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | Ditch | Invertebrates | Acute | 350 | 11.6 | **30** | 100 |
| a.s. | D4 | Pond | Invertebrates | Acute | 350 | 0.99 | 354 | 100 |
| a.s. | D4 | Stream | Invertebrates | Acute | 350 | 11.1 | **32** | 100 |
| a.s. | D5 | Pond | Invertebrates | Acute | 350 | 0.88 | 398 | 100 |
| a.s. | D5 | Stream | Invertebrates | Acute | 350 | 11.3 | **31** | 100 |
| a.s. | R1 | Pond | Invertebrates | Acute | 350 | 0.86 | 407 | 100 |
| a.s. | R1 | Stream | Invertebrates | Acute | 350 | 9.4 | **37** | 100 |
| a.s. | R2 | Stream | Invertebrates | Acute | 350 | 12.5 | **28** | 100 |
| a.s. | R3 | Stream | Invertebrates | Acute | 350 | 13.2 | **26** | 100 |
| a.s. | R4 | Stream | Invertebrates | Acute | 350 | 9.4 | **37** | 100 |
| Preparation[2] | D3 | Ditch | Invertebrates | Acute | 1500 | 11.6 | 129 | 100 |
| Preparation[2] | D4 | Pond | Invertebrates | Acute | 1500 | 0.99 | 1515 | 100 |
| Preparation[2] | D4 | Stream | Invertebrates | Acute | 1500 | 11.1 | 135 | 100 |
| Preparation[2] | D5 | Pond | Invertebrates | Acute | 1500 | 0.88 | 1705 | 100 |
| Preparation[2] | D5 | Stream | Invertebrates | Acute | 1500 | 11.3 | 133 | 100 |
| Preparation[2] | R1 | Pond | Invertebrates | Acute | 1500 | 0.86 | 1744 | 100 |
| Preparation[2] | R1 | Stream | Invertebrates | Acute | 1500 | 9.4 | 160 | 100 |
| Preparation[2] | R2 | Stream | Invertebrates | Acute | 1500 | 9.4 | 120 | 100 |

| Test substance | Scenario | Water body type | Test organism | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L) | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| Preparation[2] | R3 | Stream | Invertebrates | Acute | 1500 | 13.2 | 113 | 100 |
| Preparation[2] | R4 | Stream | Invertebrates | Acute | 1500 | 9.4 | 160 | 100 |
| a.s. | D3 | Ditch | invertebrates | Chronic | 0.0016 | 11.6 | **0.00014** | 10 |
| a.s. | D4 | Pond | invertebrates | Chronic | 0.0016 | 0.99 | **0.0016** | 10 |
| a.s. | D4 | Stream | invertebrates | Chronic | 0.0016 | 11.1 | **0.00014** | 10 |
| a.s. | D5 | Pond | invertebrates | Chronic | 0.0016 | 0.88 | **0.0018** | 10 |
| a.s. | D5 | Stream | invertebrates | Chronic | 0.0016 | 11.3 | **0.00014** | 10 |
| a.s. | R1 | Pond | invertebrates | Chronic | 0.0016 | 0.86 | **0.0019** | 10 |
| a.s. | R1 | Stream | invertebrates | Chronic | 0.0016 | 9.4 | **0.00017** | 10 |
| a.s. | R2 | Stream | invertebrates | Chronic | 0.0016 | 9.4 | **0.00013** | 10 |
| a.s. | R3 | Stream | invertebrates | Chronic | 0.0016 | 13.2 | **0.00012** | 10 |
| a.s. | R4 | Stream | invertebrates | Chronic | 0.0016 | 9.4 | **0.00017** | 10 |
| a.s. | D4 | Pond | invertebrates | Chronic | 3.2[1] | 0.99 | 3.2 | 10 |
| a.s. | D5 | Pond | invertebrates | Chronic | 3.2[1] | 0.88 | 3.6 | 10 |
| a.s. | R1 | Pond | invertebrates | Chronic | 3.2[1] | 0.86 | 3.7 | 10 |

[1] Data from a study in which exposure concentrations were manipulated so as to gradually achieve a reduction of 50% in concentration after each ten-hour period throughout the duration of the study.
[2] A-8995 B

Apples and pears, Northern Europe, 1 x 0.150 kg a.s./ha (single early application as worst case)

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | Ditch | Sediment-dwelling organisms | Chronic | 0.75 | 11.6 | **0.065** | 10 |
| a.s. | D4 | Pond | Sediment-dwelling organisms | Chronic | 0.75 | 0.99 | **0.76** | 10 |
| a.s. | D4 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 11.1 | **0.068** | 10 |
| a.s. | D5 | Pond | Sediment-dwelling organisms | Chronic | 0.75 | 0.88 | **0.85** | 10 |
| a.s. | D5 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 11.3 | **0.066** | 10 |
| a.s. | R1 | Pond | Sediment-dwelling organisms | Chronic | 0.75 | 0.86 | **0.87** | 10 |
| a.s. | R1 | Stream | Sediment-dwelling | Chronic | 0.75 | 9.4 | **0.080** | 10 |

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/L) | $PEC_{sw}$ (max., µg/L)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| | | | organisms | | | | | |
| a.s. | R2 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 12.5 | **0.060** | 10 |
| a.s. | R3 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 13.2 | **0.057** | 10 |
| a.s. | R4 | Stream | Sediment-dwelling organisms | Chronic | 0.75 | 9.4 | **0.080** | 10 |

Apples and pears, Northern Europe, 2 x 0.150 kg a.s./ha with 10 day interval

| Test substance | Scenario[1] | Water body type[2] | Test organism[3] | Time scale | Toxicity end point (µg/kg) | $PEC_{sed}$ (max., µg/kg)[4] | TER | Annex VI trigger |
|---|---|---|---|---|---|---|---|---|
| a.s. | D3 | ditch | Sediment-dwelling organisms | Chronic | 2.8 | 7.84 | **0.36** | 10 |
| a.s. | D4 | Pond | Sediment-dwelling organisms | Chronic | 2.8 | 3.99 | **0.70** | 10 |
| a.s. | D4 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 0.737 | **3.8** | 10 |
| a.s. | D5 | Pond | Sediment-dwelling organisms | Chronic | 2.8 | 3.743 | **0.75** | 10 |
| a.s. | D5 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 0.592 | **4.73** | 10 |
| a.s. | R1 | pond | Sediment-dwelling organisms | Chronic | 2.8 | 3.42 | **0.82** | 10 |
| a.s. | R1 | stream | Sediment-dwelling organisms | Chronic | 2.8 | 1.12 | **2.5** | 10 |
| a.s. | R2 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 0.831 | **3.37** | 10 |
| a.s. | R3 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 3.26 | **0.86** | 10 |
| a.s. | R4 | Stream | Sediment-dwelling organisms | Chronic | 2.8 | 1.33 | **2.11** | 10 |

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond

[3] include critical groups which fail at Step 2.
[4] indicate whether $PEC_{sw}$, or $PEC_{sed}$ and whether maximum or twa values used

Refined TERs for fenoxycarb based on FOCUS STEP 4

| Crop[(A)] | Dose (kg a.s./ha) | Scenario | bufferzone (m) | Toxicity endpoint (µg/L) | PECsw (µg a.s./L) | TER | trigger |
|---|---|---|---|---|---|---|---|
| **FISH acute** | | | | | | | |
| EU N 2 x 0.150 | | D3 ditch | 25 | 660 | 0.755 | 874 | 100 |
| | | D4 stream | 25 | 660 | 0.791 | 834 | 100 |
| | | D5 stream | 25 | 660 | 0.801 | 824 | 100 |
| | | R1 stream | 25 | 660 | 0.668 | 988 | 100 |
| | | R2 stream | 25 | 660 | 0.885 | 746 | 100 |
| | | R3 stream | 25 | 660 | 0.941 | 701 | 100 |
| | | R4 stream | 25 | 660 | 0.668 | 988 | 100 |
| **FISH chronic** | | | | | | | |
| EU N 2 x 0.150 | | D3 ditch | 25 | 48 | 0.755 | 64 | 10 |
| | | D4 stream | 25 | 48 | 0.791 | 61 | 10 |
| | | D5 stream | 25 | 48 | 0.801 | 60 | 10 |
| | | R1 stream | 25 | 48 | 0.668 | 72 | 10 |
| | | R2 stream | 25 | 48 | 0.885 | 54 | 10 |
| | | R3 stream | 25 | 48 | 0.941 | 51 | 10 |
| | | R4 stream | 25 | 48 | 0.668 | 72 | 10 |
| **INVERTEBRATES acute** | | | | | | | |
| EU N 2 x 0.150 | | D3 ditch | 25 | 350 | 0.755 | 464 | 100 |
| | | D4 stream | 25 | 350 | 0.791 | 442 | 100 |
| | | D5 stream | 25 | 350 | 0.801 | 437 | 100 |
| | | R1 stream | 25 | 350 | 0.668 | 524 | 100 |
| | | R2 stream | 25 | 350 | 0.885 | 395 | 100 |
| | | R3 stream | 25 | 350 | 0.941 | 372 | 100 |
| | | R4 stream | 25 | 350 | 0.668 | 524 | 100 |
| **INVERTEBRATES chronic** | | | | | | | |
| EU N 2 x 0.150 | | D3 ditch | 25 | 0.0016 | 0.755 | **0.002** | 10 |
| | | D4 pond | 25 | 0.0016 | 0.095 | **0.017** | 10 |
| | | D4 stream | 25 | 0.0016 | 0.791 | **0.002** | 10 |
| | | D5 pond | 25 | 0.0016 | 0.095 | **0.017** | 10 |
| | | D5 stream | 25 | 0.0016 | 0.801 | **0.002** | 10 |
| | | R1 pond | 25 | 0.0016 | 0.095 | **0.017** | 10 |
| | | R1 stream | 25 | 0.0016 | 0.668 | **0.002** | 10 |
| | | R2 stream | 25 | 0.0016 | 0.885 | **0.002** | 10 |
| | | R3 stream | 25 | 0.0016 | 0.941 | **0.002** | 10 |
| **SEDIMENT DWELLING ORGANISMS** | | | | | | | |
| EU N 2 x 0.150 | | D3 ditch | 25 | 0.75 | 0.755 | **1.0** | 10 |
| | | D4 pond | 25 | 0.75 | 0.095 | **7.9** | 10 |
| | | D4 stream | 25 | 0.75 | 0.791 | **0.9** | 10 |
| | | D5 pond | 25 | 0.75 | 0.095 | **7.9** | 10 |
| | | D5 stream | 25 | 0.75 | 0.801 | **0.9** | 10 |
| | | R1 pond | 25 | 0.75 | 0.095 | **7.9** | 10 |
| | | R1 stream | 25 | 0.75 | 0.668 | **1.1** | 10 |
| | | R2 stream | 25 | 0.75 | 0.885 | **0.8** | 10 |
| | | R3 stream | 25 | 0.75 | 0.941 | **0.8** | 10 |

(A) Apples and pears in EU N (Northern Europe) and EU S (Southern Europe). For Northern Europe a single early application has been taken as the worst case.

| Crop[A] | Dose (kg a.s./ha) | Scenario | bufferzone (m) | Toxicity endpoint (µg/L) | PECsw (µg a.s./L) | TER | trigger |
|---|---|---|---|---|---|---|---|
| **FISH acute** | | | | | | | |
| EU S 2 x 0.225 | | D3 ditch | 30 | 660 | 0.734 | 899 | 100 |
| | | D4 stream | 30 | 660 | 0.77 | 857 | 100 |
| | | D5 stream | 30 | 660 | 0.779 | 847 | 100 |
| | | R1 stream | 30 | 660 | 0.65 | 1015 | 100 |
| | | R2 stream | 30 | 660 | 0.861 | 767 | 100 |
| | | R3 stream | 30 | 660 | 0.915 | 721 | 100 |
| | | R4 stream | 30 | 660 | 0.65 | 1015 | 100 |
| **FISH chronic** | | | | | | | |
| EU S 2 x 0.225 | | D3 ditch | 30 | 48 | 0.734 | 65 | 10 |
| | | D4 stream | 30 | 48 | 0.77 | 62 | 10 |
| | | D5 stream | 30 | 48 | 0.779 | 62 | 10 |
| | | R1 stream | 30 | 48 | 0.65 | 74 | 10 |
| | | R2 stream | 30 | 48 | 0.861 | 56 | 10 |
| | | R3 stream | 30 | 48 | 0.915 | 52 | 10 |
| | | R4 stream | 30 | 48 | 0.65 | 74 | 10 |
| **INVERTEBRATES acute** | | | | | | | |
| EU S 2 x 0.225 | | D3 ditch | 30 | 350 | 0.734 | 477 | 100 |
| | | D4 stream | 30 | 350 | 0.77 | 455 | 100 |
| | | D5 stream | 30 | 350 | 0.779 | 449 | 100 |
| | | R1 stream | 30 | 350 | 0.65 | 538 | 100 |
| | | R2 stream | 30 | 350 | 0.861 | 407 | 100 |
| | | R3 stream | 30 | 350 | 0.915 | 383 | 100 |
| | | R4 stream | 30 | 350 | 0.65 | 538 | 100 |
| **INVERTEBRATES chronic** | | | | | | | |
| EU S 2 x 0.225 | | D3 ditch | 30 | 0.0016 | 0.734 | **0.00218** | 10 |
| | | D4 pond | 30 | 0.0016 | 0.102 | **0.01569** | 10 |
| | | D4 stream | 30 | 0.0016 | 0.77 | **0.00208** | 10 |
| | | D5 pond | 30 | 0.0016 | 0.102 | **0.01569** | 10 |
| | | D5 stream | 30 | 0.0016 | 0.779 | **0.00205** | 10 |
| | | R1 pond | 30 | 0.0016 | 0.102 | **0.01569** | 10 |
| | | R1 stream | 30 | 0.0016 | 0.65 | **0.00246** | 10 |
| | | R2 stream | 30 | 0.0016 | 0.861 | **0.00186** | 10 |
| | | R3 stream | 30 | 0.0016 | 0.915 | **0.00175** | 10 |
| **SEDIMENT DWELLING ORGANISMS** | | | | | | | |
| EU S 2 x 0.225 | | D3 ditch | 30 | 0.75 | 0.734 | **1.0** | 10 |
| | | D4 pond | 30 | 0.75 | 0.102 | **7.4** | 10 |
| | | D4 stream | 30 | 0.75 | 0.77 | **1.0** | 10 |
| | | D5 pond | 30 | 0.75 | 0.102 | **7.4** | 10 |
| | | D5 stream | 30 | 0.75 | 0.779 | **1.0** | 10 |
| | | R1 pond | 30 | 0.75 | 0.102 | **7.4** | 10 |
| | | R1 stream | 30 | 0.75 | 0.65 | **1.2** | 10 |
| | | R2 stream | 30 | 0.75 | 0.861 | **0.9** | 10 |
| | | R3 stream | 30 | 0.75 | 0.915 | **0.8** | 10 |

(A) Apples and pears in EU N (Northern Europe) and EU S (Southern Europe). For Northern Europe a single early application has been taken as the worst case.

| **Bioconcentration** | | | |
|---|---|---|---|
| | Active substance | CGA294847 | Phenol |
| $logP_{OW}$ | 4.07 | 1.70[2] | 1.51[2] |
| Bioconcentration factor (BCF)[1] | 215 (fenoxycarb, 6% lipid content) | No data available- no data required | No data available- no data required |
| Annex VI Trigger for the bioconcentration factor | 100 | | |
| Clearance time (days) ($CT_{50}$) | 0.62-1.1 | | |
| ($CT_{90}$) | 2.0-3.7 | | |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | ≤5%; nature not investigated | | |

[1] only required if log $P_{O/W}$ >3.
[2] estimated by EPA EPI Suite software

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

| Test substance | Acute oral toxicity ($LD_{50}$ µg/bee) | Acute contact toxicity ($LD_{50}$ µg/bee) |
|---|---|---|
| a.s. ‡ | No data available – no data required | No data available – no data required |
| Preparation[1] (A-8995 B, a WG formulation) | >204 (a.s.) | >204 (a.s.) |
| Field or semi-field tests | | |
| 0.06-1.2% brood loss after application of fenoxycarb at 150 g a.s./ha before bloom with mowing of weeds and leaving cut weeds as a mulch. | | |

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Apples and pears, Southern Europe, 2 x 225 g a.s./ha

| Test substance | Route | Hazard quotient | Annex VI Trigger |
|---|---|---|---|
| Preparation | Contact | <1.1 | 50 |
| Preparation | Oral | <1.1 | 50 |

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

Laboratory tests with standard sensitive species

| Species | Test Substance | End point | Effect ($LR_{50}$ g/ha[1]) |
|---|---|---|---|
| *Typhlodromus pyri* ‡ | Preparation | Mortality | No data available - no data required |
| *Aphidius rhopalosiphi* ‡ | Preparation | Mortality | No data available - no data required |

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Further laboratory and extended laboratory studies ‡

| Species | Life stage | Test substance, substrate and duration | Dose (g a.s./ha) | End point | % effect | Trigger |
|---|---|---|---|---|---|---|
| *Aphidius rhopalosiphi* | Adults | Preparation[1], extended laboratory, barley seedlings, 2 days | 29; 58; 116; 231; 463 (fresh residues) | Mortality<br><br>Reduction of reproduction | 0; 0; 0; 3.3; 0<br>LR50 (g a.s./ha): >463<br>12; -17[2]; 5.7; -24[2]; 15<br>ER50 (g a.s./ha): >463 | 50 %<br><br>50 % |
| | Mummies | Preparation[1], extended laboratory, direct exposure of mummies (overspray) on barley leaf pieces, 7 days | 14; 29; 58; 116; 231; 463 (fresh residues) | Mortality<br><br>Reduction of reproduction | -4.0[2]; -3.2[2]; -9.9[2]; -9.3[2]; -1.5[2]; 3.2<br>LR50 (g a.s./ha): >463<br>-25[2]; 19; 1.8; 14; 16; 8.7<br>ER50 (g a.s./ha): >463 | 50 %<br><br>50 % |
| *Typhlodromus pyri* | Proto-nymphs | Preparation[1], laboratory, leaf discs, 14 days | 1.8; 3.6; 7.2; 14; 29; 29[3]; 58; 116; 231; 463 (fresh residues) | Mortality<br><br>Reduction of reproduction | -3.6[2]; -1.7[2]; 0; 3.7; 3.7; 11; 9.2; -1.7[2]; 0; 16<br>LR50 (g a.s./ha): >463<br>4.7; 10; 29; 38; 43; 33; 46; 54; 48; 45<br>ER50 (g a.s./ha): 29 | 50 %<br><br>50 % |
| | Eggs | Preparation[1], extended laboratory, direct exposure of eggs (overspray) + leaf discs, 18 days | 29; 58; 116; 231; 463 (fresh residues) | Reduction of hatching<br><br>Mortality | -5.4[2]; -7.2[2]; -3.6[2]; -5.4[2]; 41<br>ER50 (g a.s./ha): >463<br>0; -5.7[2]; 0; 23; 59<br>LR50 (g a.s./ha): 396 | 50 %<br><br>50 % |

| Species | Life stage | Test substance, substrate and duration | Dose (g a.s./ha) | End point | % effect | Trigger |
|---|---|---|---|---|---|---|
| *Chrysoperla carnea* | 1st instar larvae | Preparation[1], extended laboratory, bean leaves, until adult emergence | 0.48; 1.4; 4.3; 13; 39; 116 (fresh residues) | Mortality<br><br>Reduction of reproduction | 6.9; 3.5; 41; 93; 97; 100<br>LR50 (g a.s./ha): 5.0<br>-24[2]; -23[2]; -22[2]; n.a.[4]; n.a.[4]; n.a.[4]<br>ER50 (g a.s./ha): >4.3 | 50 %<br><br>50 % |
| | Eggs | Preparation[1], extended laboratory, direct exposure of eggs (overspray) + bean leaves, until adult emergence | 0.48; 1.4; 4.3; 13; 39; 116 (fresh residues) | Reduction of hatching<br>Mortality | 0; -21[2]; 0; -21[2]; 0; 17<br>ER50 (g a.s./ha): >116<br>-9.5[2]; -4.8[2]; 48; 95; 100; 100<br>LR50 (g a.s./ha): 4.6 | 50 %<br><br>50 % |
| *Orius laevigatus* | 2nd instar larvae | Preparation[1], extended laboratory, bean leaves, 9 days | 14; 29; 58; 115; 230; 461 (fresh residues) | Mortality<br><br>Reduction of reproduction | 15; 17; 17; 32; 79; 58<br>LR50 (g a.s./ha): 169<br>24; 2.4; 38; 36; 97; n.a.[4]<br>ER50 (g a.s./ha): 135 | 50 %<br><br>50 % |
| | Eggs | Preparation[1], extended laboratory, direct exposure of eggs (overspray) + bean leaves, until adult development | 7.2; 14; 29; 58; 116; 231; 463 (fresh residues) | Reduction of hatching<br><br>Mortality | 4.2; -5.6[2]; -4.5[2]; -3.9[2]; 15; 16; 21<br>ER50 (g a.s./ha): >463<br>-5.2[2]; 5.6; -23[2]; -17[2]; 5.8; 23; 67<br>LR50 (g a.s./ha): 333 | 50 %<br><br>50 % |
| *Coccinella septempunctata* | adult | Laboratory , dried residues on sprayed glass plates | 0.00975, 0.039, 0.156, 0.625 and 2.5 g as/ha | Mortality | LR50 (g a.s./ha ) > 2.5 | |
| | | | | Reduction of reproduction | 53% (at 2.5 g a.s./ha) | 30 |

| Species | Life stage | Test substance, substrate and duration | Dose (g a.s./ha) | End point | % effect | Trigger |
|---|---|---|---|---|---|---|
| *Coccinella septempunctata* | 2nd instar larvae | Preparation[1], extended laboratory, bean leaves, until adult emergence | 0.16; 0.48; 1.4; 4.3; 13; 39; 116 (fresh residues) | Mortality<br><br>Reduction of reproduction | 30; 78; 96; 100; 100; 100; 100<br>LR50 (g a.s./ha): 0.25<br>-8.5[2]; n.a.[4]; n.a.[4]; n.a.[4]; n.a.[4]; n.a.[4]; n.a.[4]<br>ER50 (g a.s./ha): >0.16 | 50 %<br><br>50 % |
| | Eggs | Preparation[1], extended laboratory, direct exposure of eggs (overspray) + bean leaves, until adult emergence | 0.0021; 0.0059; 0.018; 0.053; 0.16; 0.48; 1.4 (fresh residues) | Reduction of hatching<br><br>Mortality | -3.6[2]; 3.5; 3.5; 11; 21; 100; 100<br>ER50 (g a.s./ha): 0.24<br>-4.8[2]; 19; 9.5; 43; 38; 100; 100<br>LR50 (g a.s./ha): 0.10 | 50 %<br><br>50 % |
| *Poecilus cupreus* | Adults | Preparation[1], extended laboratory, direct exposure (overspray) + soil, 14 days | 15; 29; 58; 116; 231; 463 (fresh residues) | Mortality<br><br>Reduction of reproduction | 0; 0; 0; 0; 0; 0<br>LR50 (g a.s./ha): >463<br>22; 18; 2.7; -7.3[2]; -31[2]; -39[2]<br>ER50 (g a.s./ha): >463 | 50 %<br><br>50 % |
| | 24-48 h old larvae | Preparation[1], extended laboratory, larval exposure to soil, 40-46 days | 15; 29; 58; 116; 231; 463 (fresh residues) | Mortality<br><br>Development time | 30; 73; 82; 88; 82; 79<br>LR50 (g a.s./ha): 19<br>ER50 (g a.s./ha): >463 | 50 %<br><br>50 % |
| *Trichogramma cacoeciae* | 24 h old wasps | Preparation[1], extended laboratory, bean leaves, 7 days | 29; 57; 115; 230; 459 (fresh residues) | Reduction of parasitisation | 30; 35; 26; 51; 60<br>ER50 (g a.s./ha): 287 | 50 % |
| | Parasitised eggs | Preparation[1], extended laboratory, direct exposure of parasitised eggs + bean leaves, 7 days | 29; 57; 115; 230; 459 (fresh residues) | Reduction of parasitisation | 11; 55; 69; 86; 93<br>ER50 (g a.s./ha): 73 | 50 % |
| | 24 h old wasps | Preparation[1], extended laboratory, leaves from apple trees, 9 days | 1 x 30; 1 x 150; 2 x 30; 2 x 150 (fresh residues) | Reduction of parasitisation | 38; 27; 54; 3.7<br>ER50 (g a.s./ha): >2x150 | 50 % |

1 A-8995 B, a WG formulation
2 Note: negative effect %, hence no adverse effect
3 This dose was tested twice
4 n.a. = not applicable (insufficient survivors from initial phase to assess reproduction)
5 No treatment related effects up to and including the highest test dose

Field or semi-field tests

Semi-field studies

| Species | Life stage | Test substance, substrate and duration | Dose (g a.s./ha) | End point | % effect | Trigger |
|---|---|---|---|---|---|---|
| *Coccinella septempunctata* | Larvae | Preparation, semi-field, confinement over treated apple trees, 12-21 days | 8.5; 43 g a.s./hL (fresh residues) | Mortality | 100; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| | Larvae | Preparation, semi-field, confinement over treated apple trees, 12-21 days | 8.5; 43 g a.s./hL (21 days aged residues) | Mortality | 100; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| | Larvae | Preparation, semi-field, confinement over treated apple trees, 12-21 days | 8.5; 43 g a.s./hL (42 days aged residues) | Mortality | 100; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| | Larvae | Preparation, extended laboratory, leaves from treated trees, 12-21 days | 8.5; 43 g a.s./hL (63 days aged residues) | Mortality | 100; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| *Chrysoperla carnea* | 1st instar larvae | Preparation, semi-field, confinement over treated apple trees, 14-28 days | 8.5; 43 g a.s./hL (fresh residues) | Mortality | 94; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| | 1st instar larvae | Preparation, semi-field, confinement over treated apple trees, 14-28 days | 8.5; 43 g a.s./hL (21 days aged residues) | Mortality | 63; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| | 1st instar larvae | Preparation, semi-field, confinement over treated apple trees, 14-28 days | 8.5; 43 g a.s./hL (42 days aged residues) | Mortality | 60; 100 LR50 (g a.s./hL): <8.5 | 50 % |
| *Chrysoperla carnea* | 1st instar larvae | Preparation, extended laboratory, leaves from treated apple trees, 14-28 days | 8.5; 43 g a.s./hL (63 days aged residues) | Mortality | 60; 80 LR50 (g a.s./hL): <8.5 | 50 % |

**Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)**

| Test organism | Test substance | Time scale | End point[1] |
|---|---|---|---|
| Earthworms | | | |
| | a.s. ‡ | Acute 14 days | $LC_{50, corr}$ 425 mg a.s./kg d.w.soil |
| | a.s. ‡ | Chronic 8 weeks | No data available - no data required |
| | Preparation (A-8995 B, a WG formulation) | Acute | $LC_{50,corr}$ >128 mg a.s./kg d.w.soil |
| | CGA294850 | Acute | $LC_{50, corr}$ 372 mg/kg d.w.soil |
| | CGA294850 | Chronic | No data available - no data required |
| Other soil macro-organisms | | | |
| Soil mite | a.s. ‡ | | No data available – no data required |
| | Preparation | | No data available – no data required |
| Collembola | | | |
| | a.s. ‡ | Chronic | No data available – no data required |
| | Preparation | | No data available – no data required |
| Soil micro-organisms | | | |
| Nitrogen mineralisation | a.s. ‡ | | 16% effect at day 28 at 3.0 mg a.s./kg d.w.soil |
| Carbon mineralisation | a.s. ‡ | | 2% effect at day 28 at 3.0 mg a.s./kg d.w.soil |
| Field studies | | | |
| Not required | | | |

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. $LC_{50corr}$)

**Toxicity/exposure ratios for soil organisms**

Apples and pears, Southern Europe, 2 x 0.225 kg a.s./ha

| Test organism | Test substance | Time scale | Soil $PEC_{(initial)}$ | TER | Trigger |
|---|---|---|---|---|---|
| Earthworms | | | | | |
| | a.s. ‡ | Acute | 0.179 | >712 | 10 |
| | CGA-294850 | Acute | 0.0085 | 43795 | 10 |

**Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)**

The phytotoxic effects of CGA 114597 25 WG on seedling emergence of six plant species

| Test species | EC50 (g product/ha) | EC50 (g a.s./ha) |
|---|---|---|
| Maize (Zea mais) | > 1800 | > 450 |
| Wild oat (Avena fatua) | > 1800 | > 450 |
| Onion (Allium cepa) | > 1800 | > 450 |
| Sugar beet (Beta vulgaris) | > 1800 | > 450 |
| Oilseed rape (Brassica napus) | > 1800 | > 450 |
| Soybean (Glycine max) | > 1800 | > 450 |

The phytotoxic effects of CGA 114597 25 WG on vegetative vigor of six plant species

| Test species | EC50 (g product/ha) | EC50 (g a.s./ha) |
|---|---|---|
| Maize (Zea mais) | > 1800 | > 450 |
| Wild oat (Avena fatua) | > 1800 | > 450 |
| Onion (Allium cepa) | > 1800 | > 450 |
| Sugar beet (Beta vulgaris) | > 1800 | > 450 |
| Oilseed rape (Brassica napus) | > 1800 | > 450 |
| Soybean (Glycine max) | > 1800 | > 450 |

**Effects on biological methods for sewage treatment (Annex IIA 8.7)**

| Test type/organism | end point |
|---|---|
| Activated sludge | 3-hour $EC_{50}$ >100 mg/L |
| Pseudomonas sp | No data available – no data required |

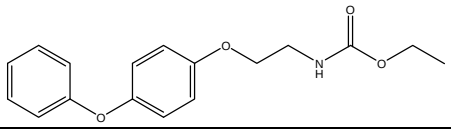
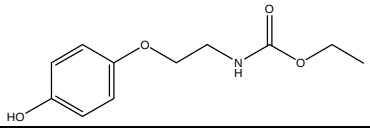
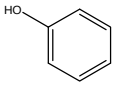
**Ecotoxicologically relevant compounds** (consider parent and all relevant metabolites requiring further assessment from the fate section)

| Compartment | |
|---|---|
| soil | Fenoxycarb |
| water | Fenoxycarb, CGA-294847, phenol |
| sediment | Fenoxycarb |
| groundwater | Fenoxycarb |

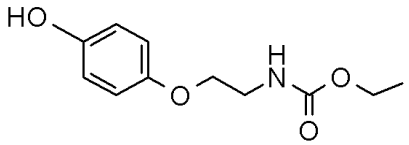
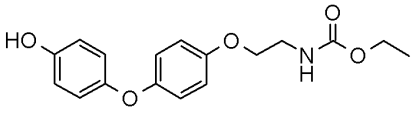
**Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)**

| | RMS/peer review proposal |
|---|---|
| Active substance | N, R50, R53 |

| | RMS/peer review proposal |
|---|---|
| Preparation | N, R51, R53 |

| Code/Trivial name | Chemical name | Structural formula |
|---|---|---|
| Fenoxycarb | [2-(4-phenoxyphenoxy)ethyl] carbamic acid, ethyl ester |  |
| CGA-294847 | [2-(4-hydroxy-phenoxy)-ethyl]-carbamic acid ethyl ester |  |
| Phenol | phenol |  |

## APPENDIX B – USED COMPOUND CODE(S)

| Code/Trivial name* | Chemical name | Structural formula |
|---|---|---|
| **CGA 294847** | [2-(4-hydroxy-phenoxy)-ethyl]-carbamic acid ethyl ester |  |
| **CGA 294850** | {2-[4-(4-hydroxy-phenoxy)-phenoxy]-ethyl}-carbamic acid ethyl ester |  |

* The metabolite name in bold is the name used in the conclusion.

## ABBREVIATIONS

| | |
|---|---|
| 1/n | slope of Freundlich isotherm |
| ε | decadic molar extinction coefficient |
| °C | degree Celsius (centigrade) |
| µg | microgram |
| µm | micrometer (micron) |
| a.s. | active substance |
| AChE | acetylcholinesterase |
| ADE | actual dermal exposure |
| ADI | acceptable daily intake |
| AF | assessment factor |
| AOEL | acceptable operator exposure level |
| AP | alkaline phosphatase |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| AST | aspartate aminotransferase (SGOT) |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| BUN | blood urea nitrogen |
| bw | body weight |
| CAS | Chemical Abstract Service |
| CFU | colony forming units |
| ChE | cholinesterase |
| CI | confidence interval |
| CIPAC | Collaborative International Pesticide Analytical Council Limited |
| CL | confidence limits |
| d | day |
| DAA | days after application |
| DAR | draft assessment report |
| DAT | days after treatment |
| DM | dry matter |
| $DT_{50}$ | period required for 50 percent disappearance (define method of estimation) |
| $DT_{90}$ | period required for 90 percent disappearance (define method of estimation) |
| dw | dry weight |
| $EbC_{50}$ | effective concentration (biomass) |
| $EC_{50}$ | effective concentration |
| ECHA | European Chemical Agency |
| EEC | European Economic Community |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of New Chemical Substances |
| EMDI | estimated maximum daily intake |
| $ER_{50}$ | emergence rate/effective rate, median |
| $ErC_{50}$ | effective concentration (growth rate) |
| EU | European Union |
| EUROPOEM | European Predictive Operator Exposure Model |
| f(twa) | time weighted average factor |
| FAO | Food and Agriculture Organisation of the United Nations |
| FIR | Food intake rate |
| FOB | functional observation battery |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| g | gram |
| GAP | good agricultural practice |
| GC | gas chromatography |
| GCPF | Global Crop Protection Federation (formerly known as GIFAP) |

| | |
|---|---|
| GGT | gamma glutamyl transferase |
| GM | geometric mean |
| GS | growth stage |
| GSH | glutathion |
| h | hour(s) |
| ha | hectare |
| Hb | haemoglobin |
| Hct | haematocrit |
| hL | hectolitre |
| HPLC | high pressure liquid chromatography or high performance liquid chromatography |
| HPLC-MS | high pressure liquid chromatography – mass spectrometry |
| HPLC-UV | high-pressure liquid chromatography with UV detector |
| HQ | hazard quotient |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| $K_{doc}$ | organic carbon linear adsorption coefficient |
| kg | kilogram |
| $K_{Foc}$ | Freundlich organic carbon adsorption coefficient |
| L | litre |
| LC | liquid chromatography |
| $LC_{50}$ | lethal concentration, median |
| LC-MS | liquid chromatography-mass spectrometry |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LDH | lactate dehydrogenase |
| LOAEL | lowest observable adverse effect level |
| LOD | limit of detection |
| LOQ | limit of quantification (determination) |
| m | metre |
| M/L | mixing and loading |
| MAF | multiple application factor |
| MCH | mean corpuscular haemoglobin |
| MCHC | mean corpuscular haemoglobin concentration |
| MCV | mean corpuscular volume |
| mg | milligram |
| mL | millilitre |
| mm | millimetre |
| MRL | maximum residue limit or level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| MTD | maximum tolerated dose |
| MWHC | maximum water holding capacity |
| NESTI | national estimated short-term intake |
| ng | nanogram |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| OM | organic matter content |

| | |
|---|---|
| Pa | Pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| $PEC_{air}$ | predicted environmental concentration in air |
| $PEC_{gw}$ | predicted environmental concentration in ground water |
| $PEC_{sed}$ | predicted environmental concentration in sediment |
| $PEC_{soil}$ | predicted environmental concentration in soil |
| $PEC_{sw}$ | predicted environmental concentration in surface water |
| pH | pH-value |
| PHED | pesticide handler's exposure data |
| PHI | pre-harvest interval |
| PIE | potential inhalation exposure |
| $pK_a$ | negative logarithm (to the base 10) of the dissociation constant |
| $P_{ow}$ | partition coefficient between *n*-octanol and water |
| PPE | personal protective equipment |
| ppm | parts per million ($10^{-6}$) |
| ppp | plant protection product |
| PT | proportion of diet obtained in the treated area |
| PTT | partial thromboplastin time |
| QSAR | quantitative structure-activity relationship |
| $r^2$ | coefficient of determination |
| RPE | respiratory protective equipment |
| RUD | residue per unit dose |
| SC | suspension concentrate |
| SD | standard deviation |
| SFO | single first-order |
| SSD | species sensitivity distribution |
| STMR | supervised trials median residue |
| $t_{1/2}$ | half-life (define method of estimation) |
| TER | toxicity exposure ratio |
| $TER_A$ | toxicity exposure ratio for acute exposure |
| $TER_{LT}$ | toxicity exposure ratio following chronic exposure |
| $TER_{ST}$ | toxicity exposure ratio following repeated exposure |
| TK | technical concentrate |
| TLV | threshold limit value |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| TSH | thyroid stimulating hormone (thyrotropin) |
| TWA | time weighted average |
| UDS | unscheduled DNA synthesis |
| UV | ultraviolet |
| W/S | water/sediment |
| w/v | weight per volume |
| w/w | weight per weight |
| WBC | white blood cell |
| WG | water dispersible granule |
| WHO | World Health Organisation |
| wk | week |
| yr | year |