**CONCLUSION ON PESTICIDE PEER REVIEW**

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

# Flurochloridone (notified active substance)

# (However this ISO name refers to a 3:1 ratio of *trans* to *cis* isomers. As the compound considered in this conclusion is not a 3:1 ratio the name flurochloridone is not used in this conclusion instead the company code FLC is used to identify this compound).

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## SUMMARY

Flurochloridone 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 Spain 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 flurochloridone 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 flurochloridone in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Makhteshim made a resubmission application for the inclusion of flurochloridone 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, Spain being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by EFSA on 03 November 2009.

1 On request from the European Commission, Question No EFSA-Q-2010-00149, issued on 14 October 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, p. 11

6 OJ L 15, 18.01.2008, p.5

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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 10 November 2009. The EFSA collated and forwarded all comments received to the Commission on 05 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 area of toxicology and deliver its conclusions on flurochloridone.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of flurochloridone as a herbicide on sunflower and potato as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No critical areas of concern were indentified in the physical chemical properties section, however several data gaps were identified for the active substance and formulation (see section 1).

A data gap was identified in the toxicology section to address the relevance of the impurities present in the technical specification. No toxicological information is available on the metabolite R42819 that may be found in groundwater at levels above the threshold value of 0.1 µg/L according to environmental models; based on the classification proposal as R61 (Repr. Cat. 2, “May cause harm to the unborn child”) and R62 (Repr. Cat. 3, “Possible risk of impaired fertility”) for the parent, this metabolite is relevant according to the Guidance document on assessment of the relevance of metabolites in groundwater (European Commission, 2003) and a critical area of concern was identified.

Based on the metabolism studies conducted on sunflower and potato (oilseeds/pulses group and tubers/roots group), the residue for monitoring and risk assessment was defined as flurochloridone (sum of cis and trans isomers). MRLs were proposed at the LOQ (0.01 mg/kg). No risk was identified for the consumers, the TMDI and IESTI being less than 0.1% of the ADI and less than 4% of the ARfD.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. A high potential for groundwater contamination by metabolite R42819 in a wide range of geoclimatic conditions above the parametric drinking water limit (0.1µg/L) is indicated by the exposure assessment that could be finalised with the available data. (All the FOCUS groundwater scenarios pertinent for sunflower and 7 of the 9 FOCUS groundwater scenarios pertinent for potato have annual average groundwater recharge concentrations predicted to be >0.1µg/L).

Two data gaps were identified in the environmental risk assessment to address the potential risk to birds and fish from flurochloridone acting as endocrine disruptor and to address the risk to algae for the representative uses.

The risk to non-target plants was assessed as low for the representative uses, based on mitigation measures equivalent to no-spray buffer zones of 5 m.

**KEY WORDS**

Flurochloridone, FLC, peer review, risk assessment, pesticide, herbicide

## TABLE OF CONTENTS

## 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(s) 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

Flurochloridone 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, Spain which was received by the EFSA on 15 March 2006 (Spain, 2006).

The peer review was initiated on 27 October 2006 by dispatching the DAR to Member States and the applicant Makhteshim for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The Reporting Table containing the RMS' evaluation of the comments in column 3 was further considered by the EFSA, resulting in a conclusion in column 4.

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of flurochloridone 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 flurochloridone in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Makhteshim made a resubmission application for the inclusion of flurochloridone 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, Spain 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 3 November 2009 (Spain, 2009).

[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

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 November 2009. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 05 January 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were 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 24 February 2010 the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on flurochloridone 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 10 February 2010 the applicant was also 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 area of mammalian toxicology and that further information should be requested from the applicant in the areas of physical-chemical properties, mammalian toxicology, residues and 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, was 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 September 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 a herbicide on sunflowers and potatoes 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 (EFSA, 2010), 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 comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1, 29 January 2010)
- the Evaluation Table (14 October 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 containing all individually submitted addenda; Spain, 2010) 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

Flurochloridone is the ISO common name for (3RS,4RS;3RS,4SR)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-tolyl)-2-pyrrolidone (IUPAC) where the ratio of (1*RS*,2*RS*)(*trans*)- and (1*RS*,2*SR*)(*cis*)-isomers is 3:1. However, the compounds evaluated in the DAR and additional report, were not exactly in a 3:1 ratio. Therefore the name flurochloridone cannot currently be used to name the substance under consideration. In this conclusion the company code FLC will be used to identify this substance.

The representative formulated product for the evaluation was 'Racer' a capsule suspension (CS) containing 250 g/l FLC.

The representative uses evaluated comprise outdoor foliar spraying against broad leafed and grass weeds in sunflower and potato. Full details of the GAP can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

FLC is a mixture of *cis* and *trans* diastereoisomer pairs. The possible preferential metabolism/degradation or conversion of each isomer in animals, plants and the environment was not investigated. Therefore this could not be considered during this peer review. The analytical methods used in the studies reported through all sections were not stereo-selective and most values mentioned as "FLC" have to be considered as "sum of isomers". Though the non chiral analytical methods used have the potential to resolve the *cis* and *trans* diastereoisomer pairs, resolution into two clear peaks was often not achieved. This is the reason why, with the exceptions noted in this conclusion, reference to FLC is for the sum of the four potential isomers. The metabolites R406639, R42819, M8, 4-dechloro-4-hydroxymethyl and 5-hydroxy-4-chloromethyl are also isomeric due to chiral carbon atoms. The impact of the potential change in isomer ratios with time on the toxicity, the consumer risk assessment and the environmental risk assessment was not and could not be evaluated with the available data. It was concluded that only the environmental risk assessment requires further information regarding this in the context of the representative uses assessed. Therefore this issue is also discussed further in section 5.

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

The minimum purity of the active substance as manufactured is 940 g/kg. The content of the diastereoisomer pairs is *trans*-FLC: 720-740 g/kg and *cis*-FLC: 220-240 g/kg. There is no FAO specification for this compound. Toluene is considered a relevant impurity and its maximum level in the technical material is 8 g/kg. For the other impurities a data gap has been identified to address their relevance (see Section 2).

The main data regarding the identity of FLC and its physical and chemical properties are given in Appendix A. Vapour pressure, Henry's law constant of the *cis* isomer and melting point/range study were identified as data gaps for the active substance. For the formulation the following data gaps were identified: low temperature stability with the amount of free and encapsulated active substance determined before and after storage, the amount of free and encapsulated active substance before and after 2 years storage and the alkalinity of the formulation. It should be noted that the formulation showed poor pourability and appropriate rinsing instructions should be considered when labelling the products.

Residues of FLC in plants can be analysed with GC-MS methods. A method of analysis for products of animal origin is not required as no MRL's are proposed. For soil, water and air GC-MS methods are available. The active substance is classified as toxic (T) and therefore a data gap is identified for a method of analysis for body fluids and tissues.

## 2. Mammalian toxicity

FLC was discussed at the PRAPeR 79 expert meeting. The technical specification is supported by the batches used in the toxicological studies, however the relevance of the impurities is not addressed; a data gap is set on the relevance of the impurities present in the technical specification. Toluene is a relevant impurity, but no concern is raised from the concentration set in the technical specification.

Low acute toxicity was observed when FLC is administered by the oral, dermal or inhalation routes, no eye or skin irritation but potential for skin sensitisation was found. The target organs of FLC are the testis and epididymides in male rats, with dogs, mice, rabbits and monkeys being less sensitive to these effects. Increased incidence of abnormal sperm and decreased sperm count at higher dose levels are the outcome. Sertoli cell vacuolation was observed in rats. As Sertoli cells are involved in hormonal control of male reproductive functions, FLC could be considered as a potential endocrine disruptor. Nevertheless, there is no further data to confirm it. The heart, great vessels and haematopoietic system are also potential target organs of FLC in the rat, dog and/or rabbit. No genotoxic, carcinogenic or neurotoxic potential is attributed to the active substance. The relevant long-term NOAEL is 3.9 mg/kg bw/day from the 2-year rat study. Classification with R62 “Possible risk of impaired fertility” (repr. Cat. 3) and R61 “May cause harm to the unborn child” (repr. Cat. 2) are proposed; R62 considering the effects on male reproduction, and R61 due to the increased incidences of visceral and skeletal malformations observed in developmental studies in rats. Acute and short-term NOAELs are set from these critical studies at 20 mg/kg bw/day, where the LOAEL is 25 mg/kg bw/day.

No toxicological information is available on the metabolite R42819 that may be found in groundwater at levels above the threshold value of 0.1 µg/L according to environmental models; based on the classification proposal as R61 and R62 for the parent, this metabolite is relevant according to the Guidance document on assessment of the relevance of metabolites in groundwater (European Commission, 2003) and a critical area of concern was identified.

The acceptable daily intake (ADI) of FLC is 0.04 mg/kg bw/day, based on the 2-year study in rat and applying a safety factor of 100. The acceptable operator exposure level (AOEL) is 0.04 mg/kg bw/day and the acute reference dose (ARfD) 0.04 mg/kg bw, based on the developmental toxicity study in rat with a NOAEL of 20 mg/kg bw/day, applying an additional safety factor of 5 (overall 500) as teratogenicity was found at the dose level of 25 mg/kg bw/day; no correction for oral absorption being needed to derive the AOEL.

Estimated operator exposure is below the AOEL without the use of personal protective equipment (PPE) according to the German model or when gloves are worn during mixing and loading operations, and during application of the plant protection product according to the UK POEM model. Worker exposure is not relevant to the representative uses and the anticipated bystander’s exposure is below the AOEL.

## 3. Residues

Metabolism in plants was investigated in sunflower (oilseeds/pulses group) and potato (root crop group) using a single spray application onto the soil surface, just after sowing/planting. Studies were conducted with the $^{14}C$ labelling on the pyrrolidone moiety only. However, taking into account the low TRRs observed in plants, and considering that no cleavage was observed in the soil studies where a second label was used, it was concluded that further investigations using an additional label are not necessary. A complete picture of the metabolic pathway could not be achieved since the identification of the metabolites was not feasible in sunflower seeds and potato tubers due to the low TRRs observed at harvest (<0.01 mg/kg). The characterisation of the residues was only possible in mature sunflower leaves, where flurochloridone accounted for 10-17% TRR and where three metabolites could be identified (5-hydroxy-4-chloromethyl, 3-hydroxy-4-chloromethyl and 4-dechloro-4-hydroxymethyl), each representing less than 3% TRR. In the same way, in the rotational crop study, the total radioactivity was less than 0.01 mg/kg in carrot roots, spinach leaves and cereals grains for all plant

back intervals and significant levels were only detected in cereal straw (0.02-0.05 mg/kg). Based on these studies it was proposed to define by default, the residue for monitoring and risk assessment as flurochloridone only (sum of cis and trans isomer pairs). No information was provided on the respective behaviour of each constituent isomer, but having regard to the supported uses and since no residues are expected in seeds and tubers, such information was considered not necessary. Data gaps have been identified for an issue on rotational and succeeding crops.

No residues were detected in the supervised residues trials conducted on sunflower and potato and the MRLs were proposed at the LOQ (0.01 mg/kg). These studies are fully supported by the storage stability data showing flurochloridone residues to be stable up to 3 years at *c.a.* -20°C. Animal metabolism study, livestock feeding study and processing studies were not provided and not requested, the residues in sunflower and potato being below the LOQ.

No risk was identified for the consumers, the TMDI being less than 0.2% of the ADI for all diets included in the EFSA PRIMo model, and the IESTI max. 4% of the ARfD.

## 4. Environmental fate and behaviour

As already discussed, the regulatory dossier reported no information on the behaviour of each individual FLC enantiomer in the environment. Whilst the methods of analysis used (that did not employ chiral chromatography) did sometimes resolve the 2 diastereoisomers (though not achieving baseline separation), usually the study reports did not report any quantification of these separately and often only a single peak was apparent in the chromatograms presented. Consequently it is not known if any of the enantiomers (including the potentially but often not resolved diastereoisomer pairs) were degraded more quickly than the others, or if any conversion of enantiomers occurred in the environmental matrices studied. Consequently a data gap was identified for this issue. References made to FLC in sections 4 and 6 therefore relate to the sum of the isomers that may constitute FLC of unknown enantiomer / diastereoisomer ratio. The one exception to this general lack of information was that the diastereoisomer ratio did not change with time in the single soil photolysis experiment (viable soil at field capacity). In this experiment the results for the analysis of the diastereoisomer pairs were reported separately and diastereoisomer resolution was achieved. The metabolite R406639 also has 2 chiral centres, but the chromatography utilised in the pertinent studies did not resolve the diastereoisomers even though it had the potential to have been able to do this.

In soil laboratory incubations under aerobic conditions in the dark, FLC exhibited moderate to high persistence, forming the metabolites that were assessed further R406639 (max. 8.1 % AR) and R42819 (max. 10.1 % AR), which exhibited low to high and low to very high persistence respectively. Mineralisation of the pyrrolidone-2-$^{14}$C ring radiolabel to carbon dioxide accounted for 28 % AR after 91 days. This value for the phenyl-U-$^{14}$C ring radiolabel was only 1.8 % AR. The formation of unextractable residues (not extracted by acetone) accounted for 36 % AR (pyrrolidone-2-$^{14}$C radiolabel) and 56 % AR (phenyl-U-$^{14}$C radiolabel) after 91 days. In anaerobic soil incubations FLC breakdown was considered less extensive than under aerobic conditions. In laboratory soil photolysis experiments no novel metabolites were identified. FLC and R406639 exhibited medium to low mobility in soil. R42819 exhibited medium soil mobility. It was concluded that the adsorption of FLC, R406639 and R42819 was not pH dependent. In satisfactory field dissipation studies carried out at 4 sites in Germany (spray application to the soil surface on bare soil plots in late spring, plots were maintained bare) and 4 in Italy (spray application to the soil surface on bare soil plots in late spring or autumn with sunflowers or wheat subsequently germinating), FLC exhibited moderate to high persistence. Sample analyses were only carried out for the parent FLC.

In laboratory incubations in dark aerobic natural sediment water systems, FLC exhibited moderate persistence, forming the major metabolites R42819 (max. 23 % AR in water and 47 % AR in sediment, exhibiting high persistence) and R406639 (max. 10.6 % AR in the sediment, exhibiting moderate persistence). The unextractable sediment fraction (not extracted by acetone followed by Soxhlet methanol / water) was a sink for both the pyrrolidone-2-14C and phenyl-U-14C radiolabels, accounting for 18 – 30 % AR at study end (100 days). Mineralisation of these radiolabels accounted

for 4-7 % AR and only 1-2 % AR respectively at the end of the study. The rate of decline of FLC in a laboratory sterile aqueous photolysis experiment was comparable to that which occurred in the aerobic sediment water incubations. It was concluded that the novel photolysis product M8 did not need to be accounted for in the natural surface water exposure assessments. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC)) in surface water and sediment were carried out for the metabolites R406639 and R42819, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator). For the active substance FLC, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available11. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 57 – 91 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in run-off by 80 % and erosion runoff by 95 %) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulationsWhilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with KFoc < 2000 mL/g (i.e. FLC), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the model PEARL 3.3.3 12 for the active substance FLC and metabolites R406639 and R42819. The potential for groundwater exposure from the representative uses by FLC and R406639 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. For the metabolite R42819 this limit was not exceeded at only the Porto and Sevilla scenarios consequent to the use on potatoes. Annual average concentrations leaving the top 1m soil layer at the other 7 scenarios defined for potatoes were 0.13-2.29 µg/L, with concentrations at 3 of these scenarios exceeding 0.75µg/L. For this metabolite and the use on sunflowers both scenarios (Sevilla and Piacenza) exceeded the parametric limit of 0.1 µg/L with Piacenza exceeding 0.75 µg/L with an annual average concentration of 2.65µg/L. This modelling was completed using the best estimates available with degradation substance parameters for R42819 being derived from the available data, following FOCUS degradation kinetics (FOCUS, 2006) guidance. With additional experimental data on the degradation rate and kinetic formation fraction of R42819, a more refined groundwater exposure assessment might be made for this metabolite. As there is no toxicological information available on this metabolite and considering the toxicological classification proposed for FLC, the metabolite R42819 needs to be considered relevant (see sections 2 and 6.2).

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

A data gap remains for the applicant to prove the compliance of ecotoxicological test material with the technical specification of FLC.

For all representative uses the acute, short-term and long-term risk to herbivorous and insectivorous birds was assessed as low at Tier I (EU, 2002), as well as the acute and long-term risk to herbivorous mammals. The long-term risk assessment for mammals was based on the more relevant rat reproduction NOAEL endpoint of 28.6 mg a.s/kg bw/d, which was agreed during the peer review. The risk to birds and mammals from secondary poisoning (eating earthworms or fish) and the consumption of contaminated drinking water was assessed as low. Toxicity data for mammals identified FLC as a potential endocrine disrupter (see section 2). Consequently, a data gap was identified to address the potential risk to birds and fish from FLC acting as endocrine disrupter.

[11] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[12] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

FLC was assessed to be very toxic to aquatic organisms based on the information available. Toxicity of the active substance was comparable to the toxicity of the representative formulation. The toxicity data for algae and *Lemna gibba* was driving the risk assessment. The toxicity study provided for the sediment dwelling midge *Chironomus riparius* was not considered acceptable by the RMS to derive a reliable endpoint for FLC as a *cis/trans* mix. The study however indicated that the toxicity to *Chironomus* did not exceed the toxicity identified for fish and daphnia. As fish and daphnia were not the most sensitive organism to FLC, these toxicity data were considered to cover the potential risk to sediment dwellers. In the Additional Report the risk to aquatic organisms was assessed based on the toxicity data for technical FLC (1cis:3trans). For the representative use in potatoes and sunflowers PEC values according to FOCUS step 3 resulted in acute and long-term TER values exceeding the Annex VI trigger for fish and daphnia. Consequently the risk to sediment dwelling organisms was also considered to be low. The risk was assessed as low for aquatic plants in 4 out of 7 $FOCUS_{sw}$ scenarios at step 3 for the use in potatoes and in 2 out of 4 $FOCUS_{sw}$ scenarios at step 3 for the use in sunflower. A low risk was identified in all scenarios for aquatic plants for the representative uses at $FOCUS_{sw}$ step 4 including mitigation measures equivalent to 20m vegetated buffer strips. For algae it was not possible to identify a low risk for any full $FOCUS_{sw}$ scenarios for the representative uses, taking into account mitigation measures equivalent to 20m vegetated buffer strips. Further refinements were considered to be necessary to address the risk to algae for all representative uses. The applicant provided refined assessments taking into account 24h toxicity studies on algae and exposure profiles predicted by $FOCUS_{sw}$. Even though the RMS acknowledged the approach used by the applicant to refine the risk to algae, further data should be required to support the refinements; more quantitative data for a full characterization of exposure profile, e.g. data across scenarios: maximum peak concentration, median duration of peak, number of peaks, AUC, median interval between peaks. If the risk assessment for algae in the run-off scenarios (R1, R2, R3 and R4) with several exposure peaks (majority of scenarios for both uses) should be based on potential for recovery, such potential for recovery should be established for several algae species. Furthermore, the aquatic risk assessment did not address the potential risk from potentially changing ratios of enantiomers and diastereoisomers (see section 4). Consequently a data gap was identified to address the risk to algae for the representative use in potatoes and sunflower considering the deficiencies mentioned above. The risk from exposure to the two metabolites R42819 and R406639 was assessed as low with a margin of safety that covered the concern related to the added uncertainty that results from not having information on the isomers of these metabolites. A BCF in fish of 292 was not considered an issue due to fast depuration.

The acute and long-term risk to earthworms was assessed as low for all representative uses. Whereas the margin of safety for the acute risk assessment to earthworms was considered to be sufficient to cover uncertainties regarding changing exposure from enantiomers and diastereoisomers of FLC, the long-term TER value only exceeded the Annex VI trigger by a factor of two. A data gap was identified to address potential effect on the long-term risk assessment to earthworms from exposure to enantiomers and diastereoisomers of FLC.

The risk to non-target plants was assessed as low for the intended uses, based on mitigation measures (e.g. non-spray buffer zones of 5 m)

Based on data available the risk to bees, non-target arthropods, non-target soil micro organisms and biological methods for sewage treatment was assessed as low for all representative uses.

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

### 6.1. Soil

| Compound (name and/or code) | Persistence | Ecotoxicology |
|---|---|---|
| FLC | moderate to high persistence<br><br>Biphasic kinetics $DT_{50}$ 9-66 days ($DT_{90}$ 76-940 days, 20ºC pF 2 soil moisture)<br><br>Field dissipation studies:<br><br>Biphasic kinetics $DT_{50}$ 11-65 days ($DT_{90}$ 75-515 days) | The risk to soil living organisms was assessed as low. However, a data gap was identified to address uncertainties relating to isomer exposure in the long-term risk assessment for earthworms (see section 5). |

### 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 |
|---|---|---|---|---|---|
| FLC | medium to low mobility $K_{Foc}$ 490-1100 mL/g | No | Yes | Yes | Yes |
| R406639 | medium to low mobility $K_{doc}$ 264-1265 mL/g | No | No | No data, data not required<br><br>Relevant based on the proposal for classification of the parent as toxic for the reproduction R61-R62 | No |

| | | | | | |
|---|---|---|---|---|---|
| R42819 | medium mobility $K_{doc}$ 302-463 mL/g | Yes, in 7 out of the 9 scenarios for potatoes, with 3 of these scenarios exceeding 0.75µg/L, concentrations up to 2.29µg/L. For sunflower both scenarios exceed with the Piacenza scenario exceeding 0.75µg/L with concentrations up to 2.65µg/L. | No | No data, relevant based on the proposal for classification of the parent as reprotox R61-R62 | **No** |

### 6.3. Surface water and sediment

| **Compound (name and/or code)** | **Ecotoxicology** |
|---|---|
| FLC | Very toxic to aquatic organisms. A data gap was identified to address the risk to algae for all the representative uses. |
| R42819 | Risk assessed as low based on data available. |
| R406639 (sediment only) | Risk assessed as low based on data available. |

### 6.4. Air

| **Compound (name and/or code)** | **Toxicology** |
|---|---|
| FLC | Rat $LC_{50}$ inhalation > 4.82 mg/L air/4 h as aerosol, nose-only exposure – no classification proposed |

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

- Vapour pressure and Henry's law constant of the *cis* diastereoisomer pair are missing. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- Information on the melting point (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- Information on the alkalinity of the formulation is missing (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- A low temperature stability study where the amount of free and encapsulated active substance should be determined before and after storage is missing. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- A shelf life stud, where the amount of free and encapsulated active substance should be determined before and after storage is missing (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- A method of analysis for body fluids and tissues is missing. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- Toxicological information allowing the assessment of the relevance of the impurities present in the technical specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2)

- The length of time the different samples where stored frozen prior analyses, in the confined rotational crop study (Mamouni, A., 2009) has to be provided. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3)

- Applicant to provide the information/data supporting the proposed waiting period of 3 months. (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3)

- The exposure patterns have not been characterised in respect of the potentially varying enantiomer and diastereoisomer ratios of FLC and its metabolites that have chiral carbons in their structure. This need to be addressed. However it was concluded that further information on this issue is not necessary to complete the risk assessments for the representative uses evaluated, with the exception of the specific issues identified in section 5 (see paragraph under 'conclusions of the evaluation' that precedes section 1, section 4 and section 5)

- The exposure patterns and consequent risk assessment for non-target organisms need to be characterised further, in relation to the impact that the potentially varying enantiomer and diastereoisomer ratios of FLC may have on the risks assessed and the extent of risk mitigation required, in particular in relation to the aquatic risk and chronic risk to earthworms, (relevant for both representative uses evaluated; submission date proposed by the applicant: unknown; see paragraph under 'conclusions of the evaluation' that precedes section 1, section 4 and section 5).

- An assessment of the compliance of ecotoxicological test material with the technical specification of FLC is missing (relevant for all representative uses evaluated ; submission date proposed by the applicant: none; see section 5)

- The potential risk to birds and fish from FLC acting as endocrine disruptor needs to be addressed. (relevant for all representative uses evaluated ; submission date proposed by the applicant: none; see section 5)

- The risk to algae needs to be addressed (relevant for all representative uses evaluated ; submission date proposed by the applicant: none; see section 5)

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

- Risk mitigation equivalent to 5m no-spray buffer zones was required in order to identify a low risk for non-target plants

## ISSUES THAT COULD NOT BE FINALISED

- An assessment of the compliance of ecotoxicological test material with the technical specification of FLC remains to be documented.

- Based on the data available it was not possible to address the potential risk to birds and fish from FLC acting as endocrine disruptor

## CRITICAL AREAS OF CONCERN

- No information is available on the toxicological profile of the groundwater metabolite R42819. Based on the proposal for classification of the parent as R61 (Repr. Cat. 2, “May cause harm to the unborn child”) and R62 (Repr. Cat. 3, “Possible risk of impaired fertility”), this metabolite has to be considered relevant in groundwater. A high potential for groundwater contamination by this metabolite in a wide range of geoclimatic conditions above the parametric drinking water limit (0.1µg/L) is indicated by the exposure assessment that could be finalised with the available data. (All the FOCUS groundwater scenarios pertinent for sunflower and 7 of the 9 FOCUS groundwater scenarios pertinent for potato have annual average groundwater recharge concentrations predicted to be >0.1µg/L).

- A high risk to algae was identified for the representative uses based on the available data.

## REFERENCES

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Spain 2010. Final Addendum to the Additional Report on flurochloridone, compiled by EFSA, August 2010

EFSA (European Food Safety Authority),2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance flurochloridone. EFSA Scientific Report

Guidance documents[13]:

European Commission, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.

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FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

FOCUS (2000). "FOCUS Groundwater Scenarios in the EU review of active substances". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000-rev.2. 202 pp, as updated by the Generic Guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002

FOCUS (2006). "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp

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

[13] 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

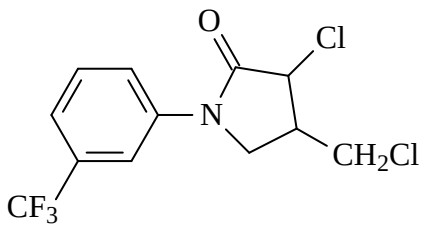
## APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

| | |
|---|---|
| Active substance (ISO Common Name) ‡ | Flurochloridone (according to the ISO definition only an isomer ratio of 3:1 *trans/cis* is named as flurochloridone, other ratios cannot be regarded as flurochloridone). As the isomer ratio for the compound considered here is not exactly 3:1 the name flurochloridone cannot be used the company code FLC is used instead. |
| Function (*e.g.* fungicide) | Herbicide |

| | |
|---|---|
| Rapporteur Member State | Spain |
| Co-rapporteur Member State | |

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

| | |
|---|---|
| Chemical name (IUPAC) ‡ | (3RS,4RS;3RS,4SR)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-m-tolyl)-2-pyrrolidone (isomers in the ratio 3:1) |
| Chemical name (CA) ‡ | 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]-2-pyrrolidinone |
| CIPAC No ‡ | 430 |
| CAS No ‡ | 61213-25-0 |
| EC No (EINECS or ELINCS) ‡ | 262-661-3 (EINECS) |
| FAO Specification (including year of publication) ‡ | No FAO specification |
| Minimum purity of the active substance as manufactured ‡ | 940 g/kg<br>trans FLC: 720-740 g/kg<br>cis FLC: 220-240 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Toluene<br>Max. 8 g/kg<br>Open for other impurities |
| Molecular formula ‡ | $C_{12}H_{10}Cl_2F_3NO$ |
| Molecular mass ‡ | 312.12 |
| Structural formula ‡ |  |

## Physical and chemical properties (Annex IIA, point 2)

| | |
|---|---|
| Melting point (state purity) ‡ | Open |
| Boiling point (state purity) ‡ | The decomposition of FLC was observed before boiling occurred; 99.5% purity |
| Temperature of decomposition (state purity) | The decomposition of FLC starts at about 290°C. |
| Appearance (state purity) ‡ | Purified: solid with a light peach colour; (98.7%, cis/trans 1:3) |
| | Technical material: Dark brown-red solid with mild disinfectant or mothball odour at r.t. (92.0%, cis/trans 1:3) |
| Vapour pressure (state temperature, state purity) ‡ | $2.7 * 10^{-4}$ Pa at 25°C , (995 g/kg)<br>*Trans* isomer: $6.0 * 10^{-5}$ Pa at 25°C; $2.5 * 10^{-5}$ Pa at 20°C, (995 g/kg)<br>*Cis* isomer: to be determined |
| Henry's law constant ‡ | $H = 2.40 * 10^{-3}$ Pa.m$^3$.mol$^{-1}$ (25 °C)<br>*Trans* isomer: $7.00 * 10^{-4}$ Pa * m$^3$/mole at 20°C<br>*Cis* isomer: to be determined |
| Solubility in water (state temperature, state purity and pH) ‡ | 31.1 mg/L at 20°C at pH 4.0 , (938 g/kg)<br>21.9 mg/L at 20°C at pH 7.0 , (938 g/kg)<br>28.6 mg/L at 20°C at pH 9.0 , (938 g/kg)<br>Trans isomer: 11.0 mg/L at 20°C (pH 7, (995 g/kg))<br>Cis isomer: 31.8 mg/L at 20°C (pH 7, (941 g/kg)) |
| Solubility in organic solvents ‡ (state temperature, state purity) | Acetone >540 g/L<br>Acetonitrile >638 g/L<br>Ethyl acetate >592 g/L<br>Hexane 9.1 g/L<br>Methanol 326 g/L<br>Methylen chloride >508 g/L<br>Toluene >616 g/L<br>(20°C, 938 g/kg) |
| Surface tension ‡ (state concentration and temperature, state purity) | 54.6 mN/m at 20°C (90% of saturation concentration)<br>Purity: 94.9% |
| Partition co-efficient ‡ (state temperature, pH and purity) | log PO/W: 3.36 at 20 °C (pH = 7), 98.7% purity (cis/trans 1:3) |
| Dissociation constant (state purity) ‡ | In the environmentally relevant pH range of pH 4 to 9 FLC is present in its neutral form and does not dissociate or protonate |
| UV/VIS absorption (max.) incl. ε ‡ (state purity, pH) | Maximum at 252 nm<br>Extinction coefficient of 1.23 * 104 m-1<br>98.7% purity (cis/trans 1:3) |
| Flammability ‡ (state purity) | Not flammable |
| Explosive properties ‡ (state purity) | Not explosive |

| | |
|---|---|
| Oxidising properties ‡ (state purity) | Not oxidising |

**Summary of representative uses evaluated FLC**

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of as. (i) | method kind (f-h) | growth stage & season (j) | number max (k) | interval between applications | g as./hL min max | water L/ha min max | kg as./ha min max | | |
| Sunflower | N/S | Racer | F | broad-leafed weeds and grass weeds | CS | 250 g/L | spray application | BBCH 00 - 07 | 1 | n.a. | 125 - 375 | 200 - 400 | 0.5 - 0.75 | n.r. | [I], [II], [III] |
| Potato | N/S | Racer | F | broad-leafed weeds and grass weeds | CS | 250 g/L | spray application | BBCH 00 - 05 | 1 | n.a. | 93.8 - 375 | 200 - 400 | 0.375 - 0.75 | n.r. | [II], [IV] |

[I] In both pertinent FOCUS scenarios the groundwater metabolite R42819 is estimated to contaminate groundwater above the parametric drinking water limit of 0.1µg/L. With the available mammalian toxicological data this metabolite has to be considered relevant.
[II] High risk to algae
[III] Safe uses for D5 with 5 m of buffer zone to mitigate the spray drift input. No safe uses are identified for run-off scenarios.
[IV] Safe uses for D3, D4, and D6 with 5 m of buffer zone No safe uses are identified for run-off scenarios and for D6

(a) For crops, the EU and Codex classifications (both) should be used: where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting or 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
(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) PHI – minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions
(*) Uses for wich the risk assessment can not be concluded are marked grey

## Chapter 2: Methods of Analysis

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

| | |
|---|---|
| Technical a.s. (principle of method) | GC-FID<br>Confirmation: GC/MS |
| Impurities in technical a.s. (principle of method) | GC-FID<br>Confirmation: GC/MS<br>Water: Karl-Fischer titration |
| Plant protection product (principle of method) | GC-FID<br>Confirmation: GC/MS |

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

**Residue definitions for monitoring purposes**

| | | |
|---|---|---|
| Food of plant origin | | FLC sum of isomers |
| Food of animal origin | | No required for the supported use |
| Soil | | FLC sum of isomers |
| Water | surface | FLC sum of isomers |
| | drinking/ground | FLC sum of isomers |
| Air | | FLC sum of isomers |

**Monitoring/Enforcement methods**

| | |
|---|---|
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | For sunflower seeds:<br>DFG method S19 (GC/MS), LOQ = 0.01 mg/kg<br>For potatoes tubers:<br>modified version of a published multiresidue method, Fillion et al., 2000<br>(GC/MS), LOQ = 0.01 mg/kg |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Not required. |
| Soil (principle of method and LOQ) | FLC:<br>GC/MSD, 0.01 mg/kg |
| Water (principle of method and LOQ) | FLC:<br>Ground, GC/MS, LOQ = 0.05 µg/l<br>Surface, GC/MS, LOQ = 0.05 µg/l<br>Drinking, GC/MS, LOQ = 0.05 µg/l |
| Air (principle of method and LOQ) | FLC:<br>GC/MS<br>LOQ = 0.75 µg/m$^3$ |
| Body fluids and tissues (principle of method and LOQ) | The active substance is classified as T and a data gap is identified for a method of analysis. |

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

| | RMS/peer review proposal |
|---|---|
| Active substance | Not classified |

## Impact on Human and Animal Health

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

| | |
|---|---|
| Rate and extent of oral absorption ‡ | > 90 % of applied dose within 42-90 h after administration based on the comparison of the excretion patterns after oral and ip administrations (rat) |
| Distribution ‡ | Low tissue residues at 72 - 90 h after administration; highest residues found in liver, kidney, epididymis (males) and blood |
| Potential for accumulation ‡ | No evidence of accumulation |
| Rate and extent of excretion ‡ | In rats, > 97 % of applied dose within 72 h after administration, 38 – 47 % in urine and 49 – 58 % in faeces<br>In rabbits, 87 – 91 % applied dose within 96 h, 62 – 67 % in urine and 22 – 24 % in faeces |
| Metabolism in animals ‡ | Extensive metabolism in rats and rabbits *in vivo* (excretion of unchanged FLC ≤ 1.5 % of applied dose). Large number of no discernible fractions (in urine, faeces and plasma), 3 metabolites in rats and 4 metabolites in rabbits identified in urine were acetylcysteine conjugates. Three oxidative metabolites identified *in vitro* |
| Toxicologically relevant compounds ‡ (animals and plants) | FLC |
| Toxicologically relevant compounds ‡ (environment) | FLC |

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

| | | |
|---|---|---|
| Rat $LD_{50}$ oral ‡ | Rat: 3650 mg/kg bw<br>Mice: 5000 mg/kg bw | |
| Rat $LD_{50}$ dermal ‡ | Rabbit: > 5000 mg/kg bw | |
| Rat $LC_{50}$ inhalation ‡ | > 4.82 mg/L air/4 h, nose-only exposure | |
| Skin irritation ‡ | Non-irritant | |
| Eye irritation ‡ | Non-irritant | |
| Skin sensitization ‡ | Sensitising (M & K test) | **R43** |

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

| | | |
|---|---|---|
| Target / critical effect ‡ | Liver and testes (high dose rat)<br>Decrease in bodyweight and bodyweight gain (rat & dog)<br>Haematological effects (dog) | |
| Relevant oral NOAEL ‡ | 90-day rat: 5.4 mg/kg bw/day<br>6-month dog: 7.1 mg/kg bw/day | |
| Relevant dermal NOAEL ‡ | No data - not required | |

| | | |
|---|---|---|
| Relevant inhalation NOAEL ‡ | No data - not required | |

**Genotoxicity ‡ (Annex IIA, point 5.4)**

| | |
|---|---|
| FLC is unlikely to be genotoxic | |

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

| | | |
|---|---|---|
| Target/critical effect ‡ | Rat: testes (reduced size/weight, tubular atrophy, interstitial cell hyperplasia) and epididymides (reduced size, spermatic degeneration, tubular hyperplasia); bodyweight decrease<br>Mouse: increased liver and adrenal weights | |
| Relevant NOAEL ‡ | 3.9 mg/kg bw/day (2-year rat)<br>6.3 mg/kg bw/day (2-year mouse) | |
| Carcinogenicity ‡ | FLC is unlikely to pose a risk to humans | |

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

**Reproduction toxicity**

| | | |
|---|---|---|
| Reproduction target / critical effect ‡ | Reproductive: Testes and epididymides/Sertoli cell vacuolation and consequently sperm degeneration.<br>Parental: reduced body weight gain, testicular and epididymides atrophy, hyperplasia<br>Offspring: reduced body weight, body weight gain, reduced testes weight decreased number of pups/litter, live birth index and reduced survival (0-4 days) | **Xn; R62** |
| Relevant parental NOAEL ‡ | 2.8 mg/kg bw/day | |
| Relevant reproductive NOAEL ‡ | 2.8 mg/kg bw/day | |
| Relevant offspring NOAEL ‡ | 27.7 mg/kg bw/day | |

**Developmental toxicity**

| | | |
|---|---|---|
| Developmental target / critical effect ‡ | Rat:<br>*Maternal*: decreased body weight gain<br>*Developmental*: Decreased body weight and increased incidence of visceral malformations (diaphragmatic hernia, heart/great vessel anomaly), skeletal malformations (exoccipital-cervical vertebrae defects) and elevated incidence of variations<br>Rabbit:<br>*Maternal*: decreased body weight gain<br>*Developmental*: increased incidence of post-implantation losses and skeletal variations | |

| | | |
|---|---|---|
| Relevant maternal NOAEL ‡ | Rat: 20 mg/kg bw/day<br>Rabbit: 5 mg/kg bw/day | |
| Relevant developmental NOAEL ‡ | Rat: 20 mg/kg bw/day<br>Rabbit: 20 mg/kg bw/day<br>Teratogenic at doses ≥ 25 mg/kg bw/day (rat) | **T; R61** |

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

| | | |
|---|---|---|
| Acute neurotoxicity ‡ | No data - not required | |
| Repeated neurotoxicity ‡ | No data - not required | |
| Delayed neurotoxicity ‡ | No data - not required | |

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

| | |
|---|---|
| Mechanism studies ‡ | Fertility and mechanistic studies on male of rat, rabbit and monkey:<br>FLC appears to affect the seminiferous epithelial cycle of the testes at the primary spermatocyte stage by acting on the Sertoli cells.<br>The Sertoli cell vacuolation produced germ cell depletion and degeneration and consequently failed spermatid release. This results in reduction of sperm and malformations in caput and cauda epididymis. Reversibility is probable since the spermatogonia and primary spermatocytes were not affected by treatment.<br>No effects on male reproductive parameters in monkey and rabbit, at doses producing effects on male rats. |
| Studies performed on metabolites or impurities ‡ | No data - not required |

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

| |
|---|
| No evidence of adverse health effects of workers. No case of poisoning in the literature. No epidemiological study available |

**Summary (Annex IIA, point 5.10)**

| | Value | Study | Safety factor |
|---|---|---|---|
| ADI ‡ | 0.04 mg/kg bw/day | rat, 2-year study | 100 |
| AOEL ‡ | 0.04 mg/kg bw/day | rat, developmental study | 500* |
| ARfD ‡ | 0.04 mg/kg bw | rat, developmental study | 500* |

* higher safety factor due to severity of effects at 25 mg/kg bw/day and NOAEL at 20 mg/kg bw/day in 2 different studies

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

| | |
|---|---|
| Flurochloridone 25 CS | Concentrate: 0.3 %<br>Spray dilution: 4 %<br>Human *in vitro* study |

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

| | |
|---|---|
| Operator | Tractor mounted equipment, application rate 750 g FLC/ha<br>German model % of AOEL<br>Without PPE: 49 %<br>UK POEM % of AOEL<br>Without PPE: 394 %<br>With PPE (gloves during M/L and application): 56 % |
| Workers | Worker exposure not relevant to the representative uses (considering the growth stage of the crops at application) |
| Bystanders | 2 % of the AOEL |

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

| | RMS/peer review proposal |
|---|---|
| Substance classified: FLC | **T** "Toxic"<br>**R43** "May cause sensitization by skin contact"<br>**Repr. Cat 2, R61** "May cause harm to the unborn child"<br>**Repr. Cat 3, R62** "Possible risk of impaired fertility" |

## Residues

**Metabolism in plants (Annex IIA, point 6.1 and 6.6; III.A, point 8.1 and 8.6)**

| | |
|---|---|
| Plant groups covered | Pulses/oilseeds (sunflower), Roots/tubers (potatoes) |
| Rotational crops | Leafy crops (spinach), root crops (carrot) and cereals (wheat) |
| Metabolism in rotational crops similar to metabolism in primary crops | Limited metabolite identification in primary and rotational crops due to the low TRRs. |
| Processed commodities | Not required |
| Residue pattern in processed commodities similar to residue pattern in raw commodities | Not relevant |
| Plant residue definition for monitoring | Flurochloridone FLC (sum cis + trans isomers) |
| Plant residue definition for risk assessment | Flurochloridone FLC (sum cis + trans isomers) |
| Conversion factor (monitoring to risk assessment | Not applicable |

**Metabolism in livestock (Annex IIA, point 6.2 and 6.7; III.A, point 8.1 and 8.6)**

| | |
|---|---|
| Animals covered | **No provided and not requested** |
| Time needed to reach a plateau concentration in milk and eggs | Not relevant |
| Animal residue definition for monitoring | Not relevant |
| Animal residue definition for risk assessment | Not relevant |
| Conversion factor (monitoring to risk assessment | Not relevant |
| Metabolism in rat and ruminants similar (yes/no) | Not relevant |
| Fat soluble residue (yes/no) | Not relevant |

**Residues in succeeding crops (Annex IIA, point 6.6; III.A, point 8.5)**

| |
|---|
| TRRs <0.01 mg/kg in spinach, carrot root and wheat grain for all plant back intervals (33, 131 and 355 days), 0.016 to 0.049 in cereal straw. |

**Stability of residues (Annex IIA, point 6 introduction; III.A, point 8 introduction)**

| |
|---|
| FLC residues stable up to 3 years in potatoes, soybeans, alfalfa, almonds, apples, corn, peppers, wheat grain, and soil when stored frozen at -20ºC. |

**Residues from livestock feeding studies (Annex IIA, point 6.4; III.A, point 8.3)**

**Not provided and not requested**

| | **Ruminants:** | **Poultry:** | **Pigs:** |
|---|---|---|---|
| Intakes by livestock ≥ 0.1 mg/kg diet (dry weight | No | No | No |

| | | | |
|---|---|---|---|
| basis)(yes/no- If yes, specify the level) | | | |
| Potential for accumulation (yes/no) | | | |
| Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no) | | | |
| | Residue levels in matrices: mg/kg | | |
| Muscle | | | |
| Liver | | | |
| Kidney | | | |
| Fat | | | |
| Milk | | | |
| Eggs | | | |

**Summary of critical residues data (Annex IIA, point 6.3; III.A, point 8.2)**

| Crop | Northern or Southern Region, field or glasshouse | Trials results relevant to the representative uses | Recommendation/comments | MRL estimated from trials according to the intended use | HR (mg/kg) | STMR (mg/kg) |
|---|---|---|---|---|---|---|
| **Sunflower** | North | 4x <0.01 | Minor crop in Northern Europe. No additional trials are requested, although sunflower is major crop in Southern Europe, as all the values are below the LOQ. | 0.01 | 0.01 | 0.01 |
| | South | 6x <0.01 | | 0.01 | 0.01 | 0.01 |
| **Potato** | North | 8x <0.01 | | 0.01 | 0.01 | 0.01 |
| | South | 8x <0.01 | | 0.01 | 0.01 | 0.01 |

8 additional studies performed in sunflowers and in potatoes. Not validated due to lacking of information

**Consumer risk assessment (Annex IIA, point 6.9; III.A, point 8.8)**

| | |
|---|---|
| **ADI** | **0.04 mg/kg bw/day** |
| TMDI (%ADI) according to EFSA PRIMo rev2 model | <0.2% ADI for all diets included in PRIMo model |
| TMDI (%ADI) according to national diet (to be specified) | Not relevant |
| IEDI (%ADI) according to WHO regional European diet | Not relevant |
| NEDI (%ADI) according to national diet (worst case) | Not relevant |
| Factors included in IEDI and NEDI | Not relevant |
| **ARfD** | **0.04 mg/kg bw** |
| IESTI (%ARfD) | Highest IESTI: 4% ARfD (Children, potatoes) |
| Refined IESTI (%ARfD) | Not relevant |
| Factors included in refined IESTI | Not relevant |

**Processing factors (Annex IIA, point 6.5; III.A, point 8.4)**

| Crop/ process/ processed product | Number of studies | Processing factors | | Amount transferred (%, (Optional) |
|---|---|---|---|---|
| | | Transfer factor | Yield factor | |
| **Not provided and not required** | | | | |
| | | | | |

**Proposed MRLs (Annex IIA, point 6.7; III.A, point 8.6)**

| | |
|---|---|
| - Sunflower seeds | 0.01* mg/kg |
| - Potato | 0.01* mg/kg |

When the MRL is proposed at the LOQ, this should be annotated by an asterix (*) after the figure.

## Chapter 5: Fate and Behaviour in the Environment

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

| | |
|---|---|
| Mineralisation after 100 days | *27.7* % after *91* d, [2-$^{14}$C-pyrrolidone]-label (n= 1 at 20ºC and 41.6% MWHC<br>*1.8* % after *91* d, [Phenyl-U-$^{14}$C]-label (n= 1 at 20ºC and 45% MWHC)<br>*16-45.5%* after *64 d* [2-$^{14}$C-pyrrolidone]-label (n=3 at 28 ºC and 40% MWHC) |
| Non-extractable residues after 100 days | *36* % after *91* d, [2-$^{14}$C-pyrrolidone]-label (n= 1 at 20ºC and 41.6% MWHC<br>*56.05* % after *91* d, [Phenyl-U-$^{14}$C]-label (n= 1 at 20ºC and 45% MWHC)<br>*32.4-39.3%* after 64 d [2-$^{14}$C-pyrrolidone]-label (n=3 at 28 ºC and 40% MWHC) |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | R406639 *5*% at *14* d, [2-$^{14}$C-pyrrolidone]-label (n= 1 at 20ºC and 41.6% MWHC<br>R406639 *4.9*% at *28* d, [Phenyl-U-$^{14}$C]-label (n= 1 at 20ºC and 45% MWHC)<br>R406639 3.4-8.1% at *21-29* d [2-$^{14}$C-pyrrolidone]-label (n=3 at 28 ºC and 40% MWHC)<br><br>R42819 *3*% at 120 d, [2-$^{14}$C-pyrrolidone] label (n= 1) (n= 1 at 20ºC and 41.6% MWHC<br>R42819 *2.8*% at 91 d, [Phenyl-U-$^{14}$C]-label (n= 1 at 20ºC and 45% MWHC)<br>R42819 2.7-10.1% at 4-8 d [2-$^{14}$C-pyrrolidone]-label (n=3 at 28 ºC and 40% MWHC) |

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

**Anaerobic degradation**[1]

| | |
|---|---|
| Non-extractable residues after 100 days | *33.3-34.3*% after *91*. d, [2-$^{14}$C-pyrrolidone]-label (n=3 at 28 ºC) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | A reduction of the metabolism is observed |

**Soil photolysis**

| | |
|---|---|
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | All metabolites were identified < 5% AR |
| | |

[1]Soils were aerobic through 30. The duration of the study was 91 d

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

| Aerobic conditions. Parent | | | Regulatory endpoint | | | | Modelling endpoin | | |
|---|---|---|---|---|---|---|---|---|---|
| Soil type | pH | t. °C/ % MWHC | $DT_{50}$ /$DT_{90}$ (d) | St. (Error level $\chi^2$) | Residual Sum of Squares | Method of calculation | $DT_{50}$ | $DT_{50}$ (d) 20°C pF2/10kPa* | Method of calculation (Error level $\chi^2$) |
| Silt loam (Richmond soil) [2-$^{14}$C-pyrrolidone]-label | 6.1 | 20°C/41.6% | 24.4/306[2] | 3.0 | 49.224 | FOMC | 82.36 | 58.013 | HS slower rate (3.8) |
| Silt loam (Richmond soil) [Phenyl-U-$^{14}$C]-label [2-$^{14}$C-pyrrolidone]-label | 6.1 | 20°C/45 % | 24/460[2] | 3.0 | 37.030 | FOMC | - | - | - |
| Sandy loam (Keeton soil) [2-$^{14}$C-pyrrolidone]-label | 7.7 | 28ºC/40 % | 38.5/545.02[2] | 2.6 | 25.6 | FOMC | 53.0 | 180 | DFOPslower rate (3.8) |
| Silt loam (Delco soil) [2-$^{14}$C-pyrrolidone]-label | 6.7 | 28ºC/40 % | 6.35/51.46 | 8.1 | 68.43 | FOMC | 15.5 | 22.8 | FOMC/3.3 2 |
| Loam (Aurora soil) [2-$^{14}$C-pyrrolidone]-label | 7.4 | 28ºC/40 % | 6.7/54.1 | 4.4 | 23.47 | FOMC | 16.3 | 33.252 | FOMC/3.3 2 |
| Geomean | | | | | | | | 53.0 | |

[2] Extrapolated;
*normalised with the assumption of a Q10 of 2.58 (EFSA, 2007) and Walker Equation coefficient of 0.7 (FOCUS)

| R406639: | Aerobic conditions | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Soil type | pH | t. °C/ % MWHC | $DT_{50}$ /$DT_{90}$ (d) | f.f | $DT_{50}$ (d) 20°C pF2/10kPa* | St. (Error level $\chi^2$) | Residual Sum of Squares | Method of calculation |
| Silt loam (Richmond soil) [2-$^{14}$C-pyrrolidone]-label | 6.1 | 20°C/41.6% | 8.4/27.9 | 0.0833 | 5.9 | 15.4 | 3.35 | FOMC-SFO |
| Silt loam (Richmond soil) [Phenyl-U-$^{14}$C]-label [2-$^{14}$C-pyrrolidone]-label | 6.1 | 20°C/45% | 15.4/51.04 | 0.1811 | 10.8 | 19 | 5.2 | FOMC-SFO |
| Sandy loam (Keeton soil) [2-$^{14}$C-pyrrolidone]-label | 7.7 | 28ºC/40% | 131.2/436[3] | 0.0881 | 226.51 | 16.2 | 1.7 | FOMC-SFO |
| Silt loam (Delco soil) [2-$^{14}$C-pyrrolidone]-label | 6.7 | 28ºC/40 % | 104/345.5[3] | 0.12883 | 153.2 | 5.4 | 1.12 | FOMC-SFO |
| Loam (Aurora soil) [2-$^{14}$C-pyrrolidone]-label | 7.4 | 28ºC/40% | 60.5/201[3] | 0.071 | 123.42 | 11.6 | 1.3 | FOMC-SFO |
| | | | Arithmetic mean<br>Geometric mean | 0.105 | 77.4 | | | |

[3] extrapolated;
*normalised with the assumption of a Q10 of 2.58 (EFSA, 2007) and Walker Equation coefficient of 0.7 (FOCUS)

| R42819 | Aerobic conditions | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Soil type | pH | t. °C/ % MWHC | $DT_{50}$ /$DT_{90}$ (d) | f.f | $DT_{50}$ (d) 20°C pF2/10kPa* | St. (Error level $\chi^2$) | Residual Sum of Squares | Method of calculation |
| Sandy loam (Keeton soil) [2-$^{14}$C-pyrrolidone]-label | 7.7 | 28ºC/40% | 42.3/140.4 | - | 73 d[6] | 11.6 | | SFO from maximum |
| Silt loam (Delco soil) [2-$^{14}$C-pyrrolidone]-label | 6.7 | 28ºC/40% | 8.7 | - | 12.81 d | 19.3 | | SFO from maximum |
| Loam (Aurora soil) [2-$^{14}$C-pyrrolidone]-label | 7.4 | 28ºC/40% | 262.8[4] | - | 536.2 d[6] | 7.0 | | DFOP Slower rate |
| | | Geometric mean | | 0.895[5] | 79.4 | | | |

[4]extrapolated; [5]calculated as 1-$ff_{406639;}$ [6]High uncertainty associated to the estimation, *normalised with the assumption of a Q10 of 2.58 (EFSA, 2007) and Walker Equation coefficient of 0.7 (FOCUS)

**Field studies**

| Parent | Aerobic conditions |
|---|---|

| Soil type (bared). | Location (country or USA state). | % MO | pH | Depth (cm) | $DT_{50}$ (d) | $DT_{90}$(d) | St. (Error level $\chi^2$) | Residual Sum of Squares | Method of calculation |
|---|---|---|---|---|---|---|---|---|---|
| Sandy loam | Varendorf (DE) | 1.6 | 5.7 | 0-10 | 31 | 234 | 58.6 | 0.199 | FOMC |
| Silty clay loam | Mechtersheim (DE) | 0.6 | 7.5 | 0-10 | 26 | 181 | 17 | 0.01 | FOMC |
| Silty loam | Inzkofen (DE) | 2.1 | 7.2 | 0-10 | 11 | 75 | 25.1 | 0.017 | FOMC |
| Sandy loam | Etzlberg (DE) | 2.4 | 7.0 | 0-10 | 37 | 249 | 9.4 | 0.004 | FOMC |
| Silty clay | Grosseto (IT) | 2.3 | 7.9 | 0-10 | 48 | 258 | 16.9 | 0.011 | FOMC |
| Sandy loam | Perugia (IT) | 1.1 | 5.0 | 0-10 | 65 | 515 | 14 | 0.007 | FOMC |
| Loam | Draseno (It) | 2.2 | 5.6 | 0-10 | 62 | 205 | 23.7 | 0.004 | FOMC |
| Sandy loam | Mezzana Bigli (It) | 2.5 | 8.0 | 0-10 | 45 | 199 | 14.2 | 0.001 | FOMC |

| | |
|---|---|
| pH dependence (yes / no) (if yes type of dependence) | no |
| Soil accumulation and plateau concentration | Not necessary |

**Supplementary Laboratory studies ‡**

| Parent | Anaerobic conditions | | | | | |
|---|---|---|---|---|---|---|
| Soil type $X^{14}$ | pH | t. °C / % MWHC | $DT_{50}$ /$DT_{90}$ (d) | $DT_{50}$ (d) 20°C pF2/10kPa | St. ($r^2$) | Method of calculation |
| Sandy loam (Keeton soil) [2-$^{14}$C-pyrrolidone]-label | 7.7 | Not calculated, there were not enough sampling points to estimate a n anaerobic $DT_{50}$ Anaerobic conditions were established after 30d of aerobic conditions. The analysis of the anaerobic conditions was performed 61 and 91 d after treatment.<br><br>A Reduction of the metabolism is observed | | | | |
| Silt loam (Delco soil) [2-$^{14}$C-pyrrolidone]-label | 6.7 | | | | | |
| Loam (Aurora soil) [2-$^{14}$C-pyrrolidone]-label | 7.4 | | | | | |

| Parent | Photolysis study:<br>Irradiation apparatus: Suntest apparatus (xenon arc lamp with filters to remove wavelengths < 290 nm)<br>Irradiation conditions: 15 d continuously irradiated. | | | | | |
|---|---|---|---|---|---|---|
| Soil type | pH | t. C º/ | Net Lab $DT_{50}$ (d) | $DT_{50}$ (d) Natural summer light | St. (r2) | Method of calculation |
| Silt loam (Fislis, France) | 7.0 | 21 | 82.3 d | 161 d (30-40 ºN)<br>167 d (50º N) | 0.9818 (light conditions)<br>0.8898 (dark conditions) | SFO |

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

| Parent | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH | $K_d$ (mg/L) | $K_F$ (mg/L) | $K_{doc}$ (mg/L) | $K_{Foc}$ (mg/L) | 1/n |
| sandy loam | 2.96 | 8.5 | 19 | 14 | 680 | 490 | 0.91 |
| sand | 0.58 | 5.1 | 7.6 | 6.5 | 1300 | 1100 | 0.92 |
| sandy loam | 1.16 | 6.7 | 10 | 7.8 | 870 | 670 | 0.89 |
| sandy clay loam | 1.74 | 7.5 | 12 | 9.4 | 720 | 540 | 0.88 |
| | | | | Average | 893 | 700 | 0.9 |
| pH dependence, Yes or No | No | | | | | | |

| R406639 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH | $K_d$ (mg/L) | $K_F$ (mg/L) | $K_{doc}$ (mg/L) | $K_{Foc}$ (mg/L) | 1/n |
| loamy sand | 2.3 | 5.6 | 10.5 | - | 463 | | - |
| loam | 1.28 | 7.4 | 16.2 | - | 1265 | - | - |
| clay loam | 4.67 | 7.5 | 12.3 | - | 264 | - | - |
| | | | | Average | 664 | - | - |
| pH dependence, Yes or No | | | No | | | | |

| R42819 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Soil Type | OC % | Soil pH | $K_d$ (mg/L) | $K_F$ (mg/L) | $K_{doc}$ (mg/L) | $K_{Foc}$ (mg/L) | 1/n |
| loamy sand | 2.3 | 5.6 | 9.6 | | 415 | - | - |
| loam | 1.28 | 7.4 | 5.9 | | 463 | - | - |
| clay loam | 4.67 | 7.5 | 14.1 | | 302 | - | - |
| | | | | Average | 393 | - | - |
| pH dependence, Yes or No | | | No | | | | |

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

| | |
|---|---|
| Column leaching | No data |
| Aged residues leaching | Test substance: 14C-pyrrolidoneFLC<br>Aged for (d): *26* d 20ºC and 40% MWHC<br>Time period (d): *x* d<br>Elution (mm): *1049 &1061 cm* |
| | Analysis of soil residues post ageing (soil residues pre-leaching): 38.4% active substance 9.2% comprises at least five different compounds |
| | Leach ate: On average, 14.3%<br><br>FLC was not found in the leachates. The degradation products were concluded to be polar intermediates. No information is given of the composition of the polar fraction |
| Lysimeter/ field leaching studies | No data |

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

| | |
|---|---|
| **Parent** | |
| Method of calculation | Kinetics: FOMC<br>Alfa parameter 1.13<br>Beta parameter: 77.1<br>Field or Lab: representative worst case from field studies. |
| Application data | Crop: sunflower and potatoes<br>Depth of soil layer: 5 cm<br>% plant interception: Pre-emergence<br>Number of applications: *1*<br>Interval (d): *n/a*<br>Application rate(s): 750 g as/ha |

| **PEC$_{(s)}$** (mg/kg) | | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---|---|---|---|---|---|
| Initial | | 1.00 | | | |
| Short term | 24h | 0.99 | 0.99 | | |
| | 2d | *0.97* | 0.99 | | |
| | 4d | 0.94 | 0.97 | | |
| Long term | 7d | 0.91 | 0.95 | | |
| | 14 d | *0.83* | 0.91 | | |
| | 28d | 0.7 | 0.84 | | |
| | 50d | *0.57* | 0.75 | | |
| | 100d | 0.39 | 0.61 | | |
| Platau reached at 2 years | | Max= 1.16 mg/kg<br>TWA= 0.38 mg/kg | | | |

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

| | |
|---|---|
| Hydrolytic degradation of the active substance and metabolites > 10%. | pH 5 stable at 25 ºC |
| | pH 7: stable at 25 ºC |
| | pH 9: stable at 25 ºC |
| Photolytic degradation of active substance and metabolites above 10% | Experimental<br>$DT_{50}$ : 6.2 d [2-$^{14}$C-pyrrolidone]-label<br>$DT_{50}$= 6.8 d [Phenyl-U-$^{14}$C]-label<br><br>Estimated $DT_{50}$ values (d) for different latitudes<br>Latitude : 50° N \| 40° N \| 30° N<br>[carbonyl-$^{14}$C] FLC 16.5 \| 15.9 \| 15.9<br>[phenyl-$^{14}$C] FLC 18.1 \| 17.4 \| 17.4<br><br>R406639: 37.7-41.5 % AR at 38.4-40 natural days (latitudes: 30-50N)<br>M8 (hydroxymethyl). 11.1-12.1% AR at 38.4-40 natural days (latitudes: 30-50N) |
| Quantum yield of direct phototransformation in water at Σ > 290 nm | 0.224± 12 mg/l |
| Readily biodegradable (yes/no) | No. Not readily biodegradable |

Degradation in water / sediment

| Parent | Distribution (eg max in water *79.7-86* after *0* d. Max. sed 25.6-42.2 % after 2-*14* d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| (Days) | Water / sediment system | $pH_w$ | °C | $DT_{50}/DT_{90}$ whole | $R^2$ | $DT_{50}/DT_{90}$ water | $R^2$ | $DT_{50}/DT_{90}$ sed | $R^2$ | Method of calculation |
| [2-$^{14}$C-pyrrolidone]-label | Clay loam | 7.5 | 20 | 19.6/65.1 | 0.99 | - | - | - | - | SFO (FOCUS_DK PI) |
| | Sand | 5.5 | 20 | 10.3/34.0 | 0.99 | - | - | - | - | SFO (FOCUS_DK PI) |
| [Phenyl-U-$^{14}$C]-label | Clay loam | 7.5 | 20 | 22.8/75.9 | 0.99 | - | - | - | - | SFO (FOCUS_DK PI) |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Sand | 5.5 | 20 | 9.2/30.5 | 0.99 | - | - | - | - | SFO (FOCUS_DK PI) |
| Geometric mean | | | | $DT_{50}$= 14.3 | | - | - | - | - | |

| R406639 | Distribution (eg max in water *2.8* after *14*d. Max. sed 10.5-10.6 % after 30 d) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Water / sediment system | $pH_w$ | °C | $DT_{50\ whole}$ | $DT_{90}$ whole | Fmet | $R^2$ | Method of calculation |
| [2-$^{14}$C-pyrrolidone]-label | Clay loam | 7.5 | 20 | 58 | 193[9] | 0.2386 | 0.961 | SFO (FOCUS_DK MI) |
| | Sand | 5.5 | 20 | - | - | - | - | SFO (FOCUS_DK MI) |
| [Phenyl-U-$^{14}$C]-label | Clay loam | 7.5 | 20 | 36.9 | 122.6[9] | 0.28791 | 0.992 | SFO (FOCUS_DK MI) |
| | Sand | 5.5 | 20 | 66.7 | 221.6 | 0.04654 | 0.906 | SFO (FOCUS_DK MI) |
| Geometric mean | | | | $DT_{50}$=52.3 | | | | |

| R42819 | Distribution (eg max in water *5.3-23.2* after 14-30 d. Max. sed 36.5-46.9 % after 100 d) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Water / sediment system | $pH_w$ | °C | $DT_{50}$ whole | $DT_{90}$ whole | F met | $R^2$ | Method of calculation |
| [2-$^{14}$C-pyrrolidone]-label | Clay loam | 7.5 | 20 | 210[7] | 698[7] | 0.55392 | 0.980 | SFO (FOCUS_DK MI) |
| | Sand | 5.5 | 20 | 184[7] | 610.3[7] | 0.8263 | 0.991 | SFO (FOCUS_DK MI) |
| [Phenyl-U-$^{14}$C]-label | Clay loam | 7.5 | 20 | 274[7] | 910.6[7] | 0.50346 | 0.981 | SFO (FOCUS_DK PI) |
| | Sand | 5.5 | 20 | 435.8[7] | 1447.8[7] | 0.73092 | 0.997 | SFO (FOCUS_DK MI) |
| Geometric mean | | | | $DT_{50}$= 261 | | | | |

[7]extrapolated

| Mineralization and non extractable residues | | | | | |
|---|---|---|---|---|---|
| | Water / sediment system | pH w | Mineralization x %. (end of the study). | Non-extractable residues in sed. Max x % after n d | Non-extractable residues in sed. Max x % (end of the study) |
| [2-$^{14}$C-pyrrolidone]-label | Clay loam | 7.5 | 4.1 | - | 25.7 |
| | Sand | 5.5 | 6.9 | - | 17.9 |
| [Phenyl-U-$^{14}$C]-label | Clay loam | 7.5 | 1.1 | - | 30.1 |
| | Sand | 5.5 | 2.2 | - | 18.6 |

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

**Parent**

Parameters used in FOCUSsw step 1 and 2

| |
|---|
| Molecular weight (g/mol):312.1<br>Water solubility (mg/L):35.1 |

| | |
|---|---|
| | Koc (L/kg): 700<br>$DT_{50}$ soil (d): 53.0days<br>$DT_{50}$ water/sediment system (d): 14.3<br><br>For PEC surface water<br>$DT_{50}$ water (d):1000 d<br>$DT_{50}$ sediment (d): 14.3 d<br><br>For PEC sediment<br>$DT_{50}$ water (d):14.3 d<br>$DT_{50}$ sediment (d): 1000 d<br>Crop interception (%): 0 |
| Parameters used in FOCUSsw step 3 (if performed) | For steps 3 and 4, as above<br>Vapour pressure: $4.4*10^{-4}$<br>Kom/Koc: 700<br>1/n: 0.9<br>Simulations used the Q10 of 2.58 and Walker equation coefiicient of 0.7 |
| Application rate | Crop: sunflower/potatoes<br>Crop interception: 0<br>Number of applications: *1*<br>Interval (d):*n a*<br>Application rate(s): *750* g as/ha<br>Depth of water body: *FOCUS value*<br>Application window: March-May |
| Main routes of entry | Defined by FOCUS |

**Step 1: Crops Potatoes and sunflower**

| | PECsw (µg/L) | | PECsed(µg/kg dry sediment) | |
|---|---|---|---|---|
| Time | Actual | TWA | Actual | TWA |
| 0 | 136.2078 | | 905.1724 | |
| 1 | 126.5908 | 131.3993 | 886.1355 | 895.6540 |
| 2 | 120.6010 | 127.4855 | 844.2073 | 880.3280 |
| 4 | 109.4584 | 121.2126 | 766.2085 | 842.4529 |
| 7 | 94.6446 | 112.9238 | 662.5121 | 787.0178 |
| 14 | 67.4122 | 96.5918 | 471.8854 | 674.4184 |
| 21 | 48.0155 | 83.4500 | 336.1082 | 583.0006 |
| 28 | 34.1998 | 72.7670 | 239.3987 | 508.5065 |
| 42 | 17.3504 | 56.7878 | 121.4527 | 396.9398 |
| 50 | 11.7734 | 50.0029 | 82.4136 | 349.5374 |
| 100 | 1.0432 | 27.2151 | 7.3021 | 190.2646 |

**Step 2 Crops Potatoes and sunflower**

| **North conditions ($DT_{50}$w: 1000 d; $DT_{50}$sed= 14.3 d)** | | | | |
|---|---|---|---|---|
| | PECsw (µg/L) | | PECsed(µg/kg dry sediment) | |
| Time after max. peak(d) | Actual | TWA | Actual | TWA |

| | | | | |
|---|---|---|---|---|
| 0 | 28.5908 | --- | 189.6305 | --- |
| 1 | 27.8470 | 28.2189 | 185.8344 | 187.7325 |
| 2 | 27.2009 | 27.8714 | 181.5230 | 185.7056 |
| 4 | 25.9534 | 27.2225 | 173.1978 | 181.5208 |
| 7 | 24.1886 | 26.2965 | 161.4205 | 175.4038 |
| 14 | 20.5234 | 24.3017 | 136.9609 | 162.1333 |
| 21 | 17.4135 | 22.5100 | 116.2076 | 150.1908 |
| 28 | 14.7749 | 20.8972 | 98.5990 | 139.4349 |
| 42 | 10.6365 | 18.1292 | 70.9820 | 120.9698 |
| 50 | 8.8154 | 16.7802 | 58.8290 | 111.9695 |
| 100 | 2.7259 | 10.9844 | 18.1913 | 73.2975 |

| **Southern conditions ($DT_{50}$w: 1000 d; $DT_{50}$sed= 14.3d)** | | | | |
|---|---|---|---|---|
| PECsw (µg/L) | | PECsed(µg/kg dry sediment) | | |
| Time after max. peak(d) | Actual | TWA | Actual | TWA |
| 0 | 53.1347 | --- | 361.4380 | --- |
| 1 | 52.3739 | 52.7543 | 349.5127 | 355.4753 |
| 2 | 51.1588 | 52.2603 | 341.4038 | 350.4668 |
| 4 | 48.8125 | 51.1195 | 325.7461 | 341.9979 |
| 7 | 45.4933 | 49.4121 | 303.5956 | 330.2368 |
| 14 | 38.5998 | 45.6831 | 257.5926 | 305.1071 |
| 21 | 32.7509 | 42.3211 | 218.5603 | 282.5891 |
| 28 | 27.7883 | 39.2916 | 185.4425 | 262.3312 |
| 42 | 20.0049 | 34.0893 | 133.5012 | 227.5738 |
| 50 | 16.5798 | 31.5534 | 110.6442 | 210.6373 |
| 100 | 5.1269 | 20.6560 | 34.2136 | 137.8800 |

**Step 3**

**Potatoes ($DT_{50}$w: 1000 d; $DT_{50}$sed= 14.3d)**

| **surface water Potaotes** | **Global Maximum** | **7-TWA** | **14- TWA** | **21-TWA** |
|---|---|---|---|---|
| D3 ditch | 3.922 | 0.572 | 0.288 | 0.192 |
| D4 pond | 0.655 | 0.651 | 0.645 | 0.636 |
| D4 stream | 3.298 | 0.565 | 0.447 | 0.428 |
| D6 ditch 1st appl | 3.883 | 0.238 | 0.123 | 0.086 |
| D6 ditch 2nd appl | 3.969 | 2.823 | 1.730 | 1.162 |
| R1 pond | 0.603 | 0.572 | 0.547 | 0.525 |
| R1 stream | 5.550 | 0.673 | 0.469 | 0.356 |
| R2 stream | 3.598 | 0.702 | 0.362 | 0.256 |
| R3 stream | 11.992 | 0.954 | 0.572 | 0.619 |

**Potatoes ($DT_{50}$w: 14.3 d; $DT_{50}$sed= 1000d)**

| **sediment Potatoes** | **Global Maximum** | **7-TWA** | **14- TWA** | **21-TWA** |
|---|---|---|---|---|
| D3 ditch | 1.866 | 1.19 | 0.901 | 0.757 |
| D4 pond | 3.386 | 3.386 | 3.383 | 3.379 |
| D4 stream | 1.944 | 1.925 | 1.898 | 1.853 |
| D6 ditch 1st appl | 1.101 | 0.664 | 0.575 | 0.553 |
| D6 ditch 2nd appl | 4.966 | 4.715 | 4.205 | 3.735 |
| R1 pond | 1.930 | 1.926 | 1.912 | 1.889 |

| | | | | |
|---|---|---|---|---|
| R1 stream | 2.667 | 1.963 | 1.832 | 1.756 |
| R2 stream | 48.939 | 45.156 | 43.053 | 41.341 |
| R3 stream | 6.210 | 4.429 | 3.819 | 3.488 |

**Sunflower ($DT_{50}$w: 1000 d; $DT_{50}$sed= 14.3d)**

| surface water Sunflower | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D5 pond | 0.254 | 0.240 | 0.230 | 0.221 |
| D5 stream | 3.360 | 0.128 | 0.100 | 0.083 |
| R1 pond | 0.660 | 0.626 | 0.600 | 0.576 |
| R1 stream | 5.728 | 0.692 | 0.484 | 0.371 |
| R3 stream | 8.052 | 1.067 | 0.754 | 0.568 |
| R4 stream | 13.668 | 1.830 | 1.196 | 0.813 |

**Sunflower ($DT_{50}$w: 14.3 d; $DT_{50}$sed= 1000d)**

| Sediment Sunflower | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D5 pond | 1.068 | 1.067 | 1.063 | 1.057 |
| D5 stream | 0.371 | 0.364 | 0.355 | 0.348 |
| R1 pond | 2.145 | 2.140 | 2.125 | 2.100 |
| R1 stream | 2.791 | 2.075 | 1.916 | 1.844 |
| R3 stream | 5.868 | 3.869 | 3.220 | 2.879 |
| R4 stream | 16.081 | 13.560 | 12.359 | 11.572 |

**Step 4 10 m VBS**

**Potatoes**

| surface water Potaotes | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D3 ditch | 0.682 | 0.0993 | 0.0499 | 0.0333 |
| D4 pond | 0.651 | 0.648 | 0.642 | 0.633 |
| D4 stream | 0.924 | 0.565 | 0.447 | 0.428 |
| D6 ditch 1st appl | 0.682 | 0.134 | 0.106 | 0.086 |
| D6 ditch 2nd appl | 2.524 | 0.796 | 0.626 | 0.440 |
| R1 pond | 0.266 | 0.253 | 0.242 | 0.232 |
| R1 stream | 2.513 | 0.302 | 0.211 | 0.158 |
| R2 stream | 1.420 | 0.316 | 0.162 | 0.113 |
| R3 stream | 5.476 | 0.440 | 0.258 | 0.282 |

| sediment Potatoes | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D3 ditch | 0.341 | 0.224 | 0.170 | 0.143 |
| D4 pond | 3.338 | 3.337 | 3.334 | 3.331 |
| D4 stream | 1.939 | 1.919 | 1.893 | 1.848 |
| D6 ditch 1st appl | 0.584 | 0.568 | 0.536 | 0.515 |
| D6 ditch 2nd appl | 2.573 | 2.467 | 2.264 | 2.147 |
| R1 pond | 0.895 | 0.893 | 0.886 | 0.876 |

| | | | | |
|---|---|---|---|---|
| R1 stream | 1.119 | 0.806 | 0.746 | 0.710 |
| R2 stream | 7.912 | 7.237 | 6.895 | 6.622 |
| R3 stream | 2.336 | 1.543 | 1.272 | 1.130 |

**Sunflower**

| surface water Sunflower | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D5 pond | 0.198 | 0.187 | 0.180 | 0.174 |
| D5 stream | 0.755 | 0.128 | 0.100 | 0.083 |
| R1 pond | 0.289 | 0.275 | 0.263 | 0.252 |
| R1 stream | 2.597 | 0.310 | 0.218 | 0.165 |
| R3 stream | 3.638 | 0.492 | 0.339 | 0.242 |
| R4 stream | 5.997 | 0.840 | 0.542 | 0.363 |

| Sediment Sunflower | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D5 pond | 0.924 | 0.923 | 0.919 | 0.914 |
| D5 stream | 0.371 | 0.364 | 0.355 | 0.348 |
| R1 pond | 0.984 | 0.982 | 0.975 | 0.964 |
| R1 stream | 1.152 | 0.830 | 0.760 | 0.729 |
| R3 stream | 2.321 | 1.435 | 1.144 | 0.996 |
| R4 stream | 4.288 | 3.356 | 2.912 | 2.645 |

**Step 4 20 m VBS**

**Potatoes**

| surface water Potaotes | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D3 ditch | 0.354 | 0.0516 | 0.0259 | 0.0173 |
| D4 pond | 0.650 | 0.646 | 0.640 | 0.631 |
| D4 stream | 0.924 | 0.565 | 0.447 | 0.428 |
| D6 ditch 1st appl | 0.359 | 0.134 | 0.106 | 0.086 |
| D6 ditch 2nd appl | 2.524 | 0.796 | 0.626 | 0.440 |
| R1 pond | 0.144 | 0.136 | 0.130 | 0.125 |
| R1 stream | 1.315 | 0.157 | 0.110 | 0.082 |
| R2 stream | 0.774 | 0.165 | 0.084 | 0.059 |
| R3 stream | 2.875 | 0.232 | 0.135 | 0.148 |

| sediment Potatoes | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D3 ditch | 0.180 | 0.120 | 0.0913 | 0.0769 |
| D4 pond | 3.308 | 3.307 | 3.305 | 3.301 |
| D4 stream | 1.938 | 1.919 | 1.893 | 1.847 |
| D6 ditch 1st appl | 0.580 | 0.564 | 0.532 | 0.511 |
| D6 ditch 2nd appl | 2.504 | 2.398 | 2.194 | 2.078 |
| R1 pond | 0.502 | 0.501 | 0.497 | 0.491 |
| R1 stream | 0.587 | 0.423 | 0.391 | 0.372 |

| | | | | |
|---|---|---|---|---|
| R2 stream | 2.804 | 2.545 | 2.419 | 2.320 |
| R3 stream | 1.198 | 0.784 | 0.639 | 0.563 |

**Sunflower**

| surface water Sunflower | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D5 pond | 0.166 | 0.165 | 0.163 | 0.161 |
| D5 stream | 0.395 | 0.128 | 0.100 | 0.083 |
| R1 pond | 0.155 | 0.147 | 0.141 | 0.135 |
| R1 stream | 1.359 | 0.162 | 0.114 | 0.086 |
| R3 stream | 1.909 | 0.259 | 0.177 | 0.126 |
| R4 stream | 3.098 | 0.442 | 0.284 | 0.190 |

| Sediment Sunflower | Global Maximum | 7-TWA | 14- TWA | 21-TWA |
|---|---|---|---|---|
| D5 pond | 0.839 | 0.838 | 0.835 | 0.830 |
| D5 stream | 0.371 | 0.364 | 0.355 | 0.348 |
| R1 pond | 0.548 | 0.547 | 0.543 | 0.536 |
| R1 stream | 0.601 | 0.433 | 0.396 | 0.380 |
| R3 stream | 1.203 | 0.741 | 0.585 | 0.506 |
| R4 stream | 1.983 | 1.521 | 1.293 | 1.158 |

**R406639**
Parameters used in FOCUSsw step 1 and 2

Molecular weight:293.7 g/mol
Water solubility (mg/l): 848.9 (EPIWEB 4.0 )
Soil or water metabolite: water metabolite (minor in soil)
Koc (L/kg): 664
$DT_{50}$ soil (d):*77.4*days (.proposed by notifier)

$DT_{50}$ water/sediment system (d): (representative worst case from sediment water studies) 52.3 d.

For PEC surface water
$DT_{50}$ water (d):1000 d
$DT_{50}$ sediment (d): 52.3 d

For PEC sediment
$DT_{50}$ water (d): 52.3 d
$DT_{50}$ sediment (d): 1000 d

Maximum occurrence in Water/Sediment: 13.9 % AR[11]

**Step 1**

| | PECsw (µg/L) | | PECsed(µg/kg dry sediment) | |
|---|---|---|---|---|
| Time (d) | Actual | TWA | Actual | TWA |
| 0 | 11.0098 | | 67.1143 | |
| 1 | 10.4599 | 10.7349 | 69.4540 | 68.2841 |
| 2 | 10.3352 | 10.5662 | 68.6260 | 68.6617 |
| 4 | 10.0903 | 10.3892 | 66.9997 | 68.2356 |
| 7 | 9.7338 | 10.1843 | 64.6321 | 67.1956 |
| 14 | 8.9500 | 9.7603 | 59.4280 | 64.5946 |
| 21 | 8.2294 | 9.3684 | 54.6430 | 62.0638 |
| 28 | 7.5668 | 8.9997 | 50.2432 | 59.6509 |
| 42 | 6.3973 | 8.3217 | 42.4780 | 55.1846 |
| 50 | 5.8121 | 7.9662 | 38.5921 | 52.8357 |
| 100 | 3.1910 | 6.1688 | 21.1881 | 40.9307 |

**Step 2**

| | Northern Conditons | | | |
|---|---|---|---|---|
| | PECsw (µg/L)[1] | | PECsed (µg/kg dry sediment)[2] | |
| Time after max. peak(d) | Actual | TWA | Actual | TWA |
| 0 | 2.5102 | --- | 16.0173 | --- |
| 1 | 2.4184 | 2.4643 | 15.9108 | 15.9640 |
| 2 | 2.4040 | 2.4377 | 15.8050 | 15.9110 |
| 4 | 2.3754 | 2.4137 | 15.5955 | 15.8055 |
| 7 | 2.3331 | 2.3882 | 15.2866 | 15.6491 |
| 14 | 2.2374 | 2.3366 | 14.5892 | 15.2922 |
| 21 | 2.1456 | 2.2881 | 13.9237 | 14.9461 |
| 28 | 2.0576 | 2.2414 | 13.2885 | 14.6105 |
| 42 | 1.8923 | 2.1522 | 12.1037 | 13.9693 |
| 50 | 1.8039 | 2.1035 | 11.4747 | 13.6200 |
| 100 | 1.3375 | 1.8313 | 8.2205 | 11.6887 |

1: Based on $DT_{50}w$= 1000 d; $DT_{50}sed$= 52.3d;
2: Based on $DT_{50}w$= 52.3; $DT_{50}$ sed= 1000 d

| | Southern Conditons | | | |
|---|---|---|---|---|
| | PECsw (µg/L)[1] | | PECsed(µg/kg dry sediment)[2] | |
| Time after max. peak(d) | Actual | TWA | Actual | TWA |
| 0 | 4.4606 | --- | 28.9588 | --- |
| 1 | 4.3674 | 4.4140 | 28.7663 | 28.8626 |
| 2 | 4.3414 | 4.3842 | 28.5751 | 28.7666 |
| 4 | 4.2897 | 4.3499 | 28.1964 | 28.5760 |
| 7 | 4.2134 | 4.3077 | 27.6378 | 28.2933 |
| 14 | 4.0406 | 4.2171 | 26.3769 | 27.6479 |
| 21 | 3.8749 | 4.1304 | 25.1736 | 27.0222 |
| 28 | 3.7159 | 4.0465 | 24.0252 | 26.4154 |
| 42 | 3.4173 | 3.8859 | 21.8832 | 25.2561 |
| 50 | 3.2576 | 3.7980 | 20.7461 | 24.6247 |
| 100 | 2.4153 | 3.3068 | 14.8625 | 21.1329 |

1: Based on $DT_{50}$w= 1000 d; $DT_{50}$sed= 52.3 d;
2: Based on $DT_{50}$w= 52.3 d; $DT_{50}$ sed= 1000 d

**R42819**
Parameters used in FOCUSsw step 1 and 2

Molecular weight: 277.7
Water solubility (mg/l): 50.97 (Derived from EPI WEB 4.0)
Soil or water metabolite: water metabolite
Koc (L/kg): 393
$DT_{50}$ soil (d): 79.4 days
$DT_{50}$ water/sediment system (d): 261 days

For PEC surface water
$DT_{50}$ water (d):1000 d
$DT_{50}$ sediment (d): 261 d

For PEC sediment
$DT_{50}$ water (d): 261 d
$DT_{50}$ sediment (d): 1000 d

Crop interception (%):
Maximum occurrence observed
Soil: 10.1% AR
Water/ Sediment:: 63.9 % AR

**Step 1: Potatoes and Sunflower**

| | PECsw (µg/L) | | PECsed(µg/kg dry sediment) | |
|---|---|---|---|---|
| Time (d) | Actual | TWA | Actual | TWA |
| 0 | 18.6638 | | 57.9363 | |
| 1 | 17.2694 | 17.9666 | 67.8689 | 62.9026 |
| 2 | 17.2236 | 17.6066 | 67.6889 | 65.3408 |
| 4 | 17.1324 | 17.3923 | 67.3303 | 66.4251 |
| 7 | 16.9964 | 17.2517 | 66.7960 | 66.6984 |
| 14 | 16.6834 | 17.0456 | 65.5658 | 66.4387 |
| 21 | 16.3761 | 16.8735 | 64.3581 | 65.9458 |
| 28 | 16.0745 | 16.7113 | 63.1728 | 65.4003 |
| 42 | 15.4878 | 16.4007 | 60.8671 | 64.2711 |
| 50 | 15.1622 | 16.2285 | 59.5876 | 63.6237 |
| 100 | 13.2768 | 15.2136 | 52.1780 | 59.7123 |

**Step 2 Potatoes and Sunflower**

| | Northern Conditions | | | |
|---|---|---|---|---|
| | PECsw (µg/L)[1] | | PECsed(µg/kg dry sediment)[2] | |
| Time after max. peak(d) | Actual | TWA | Actual | TWA |
| 0 | 5.7190 | --- | 21.1117 | --- |
| 1 | 5.3819 | 5.5505 | 21.0700 | 21.0909 |
| 2 | 5.3746 | 5.4644 | 21.0283 | 21.0700 |
| 4 | 5.3599 | 5.4158 | 20.9452 | 21.0283 |
| 7 | 5.3380 | 5.3872 | 20.8211 | 20.9661 |
| 14 | 5.2871 | 5.3498 | 20.5344 | 20.8217 |
| 21 | 5.2367 | 5.3205 | 20.2517 | 20.6787 |
| 28 | 5.1869 | 5.2933 | 19.9729 | 20.5371 |
| 42 | 5.0885 | 5.2414 | 19.4267 | 20.2575 |
| 50 | 5.0331 | 5.2125 | 19.1213 | 20.1001 |
| 100 | 4.7005 | 5.0387 | 17.3186 | 19.1526 |

1: Based on $DT_{50}w$= 1000 d; $DT_{50}sed$= 261 d;
2: Based on $DT_{50}w$= 261 d; $DT_{50}$ sed= 1000 d

| | Southern conditins | | | |
|---|---|---|---|---|
| | PECsw (µg/L)[1] | | PECsed(µg/kg dry sediment)[2] | |
| Time after max. peak(d) | Actual | TWA | Actual | TWA |
| 0 | 8.5436 | --- | 32.2045 | --- |
| 1 | 8.2045 | 8.3741 | 32.1408 | 32.1727 |
| 2 | 8.1933 | 8.2865 | 32.0772 | 32.1408 |
| 4 | 8.1709 | 8.2343 | 31.9504 | 32.0773 |
| 7 | 8.1375 | 8.2000 | 31.7611 | 31.9823 |
| 14 | 8.0600 | 8.1493 | 31.3239 | 31.7622 |
| 21 | 7.9832 | 8.1067 | 30.8926 | 31.5440 |
| 28 | 7.9071 | 8.0663 | 30.4673 | 31.3279 |
| 42 | 7.7572 | 7.9882 | 29.6341 | 30.9015 |
| 50 | 7.6728 | 7.9445 | 29.1683 | 30.6614 |
| 100 | 7.1657 | 7.6804 | 26.4183 | 29.2160 |

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

| | |
|---|---|
| Method of calculation | Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance.<br><br>Model(s) used: FOCUS PEARL 3.3.3<br>Scenarios (list of names):<br>Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva<br>Crop: potatoes and sunflowers<br><br>Average parent $DT_{50lab}$ 53.0d(normalization to 10kPa, 20°C with Q10 of 2.58).<br>Kom: 700/1.72<br>1/n: 0.9<br><br>Metabolites:<br><br>R406639: 77.4 d Average (normalisation to 10kPa with Q10 of 2.58); f.f= 0.105 Kom= 664/1.72; 1/n: 1.0;<br>solubility (25 ºC): 848.9 mg/l, Vapour pressure (25ºC) : $2.97E^{-06}$ Pa. Solubility and vapour pressure derived with EPIWEB 4.0<br><br>R42819 :$DT_{50}$ 79.4 d (normalisation to 10kPa with Q10 of 2.58); f.f =0.895; Kom = 393/1.72; 1/n: 1.0<br>solubility (25 ºC): 50.97mg/l, Vapour pressure (25ºC) : 0.0016 Pa. Solubility and vapour pressure derived with EPIWEB 4.0. $DT_{50}$ derived from decline from the maximum observed in studies dosed with FLC and have a greater than usual uncertainty. The f.f (0.895, calculated as 1-f.$f_{R406639}$) is likely to be a conservative estimate.<br>Simulations used the Arrhenius activation energy of 65.4kJ/mol (Q10 of 2.58) and Walker equation coefiicient of 0.7. |
| Application rate | Application rate: FLC 750 g/ha<br>No. of applications: 1 |

| |
|---|
| Time of application (month or season): FLC five days after planting ; Potatoes: Jan- May<br>Sunflowers: Feb-March |

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

| Potatoes | Scenario | Parent (µg/L) | Metabolite (µg/L) | |
|---|---|---|---|---|
| | | | R406639 | R42819 |
| | Châteaudun | 0.000000 | 0.006462 | 0.596723 |
| | Hamburg | 0.000000 | 0.009614 | 0.758810 |
| | Jokioinen | 0.000000 | 0.000579 | 0.136065 |
| | Kremsmünster | 0.000000 | 0.007821 | 0.636933 |
| | Okehampton | 0.000000 | 0.010906 | 0.855812 |
| | Piacenza | 0.000043 | 0.058226 | 2.293274 |
| | Porto | 0.000000 | 0.000003 | 0.002525 |
| | Sevilla | 0.000000 | 0.000115 | 0.023318 |
| | Thiva | 0.000000 | 0.002858 | 0.317775 |
| Sunflowers | Scenario | Parent (µg/L) | Metabolite (µg/L) | |
| | | | R406639 | R42819 |
| | Piacenza | 0.000082 | 0.074987 | 2.645095 |
| | Sevilla | 0.000000 | 0.000684 | 0.120193 |

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

| | |
|---|---|
| Direct photolysis in air | No data |
| Photochemical oxidative degradation in air | $DT_{50}$ of *6.4* hours derived by the Atkinson method of calculation: 12 h; 1.5 $10^6$ $OH/cm^3$ |
| Volatilisation | from plant surfaces (no cited ): 6.3 % after *24* hours |
| | from soil (no cited) 6.5 % loss after *24* hours |
| Metabolites | No volatiles other than $CO_2$ were identified in the environmental studies. |

**Residues requiring further assessement**

| | |
|---|---|
| Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure. | Soil: FLC<br>Ground water: FLC, R406639, R42819<br>Surface Water: FLC, R42819<br>Sediment: FLC, R42819, R406639<br>Air: FLC |

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

| | |
|---|---|
| Soil (indicate location and type of study) | No data provided |
| Surface water (indicate location and type of study) | No data provided |
| Ground water (indicate location and type of study) | No data provided |
| Air (indicate location and type of study) | No data provided |

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

| |
|---|
| Not ready biodegradable |

**Chapter 6:** **Effects on Non-target Species**

**Chapter 6:** **Effects on Non-target Species**

**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 ‡ | | | | |
| Bobwhite quail | Technical FLC | Acute | $LD_{50}$ > 2150 mg a.s./kg $_{bw}$ | |
| Bobwhite quail | Technical FLC | Short-term | $LD_{50}$ > 590 | > 5000 |
| Mallard duck | Technical FLC | Long-term | NOEL = 149 | 1000 |
| Mammals ‡ | | | | |
| Mouse (f/m) | Technical FLC | Acute-oral | 5000 | |
| Rat | Technical FLC | Long-term, 3 years generation study | Ecotoxicological NOAEL = 27.7 | |
| | | | | |
| Additional higher tier studies ‡ | | | | |
| | | | | |
| | | | | |

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

Crop and application rate. Potatoes and sunflowers. 1 x 0.750 kg as/ha

| Indicator species/Category[2] | Time scale | ETE | TER[1] | Annex VI Trigger[3] |
|---|---|---|---|---|
| Tier 1 – uptake via diet (Birds) | | | | |
| Herbivorous bird-0.750 kg as/ha | Acute | 49.59 | > 43.4 | 10 |
| Insectivorous bird-0.750 kg as/ha | Acute | 40.56 | > 53 | 10 |
| Herbivorous bird- 0.750 kg as/ha | Short-term | 22.8 | > 25.9 | 10 |
| Insectivorous bird- 0.750 kg as/ha | Short-term | 22.6 | > 26.1 | 10 |
| Herbivorous bird- 0.750 kg as/ha | Long-term | 12.08 | 12.3 | 5 |
| Insectivorous bird- 0.750 kg as/ha | Long-term | 22.62 | 6.6 | 5 |

| Indicator species/Category[2] | Time scale | ETE | TER[1] | Annex VI Trigger[3] |
|---|---|---|---|---|
| Tier 1– uptake via drinking water (Birds) | | | | |
| Herbivorous bird- 0.750 kg as/ha | Acute | 65.0 | 33 | 10 |
| Insectivorous bird- 0.750 kg as/ha | Acute | 202.5 | 10.6 | 10 |
| Tier 1 – secondary poisoning (Birds) | | | | |
| Earthworm-eating bird | Long-term | 1.26 | 119 | 5 |
| Fish-eating bird | Long-term | 5.08 | 29 | 5 |
| Tier 1– uptake via diet (Mammals) | | | | |
| Herbivorous mammals- 0.750 kg as/ha | Acute | 18.27 | 273 | 10 |
| Tier 1– uptake via drinking water (Mammals) | | | | |
| Herbivorous mammals- 0.750 kg as/ha | Acute | 66.5 | 75.2 | 5 |
| Tier 1 – secondary poisoning (Mammals) | | | | |
| Earthworm-eating mammals | Long-term | 1.13 | 16.5[4] | 5 |
| Fish-eating mammals | Long-term | 3.14 | 9.1 | 5 |

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)- *TER refined values using specific residue data
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.
[4] 21d-PECtwa = 0.93mg/kg soil

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

| Group | Test substance | Time-scale | Endpoint | Toxicity (mg a.i/l) |
|---|---|---|---|---|
| **Laboratory tests** | | | | |
| **Fish** | | | | |
| *Oncorynchus mykiss*<br><br>*Lepomis macrochirus* | Technical<br>Tehnical | 96h (dynamic)<br>96h (static) | Mortality-$LC_{50}$<br>Mortality-$LC_{50}$ | 3.0<br>10.2 |
| *Oncorynchus mykiss* | Technical | 28d (flow-trough) | Growth-NOEC | 0.36 |
| **Aquatic Invertebrates** | | | | |
| *Daphnia magna*<br><br>*Daphnia magna* | Technical<br>Technical | 48h (static)<br>48h (static) | Mortality-$EC_{50}$<br>Mortality-$EC_{50}$ | 5.1<br>3.5 |
| *Daphnia magna* | Flurochloridone CS 250 | Mortality- | Mortality-$EC_{50}$ | 37<br>0.132 ml formualtion/L |
| *Daphnia magna* | Technical | 21d (semistatic) | Growth-NOEC | 0.83 |
| Sediment dwelling organisms | | | | |
| *Chironomus riparius* | ***Trans*- isomer** of technical | 21d (semistatic) | Growth-NOEC | ≥ 0.25 |
| **Algae** | | | | |

| | | | | |
|---|---|---|---|---|
| *S. subspicatus* | Technical | 72 hours (static) | Biomass-$EbC_{50}$<br>Growth rate-$ErC_{50}$ | 0.0021<br>0.0047 |
| *S. subspicatus* | Technical | 24h (static)/72 h recovery | Biomass-EbC50<br>Growth rate-ErC50 | 0.0206<br>0.320 |
| *S. capricornutum* | Flurochloridone 25 CS | 96 h (static) | Biomass-EbC50<br>Growth rate-ErC50 | 0.02 ( = 0.097 ml product/L)<br>0.044 (0.175 ml product/L) |
| *S. subspicatus* | Metabolite: R42819 | 72 h (static) | Biomass-EbC50<br>Growth rate-ErC50 | 0.99<br>2.3 |
| *S. subspicatus* | Metabolite: R406639 | 72 h (static) | Biomass-EbC50<br>Growth rate-ErC50 | 1.9<br>3.3 |
| *S. subspicatus* | cis-isomer | 72 h (static) | Biomass-EbC50<br>Growth rate-ErC50 | 0.0045<br>0.0069 |
| *S. subspicatus* | trans-isomer | 72 h (static) | Biomass-EbC50<br>Growth rate-ErC50 | 0.00054<br>0.00088 |
| **Higher Plant** | | | | |
| *Lemna gibba* | Technica1 | 14d (semistatic) | Dry weight-$EC_{50}$ | 0.048 |
| *Lemna gibba* | Technical | 14d (semistatic) | Dry weight-NOEb/rC | 0.015 |
| *Lemna gibba* | R42819 | 14d (semistatic) | Dry weight-EbC50<br>Dry weight-ErC50 | 3.2<br>8.2 |
| *Lemna gibba* | cis-isomer | 7d (semistatic) | Dry weight-$EbC_{50}$<br>Dry weight-$ErC_{50}$<br>Dry weight-NOEC | 0.013<br>0.047<br>< 0.007 |
| *Lemna gibba* | trans-isomer | 7d (semistatic) | Dry weight-$EbC_{50}$<br>Dry weight-$ErC_{50}$<br>Dry weight-NOEC | <0.004<br>0.010<br>n.d. |

| **Microcosm or mesocosm tests** |
|---|
| Not submitted. |

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

**Maximum $PEC_{sw}$ values and TER values for FLC – application to potatoes at 750 g a.s./ha**

| Scenario | PEC global max (µg L) | PEC twa, 28d* (µg L) | fish acute | fish prolonged | Daphnia acute | Daphnia prolonged | Algae acute | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | ***O. mykiss*** | ***O. mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***S. subspicatus*** | ***Lemna* sp.** | ***C. riparius*** | |
| | | | $LC_{50}$ | NOEC | $EC_{50}$ | NOEC | $EbC_{50}$ | $EbC_{50}$ | NOEC | NOEC |
| | | | 3000µg/L | 360 µg/L | 3500 µg/L | 830 µg/L | 2.1 µg/L | 48 µg/L | > 250µg/L (trans-isomer) | µg/L not data |
| **FOCUS Step 1** | 136.20 | | 22 | 2.6 | 25.7 | 6 | 0.015 | 0.35 | > 1.8 | |
| **FOCUS Step 2** | | | | | | | | | | |
| North Europe | 28.22 | | 106.3 | 12.75 | 124 | 29.41 | 0.07 | 1.70 | > 8.85 | |
| South Europe | 52.76 | | 56.86 | 6.82 | 66.34 | 15.73 | 0.04 | 0.91 | > 4.73 | |
| **FOCUS Step 3** | | | | | | | | | | |
| D3 / ditch | 3.92 | | 765 | 91.8 | 892 | 211 | 0.53 | 12 | > 63.7 | |
| D4 / pond | 0.655 | | 4580.2 | 549.6 | 5343.5 | 1267.2 | 3.2 | 73.3 | > 381.7 | |
| D4 / stream | 3.298 | | 909 | 109 | 1061 | 252 | 0.64 | 14 | > 75 | |
| D6 /ditch early | 3.883 | | 772 | 92 | 901 | 214 | 0.54 | 12 | > 64 | |
| D6 / ditch late | 3.968 | | 756 | 91 | 882 | 209 | 0.53 | 12 | > 63 | |
| R1 / pond | 0.603 | | 4975.1 | 597.0 | 5804.3 | 1376.5 | 3.5 | 79.6 | > 414.6 | |
| R1 / stream | 5.550 | | 540.5 | 64.9 | 630.6 | 149.5 | 0.4 | 8.6 | > 45.0 | |
| R2 / stream | 3.598 | | 834 | 100 | 973 | 230 | 0.58 | 13 | > 69 | |
| R3 / stream | 11.989 | | 250.2 | 30.0 | 291.9 | 69.2 | 0.2 | 4.0 | > 20.9 | |
| R4 / stream | Not relevant | | | | | | | | | |
| Annex VI Trigger** | | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 5 |

* 28 d-PECtwa to be used in connection with the 34 d-NOEC from the ELS with *P. promelas*.

** If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

**FOCUS$_{sw}$ step 4**

**TER calculation for the most critical algae endpoint (*S. subspicatus* = 2.1 µg/L) including different mitigation options for FOCUS Step 4 Scenario – application to potatoes at 750g a.s./ha.**

| Mitigation options | 20* m non-spray buffer zone (VBS) | | Xx % input reduction required – all scenarios. | | Max drift reduction (95 %) | | Max run-off reduction (90%) | | Max drainage reduction (90%) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PECsw | TER | PECsw | TER | PECsw | TER | PECsw | TER | PECsw | TER |
| **FOCUS Step 4**** | | | | | | | | | | |
| D3 / ditch | 0.354 | 5.9 | | | | | | | | |
| D4 / pond | 0.650 | 3.2 | | | | | | | | |
| D4 / stream | 0.924 | 2.3 | | | | | | | | |
| D6 /ditch 1st appl. | 0.359 | 5.8 | | | | | | | | |
| D6 / ditch 2nd appl. | 2.524 | 0.8 | | | | | | | | |
| R1 / pond | 0.144 | 14.6 | | | | | | | | |
| R1 / stream | 1.315 | 1.6 | | | | | | | | |
| R2 / stream | 0.774 | 2.7 | | | | | | | | |
| R3 / stream | 2.875 | 0.7 | | | | | | | | |
| R4 / stream | Not relevant | Not relevant | | | | | | | | |

* 30 m or less as required obtaining acceptable trigger levels

** (Only scenarios where the Annex VI trigger is not met at FOCUSsw step 3 should be included in step 4).

**Maximum PEC$_{sw}$ values and TER values for FLC – application to sunflowers at 750 g a.s./ha**

| Scenario | PEC global max (µg L) | PEC twa, 28d* (µg L) | fish acute | fish prolonged | Daphnia acute | Daphnia prolonged | Algae acute | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | ***O. mykiss*** | ***O. mykiss*** | ***Daphnia*** | ***Daphnia*** | ***S.*** | ***Lemna* sp.** | ***C. riparius*** | |

| | | | | *magna* | *magna* | *subspicatus* | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | $LC_{50}$ | NOEC | $EC_{50}$ | NOEC | $EbC_{50}$ | $EbC_{50}$ | NOEC | NOEC |
| | | 3000µg/L | 360 µg/L | 3500 µg/L | 830 µg/L | 2.1 µg/L | 48 µg/L | > 250µg/L (trans-isomer) | µg/L not data |
| **FOCUS Step 1** | 136.20 | 22 | 2.6 | 25.7 | 6 | 0.015 | 0.35 | > 1.83 | |
| **FOCUS Step 2** | | | | | | | | | |
| North Europe | 28.22 | 106 | 13 | 124.0 | 29 | 0.07 | 1.7 | > 8.9 | |
| South Europe | 52.76 | 57 | 7 | 66.3 | 16 | 0.04 | 0.9 | > 4.7 | |
| **FOCUS Step 3** | | | | | | | | | |
| D5 pond | 0.254 | 11811.0 | 1417.3 | 13779.5 | 3267.7 | 8.3 | 189.0 | > 984.3 | |
| D5 stream | 3.360 | 893 | 107 | 1041.7 | 247 | 0.63 | 14.3 | > 74.4 | |
| R1 pond | 0.66 | 4545.5 | 545.5 | 5303.0 | 1257.6 | 3.2 | 72.7 | > 378.8 | |
| R1 stream | 5.728 | 523.7 | 62.8 | 611.0 | 144.9 | 0.4 | 8.4 | > 43.6 | |
| R3 stream | 8.052 | 372.6 | 44.7 | 434.7 | 103.1 | 0.3 | 6.0 | > 31.0 | |
| R4 stream | 13.668 | 219.5 | 26.3 | 256.1 | 60.7 | 0.2 | 3.5 | > 18.3 | |
| Annex VI Trigger** | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 5 |

* 28 d-PECtwa to be used in connection with the 34 d-NOEC from the ELS with *P. promelas*.

** If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

**FOCUS$_{sw}$ step 4**

**TER calculation for the most critical endpoint (*S. subspicatus* = *2.1 µg/L*) including different mitigation options for FOCUS Step 4 Scenario – application to sunflowers at 750g a.s./ha.**

| Mitigation options | 20* m non-spray buffer zone (VBS) | | Xx % input reduction required – all scenarios. | | Max drift reduction (95 %) | | Max run-off reduction (90%) | | Max drainage reduction (90%) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PECsw | TER | PECsw | TER | PECsw | TER | PECsw | TER | PECsw | TER |
| **FOCUS Step 4**** | | | | | | | | | | |
| D5 pond | 0.166 | 12.7 | | | | | | | | |
| D5 stream | 0.395 | 5.3 | | | | | | | | |
| R1 pond | 0.155 | 13.5 | | | | | | | | |
| R1 stream | 1.359 | 1.5 | | | | | | | | |
| R3 stream | 1.909 | 1.1 | | | | | | | | |
| R4 stream | 3.098 | 0.7 | | | | | | | | |

* 30 m or less as required obtaining acceptable trigger levels

** (Only scenarios where the Annex VI trigger is not met at FOCUSsw step 3 should be included in step 4).

**TER calculation for aquatic plants most critical endpoint (*L. gibba* = *48 µg/L*) including different mitigation options for FOCUS Step 4 Scenario – application to sunflowers at 750g a.s./ha.**

| Mitigation options | 20* m non-spray buffer zone (VBS) | | Xx % input reduction required – all scenarios. | | Max drift reduction (95 %) | | Max run-off reduction (90%) | | Max drainage reduction (90%) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PECsw | TER | PECsw | TER | PECsw | TER | PECsw | TER | PECsw | TER |
| **FOCUS Step 4**** | | | | | | | | | | |
| D5 pond | 0.166 | 289 | | | | | | | | |
| D5 stream | 0.395 | 121 | | | | | | | | |
| R1 pond | 0.155 | 309 | | | | | | | | |
| R1 stream | 1.359 | 35 | | | | | | | | |
| R3 stream | 1.909 | 25 | | | | | | | | |
| R4 stream | 3.098 | 15 | | | | | | | | |

* 30 m or less as required obtaining acceptable trigger levels

** (Only scenarios where the Annex VI trigger is not met at FOCUSsw step 3 should be included in step 4).

**Maximum PEC$_{sw}$ values and TER values for FLC metabolite R48219– application to potatoes and sunflowers at 750 g a.s./ha**

| Scenario | PEC global max (µg L) | PEC twa, 28d* (µg L) | fish acute | fish prolonged | Daphnia acute | Daphnia prolonged | Algae acute | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | ***O. mykiss*** | ***O. mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***S. subspicatus*** | ***Lemna* sp.** | ***C. riparius*** | |
| | | | $LC_{50}$ | NOEC | $EC_{50}$ | NOEC | $EbC_{50}$ | $EbC_{50}$ | NOEC | NOEC |
| | | | µg/L | µg/L | µg/L | µg/L | 990 µg/L | 3000 µg/L | | µg/L not data |
| **FOCUS Step 1** | 18.7 | | | | | | 53 | 160 | | |
| | | | | | | | | | | |
| **FOCUS Step 2** | | | | | | | | | | |
| North Europe | | | | | | | | | | |
| South Europe | | | | | | | | | | |
| **FOCUS Step 3** | | | | | | | | | | |
| Annex VI Trigger** | | | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 5 |

* 28 d-PECtwa to be used in connection with the 34 d-NOEC from the ELS with *P. promelas*.

** If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

**Maximum $PEC_{sw}$ values and TER values for FLC metabolite R406339– application to potatoes and sunflowers at 750 g a.s./ha**

| Scenario | PEC global max (µg L) | PEC twa, 28d* (µg L) | fish acute | fish prolonged | Daphnia acute | Daphnia prolonged | Algae acute | Higher plant | Sed. dweller prolonged | Microcosm / Mesocosm |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | ***O. mykiss*** | ***O. mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***S. subspicatus*** | ***Lemna* sp.** | ***C. riparius*** | |
| | | | $LC_{50}$ | NOEC | $EC_{50}$ | NOEC | $EbC_{50}$ | $EbC_{50}$ | NOEC | NOEC |
| | | | µg/L | µg/L | µg/L | µg/L | 1900µg/L | µg/L | | µg/L not data |
| **FOCUS Step 1** | 11.0 | | | | | | 173 | | | |
| | | | | | | | | | | |
| **FOCUS Step 2** | | | | | | | | | | |
| North Europe | | | | | | | | | | |
| South Europe | | | | | | | | | | |
| **FOCUS Step 3** | | | | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Annex VI Trigger** | 100 | 10 | 100 | 10 | 10 | 10 | 10 | 5 |

* 28 d-PECtwa to be used in connection with the 34 d-NOEC from the ELS with *P. promelas*.

** If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

.

**Bioconcentration**

| | Active substance |
|---|---|
| Log Pow | 3.36 |
| Bioconcentration factor (BCF) | 220 at steady-state,<br>292 at end of exposure (28 days) |
| Annex VI Trigger for de Bioconcentration factor | 100 |
| Clearance time ($CT_{50}$)<br>($CT_{90}$) | < 1 day<br>< 3 days |
| Level and nature of residues (%) in organisms after the 14d depuration phase | 0.93 mg/kg whole fish (4% of [14C]-FLC) |

**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) |
|---|---|---|
| Technical FLC | 100 | 100 |

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

Potatoes and sunflowers 750 g as/ha

| **Test substance** | **Route** | **Hazard quotient** | **Annex VI Trigger** |
|---|---|---|---|
| Technical FLC | Oral<br>Contact | < 7.5<br>< 7.5 | 50<br>50 |

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

Laboratory tests with standard sensitive species

| Species | Test substance | Endpoint | Effect ($LR_{50}$ g ai/ha)[1] |
|---|---|---|---|
| *Typhlodromus pyri* | Preparation | Mortality or Fecundity | > 1000 |
| *Aphidius rhopalosiphi* | Preparation | Mortality or Fecundity* | > 1000 |
| | | | |

* Fecundity was not significantly affected up to 1000 g a.s./ha of FLC technical.

Potatoes and sunflower crops (750 g ai/ha)

| Species | Effect ($LR_{50}$ g/ha) | HQ in -field | HQ off-field | Trigger |
|---|---|---|---|---|
| *Typhlodromus pyri* | > 1000 | 0.75 | 0.02 | 2 |
| *Aphidius rhopalosiphi* | > 1000 | 0.75 | 0.02 | 2 |

Further laboratory and extended laboratory studies

| Species | Life Stage | Test substance, substrate and duration | Dose (g/ha) [1,2] | End point | % effect[3] | Trigger value |
|---|---|---|---|---|---|---|
| | | | | | | 50% |
| | | | | | | 50% |
| | | | | | | 50% |

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in unit of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

| **Field or semi-field tests** |
|---|
| Not semifield or field studies are required |

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

| Test organism | Test substance | Time scale | End-point[1] |
|---|---|---|---|
| Earthworms | | | |
| | a.s. | Acute 14 days | $LC_{50}$ 227 mg ai/kg soil |
| | Preparation | Acute 14 days | $LC_{50}$ 90 mg ai/kg soil |
| | a.s. | Chronic 8 weeks | Not required |
| | Preparation | Chronic 8 weeks | NOEC 10 mg ai/kg (highest concentration tested). Correction is not needed. |
| Other soil macro-organisms | | | |
| Soil mite | | | |
| | a.s. | | Not required |
| | Preparation | | |
| | Metabolite 1 | | |
| Collembola | | | |
| | a.s. | Chronic | Not required |
| | Preparation | | |
| | Metabolite 1 | | |
| Soil microorganisms | | | |
| Nitrogen mineralisation | a.s. | | Effects lower than 25% at 10 times application rate |
| | Metabolite 1 | | Not required |
| Carbon mineralisation | a.s. | | Effects lower than 25% at 10 times application rate |

| | | | |
|---|---|---|---|
| | Metabolite 1 | | Not required |

[1] End point has been corrected due to log Pow > 2.0

**Toxicity/exposure ratios for soil organisms**

Sunflowers at 750 g as/ha

| Test organism | Test substance | Time scale | Soil PEC | TER | Trigger |
|---|---|---|---|---|---|
| Earthworms | | | | | |
| | a.s. | Acute | | | 10 |
| | a.s. | Chronic | | 90 | 5 |
| | Preparation | Acute | | | 10 |
| | Preparation | Chronic | | 10 | 5 |

| **Additional studies** |
|---|
| Field study is not available and not required.<br>Additional testing specie (as result of $DT_{90}$>100 days) is not required since effects (both acute and long term) on arthropods and earthworms are of no significance at higher concentrations than 0.750 kg as/ha. Moreover, FLC does not affect the soil microflora even at a 10-fold overdose. |

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

Laboratory dose response tests

| Most sensitive species | Test substance | $ER_{50}$ (g/ha)[2] vegetative vigour | $ER_{50}$ (g/ha)[2] emergence | Exposure[1] (g as/ha)[2] (buffer zone) | TER | Trigger |
|---|---|---|---|---|---|---|
| Rape | Racer 25CS | 59 | | 20.77 (1m) | 2.8 | 5 |
| Rape | Racer 25CS | 59 | | 4.27 (5m) | 13.8 | 5 |

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

| Risk mitigation measures (5 m buffer zone) are needed to protect non target plants |
|---|

**Additional studies (e.g. semi-field or field studies)**

| No data |
|---|

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

| Test type/organism | end point |
|---|---|
| Activated sludge | |
| *Pseudomonas putida* | EC10 = 10.2 mg as./L<br>EC50 value of >10.8 mg as./L<br>No unacceptable effects |

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

| Compartment | |
|---|---|
| soil | FLC |
| water | FLC |
| sediment | FLC |
| groundwater | FLC |

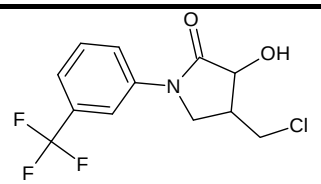
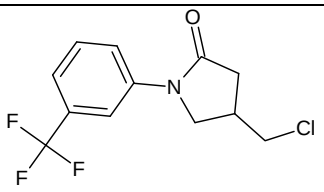
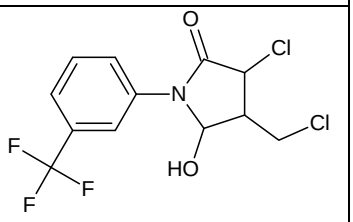
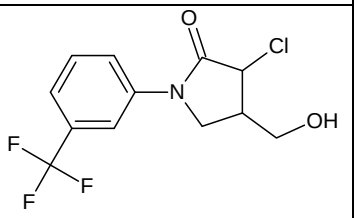
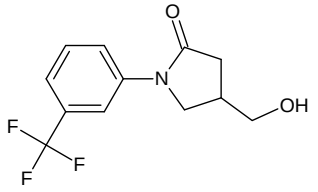
**Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)**

| RMS/peer review proposal |
|---|

| | |
|---|---|
| Active substance | N, R50/R53 Very toxic to aquatic organisms based on EC50<1 mg a.s/L for algae and aquatic plants. May cause long-term adverse effects in the aquatic environment. Log Pow >3 and BCF>100. |

| | RMS/peer review proposal |
|---|---|
| Preparation (Racer 25 CS) | N, R50/R53 based on EC50 < 1 mg /L (expressed as technical) for algae and assuming the following data from technical Log Pow >3 and BCF>100. |

## APPENDIX B – USED COMPOUND CODE(S)

| Code/Trivial name* | Chemical name | Structural formula |
|---|---|---|
| **R406639**<br>3-hydroxy-4-chloromethyl | (3*RS*,4*RS*;3*RS*,4*SR*)-4-(chloromethyl)-3-hydroxy-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one |  |
| **R42819** | (4*RS*)-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one |  |
| **5-hydroxy-4-chloromethyl** | (3*RS*,4*RS*,5*RS*;3*RS*,4*SR*,5*RS*;3*RS*,4*RS*,5*SR*;3*RS*,4*SR*,5*SR*)--3-chloro-4-(chloromethyl)-5-hydroxy-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one |  |
| **4-dechloro-4-hydroxymethyl** | (3*RS*,4*RS*;3*RS*,4*SR*)-3-chloro-4-(hydroxymethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one |  |
| **M8** | (4*RS*)-4-(hydroxymethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one |  |

* 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 |
| HQ | hazard quotient |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ip | intraperitoneal |
| 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 |
| n.r. | not relevant |

| | |
|---|---|
| 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 |
| POEM | Predictive Operator Exposure Model |
| $P_{ow}$ | 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 |
| r.t. | room temperature |
| 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 |