

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance clethodim¹

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SUMMARY

Clethodim is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002³, as amended by Commission Regulation (EC) No 1095/2007⁴. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as „the Commission”), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by The Netherlands, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant’s decision, in accordance with Article 11e, to withdraw support for the inclusion of clethodim 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 clethodim in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Arysta LifeScience made a resubmission application for the inclusion of clethodim in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008⁶. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, The Netherlands, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 1 December 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 3 December 2009. The EFSA collated and forwarded all comments received to the Commission on 18 January 2010.

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

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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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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of clethodim as a herbicide on sugar beet, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

A data gap is identified with regard to the formulation in the section physical and chemical properties.

No critical areas of concern are identified in the mammalian toxicology section. Data gaps are identified for an assessment of the relative toxicity of the plant metabolites M17R, M18R and M15R in comparison to clethodim, and for an assessment of the toxicological relevance of some groundwater metabolites.

The representative uses of clethodim in sugar beet are not considered to result in a high risk to the consumer. The identified data gaps are not expected to significantly alter this conclusion, since the exposure of the consumer to residues in sugar beet is in general very low.

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, with the notable exception for experimental degradation rates in soil and soil adsorption values for the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid to address the soil and groundwater exposure assessments of the two photodegradates. A data gap is also identified for the characterisation of the chromatographic peak M20 found in a soil metabolism study in order to support the exclusion of the content of this peak from the overall quantification of metabolite clethodim oxazole sulfoxide. In case this fraction is part (one of the isomers) of clethodim oxazole sulfoxide and the quantitative determination makes the metabolite occur at more than 5 % at two consecutive time points, then a groundwater assessment would be needed. The potential for groundwater exposure by the metabolites clethodim sulfone and clethodim oxazole sulfone is predicted to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios. On the basis of the available mammalian toxicology data, the metabolites clethodim sulfone and clethodim oxazole sulfone were considered to be toxicologically non-relevant.

The risk for earthworm-eating birds and mammals was assessed as high at first tier for soils with pH < 5.5, indicating the need for further refinement, therefore a data gap has been identified and the issue has been indicated as a critical area of concern. The long-term risk for insectivorous birds was assessed as high after a refinement for the southern Europe use of 384 g a.s./ha, and therefore a data gap was identified. Clethodim technical is toxic to aquatic organisms. Based on the data for the formulation, a high risk was identified for the majority of scenarios at FOCUS step 3 for all the representative uses. The TER values are expected to still be below the Annex VI trigger at FOCUS step 4 in the majority of scenarios, with a no-spray buffer zone up to 30m, for the southern Europe use of 384 g a.s./ha. Data to further refine the risk are needed. At FOCUS step 4 the risk was low with a no-spray buffer zone up to 18 m for the southern Europe use of 2x192 g a.s./ha, except for the R3-stream scenario. For the northern Europe use of 300 g a.s./ha, the risk was assessed as low with a no-spray buffer zone up to 30m, except for the D3-ditch and R3-stream scenarios. The risk was assessed as low for bees, non-target arthropods, soil macro- and micro-organisms, non-target terrestrial plants, and biological methods of sewage treatment.

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KEY WORDS

Clethodim, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002⁷, as amended by Commission Regulation (EC) No 1095/2007⁸ 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 33/2008⁹ 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

Clethodim is one of the 79 substances of the third stage part A 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 (The Netherlands, 2005) provided by the designated rapporteur Member State, The Netherlands, which was received by the EFSA on 5 October 2005.

The peer review was initiated on 19 April 2006 by dispatching the DAR to Member States and the applicant Arysta Paris S.A.S 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.

All points that were identified as unresolved at the end of the comment evaluation phase, and which required further consideration in the peer review process, were compiled by the EFSA in the format of an Evaluation Table. The issues identified in the Evaluation Table, as well as further information made available by the applicant upon request, were evaluated in a series of scientific meetings with Member State experts in October 2007 (PRAPeR 31 - 35). The outcome of the expert discussions phase was reported in the final column of the Evaluation Table.

The peer review process was subsequently terminated following the applicant’s decision, in accordance with Article 11e, to withdraw support for the inclusion of clethodim 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 clethodim in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Arysta LifeScience made a resubmission application for the inclusion of clethodim in Annex I in accordance with the

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

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 PRAPeR expert meeting reports, in the sections for physical, chemical properties and methods of analysis, mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

In accordance with Article 18, The Netherlands, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (The Netherlands, 2009). The Additional Report was received by the EFSA on 1 December 2009.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 3 December 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 18 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 was evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 22 February 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on clethodim 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 18 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 areas of mammalian toxicology, residues and environmental fate and behaviour, and that further information should be requested from the applicant in the areas of mammalian toxicology, residues and environmental fate and behaviour.

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

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

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

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

- the comments received on the DAR and the Additional Report,
- the Reporting Tables (revision 1-1 of 23 January 2007 and revision 1-1 of 22 February 2010),
- the Evaluation Tables (3 September 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Clethodim is the ISO common name for (5*RS*)-2-[(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl]-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one (IUPAC). It should be noted that amendments have been made to the ISO definition of the active substance to match the chemical definition of the technical material manufactured, which has *E* geometry on the allyl group but is a mixture of *E* and *Z* isomers at the oxime ether, and the carbon at position 5 appears to exhibit potential chirality, but is not considered as a chiral centre because of the rapid keto-enol tautomerism.

The representative formulated product for the evaluation was „Select 240“, an emulsifiable concentrate (EC), containing 240 g/L clethodim, registered under different trade names in Europe.

The representative uses evaluated comprise spraying applications to control annual and perennial grass weeds in sugar beet. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of clethodim technical material is 930 g/kg. No FAO specification exists.

It should be noted that the specification of the technical material of the resubmission, presented only in the Addendum to Volume 4 of March 2010 (The Netherlands, 2010), was accepted by the rapporteur Member State and EFSA. Toluene was considered as a relevant impurity with a maximum amount of 4 g/kg.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of clethodim or the respective formulation. However, the formulation was considered not stable in the two-year shelf-life study as the loss of the active substance was greater than 5%, and as a consequence, a data gap has been identified for the identification of the breakdown products.

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

Analytical methods are available for the determination of clethodim and the impurities in the technical material and for the determination of the active substance in the representative formulation. Adequate analytical methods are available for the determination of the compounds in the residue definition for monitoring in food of plant origin and in the environmental matrices. Methods for food of animal origin are not relevant as no MRL is proposed. Analytical methods for the determination of residues in body fluids and tissues are not required as clethodim is not classified as toxic or highly toxic.

2. Mammalian toxicity

Clethodim was discussed by the experts on mammalian toxicology in the PRAPeR meetings 34 (October 2007) and 76 (May-June 2010).

A material of lower purity than the technical specification was used in the toxicological studies, therefore it was considered that the levels of impurities in the technical specification were covered by the batches used in the toxicological studies, as they represented a worst case. Toluene was considered as a toxicologically relevant impurity. The NOAELs of the studies were corrected considering the purity level of the batches in order to express the content of clethodim only.

In the acute toxicity studies, clethodim was shown to be harmful if swallowed (**R22**), irritating to skin (**R38**), and a skin sensitizer (**R43**). In short-term toxicity studies, after oral administration, the target organs were the liver and the red blood cells (with changes indicative of anaemia) in all tested species (rat, dog, mouse). The liver findings also triggered the NOAELs in the long-term studies in rats and

mice. Clethodim is unlikely to be genotoxic based on the available studies, and did not show any carcinogenic potential in rats or mice. In reproductive toxicity studies, no adverse effects were observed in the fertility parameters or in the development of the pups, even though some maternal toxicity was observed at the high dose. Considering the developmental toxicity studies in rats and rabbits, some effects were observed in the rat study (reduced foetal weight, delayed ossification, increased post-implantation loss) in the presence of maternal toxicity.

Several studies were performed with metabolites of clethodim, and the results were discussed by Member State experts. For clethodim imine sulfone and clethodim 5-OH sulfone, it was agreed that the reference values of clethodim could be applied. Clethodim sulfoxide, a major rat metabolite, was considered to be covered by the toxicological studies with clethodim. For the groundwater metabolite clethodim oxazole sulfoxide no toxicological evaluation was available. A data gap has been identified for an assessment of the toxicological relevance, pending on the outcome of further evaluation required in the area of environmental fate and behaviour (see section 4). The groundwater metabolites clethodim oxazole sulfone and clethodim sulfone were considered as having no genotoxic potential and are therefore not toxicologically relevant. The experts also concluded that the reference values of clethodim could be applied for these metabolites if needed. For the plant metabolites M17R and M18R, it could not be concluded whether they are more/less, or equally toxic as clethodim. Similarly, the toxicological profile of the plant metabolite M15R, structurally closely related to M17R, cannot be concluded. Therefore a data gap is identified for these three plant metabolites. Furthermore, a data gap is also identified for an assessment of the toxicological relevance of the two groundwater metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

The Acceptable Daily Intake (ADI) is 0.16 mg/kg bw/day, based on the 2-year rat study and applying a safety factor of 100. The Acceptable Operator Exposure Level (AOEL) is 0.2 mg/kg bw/day, based on the 90-day and 1-year dog studies and using a safety factor of 100. Considering the toxicological profile of clethodim, the experts agreed that an Acute Reference Dose (ARfD) is not needed. Considering the highest application rate (0.384 kg active substance in 300 L of water per hectare), only the German model provides an operator exposure level below the AOEL, without personal protective equipment (PPE). With the UK POEM model, the use of gloves during mixing/loading and application is required to have an exposure level below the AOEL. The calculations of worker exposure with EUROPOEM II show an exposure level below the AOEL (83%), without the use of PPE. It should be noted that the calculations were performed considering 6 hours exposure for scouting, which is highly unlikely. Taking into account 2 hours of exposure (more realistic but still conservative), the estimated worker exposure would be around 30 % of the AOEL. It should be noted that clethodim is a mixture of isomers in a variable ratio, and the ratio the re-entry workers are exposed to is unknown. As an extreme worst case, if only one of the two isomers (R and S) is considered responsible for the toxicity, the exposure estimates for the re-entry workers would be about 60 % of the AOEL, without the use of PPE. Bystander exposure estimates are well below the AOEL (~2%) according to EUROPOEM II.

3. Residues

The metabolism of clethodim was studied in cotton and soybean, and in carrots grown in the greenhouse and outdoor. Considering the representative uses of clethodim on sugar beet, the carrot metabolism data were considered most relevant. Clethodim is extensively metabolised in carrot leaves and roots, leading to a variety of imine metabolites and pentanedioic acid metabolites in the terminal residue. The metabolic picture was found to differ in carrots grown outdoors from carrots grown indoors. It was agreed to include clethodim, clethodim sulfone, clethodim sulfoxide, and metabolites M3A, M15R, M17R and M18R in the residue definition for risk assessment. Data gaps were identified to assess the toxicological properties of metabolites M15R, M17R and M18R (see section 2), as well as to address the identity of metabolite M3A. Therefore, the residue definition for risk assessment is currently provisional. For monitoring, it was proposed to include clethodim, clethodim sulfone and clethodim sulfoxide in the residue definition. Two different sets of residue trials are available in sugar beet that either analyse residues with a common moiety method as DME (dimethyl ester sulfone) and

DME-OH (dimethyl ester hydroxy sulfone), or separately determine clethodim, clethodim sulfoxide and clethodim sulfone. Residues in roots were mostly below the LOQ of the respective analytical methods. Based on the results for residues in roots an MRL of 0.05 mg/kg was set. In sugar beet leaves residues ranged up to 0.25 mg/kg. Depending on the compounds determined in the residue trials, different conversion factors based on metabolism data were employed to calculate the residues according to the residue definition for risk assessment. Residues in livestock were assessed and found to be insignificant, as they are unlikely to exceed 0.01 mg/kg in food of animal origin. Total residues in rotational crops are expected to be below the trigger value for food and feed when clethodim is used according to the representative GAP.

In a provisional consumer risk assessment it was demonstrated that the intakes amount to less than 3 % of the ADI for the most critical consumer group. An acute risk assessment is not required since an ARfD was not set. A data gap is identified for further information on the isomer ratio in treated crop residues, because no sufficient information was provided on the behaviour of each individual clethodim isomer in crops. It is not known if either isomer is degraded more quickly than the other or if any other conversion may occur. However, for the representative uses on sugar beet, exposure to residues will in general be very low regardless of the ratio of isomers present that may influence the toxicological profile of clethodim. The uncertainty in the isomer ratio in the current consumer risk assessment is acknowledged, as well as the outstanding information on metabolites M3A, M15R, M17R and M18R, however the margin of safety for consumers is considered to be large. Moreover, it was agreed that in practice no conversion factor will be necessary to convert from the residue definition for monitoring to the residue definition for risk assessment because of the low residues and the high margin of safety in terms of the representative uses on sugar beet. Finally, it is noted that the level of clethodim sulfone, clethodim sulfoxide, and clethodim oxazole sulfone in groundwater is expected to exceed 0.1 µg/L in FOCUS groundwater scenarios, with clethodim sulfone exceeding 0.75 µg/L in one scenario (see section 4). When in the consumer risk assessment the possible intake of clethodim sulfone and clethodim sulfoxide through drinking water derived from groundwater is considered in addition to the exposure through food, the intakes will be insignificantly increased by less than 0.2 % of the ADI. As clethodim oxazole sulfone is not considered as a metabolite occurring in food, a consumer risk assessment is not required for levels in groundwater below the acceptable upper limit of 0.75 µg/L.

4. Environmental fate and behaviour

The regulatory dossier provides no information on the behaviour of each individual clethodim R and S isomer in the environment. It is not known if either isomer is degraded more quickly than the other or if any other conversion may occur in the environmental matrices studied. References made to clethodim in section 4 therefore relate to the sum of R and S isomers of unknown ratio. The ratio of the geometric isomers in any environmental system can vary depending on various factors including delivery vehicle, temperature, pH, etc. It is not possible to evaluate the effects of either the (E,E) or (Z,E) isomers, since isolation of either form would result in a re-established equilibrium when introduced to any test system. References made to clethodim in section 4 therefore relate to the sum of the determined (E,E) and (Z,E) geometric isomers, expressed as total clethodim.

In laboratory soil incubations under aerobic conditions in the dark, clethodim exhibits very low to low persistence. Major (> 10 % applied radioactivity (AR)) metabolites were clethodim sulfoxide (max. 73 % AR after 3 days), clethodim sulfone (max. 33.3 % AR after 14 days), and clethodim oxazole sulfone (max. 10 % AR after 380 days). In the resubmission dossier the applicant provided a position paper to address the data gap set in PRAPeR 32 for further information to demonstrate that the unknown fraction identified with the chromatographic peak M20 in the soil metabolism study by Mamouni (2006a), reported in the DAR, is not a diastereoisomer of clethodim oxazole sulfoxide. The experts at PRAPeR 78 confirmed that it cannot be excluded that the formation of the metabolite clethodim oxazole sulfoxide would exceed the formation of 5 % at two consecutive sampling points, triggering a groundwater exposure assessment (refer to Report of PRAPeR Expert Meeting 78; EFSA, 2010). Therefore a data gap was identified for the characterisation of the chromatographic peak M20

in order to support the exclusion of the content of this peak from the overall quantification of metabolite clethodim oxazole sulfoxide. In case this fraction is part (one of the isomers) of clethodim oxazole sulfoxide, and the quantitative determination makes the metabolite occur at more than 5 % at two consecutive time points, then a groundwater assessment would be needed. Clethodim sulfoxide and clethodim sulfone exhibit low to moderate persistence in soil. Mineralisation of clethodim was significant: 47 % AR at 124d (propyl-radiolabelled), and 34.2 % - 63.6 % AR at 119d and 57d (allyl- and ring-radiolabelled). The formation of non-extractable residues accounted for 17 % AR at 124d (propyl-radiolabelled), and 13 % - 29 % AR at 119d and 125d (allyl- and ring-radiolabelled).

In a soil photolysis study clethodim was rapidly photo-degraded in the irradiated soil samples with a calculated degradation rate < 1 day. The major photodegradation product formed from both labels of the test item was clethodim sulfoxide, peaking at levels of between 54 % and 60 % AR. Other significant degradates were *trans*-3-chloroacrylic acid (max. 18 % AR at 3d) and 2-[3-chloroallyloxyimino]butanoic acid (max. 18.7 % AR at 15d). Although the guidance photolysis study in soil does not represent realistic conditions and should not be considered quantitatively, the qualitative assessment of the levels observed of these metabolites, together with the fact that soil photolysis can be considered as important as microbial degradation (degradation rates are comparable) and considering the representative uses, does not allow to exclude that the two photodegradates will reach 10 % of applied clethodim in molar bases under realistic conditions of use. Therefore, the metabolites *trans*-3-chloroacrylic acid and 2-[3-chloroallyloxyimino]butanoic acid need to be addressed with respect to soil and groundwater compartments, and a data gap is identified.

Clethodim and its soil metabolites clethodim sulfoxide and clethodim sulfone are very highly mobile in soil. Metabolites clethodim oxazole sulfone and clethodim oxazole sulfoxide exhibit very high to high mobility in soil. Although a narrow range of soil pH was tested for clethodim (4 soils with pH values of 5.4, 5.6, 7.4 and 7.5), a higher adsorption was observed for the acidic soils. The soil pH dependant adsorption of clethodim used in FOCUS groundwater modelling was discussed in PRAPeR 32. It was agreed that the pH dependent relationship with adsorption values as determined in the Addendum dated September 2007 (The Netherlands, 2010) was considered inadequate. The experts at PRAPeR 78 confirmed that the use of the worst-case K_{Foc} value of 4 mL/g for clethodim¹¹ for all the FOCUS groundwater scenarios is a conservative approach and was considered appropriate for groundwater modelling. There was no evidence of pH dependence of adsorption for the soil metabolites clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone and clethodim oxazole sulfoxide.

In aerobic natural sediment water systems (laboratory incubations) clethodim dissipated relatively rapidly from the water phase and the total system. Besides clethodim, four major degradation products were identified: two in the water phase (clethodim sulfoxide, max. 57.8 % AR at 14d; clethodim sulfone, max. 10.4 % AR at 68d), and two in the sediment (clethodim imine, max. 35.8 % AR at 33d; and clethodim imine sulfoxide, max. 15.5 % AR at 61d). Mineralisation was significant throughout the study and accounted for maximum 43.7 % AR after 174 days. Non-extractable radioactivity in sediment increased throughout the study, reaching maximum levels of 33 % AR after 174 days. Predicted environmental concentrations (PEC) in surface water were calculated for clethodim and metabolites clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone, clethodim imine and clethodim imine sulfoxide, according to the representative GAP, and up to step 3 of the FOCUS SW procedure (FOCUS, 2001). Step 4 calculations for clethodim were also conducted, however the application of buffer zones > 30 m was considered not appropriate, as it has not been demonstrated that this mitigation measure will not exceed the maximum levels of exposure mitigation in the risk assessment for Annex I listing recommended by the FOCUS Landscape and Mitigation Working Group (FOCUS, 2007).

The necessary groundwater exposure assessment was appropriately carried out using FOCUS (2000) scenarios and models (PEARL 3.3.3 and PELMO 3.3.2) for clethodim and its soil metabolites clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone. The potential for groundwater

¹¹ geometric mean of K_{Foc} values at alkaline pH

exposure by clethodim above the parametric drinking water limit of 0.1 µg/L from the representative uses assessed was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. PEC_{gw} for clethodim sulfoxide were below the 0.1 µg/L regulatory threshold in all scenarios, except the Sevilla scenario with the PEARL model, where concentrations up to 0.5663 µg/L were predicted. PEC_{gw} for clethodim sulfone exceeded 0.1 µg/L in all but two of the nine scenarios modelled with PEARL, with the Sevilla scenario > 0.75 µg/L. In 8 scenarios PEC_{gw} for clethodim oxazole sulfone ranged from 0.249 to 0.526 µg/L. On the basis of the available mammalian toxicology data, metabolites clethodim sulfone and clethodim oxazole sulfone were considered to be toxicologically non-relevant (see section 2). A data gap was identified in PRAPeR 78 for a groundwater exposure assessment for the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid, and pending on the characterisation of the chromatographic peak M20 in a soil metabolism study, a groundwater assessment might be needed also for clethodim oxazole sulfoxide.

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

5. Ecotoxicology

A low acute and short-term risk was assessed for birds, and a low acute and long-term risk was assessed for mammals at first tier via dietary exposure. A low risk was indicated from consumption of contaminated drinking water. A high long-term risk was identified at first tier for insectivorous and herbivorous birds. The subsequent refinement, taking into account residue decline, gave TERs above the Annex VI trigger for herbivorous birds. However, the refined TER for insectivorous birds, including PD of 76.4 % large insects and 23.6 % small insects, was slightly below the Annex VI trigger for the use in southern Europe of 384 g a.s./ha (TER=4.7), indicating the need for further refinement and therefore a data gap is identified. The risk for earthworm-eating birds and mammals was assessed as high at first tier for soils with pH < 5.5 for all the representative uses, and therefore a data gap has been identified to provide data for further refinement. For soils with pH > 5.5, a low risk was indicated. The risk for the metabolites clethodim sulfoxide, clethodim sulfone, and clethodim oxazole sulfone was assessed as low for birds and mammals based on the toxicity of the parent compound.

Clethodim technical was toxic to aquatic organisms, based on the *Lemna* end point. The representative formulation, which includes an oily adjuvant, showed a higher toxicity than the active substance. Toxicity data on algae, *Lemna* and fish were also available for the metabolite clethodim sulfoxide, and data on *Chironomus* were also available for the metabolite clethodim imine. The lowest end point driving the risk assessment was observed in a reproduction study with *Daphnia magna* (NOEC = 0.84 µg a.s./L) with the formulation. Based on this value, a high risk was identified for the majority of scenarios at FOCUS step 3 for all the representative uses. The subsequent assessment at FOCUS step 4 including mitigation measures comparable to no-spray buffer zones greater than 30m could not be taken into account (see section 4). However, with a no-spray buffer zone up to 30m, the TER values would be expected to still be below the Annex VI triggers in the majority of the scenarios for the southern Europe use of 384 g a.s./ha. Therefore further data are required to refine the risk, and a data gap has been identified. The risk was assessed as low with a no-spray buffer zone up to 18m for the southern Europe use of 2x192 g a.s./ha for all scenarios, except for the R3-stream; for this scenario the available TER value, calculated with a no-spray buffer zone up to 16 m, is below the Annex VI trigger and no PEC_{sw} at 18m was available. For the northern Europe use of 300 g a.s./ha, the risk was assessed as low with a no-spray buffer zone up to 30m, except for the D3-ditch and the R3-stream scenarios; for these scenarios the PEC_{sw} values at 30m were not available.

The risk was assessed as low for bees, non-target arthropods, soil macro- and micro-organisms, non-target terrestrial plants, and biological methods of sewage treatment.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
clethodim	Very low to low persistence First-order laboratory DT ₅₀ 0.17-3.04 days (20°C, pF2 soil moisture)	The risk for soil-dwelling organisms was assessed as low.
clethodim sulfoxide	Low to moderate persistence First-order laboratory DT ₅₀ 2.64-26.26 days (20°C, pF2 soil moisture)	The risk for soil-dwelling organisms is expected to be low based on the available toxicity data.
clethodim sulfone	Low to moderate persistence First-order laboratory DT ₅₀ 2.89-55.92 days (20°C, pF2 soil moisture)	The risk for soil-dwelling organisms is expected to be low based on the available toxicity data.
clethodim oxazole sulfone	Moderate to medium persistence First-order laboratory DT ₅₀ 20-68 days (20°C, pF2 soil moisture)	The risk for soil-dwelling organisms is expected to be low based on the available toxicity data.
2-[3-chloroallyloxyimino]butanoic acid (CBA) (soil photolysis metabolite)	no data, data required	The risk for soil-dwelling organisms is expected to be low based on the available toxicity data.
<i>trans</i> - 3- chloroacrylic acid (CAA) (soil photolysis metabolite)	no data, data required	The risk for soil-dwelling organisms is expected to be low based on the available toxicity data.

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
clethodim	Very high mobility K _{Foc} 3-43 mL/g	FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3: no	yes	yes	yes
clethodim sulfoxide	Very high mobility K _{Foc} 2-24 mL/g	FOCUS PELMO 3.3.2: no FOCUS PEARL 3.3.3: 1 scenario (Sevilla: 0.567 µg/L) out of 9	no	Major rat metabolite Not relevant	no
clethodim sulfone	Very high mobility K _{Foc} 5-16 mL/g	FOCUS PELMO 3.3.2: 1 scenario (Okehampton: 0.113 µg/L) FOCUS PEARL 3.3.3: 7 scenarios out of 9 (Sevilla: 1.09 µg/L)	no	Unlikely to be genotoxic Not relevant	no
clethodim oxazole sulfone	Very high to high mobility K _{Foc} 12-96 mL/g	FOCUS PELMO 3.3.2: 7 scenarios out of 9 (0.102- 0.356 µg/L) FOCUS PEARL 3.3.3: 8 scenarios out of 9 (0.249- 0.526 µg/L)	no	Unlikely to be genotoxic Not relevant	no
clethodim oxazole sulfoxide	Very high to high mobility K _{doc} 26-130 mL/g	No data, data required pending on the characterisation of the chromatographic peaks of M20 identified in the soil metabolism study by Mamouni (2006a).	no	No data	no

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
2-[3-chloroallyloxyimino]butanoic acid (CBA) (soil photolysis metabolite)	no data, data required	no data, data required	no	No data, data required	no
<i>trans</i> - 3- chloroacrylic acid (CAA) (soil photolysis metabolite)	no data, data required	no data, data required	no	No data, data required	no

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
clethodim	Clethodim was toxic to aquatic organisms, based on <i>Lemna</i> end point. The lowest end point was observed in a reproduction study with <i>Daphnia magna</i> (NOEC = 0.84 µg a.s./L). A high risk was identified for the majority of scenarios at FOCUS step 3 for all the representative uses. It is expected that mitigation measures would not be sufficient to achieve a low risk in the majority of scenarios for the southern Europe use of 384 g a.s./ha.
clethodim sulfoxide	The risk for aquatic organisms is expected to be low.
clethodim sulfone	The risk for aquatic organisms is expected to be low.
clethodim oxazole sulfone	The risk for aquatic organisms is expected to be low.
clethodim imine (sediment)	The risk for aquatic organisms is expected to be low.
clethodim imine sulfoxide (sediment)	The risk for aquatic organisms is expected to be low.

6.4. Air

Compound (name and/or code)	Toxicology
clethodim	Rat LC ₅₀ > 3.25 mg a.s./L air/4h (whole body)

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

- Identification of the breakdown products in the shelf-life study (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see section 1).
- Assessment of the toxicological relevance of the groundwater metabolite clethodim oxazole sulfoxide, pending on the results of the data gap in section 4 for the characterisation of the chromatographic peak M20 found in the soil metabolism study (relevant for all representative uses; no submission data proposed by the applicant; see sections 2 and 4).
- Assessment of the relative toxicity of the plant metabolites M17R, M18R and M15R in comparison to clethodim (relevant for all representative uses; no submission date proposed by the applicant; see section 2).
- Assessment of the toxicological relevance of the groundwater metabolites *trans*-3-chloroacrylic acid and 2-[3-chloroallyloxyimino]butanoic acid (relevant for all representative uses evaluated; no submission date proposed by the applicant; see section 2).
- Investigation of the structure of metabolite M3A (relevant for all representative uses; no submission date proposed by the applicant; see section 3).
- Information on the ratio of isomers in treated crops (relevant for all representative uses; no submission date proposed by the applicant; see section 3).
- Characterisation of the chromatographic peak M20 found in the soil metabolism study by Mamouni (2006a) in order to support the exclusion of the content of this peak from the overall quantification of metabolite clethodim oxazole sulfoxide. In case this fraction is part (one of the isomers) of clethodim oxazole sulfoxide and the quantitative determination makes the metabolite occur at more than 5 % at two consecutive time points, then a groundwater assessment would be needed (relevant for all representative uses evaluated; no submission date proposed by the applicant; see section 4).
- Experimental degradation rates in soil and soil adsorption values for the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid to address the soil and groundwater exposure assessments of the two photodegradates (relevant for all representative uses evaluated; no submission date proposed by the applicant; see section 4).
- The long-term risk for insectivorous birds needs to be further addressed (relevant for the highest application rate of 384 g a.s./ha in southern Europe; no submission date proposed by the applicant; see section 5).
- The risk for earthworm-eating birds and mammals for soils with pH < 5.5 needs to be further addressed (relevant for all representative uses evaluated; no submission date proposed by the applicant; see section 5).
- The long-term risk for aquatic organisms needs to be further addressed (relevant for the highest application rate of 384 g a.s./ha in southern Europe; no submission date proposed by the applicant; see section 5).

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

- Mitigation measures comparable to a no-spray buffer zone up to 18m and 30m were necessary to achieve a low risk for aquatic organisms in the majority of scenarios for the southern Europe use of 2x192 g a.s./ha, and for the northern Europe use of 300 g a.s./ha, respectively.

ISSUES THAT COULD NOT BE FINALISED

- The residue definition for risk assessment and consequently the consumer risk assessment is not finalised pending the data gaps in relation to the metabolites M3A, M15R, M17R and M18R and the isomer ratio present in the residue in treated crops.
- A proper quantification of the soil metabolite clethodim oxazole sulfoxide in one soil metabolism study is outstanding. In case the quantitative determination makes the metabolite occur at more than 5 % at two consecutive time points, then a groundwater assessment for this metabolite would be needed.
- Soil and groundwater exposure assessments for the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.
- The long-term risk for insectivorous birds could not be finalised on the basis of available data for the southern Europe use of 384 g a.s./ha.
- The risk to aquatic organisms could not be finalised on the basis of available data for the southern Europe use of 384 g a.s./ha.

CRITICAL AREAS OF CONCERN

- A high risk is identified for earthworm-eating birds and mammals for soils with pH < 5.5. A data gap was identified for further refinement.

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APPENDICES

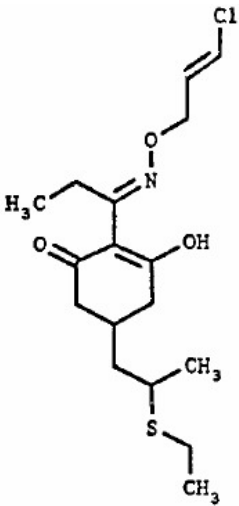
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

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

Active substance (ISO Common Name)	Clethodim
Function (<i>e.g.</i> fungicide)	herbicide
Rapporteur Member State	The Netherlands

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	(5 <i>RS</i>)-2-[(1 <i>EZ</i>)-1-[(2 <i>E</i>)-3-chloroallyloxyimino]propyl]-5-[(2 <i>RS</i>)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one
Chemical name (CA)	2-[1-[[[(2 <i>E</i>)-3-chloro-2-propen-1-yl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one
CIPAC No	508
CAS No	99129-21-2
EEC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured (g/kg)	930 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	toluene max. 4 g/kg
Molecular formula	C ₁₇ H ₂₆ ClNO ₃ S
Molecular mass	359.92 g/mol
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point	-80°C (98.3%)
Boiling point	not available (thermal decomposition below the boiling temperature)
Temperature of decomposition	Decomposition starts at 406±0.5 K (133±0.5°C) at 100.52
Appearance	green yellow liquid (98.3%) amber viscous liquid (technical material)
Vapour pressure (state temperature, state purity) ‡	2.08 x 10 ⁻⁶ at 20°C 4.92 x 10 ⁻⁶ at 25°C (98.5%)
Henry's law constant	1.4 x 10 ⁻⁷ Pa.m ³ .mol ⁻¹ at 20°C (calculated from vapour pressure and aqueous solubility)
Solubility in water (state temperature, state purity and pH)	Purity 98.3%, at 20°C: At pH 4: 0.0530 g/L At pH 7: 5.45 g/L At pH 9: 58.9 g/L At pH 10: 30.0 g/L
Solubility in organic solvents (state temperature, state purity)	purity 93%, at 25°C: xylene >100 g/L 1,2-dichloroethane >100 g/L methanol >100 g/L technical material, at 25°C: acetone >900 g/L hexane >900 g/L ethyl acetate >900 g/L dimethylformamide >900 g/L
Surface tension (state concentration and temperature, state purity)	purity 100%: 52.9 mN/m at 21°C (70% saturated aqueous solution), 59.2 mN/m at 18°C (35% saturated aqueous solution), 64.3 mN/m at 18°C (14% saturated aqueous solution)
Partition co-efficient (state temperature, pH and purity)	Log P _{ow} = 4.14 at pH 7 (99,0%) Log P _{ow} = 4.22 at pH 9 (99,0%) => Log P _{ow} = 4.2 for the non-dissociated form of clethodim Metabolites (Estimated using EPA EPI Suite program): Clethodim sulfoxide: Log P _{ow} = 2.07 Clethodim imine: Log P _{ow} = 1.38 Clethodim imine sulfoxide: Log P _{ow} = -0.76
Dissociation constant (state purity)	purity 98.5%, at 20°C: pKa = 4.47
UV/VIS absorption (max.) incl. ε (state purity, pH)	UV-spectrum, in methanol Neutral conditions: 1e λ max : 256 nm ;ε = 13183 (1/(mol.cm)) 2e λ max : 203 nm ;ε = 13490 (1/(mol.cm)) at 290 nm: ε = 4255 (1/(mol.cm)) acidic solution: 1e λ max : 258 nm;ε = 12882 (1/(mol.cm)) 2e λ max : 207 nm;ε = 12589 (1/(mol.cm)) basic solution: 1e λ max : ca 210 nm; ε unknown 2e λ max : 282 nm; ε = 21878 (1/(mol.cm))
Flammability (state purity)	Self-ignition temperature: 280°C (94.8%) No flash point up to 78°C (degradation, 93.8%).
Explosive properties (state purity)	not explosive (92.4%)

Oxidising properties (state purity)

not oxidizing (statement)

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical and chemical data

No classification is proposed

List of representative uses evaluated (clethodim)*

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 min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Sugar beet	Northern Europe	Select 240	F	Annual and perennial grass weeds	EC	240 g/L	Downwards spraying with tractor mounted equipment	Ca. 40	1	n.a.	0.15	200	0.3	56	Select 240 is to be used in combination with an oily adjuvant (0.5% v/v) [1] [3] [4]
Sugar beet	Southern Europe	Select 240	F	Annual and perennial grass weeds	EC	240 g/L	Downwards spraying with tractor mounted equipment	Ca. 40	1	n.a.	0.128	300	0.384	56	Select 240 is to be used in combination with an oily adjuvant (0.5% v/v) [1] [2] [3] [4]
Sugar beet	Southern Europe	Select 240	F	Annual and perennial grass weeds	EC	240 g/L	Downwards spraying with tractor mounted equipment	Ca. 40	2	2 weeks	0.064	300	0.192	56	Select 240 is to be used in combination with an oily adjuvant (0.5% v/v) [1] [3] [4]

[1] High risk is identified for earthworm-eating birds and mammals for soils with pH<5.5

[2] The risk was expected to be high for aquatic organisms in the majority of scenarios at FOCUS step 4. The long-term risk was assessed as high for insectivorous birds.

[3] Soil and groundwater exposure assessments for the two soil photolysis metabolites *trans*-3-chloroacrylic acid and 2-[3-chloroallyloxyimino]butanoic acid have not been finalized. A proper quantification of the soil metabolite clethodim oxazole sulfoxide in one soil metabolism study is outstanding.

[4] The residue definition for risk assessment, and consequently the consumer risk assessment is not finalised pending the data gaps identified.

Remarks:	<p>* Uses for which risk assessment could not been concluded due to lack of essential data are marked grey</p> <p>(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)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(g) All abbreviations used must be explained</p>	<p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> <p>(i) g/kg or g/l</p> <p>(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</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> <p>(m) Remarks may include: Extent of use/economic importance/restrictions</p>
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Methods of Analysis

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

Technical as (principle of the method)	Dissolution in acetonitrile followed reversed phase HPLC-UV analysis
Impurities in technical as (principle of the method)	Dissolution in acetonitrile or dichloromethane followed by HPLC-UV or GC-FID analysis.
Plant protection product (principle of the method)	Dissolution in acetonitrile followed reversed phase HPLC-UV analysis

Residue definitions for monitoring purposes

Food of plant origin	clethodim + clethodim sulfoxide + clethodim sulfone measured as clethodim sulfone and expressed as clethodim equivalents
Food of animal origin	no definition of residues in animal products is required
Soil	Clethodim, clethodim oxazole sulfone
Water surface	Clethodim, clethodim imine sulfoxide, clethodim imine
drinking/ground	Clethodim
Air	Clethodim
Body fluids	Not required

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Extraction with methanol/water and determination with LC-MS/MS: LOQ (clethodim, clethodim sulfoxide and clethodim sulfone, individually): 0.005 mg/kg (soybean, sugar beet roots and leaves, proteinaceous peas)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No method required, however the following method was submitted: After extraction conversion to sulfones, detection by LC-MS/MS. LOQ (clethodim sulfoxide/clethodim sulfone as sum): 0.05 mg/kg (Beef meat, fat, liver, kidney and milk and chicken meat and eggs).
Soil (principle of the method and LOQ)	Soil was extracted with MeOH:water and analysed by LC-MS/MS. LOQ (clethodim): 0.005 mg/kg Almost the same method is used for some metabolites. LOQ (clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone): 0.005 mg/kg (individually)
Water (principle of the method and LOQ)	Surface, ground- and tap water were subjected to C-18 SPE. After elution (MeOH) and clean-up over a SAX SPE column, the rinsate was reconstituted in acetonitrile:ammonium acetate and analysed by LC-MS/MS. LOQ (clethodim and clethodim sulfoxide individually): 0.1 µg/L Direct analyzing the water with LC-MS/MS. LOQ (clethodim imine and clethodim imine sulfoxide): 0.05 µg/L (individually)
Air (principle of the method and LOQ)	Air sampling cartridges (XAD-2) were extracted with acetonitril and analysed by LC-MS/MS. LOQ: 1.0 µg/m ³ (clethodim and clethodim sulfoxide)
Body fluids and tissues (principle of the method and LOQ)	Not required, not a toxic compound

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 6.1)

Rate and extent of absorption:	88-95% based on urine, tissues, expired CO ₂ , cage wash, and residual carcass within 168 h.
Distribution:	Widely (0.2-0.7% in tissues); highest residues in adrenals, liver and kidneys.
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Urinary: 80-86% in 24 h; faecal 8.5-14% in 24 h
Metabolism in animals	Extensively metabolised, > 99% by oxidation to clethodim sulfoxide.
Toxicologically relevant compounds (animals and plants)	Parent compound
Toxicologically relevant compounds (environment)	Parent compound

Acute toxicity (Annex IIA, point 6.2)

Rat LD ₅₀ oral	1133 mg a.s./kg bw	R22
Rat LD ₅₀ dermal	> 4167 mg a.s./kg bw	
Rat LC ₅₀ inhalation	> 3.25 mg a.s./L air/4h (whole body) (maximal attainable concentration)	
Skin irritation	Irritating, R38	
Eye irritation	Non-irritant	
Skin sensitization (test method used and result)	Sensitizer, R43 (M&K test)	

Short term toxicity (Annex IIA, point 6.3)

Target / critical effect	Liver, red blood cells (rat, mouse, dog)
Relevant oral NOAEL	21 mg a.s./kg bw/d (90-d and 1-yr dog) 25 mg a.s./kg bw/d (90-d rat) 74 mg a.s./kg bw/d (4-wk, range-finding, mouse)
Relevant dermal NOAEL	83 mg a.s./kg bw/d (4-wk rat)
Relevant inhalation NOAEL	No data – not required

Genotoxicity (Annex IIA, point 6.4)

Unlikely to be genotoxic.

Long term toxicity and carcinogenicity (Annex IIA, point 6.5)

Target/critical effect	Decreased body weight (rat) Liver: increased weight and associated histopathological findings (rat, mouse) Lungs: increased incidence of alveolar macrophages (mouse).
Lowest relevant NOAEL / NOEL	16 mg a.s./kg bw/d (2-yr rat) 24 mg a.s./kg bw/d (18-month mouse)
Carcinogenicity	No carcinogenic potential.

Reproductive toxicity (Annex IIA, point 6.6)

Reproduction target / critical effect

Parental: decreased body weight and food consumption
Pups: no adverse effects
Reproductive: no adverse effects

Relevant parental NOAEL

26.7 mg a.s./kg bw/d

Relevant reproductive NOAEL

133.7 mg a.s./kg bw/d

Relevant offspring NOAEL

133.7 mg a.s./kg bw/d

Developmental toxicity

Developmental target / critical effect

Maternal: clinical signs, decreased body weight and food consumption (rat, rabbit), increased mortality at higher dose (rats)
Developmental: reduced foetal weight, delayed ossification, increased post-implantation loss at higher dose (rats); no adverse effect in rabbits

Relevant maternal NOAEL

83.3 mg a.s./kg bw/d (rat)
20.8 mg a.s./kg bw/d (rabbit)

Relevant developmental NOAEL / NOEL

83.3 mg a.s./kg bw/d (rat)
250 mg a.s./kg bw/d (rabbit)

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 6.7)

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No data, no indication from other studies.

Other toxicological studies (Annex IIA, point 6.8)

Studies with metabolite clethodim imine sulfone:
- LD₅₀, oral rat: > 1400 mg/kg bw
- no genotoxic potential (Ames, chrom. aberr. *in vitro*)
- subacute toxicity, oral, rat: NOAEL 70.9 mg/kg bw/d
- teratogenicity, oral, rat: NOAEL maternal toxicity 10 mg/kg bw/d, NOAEL developmental 100 mg/kg bw/d

Studies with metabolite clethodim 5-OH sulfone:
- LD₅₀, oral rat: > 1400 mg/kg bw
- no genotoxic potential (Ames, chrom. aberr. *in vitro*)
- subacute toxicity, oral, rat: NOAEL 5.94 mg/kg bw/d
- teratogenicity, oral, rat: NOAEL maternal and developmental toxicity 100 mg/kg bw/d

Studies with metabolite clethodim oxazole sulfone:
- Unlikely to be genotoxic (*in vitro*: negative Ames test, positive chrom. aberr., equivocal gene mutation; *in vivo*: negative mouse micronucleus).

Studies with clethodim sulfone:
- genotoxicity: *in vitro* some positive result (Ames test, chrom. aberr.), *in vivo* negative (mouse liver UDS), *in vivo* equivocal (mouse micronucleus)
Unlikely to be genotoxic.

Medical data (Annex IIA, point 6.9)

No evidence of toxicological concern from medical surveillance of manufacturing plant personnel.

Summary (Annex IIA, point 6.10)

ADI

AOEL

ARfD (acute reference dose)

Dermal absorption (Annex IIIA, point 7.3)

Formulation: **Select 2.0 EC**

Acceptable exposure scenarios (including method of calculation)

Operator

Workers

Bystanders

No human cases of poisoning by clethodim reported.		
Value	Study	Safety factor
0.16 mg a.s./kg bw/d	2-yr rat	100
0.2 mg a.s./kg bw/d	90-d dog 1-yr dog	100
not necessary, not allocated		

15% for the undiluted formulation and 42% for the spray dilution, based on an <i>in vivo</i> dermal absorption study in rats.

Model	Exposure estimates (% of AOEL)	
	Without PPE	With PPE
Sugar beet – 0.3 kg active substance in 200 L water/ha		
UK POEM – 75 th	240	36 [£]
DE BBA – GM*	50	2 [§]
EUROPOEM – 75 th	87	9 ^{&}
Sugar beet – 0.384 kg active substance in 300 L water/ha		
UK POEM – 75 th	220	33 [£]
DE BBA – GM*	64	3 [§]
EUROPOEM – 75 th	110	11 ^{&}
According to EUROPOEM II: 83% of AOEL without PPE, 8% of AOEL with gloves		
According to EUROPOEM II: 1.6 – 1.7 % of AOEL		

*DE BBA – GM: German model, geometric mean values
PPE = personal protective equipment
PPE[£]: gloves during mixing/loading (m/l) plus application (a)
PPE[§]: gloves (m/l and a), coverall and sturdy footwear (a)
PPE[&]: reducing the exposure by a factor of 10

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data

Symbol	: Xn
Risk phrase	: R22, R38, R43

Residues

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

Plant groups covered	Root vegetables (carrot), pulses and oil seeds (soybean and cotton)
Rotational crops	Carrot, lettuce and wheat
Plant residue definition for monitoring	Clethodim + clethodim sulfoxide + clethodim sulfone
Plant residue definition for risk assessment	For root crops, provisional : Clethodim, clethodim sulfone, clethodim sulfoxide, M3A (no structure identified), M15R, M17R and M18R (data gap for toxicological properties)
Conversion factor (monitoring to risk assessment)	None required for sugar beet use based on the low residues and the high margin of safety for the consumer

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

Animals covered	Goat, hen.
Animal residue definition for monitoring	Not required for sugar beet use, since residues in food of animal origin were assessed to be insignificant and MRLs were not proposed.
Animal residue definition for risk assessment	For ruminant: Clethodim + clethodim sulfoxide + S-methyl sulfoxide, expressed as clethodim For poultry: Not required for sugar beet use
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex II A, point 6.6, Annex III A, point 8.5)

	Total radioactive residue (TRR):
	Plant back interv. 30 d: carrot leaf: 0.34 mg eq/kg carrot root: 0.021 mg eq/kg lettuce: 0.084 mg eq/kg wheat straw: 0.48 mg eq/kg wheat grain: 0.025 mg eq/kg
	Plant back interv. 120 d: carrot leaf: 0.42 mg eq/kg carrot root: 0.019 mg eq/kg lettuce: 0.045 mg eq/kg wheat straw: 0.65 mg eq/kg wheat grain: 0.012 mg eq/kg
	Plant back interv. 366 d: carrot leaf: 0.053 mg eq/kg carrot root: 0.005 mg eq/kg lettuce: 0.016 mg eq/kg wheat straw: 0.42 mg eq/kg

wheat grain: 0.021 mg eq/kg
(application to bare soil at 1.1 kg as/ha)

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

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Common moiety residue trials: Clethodim (measured as dimethyl ester sulfone (DME)) and 5-OH clethodim sulfone (measured as dimethyl ester hydroxy sulfone (DME-OH)) were stable in sugar beet roots stored at -20°C for one year and in sugar beet tops stored at -20°C for 9 months.

LC-MS/MS trials: Clethodim, clethodim sulfoxide and clethodim sulfone residues in sugar beet roots and leaves were stable during frozen storage for at least 11 and 9 months, respectively.

Clethodim (measured as DME), S-methyl clethodim sulfoxide (measured as S-methyl-DME) and 5-OH clethodim sulfone (measured as DME-OH) were stable during storage at -18°C for approximately 2 months in egg, for at least 6 weeks in gizzard, liver (poultry), muscle (poultry) and fat (poultry), and for approximately 5 months in bovine milk, fat, kidney, liver and muscle.

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:

	Ruminant: yes ¹	Poultry: No ²	Pig: yes ³
Muscle	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴
Liver	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴
Kidney	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴
Fat	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴	<0.01 mg/kg ⁴
Milk	<0.01 mg/kg ⁴	Not applicable	Not applicable
Eggs	Not applicable	<0.01 mg/kg ⁴	Not applicable

¹ The maximum estimated intake is 0.67 mg/kg dry matter diet.

² The maximum estimated intake is 0 mg/kg dry matter diet.

³ The maximum estimated intake is 0.56 mg/kg dry matter diet.

⁴ Estimated from livestock feeding studies at maximum estimated intake levels.

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

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP expressed as clethodim equivalents (mg/kg)		Recommendation/comments	MRL mg/kg	STMR mg/kg
		DME ¹	DME-OH ²			
Sugar beet roots	2NMS	2x<0.015 0.05	34 x <0.05 4		0.05	0.05
Sugar beet leaves	SMS	9 x <0.05 2x<0.015	59 x <0.05		0.05	0.05
	NMS	3x<0.015 <0.05 0.07 0.17 0.25	0.05 0.05 0.06 0.05			
	SMS	2x<0.015 6x<0.05 0.06 0.09 0.179 0.22	0.05 0.05 0.05 0.05 0.05 0.05 0.12 0.05			

¹ clethodim + clethodim sulfoxide + clethodim sulfone + imine sulfoxide + imine sulfone, determined as dimethyl ester sulfone (DME) and expressed as clethodim equivalents (common moiety method).

² 5-OH clethodim + 5-OH clethodim sulfoxide + 5-OH clethodim sulfone, determined as dimethyl ester hydroxy sulfone (DME-OH) and expressed as clethodim equivalents (common moiety method).

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

ADI	0.16 mg/kg bw/day
TMDI (PRIMo rev. 2, (% ADI)	Provisional: < 3 % ¹² (UK toddlers, all other national diets use less of ADI) (residue definition to be concluded, data gap on isomer ratio of residues)
ARfD	Not allocated
Acute exposure (% ARfD)	n/a

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

Crop/processed crop	Number of studies	Transfer factor	% Transference
no acceptable data			-
			-
			-

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

Proposed MRLs	Sugar beet root: 0.05 mg/kg
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¹² Additional contribution from groundwater metabolites (clethodim sulfone and clethodim sulfoxide) less than 0.2% ADI

Fate and Behaviour in the Environment

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

Mineralization after 100 days
% refers to the applied radioactivity

Soil	Propyl label
Sandy loam I	47% AR (d124), 55% (d380)
Soil	Allyl label, Ring label
Sandy loam II	45%-57% AR (d125-121)
Clay loam	34.2%-63.6% AR (d119-57)
Loam	45.4%-57% AR (d119-57)
Loamy sand	36%-58.4% AR (d119-57):

Non-extractable residues after 100 days
% refers to the applied radioactivity

Soil	Propyl label
Sandy loam I (d380)	17% AR (d124), 16% AR
Soil	Allyl label, Ring label
Sandy loam II	13%-29% AR (d119-125)
Clay loam	53.3%-27.6% AR (d119-57)
Loam	45%-27.3% (AR d119-57)
Loamy sand	49.9%-19.3% AR (d119-57)

Major metabolites – name and/or code, % of
Applied radioactivity (range and maximum)

Clethodim sulfoxide:	
Sandy loam I :	max 63% AR at day 7 (Propyl label)
Soil	Allyl label, Ring label
Sandy loam II :	max 65%-73% AR at day 7-3
Clay loam :	max 59.6%-72% AR at day 1-2
Loam :	max 65.2%-67.5% AR at day 1-2
Loamy sand :	max 53.8% AR at day 1-2
Clethodim sulfone:	
Sandy loam I :	max 11% AR at day 61 (Propyl label)
Soil	Allyl label, Ring label
Sandy loam II :	max 15%-16% AR at day 30
Clay loam :	max 25.8%-33.3% AR at day 7-14
Loam :	max 20.9%-24.4% AR at day 11-14
Loamy sand :	max 11.9%-12.6% AR at day 7
Clethodim oxazole sulfone :	
Sandy loam I :	max 10% AR at day 380 (propyl label)
Sandy loam II :	max 8.6% AR at day 121 (ring label)
Loamy sand :	max 7.5% AR at 57 days (ring label)

Anaerobic degradation

Mineralisation maximum 6.8% AR at 31 d
Non-extractable residues maximum 22% AR at 62 d
Metabolites
clethodim sulfoxide, maximum 79% AR at 1 d
clethodim imine, maximum 44% AR at 31 d
clethodim imine sulfoxide, maximum 14% AR at 31 d
[ring-4,6- ¹⁴ C] (n=1)

Soil photolysis

Clay loam, 20 ± 1°C

Clethodim :

max DT₅₀ = 0.16 days (irradiated samples)

max DT₅₀ = 2.88 days (dark samples)

Major metabolites :

Clethodim sulfoxide: (allyl – ring labels)

max 60.4%- 53.7% at d 1 (irradiated)

max 89.2%- 88.1% at d 15-10 (dark)

max DT₅₀ : 1.55 days (irradiated-ring label)

stable in dark

Trans-3-chloroacrylic acid: max 18.1% at d 3 (irr)

DT₅₀ : 6.49 days (irradiated-allyl label)

2-[3-chloroallyloxyimino]butanoic acid isomers :

max 18.7% at the end of irradiation period (irr)

No DT₅₀ value

% refers to the applied radioactivity

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

Method of calculation

First order kinetics; integrated fit. Normalisation according to temperature (ref 20°C) and moisture content (pF2) using a Walker equation coefficient of 0.7 and Q10 of 2.58.

Field: no reliable data available

Clethodim						
Soil type	label	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ²
Sandy loam	Propyl	7.1	25°C / 75% FC	2.55/8.50	3.04	9.3
Sandy loam	Allyl	7.5	20°C / 75% FC	1.08/3.59	1.28	14.3
	Ring	7.5	20°C / 75% FC	1.18/3.92	1.40	14.5
	geometric mean				1.34	
Clay loam	Allyl	7.3	20°C / 40-50% MWC	0.23/0.76	0.17	11.8
	Ring	7.3	20°C / 40-50% MWC	0.36/1.20	0.27	113.1 [#]
	geometric mean				0.21	
Loam	Allyl	6.8	20°C / 40-50% MWC	0.38/1.26	0.28	11.8
	Ring	6.8	20°C / 40-50% MWC	0.36/1.21	0.26	108 [#]
	geometric mean				0.27	
Loamy sand	Allyl	5.7	20°C / 40-50% MWC	0.40/1.33	0.48	21.4
	Ring	5.7	20°C / 40-50% MWC	0.52/1.73	0.62	67.8 [#]

	geometric mean	0.55
Geometric mean/median		0.66/0.55

* The high chi2 values for the ring-labelled studies in the Mamouni study are due to inaccurate study design on sampling times (first sampling point after time zero was after 2 days which is a too long period for such a fast degrading substance). Nevertheless, because the results in DT₅₀ are very similar between the allyl and the ring-labelled studies, overall the results are acceptable.

pH dependence ‡
(yes / no) (if yes type of dependence)

No

Clethodim sulfoxide						
Soil type	label	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa [#]	ff
Sandy loam	Propyl	7.1	25°C / 75% FC	22.14/73.55	26.26	80.99
Sandy loam	Allyl	7.5	20°C / 75% FC	15.92/52.89	18.18	87
	Ring	7.5	20°C / 75% FC	16.42/54.55	19.47	89.3
	geometric mean DT ₅₀ , arithmetic mean ff				18.81	88.15
Clay loam	Allyl	7.3	20°C / 40-50% MWC	3.67/12.19	2.71	83.22
	Ring	7.3	20°C / 40-50% MWC	3.58/11.89	2.64	100
	geometric mean DT ₅₀ , arithmetic mean ff				2.67	91.61
Loam	Allyl	6.8	20°C / 40-50% MWC	7.82/25.98	5.66	91.76
	Ring	6.8	20°C / 40-50% MWC	5.42/18.00	3.93	91.61
	geometric mean DT ₅₀ , arithmetic mean ff				4.72	91.69
Loamy sand	Allyl	5.7	20°C / 40-50% MWC	3.7/12.29	4.42	100
	Ring	5.7	20°C / 40-50% MWC	5.04/16.74	6.01	67.89
	geometric mean DT ₅₀ , arithmetic mean ff				5.15	83.95
Geometric mean/median DT ₅₀ ; arithmetic mean ff					7.97/5.15	87.28

[#] For Chi2 values reference is made to the table of clethodim.

Clethodim sulfone						
Soil type	label	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa [#]	ff
Sandy loam	Propyl	7.1	25°C / 75% FC	22.14/73.55	35.32	27.46
Sandy loam	Allyl	7.5	20°C / 75% FC	15.92/52.89	55.92	31.8
	Ring	7.5	20°C / 75% FC	16.42/54.55	31.62	40.5
	geometric mean DT ₅₀ , arithmetic mean ff				42.05	36.15
Clay loam	Allyl	7.3	20°C / 40-50%	3.67/12.19	9.29	66.9

			MWC			
	Ring	7.3	20°C / 40-50% MWC	3.58/11.89	9.23	40.92
	geometric mean DT ₅₀ , arithmetic mean ff				9.26	53.91
Loam	Allyl	6.8	20°C / 40-50% MWC	7.82/25.98	8.52	54.99
	Ring	6.8	20°C / 40-50% MWC	5.42/18.00	10.47	50.54
	geometric mean DT ₅₀ , arithmetic mean ff				9.44	52.77
Loamy sand	Allyl	5.7	20°C / 40-50% MWC	3.7/12.29	5.49	15
	Ring	5.7	20°C / 40-50% MWC	5.04/16.74	2.89	79.78
	geometric mean DT ₅₀ , arithmetic mean ff				3.98	47.39
Geometric mean/median DT ₅₀ ; arithmetic mean ff					13.89/9.44	43.54

For Chi2 values reference is made to the table of clethodim.

Clethodim oxazole sulfone							
Soil type	label	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ²	ff
Sandy loam	§	6.4	20°C / 40-60% MWC	20/66	20	8.5	*
Loamy sand	§	5.4	20°C / 40-60% MWC	24/79	24	6.4	*
Clay	§	7.2	20°C / 40-60% MWC	68/227	68	7.3	*
Geometric mean					32		16.95#

§ cold study

* applied as test compound

based on ring label loamy sand study (pH 5.7)

Data gap identified for experimental degradation rates in soil of the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

Field studies (state location, range or median with n value)

Soil accumulation and plateau concentration

No acceptable field study. DT _{50f} : no reliable data submitted DT _{90f} : no reliable data submitted
No accumulation is expected for clethodim, clethodim sulfoxide, clethodim sulfone or clethodim oxazole sulfone. No accumulation study was conducted.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Clethodim							
Soil Type	OC %	Soil pH (CaCl ₂)	K _d (mL/g)	K _{oc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Sandy loam	2.3	5.6	-	-	0.993	43.17	1.04
Loam	1.28	7.4	-	-	0.065	5.08	0.97
Clay loam	4.13	7.5	-	-	0.112	2.71	0.98
Silt loam	2	5.4	-	-	0.794	39.7	1.05
Arithmetic mean						22.7	1.01
pH dependence, Yes or No			Yes. Although a very narrow range of soil pH was tested for clethodim, a higher adsorption was observed for the acidic soils.				

K_F

K_{oc}

K_d = (K_{oc} × % o.c)

pH dependence (yes/no) if yes, type of dependence

Clethodim sulfoxide

K_{Foc} = 24/14/2 L/kg (arithmetic mean = 13.3 L/kg)

K_F = 0.550/0.184/0.072

1/n = 0.71/0.78/1.02 (arithmetic mean = 0.83)

No effect of pH

Clethodim sulfone

K_{Foc} = 16/11/5 L/kg (arithmetic mean = 10.7 L/kg)

K_F = 0.366/0.146/0.194

1/n = 0.77/0.87/0.74 (arithmetic mean = 0.79)

No effect of pH

Clethodim oxazole sulfoxide

K_d = 26/58/130 L/kg (arithmetic mean = 71.3 L/kg)

K_d = 0.6/1.66/2.4

1/n = no data

No effect of pH

Clethodim oxazole sulfone

K_{Foc} = 12/96/43 L/kg (arithmetic mean = 50.3 L/kg)

K_F = 0.277/1.249/1.779

1/n = 1.09/1.00/1.01 (arithmetic mean = 1.03)

No effect of pH

K_{oc} and 1/n used for FOCUS PEC_{gw} modeling:

Clethodim: worst-case K_{Foc} = 4 L/kg for all the FOCUS scenarios and 1/n = 0.975 (agreed in PRAPeR 78) (geometric mean of K_{Foc} values at alkaline pH)

Arithmetic mean K_{oc} (L/kg) / 1/n

Clethodim sulfoxide: 13 / 0.83

Clethodim sulfone: 11 / 0.79

Clethodim oxazole sulfone: 51 / 1.03

Data gap identified for experimental soil adsorption values of the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

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

Column leaching

Guideline: BBA IV, 4-2
Precipitation: 200 mm
Time period: 2 d
Leachate: 30-68% of applied; parent 2.4-7.1%, clethodim sulfoxide 26-59%, clethodim sulfone 1.6-5.3%, clethodim oxazole sulfoxide, clethodim oxazole sulfone <2.4%; soil concentrations not determined.
[unlabelled clethodim]

Aged residues leaching

Guideline: BBA IV, 4-2
Precipitation: 200 mm
Time period: 2 d
Leachate: parent, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfoxide, clethodim oxazole sulfone: all <1.8%; soil concentrations not determined.
[unlabeled clethodim]

Lysimeter/ field leaching studies

No data submitted.

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation

First order kinetics with a normalized max DT_{50} of 3.04 days
Bulk density of soil : 1.5 g/cm³
Depth of the soil layer : 5 cm

Application data

Crop: sugar beet
Northern Europe:
90 g as/ha about BBCH 40 (GAP 300 with 70% foliar interception)

Southern Europe:
116.7 g as/ha at BBCH 40 (GAP 384 with 70% foliar interception)
2*57.6 g as/ha at BBCH 40 with a 14-day interval (GAP 2x192 with 70% foliar interception)

Metabolites – parameters used for PECs calculation

Clethodim sulfoxide
Molar mass = 375.9 g/mol
Laboratory -SFO- DT_{50} = 26.26 days (worst-case normalised)
Formation fraction = 100%

Clethodim sulfone
Molar mass = 391.9 g/mol
Laboratory -SFO- DT_{50} = 42.05 days
Formation fraction = 79.78% (highest of 2 replicates)

Clethodim oxazole sulfone
Molar mass = 299.4 g/mol
Laboratory -SFO- DT_{50} = 121.15 days
Formation fraction = 16.95%
The DT_{50} for clethodim oxazole sulfone has been determined in a new study and has been shown to be 68 days as opposed to 121.15 days. Revised short-term and long-term PECs have not been calculated, as the existing values are worst case. Moreover, PECmax is used for risk assessment.
PEC accumulation is not relevant.

GAP 300 NORTHERN EUROPE: 1 application of 300 g Clethodim/ha

PEC	Days	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.120	0.120
Short-term	1	0.096	0.107
	2	0.076	0.096
	4	0.048	0.079
Long-term	7	0.024	0.060
	21	0.001	0.025
	28	0.000	0.019
	50	0.000	0.011
	100	0.000	0.005

PECsoil Clethodim sulfoxide	Days after maximum	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.095	0.095
Short-term	1	0.094	0.095
	2	0.094	0.094
	4	0.091	0.093
Long-term	7	0.086	0.092
	21	0.061	0.080
	28	0.051	0.074
	50	0.029	0.058
	100	0.008	0.037

PECsoil Clethodim sulfone	Days after maximum	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.047	0.047
Short-term	1	0.047	0.047
	2	0.047	0.047
	4	0.047	0.047
Long-term	7	0.047	0.047
	21	0.044	0.046
	28	0.042	0.045
	50	0.034	0.042
	100	0.019	0.034

PEC _{soil} Clethodim oxazole sulfone	Days after maximum	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.007091	0.007091
Short-term	1	0.007091	0.007091
	2	0.007090	0.007091
	4	0.007087	0.007090
Long-term	7	0.007079	0.007087
	21	0.006984	0.007055
	28	0.006908	0.007028
	50	0.006576	0.006907
	100	0.005537	0.006491

GAP 384 SOUTHERN EUROPE: 1 application of 384 g/ha

PEC _{soil}	Days after application	Actual Concentration (mg/kg soil)	Time Weighted Average Concentration (mg/kg soil)
Initial	0	0.154	0.154
Short-term	1	0.122	0.137
	2	0.097	0.123
	4	0.062	0.101
Long-term	7	0.031	0.077
	21	0.001	0.032
	28	0.000	0.024
	50	0.000	0.014
	100	0.000	0.007

PEC _{soil} Clethodim sulfoxide	Days after max peak	Actual Concentration (mg/kg soil)	Time Weighted Average Concentration (mg/kg soil)
Initial	0	0.121	0.121
Short-term	1	0.121	0.121
	2	0.120	0.121
	4	0.117	0.120
Long-term	7	0.111	0.117
	21	0.079	0.102
	28	0.065	0.094
	50	0.037	0.075
	100	0.010	0.048

PECsoil Clethodim sulfone	Days after max peak	Actual Concentration (mg/kg soil)	Time Weighted Average Concentration (mg/kg soil)
Initial	0	0.061	0.061
Short-term	1	0.061	0.061
	2	0.061	0.061
	4	0.061	0.061
Long-term	7	0.060	0.061
	21	0.056	0.059
	28	60.054	0.058
	50	0.044	0.054
	100	0.024	0.044

PECsoil Clethodim oxazole sulfone	Days after max peak	Actual Concentration (mg/kg soil)	Time Weighted Average Concentration (mg/kg soil)
Initial	0	0.00908	0.00908
Short-term	1	0.00908	0.00908
	2	0.00908	0.00908
	4	0.00907	0.00908
Long-term	7	0.00906	0.00907
	21	0.00894	0.00903
	28	0.00884	0.00900
	50	0.00842	0.00884
	100	0.00709	0.00831

GAP 2x192 SOUTHERN EUROPE: 2 applications of 192 g Clethodim/ha at 14 d interval

PEC	Days	Actual Concentration (in mg/kg soil)	Time Weighted average (in mg/kg soil)
Initial	0	0.080	0.080
Short-term	1	0.064	0.072
	2	0.051	0.064
	4	0.032	0.053
Long-term	7	0.016	0.040
	21	0.001	0.017
	28	0.000	0.013
	50	0.000	0.007
	100	0.000	0.004

PECsoil Clethodim sulfoxide	Days after maximum	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.109	0.109
Short-term	1	0.109	0.109
	2	0.108	0.109
	4	0.105	0.108
Long-term	7	0.100	0.106
	21	0.071	0.092
	28	0.059	0.085
	50	0.033	0.067
	100	0.009	0.043

PECsoil Clethodim sulfone	Days after maximum	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.060	0.060
Short-term	1	0.060	0.060
	2	0.060	0.060
	4	0.060	0.060
Long-term	7	0.060	0.060
	21	0.056	0.059
	28	0.053	0.058
	50	0.044	0.054
	100	0.024	0.043

PECsoil Clethodim oxazole sulfone	Days after maximum	Actual Concentration (mg/kg soil)	Time Weighted average (mg/kg soil)
Initial	0	0.00906	0.00906
Short-term	1	0.00906	0.00906
	2	0.00906	0.00906
	4	0.00905	0.00906
Long-term	7	0.00904	0.00905
	21	0.00892	0.00901
	28	0.00883	0.00898
	50	0.00840	0.00882
	100	0.00708	0.00829

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

Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature)

Photolytic degradation of active substance and relevant metabolites % refers to the applied radioactivity

Readily biodegradable (yes/no)

Degradation in water/sediment

- DT₅₀ water
- DT₉₀ water

- DT₅₀ total system
- DT₉₀ total system

propyl-label pH 5: 28 d at 25 °C (1st order, r2=0.99) allyl-label pH 5: 54 d at 25 °C (1st order, r2=0.94)					
propyl-label pH 7: 300 d at 25 °C (1st order, r2=0.96) allyl-label pH 7: 499 d at 25 °C (1st order, r2=0.82)					
propyl-label pH 9: 310 d at 25 °C (1st order, r2=0.96)					
propyl-label: the major hydrolysis product oxazole RE-47365 (maximum levels recorded after 32 days: 50.5, 6.8 and 4.9% at pH 5, 7 and 9, respectively). allyl-label, the major hydrolysis product was chloroallyl alcohol (RE-46261; maximum levels recorded after 30 days were 30.7 and 4.3% at pH 5 and 7, respectively).					
Not sensitised: pH 5: DT ₅₀ = 1.49 - 1.71 (25°C) pH 7: DT ₅₀ = 4.05 - 6.84 (25°C) pH 9: DT ₅₀ = 6.0 - 9.57 (25°C) Sensitised (with acetone) pH 5: DT ₅₀ = 0.20 - 0.94 (25°C) pH 7: DT ₅₀ = 0.61 - 1.22 (25°C) pH 9: DT ₅₀ = 0.33 - 0.52 (25°C)					
DME sulfoxide: maximum 48.9% clethodim imine sulfoxide: maximum 23.0% clethodim imine: maximum 18.2% clethodim sulfoxide: maximum 14.2% imine ketone: maximum 11.8% clethodim oxazole sulfoxide: maximum 6.9% clethodim oxazole: maximum 5.5% chloroallyl alcohol: maximum 31.3% 3-chloropropenal: maximum 31.3%					
The maximum amounts of a.s. in the dark control samples at the end of the study are 88.8%, 94.5% and 85.7% at pH 5, 7 and 9.					
Yes					

Clethodim – Water Phase					
River			Pond		
Ring	Allyl	geomean	Ring	Allyl	geomean
8.9	5.5	7.0	13.2	9.2	11.0
29.4	18.3	-	44.0	30.4	-

Clethodim – Total System					
River			Pond		
Ring	Allyl	geomean	Ring	Allyl	geomean
11.1	7.38	9.0	15.0	13.6	14.3
36.8	25.9		49.9	45.2	

- DT₅₀ total system

- DT₉₀ total system

- DT₅₀ total system

- DT₉₀ total system

Mineralization (allyl-ring labels)

Non-extractable residues (allyl-ring labels)

Distribution in water / sediment systems
(active substance)

Distribution in water / sediment systems
(relevant metabolites) % AR.

Clethodim sulfoxide– Total System					
River			Pond		
Ring	Allyl	geomean	Ring	Allyl	geomean
31.3	27.4	29.3	24.5	13.3	18.1
104	91	-	83	44	-

Clethodim imine		Clethodim imine sulfoxide		Clethodim sulfone	
Total System		Total System		Total System	
River	Pond	River	Pond	River	Pond
50.0*	46.9*	41.5*	34.5*	360*	---
166*	156*	138*	156*	1196*	---

* mean from both labels

River : 32.3-34.7% of AR at d 174
Pond I : 26.8-43.7% of AR at d 174
Pond II : 18.3% of AR at d 196 (ring)

River : 22.1-24.4% at d 174
Pond I : 27.7-32.9% at d 174
Pond II : 32.5% at d 196

River : at day 0, 96.1% of AR in water, less than 2% from d 42
Pond I : at day 0, 96.5% of AR in water, less than 4% from d 56
Pond II : at day 0, 70.5% of AR in water, less than 5% from day 103

Maximum observed in sediment
River : 10.8-11.1% of AR at d 7-14 (ring-allyl)
Pond I : 8.6-12% of AR at d 2-7 (ring-allyl)
Pond II : 2.6% of AR at d 28 (ring)

Water:
Clethodim sulfoxide: max 57.8% day 14 (allyl-river)
Clethodim sulfone: max 10.4% at day 68 (allyl-pond)
Clethodim imine sulfoxide: max 7.1 % at day 33 (ring-river)
Clethodim imine: <2.1%

Sediment:
Clethodim sulfoxide: < 5.3%
Clethodim sulfone: < 3.1%
Clethodim imine: max 35.8% at day 33 (ring-pond)
Clethodim imine sulfoxide: max 15.5% at d 61 (ring-pond)

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

Method of calculation

Application rate

Main routes of entry

STEPS 1-2 in FOCUS, STEP 3 in FOCUS Only highest tier in LOEP. All tiers are presented in the addendum.
<p>Crop: sugar beet</p> <p>NORTHERN EUROPE GAP 300: 1 application of 300 g a.s./ha GAP 240: 1 application of 240 g as/ha GAP 180: 1 application of 180 g as/ha</p> <p>SOUTHERN EUROPE GAP 384: 1 application of 384 g a.s./ha GAP 2x192: 2 applications of 192 g a.s./ha at 14 d interval GAP 192: 1 application of 192 g as/ha</p> <p>GAP 300, 384 with 70% foliar interception GAP 240, 2x192, 192, 180 with 20% foliar interception</p>
Drift, drainage and run-off.
<p>Active substance Clethodim</p> <p>Molecular mass 359.92 g/mol</p> <p>Water solubility 5450 mg/L</p> <p>Mean DT₅₀ soil 0.56 days</p> <p>Koc 4 mL/g (worst case)</p> <p>Max DT₅₀ water 19.7 days (conservative)</p> <p>Max DT₅₀ total system 23 days (conservative 14.3 days could have been used)</p> <p>DT₅₀ sediment 1000 days</p>

Metabolites	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone	Clethodim imine	Clethodim imine sulfoxide
Molecular mass (g/mol)	375.9	391.9	299.4	269	285
Solubility (mg/L)	73	46.43	1468	0.6644	103.13
Max formed in total system (%)	61.5	13.5	-	36.3	21.7
Max formed in soil (%)	73	33.3	10	Not detected in soil	Not detected in soil
Mean DT ₅₀ soil (days)	7.01	12.53	&121.15	Not detected in soil	Not detected in soil
Koc (mL/g)	9	9.66	&55	240*	49.9*
Max DT ₅₀ water (days)	31.3	360	1000 default value	50	46
Max DT ₅₀ total system (days)	31.3	360	Not major in water sediment study	50	46
Max DT ₅₀ sed (days)	1000	1000	1000 default value	1000	1000

& Values very different but conservative compared to the 32 days and 71 mL/g that could have been selected.

* EPIWIN v3.11 estimation

DT₅₀ (days) used in FOCUS PEC_{sw} modeling for

the both compartments in STEP 1 and the water compartment in STEP 2 and 3 (sediment compartment default of 1000 days for STEP 2/3):
Clethodim: 23 d for STEP 1, 19.7 d for STEP 2/3 (worst-case values)
Clethodim sulfoxide: 31.3 d
Clethodim sulfone: 360 d
Clethodim imine: 50 d
Clethodim imine sulfoxide: 46 d

CLETHODIM STEP 3

Step 3 results for Clethodim with GAP300–D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.571	-	0.115	-
1	0.713	1.216	0.082	0.109
2	0.075	0.762	0.058	0.097
4	0.001	0.389	0.041	0.076
7	0.000	0.223	0.031	0.060
14	0.000	0.111	0.021	0.043
21	0.000	0.074	0.016	0.035
28	0.000	0.056	0.013	0.030
42	0.000	0.016	0.009	0.024

Step 3 results for Clethodim with GAP300–D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.064	-	0.021	-
1	0.061	0.062	0.021	0.021
2	0.060	0.061	0.021	0.021
4	0.056	0.060	0.021	0.021
7	0.051	0.057	0.021	0.021
14	0.041	0.052	0.020	0.021
21	0.033	0.047	0.018	0.021
28	0.026	0.042	0.017	0.021
42	0.017	0.035	0.014	0.020

Step 3 results for Clethodim with GAP300–D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.244	-	0.021	-
1	0.000	0.058	0.003	0.006
2	0.000	0.029	0.002	0.004
4	0.000	0.015	0.002	0.003
7	0.000	0.008	0.001	0.002
14	0.000	0.005	0.001	0.002
21	0.000	0.003	0.001	0.002
28	0.000	0.002	0.001	0.001
42	0.000	0.002	0.001	0.001

Step 3 results for Clethodim with GAP300–R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.064	-	0.022	
1	0.061	0.062	0.022	0.022
2	0.059	0.061	0.022	0.022
4	0.056	0.059	0.021	0.022
7	0.051	0.057	0.021	0.022
14	0.042	0.052	0.020	0.021
21	0.033	0.047	0.018	0.021
28	0.026	0.043	0.016	0.021
42	0.016	0.035	0.013	0.020

Step 3 results for Clethodim with GAP300–R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.091	-	0.042	-
1	0.000	0.228	0.012	0.023
2	0.000	0.114	0.009	0.017
4	0.000	0.057	0.006	0.012
7	0.000	0.032	0.005	0.009
14	0.000	0.018	0.004	0.0077
21	0.000	0.012	0.003	0.006
28	0.000	0.009	0.002	0.005
42	0.000	0.006	0.002	0.004

Step 3 results for Clethodim with GAP300 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.534	-	0.071	-
1	0.003	0.513	0.027	0.049
2	0.000	0.257	0.019	0.037
4	0.000	0.128	0.014	0.027
7	0.000	0.086	0.014	0.023
14	0.000	0.043	0.009	0.017
21	0.000	0.029	0.007	0.014
28	0.000	0.022	0.005	0.012
42	0.000	0.014	0.004	0.009

Step 3 results for Clethodim with GAP384–D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	2.011	-	0.147	-
1	0.913	1.556	0.105	0.139
2	0.096	0.975	0.074	0.123
4	0.001	0.498	0.052	0.097
7	0.000	0.285	0.040	0.076
14	0.000	0.143	0.027	0.055
21	0.000	0.095	0.021	0.045
28	0.000	0.071	0.016	0.038
42	0.000	0.047	0.011	0.030

Step 3 results for Clethodim with GAP384–D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.081	-	0.027	-
1	0.079	0.080	0.027	0.027
2	0.076	0.079	0.027	0.027
4	0.072	0.076	0.027	0.027
7	0.066	0.073	0.027	0.027
14	0.053	0.066	0.025	0.027
21	0.042	0.060	0.023	0.027
28	0.033	0.054	0.021	0.026
42	0.021	0.045	0.018	0.025

Step 3 results for Clethodim with GAP384–D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.592	-	0.026	-
1		0.074	0.004	0.008
2	0.000	0.037	0.003	0.005
4	0.000	0.018	0.002	0.004
7	0.000	0.011	0.002	0.003
14	0.000	0.006	0.001	0.002
21	0.000	0.004	0.001	0.002
28	0.000	0.003	0.001	0.002
42	0.000	0.002	0.000	0.001

Step 3 results for Clethodim with GAP384–R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.081	-	0.028	-
1	0.078	0.080	0.028	0.028
2	0.076	0.079	0.027	0.028
4	0.071	0.076	0.027	0.028
7	0.065	0.073	0.027	0.027
14	0.054	0.066	0.025	0.027
21	0.042	0.060	0.023	0.027
28	0.033	0.055	0.021	0.026
42	0.020	0.045	0.017	0.025

Step 3 results for Clethodim with GAP384–R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.396	-	0.053	-
1	0.000	0.292	0.016	0.029
2	0.000	0.146	0.011	0.022
4	0.000	0.073	0.008	0.016
7	0.000	0.042	0.006	0.012
14	0.000	0.023	0.005	0.009
21	0.000	0.016	0.004	0.008
28	0.000	0.012	0.003	0.006
42	0.000	0.008	0.002	0.005

Step 3 results for Clethodim with GAP384 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.964	-	0.091	-
1	0.003	0.656	0.035	0.063
2	0.000	0.329	0.025	0.047
4	0.000	0.164	0.018	0.034
7	0.000	0.110	0.018	0.029
14	0.000	0.055	0.011	0.022
21	0.000	0.037	0.008	0.018
28	0.000	0.028	0.007	0.015
42	0.000	0.018	0.005	0.012

Step 3 results for Clethodim with GAP2x192 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.874	-	0.081	-
1	0.504	0.717	0.064	0.079
2	0.097	0.491	0.049	0.072
4	0.002	0.258	0.037	0.060
7	0.000	0.148	0.029	0.050
14	0.000	0.074	0.021	0.038
21	0.000	0.090	0.016	0.031
28	0.000	0.068	0.013	0.030
42	0.000	0.045	0.009	0.026

Step 3 results for Clethodim with GAP2x192 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.055	-	0.021	-
1	0.053	0.054	0.021	0.021
2	0.051	0.053	0.021	0.021
4	0.048	0.051	0.021	0.021
7	0.043	0.049	0.021	0.021
14	0.034	0.043	0.020	0.021
21	0.027	0.039	0.018	0.021
28	0.022	0.036	0.017	0.021
42	0.014	0.033	0.014	0.020

Step 3 results for Clethodim with GAP2x192 –D4 stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.702	-	0.014	-
1	0.000	0.039	0.003	0.005
2	0.000	0.020	0.002	0.003
4	0.000	0.010	0.002	0.003
7	0.002	0.006	0.001	0.002
14	0.000	0.003	0.001	0.002
21	0.000	0.004	0.001	0.001
28	0.000	0.003	0.001	0.001
42	0.000	0.002	0.000	0.001

Step 3 results for Clethodim with GAP2x192 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.050	-	0.021	-
1	0.048	0.049	0.021	0.021
2	0.047	0.048	0.020	0.021
4	0.043	0.047	0.020	0.021
7	0.039	0.044	0.020	0.020
14	0.030	0.039	0.019	0.020
21	0.023	0.035	0.017	0.020
28	0.018	0.031	0.015	0.020
42	0.011	0.030	0.012	0.019

Step 3 results for Clethodim with GAP2x192 –R1 stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.601	-	0.025	-
1	0.000	0.129	0.009	0.015
2	0.000	0.065	0.007	0.011
4	0.000	0.032	0.005	0.009
7	0.000	0.019	0.004	0.007
14	0.000	0.010	0.003	0.005
21	0.000	0.007	0.002	0.004
28	0.000	0.010	0.002	0.004
42	0.000	0.006	0.001	0.004

Step 3 results for Clethodim with GAP2x192 –R3 stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.846	-	0.043	-
1	0.002	0.297	0.018	0.031
2	0.000	0.149	0.014	0.024
4	0.000	0.075	0.011	0.018
7	0.000	0.049	0.011	0.016
14	0.000	0.024	0.007	0.012
21	0.000	0.016	0.006	0.010
28	0.000	0.023	0.004	0.009
42	0.000	0.015	0.003	0.009

STEP 4 CLETHODIM

Step 4 results for Clethodim with GAP 300

Scenario	Relevant water body for sugar beet	PEC max Step3 (µg/L)	Buffer distance between crop and water body (m)	PEC max Step4 (µg/L)	PEC21 Step4 (µg/L)
D3 (Vreedepeel)	Ditch	1.571	n.a.	n.a.	n.a.
D4 (Skousbo)	Pond	0.064	3.8	0.064	0.047
D4 Skousbo)	Stream	1.224	30	0.082	0.001
R1 Weiherbach)	Pond	0.064	3.8	0.064	0.047
R1 Weiherbach)	Stream	1.091	30	0.072	0.002
R3 (Bologna)	Stream	1.534	25	0.157	0.006

Step 4 results for Clethodim with GAP 384

Scenario	Relevant water body for sugar beet	PEC max Step3 (µg/L)	Buffer distance between crop and water body (m)	PEC max Step4 (µg/L)	PEC21 Step4 (µg/L)
D3 (Vreedepeel)	Ditch	2.011	n.a.	n.a.	n.a.
D4 (Skousbo)	Pond	0.081	3.8	0.081	0.060
D4 (Skousbo)	Stream	1.592	n.a.	n.a.	n.a.
R1 Weiherbach)	Pond	0.081	3.8	0.080	0.060
R1 Weiherbach)	Stream	1.396	n.a.	n.a.	n.a.
R3 (Bologna)	Stream	1.964	n.a.	n.a.	n.a.

Step 4 results for Clethodim with GAP 2x192

Scenario	Relevant water body for sugar beet	PEC max Step3 (µg/L)	Buffer distance between crop and water body (m)	PEC max Step4 (µg/L)	PEC21 Step4 (µg/L)
D3 (Vreedepeel)	Ditch	0.874	18	0.081	0.004
D4 (Skousbo)	Pond	0.055	3.8	0.055	0.035
D4 (Skousbo)	Stream	0.702	16	0.079	0.001
R1 (Weiherbach)	Pond	0.050	3.8	0.050	0.033
R1 (Weiherbach)	Stream	0.601	14	0.077	0.002
R3 (Bologna)	Stream	0.846	16	0.100	0.003

STEP 3 METABOLITES

CLETHODIM SULFOXIDE – STEP3 results

Step 3 results for Clethodim sulfoxide with GAP300 – D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0002	-	0.0004	
1	0.0002	0.0002	0.0004	0.0004
2	0.0002	0.0002	0.0004	0.0004
4	0.0002	0.0002	0.0004	0.0004
7	0.0002	0.0002	0.0004	0.0004
14	0.0002	0.0002	0.0004	0.0004
21	0.0002	0.0002	*	0.0004
28	0.0002	0.0002	*	0.0004
42	0.0002	0.0002	*	0.0004

Step 3 results for Clethodim sulfoxide with GAP300 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.004	-	0.005	-
1	0.004	0.004	0.005	0.005
2	0.004	0.004	0.005	0.005
4	0.004	0.004	0.005	0.005
7	0.004	0.004	0.005	0.005
14	0.004	0.004	0.005	0.005
21	0.003	0.004	0.005	0.005
28	0.003	0.004	0.005	0.005
42	0.002	0.003	0.005	0.005

Step 3 results for Clethodim sulfoxide with GAP300 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0209	-	0.0085	-
1	0.0199	0.0207	0.0084	0.0084
2	0.0177	0.0203	0.0080	0.0084
4	0.0119	0.0188	0.0075	0.0083
7	0.0057	0.0160	0.0069	0.0080
14	0.0029	0.0107	0.0060	0.0075
21	0.0021	0.0081	0.0054	0.0070
28	0.0021	0.0066	0.0051	0.0066
42	0.0024	0.0052	0.0050	0.0061

Step 3 results for Clethodim sulfoxide with GAP300 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.618	-	0.278	-
1	0.603	0.611	0.278	0.278
2	0.589	0.604	0.278	0.278
4	0.562	0.590	0.277	0.278
7	0.525	0.571	0.274	0.278
14	0.442	0.528	0.264	0.277
21	0.370	0.488	0.251	0.275
28	0.310	0.451	0.235	0.272
42	0.217	0.389	0.204	0.265

Step 3 results for Clethodim sulfoxide with GAP300 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	8.3170	-	0.8410	-
1	0.1450	6.6710	0.3870	0.6690
2	0.0021	3.3540	0.2890	0.5330
4	0.0006	1.6770	0.2110	0.4020
7	0.0002	0.9590	0.1630	0.3130
14	0.0001	0.4790	0.1150	0.2270
21	0.0001	0.3200	0.0915	0.1860
28	0.0000	0.2400	0.0755	0.1610
42	0.0000	0.1600	0.0545	0.1290

Step 3 results for Clethodim sulfoxide with GAP300 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	8.696	-	0.638	-
1	0.015	4.953	0.294	0.515
2	0.002	2.492	0.216	0.402
4	0.749	1.247	0.213	0.299
7	0.000	0.768	0.134	0.243
14	0.000	0.384	0.093	0.178
21	0.000	0.256	0.073	0.146
28	0.000	0.192	0.060	0.127
42	0.000	0.128	0.044	0.102

Step 3 results for Clethodim sulfoxide with GAP384 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0003		0.0005	
1	0.0003	0.0003	0.0005	0.0005
2	0.0003	0.0003	0.0005	0.0005
4	0.0003	0.0003	0.0005	0.0005
7	0.0003	0.0003	0.0005	0.0005
14	0.0003	0.0003	0.0005	0.0005
21	0.0003	0.0003	*	0.0005
28	0.0003	0.0003	*	0.0005
42	0.0003	0.0003	*	0.0005

Step 3 results for Clethodim sulfoxide with GAP384 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.019	-	0.014	-
1	0.018	0.019	0.014	0.014
2	0.018	0.018	0.014	0.014
4	0.017	0.018	0.014	0.014
7	0.016	0.017	0.014	0.014
14	0.017	0.017	0.014	0.014
21	0.015	0.017	0.014	0.014
28	0.013	0.016	0.013	0.014
42	0.010	0.014	0.012	0.014

Step 3 results for Clethodim sulfoxide with GAP384 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0275	-	0.0110	-
1	0.0262	0.0272	0.0108	0.0109
2	0.0233	0.0267	0.0104	0.0109
4	0.0156	0.0247	0.0097	0.0108
7	0.0075	0.0210	0.0089	0.0104
14	0.0039	0.0141	0.0078	0.0096
21	0.0027	0.0106	0.0070	0.0090
28	0.0027	0.0087	0.0066	0.0085
42	0.0031	0.0069	0.0064	0.0079

Step 3 results for Clethodim sulfoxide with GAP384 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.791	-	0.353	-
1	0.772	0.781	0.353	0.353
2	0.753	0.772	0.353	0.353
4	0.719	0.755	0.351	0.353
7	0.672	0.730	0.348	0.353
14	0.566	0.676	0.335	0.351
21	0.474	0.624	0.318	0.349
28	0.397	0.578	0.298	0.346
42	0.277	0.498	0.258	0.337

Step 3 results for Clethodim sulfoxide with GAP384 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	10.643	-	1.069	-
1	0.186	8.537	0.492	0.850
2	0.003	4.292	0.367	0.677
4	0.001	2.147	0.268	0.511
7	0.000	1.227	0.207	0.398
14	0.000	0.614	0.146	0.288
21	0.000	0.409	0.116	0.236
28	0.000	0.307	0.096	0.204
42	0.000	0.205	0.069	0.163

Step 3 results for Clethodim sulfoxide with GAP384 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	11.105		0.810	-
1	0.020	6.325	0.373	0.653
2	0.003	3.183	0.274	0.510
4	0.950	1.592	0.270	0.380
7	0.001	0.980	0.170	0.309
14	0.000	0.490	0.117	0.226
21	0.000	0.327	0.092	0.186
28	0.000	0.245	0.076	0.160
42	0.000	0.163	0.055	0.129

Step 3 results for Clethodim sulfoxide with GAP2x192 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0005		0.0009	
1	0.0005	0.0005	0.0009	0.0009
2	0.0005	0.0005	0.0009	0.0009
4	0.0005	0.0005	0.0009	0.0009
7	0.0005	0.0005	0.0009	0.0009
14	0.0005	0.0005	*	0.0009
21	0.0005	0.0005	*	0.0009
28	0.0005	0.0005	*	0.0009
42	0.0005	0.0005	*	0.0009

Step 3 results for Clethodim sulfoxide with GAP2x192 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.013	-	0.010	-
1	0.013	0.013	0.010	0.010
2	0.012	0.013	0.010	0.010
4	0.012	0.012	0.010	0.010
7	0.011	0.012	0.010	0.010
14	0.010	0.011	0.010	0.010
21	0.009	0.011	0.010	0.010
28	0.007	0.010	0.010	0.010
42	0.006	0.009	0.009	0.010

Step 3 results for Clethodim sulfoxide with GAP2x192 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.013	-	0.007	-
1	0.013	0.013	0.007	0.007
2	0.012	0.013	0.007	0.007
4	0.008	0.012	0.006	0.007
7	0.005	0.011	0.006	0.007
14	0.003	0.007	0.006	0.006
21	0.002	0.006	0.005	0.006
28	0.002	0.005	0.005	0.006
42	0.003	0.004	0.005	0.006

Step 3 results for Clethodim sulfoxide with GAP2x192 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.428	-	0.233	-
1	0.418	0.423	0.233	0.233
2	0.408	0.418	0.233	0.233
4	0.390	0.409	0.232	0.233
7	0.364	0.395	0.230	0.233
14	0.354	0.367	0.221	0.232
21	0.296	0.353	0.210	0.230
28	0.289	0.341	0.197	0.227
42	0.203	0.309	0.171	0.221

Step 3 results for Clethodim sulfoxide with GAP2x192 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	5.3240	-	0.5450	-
1	0.0932	2.1470	0.2510	0.4330
2	0.0014	1.0740	0.1870	0.3460
4	0.0004	0.6140	0.1370	0.2610
7	0.0002	0.3070	0.1060	0.2030
14	0.0001	0.2050	0.0751	0.1470
21	0.0000	0.2560	0.0597	0.1240
28	0.0002	0.1710	0.1290	0.1330
42	0.0000	2.1470	0.0776	0.1220

Step 3 results for Clethodim sulfoxide with GAP2x192 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	5.5840	-	0.4150	-
1	0.0100	3.1810	0.1910	0.3350
2	0.0015	1.6010	0.1410	0.2610
4	0.4870	0.8010	0.1390	0.1950
7	0.0003	0.4940	0.0875	0.1590
14	0.0001	0.2470	0.0605	0.1160
21	0.0001	0.1650	0.0479	0.0956
28	0.0000	0.1240	0.0396	0.0827
42	0.0000	0.0825	0.0287	0.0665

CLETHODIM SULFONE – STEP3 results

Step 3 results for Clethodim sulfone with GAP300 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.004	-	0.008	-
1	0.004	0.004	0.008	0.008
2	0.004	0.004	0.008	0.008
4	0.004	0.004	0.008	0.008
7	0.004	0.004	0.008	0.008
14	0.004	0.004	*	0.008
21	0.004	0.004	*	0.008
28	0.004	0.004	*	0.008
42	0.004	0.004	*	0.008

Step 3 results for Clethodim sulfone with GAP300 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.029	-	0.044	-
1	0.029	0.029	0.044	0.044
2	0.029	0.029	0.044	0.044
4	0.029	0.029	0.044	0.044
7	0.029	0.029	0.044	0.044
14	0.028	0.029	0.044	0.044
21	0.027	0.029	0.044	0.044
28	0.027	0.028	0.044	0.044
42	0.025	0.028	0.043	0.044

Step 3 results for Clethodim sulfone with GAP300 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.023	-	0.021	-
1	0.022	0.022	0.021	0.021
2	0.021	0.022	0.021	0.021
4	0.020	0.021	0.021	0.021
7	0.018	0.020	0.020	0.021
14	0.014	0.019	0.020	0.021
21	0.011	0.019	0.020	0.021
28	0.010	0.018	0.020	0.021
42	0.017	0.018	0.019	0.020

Step 3 results for Clethodim sulfone with GAP300 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.118	-	0.085	-
1	0.117	0.117	0.085	0.085
2	0.116	0.117	0.085	0.085
4	0.113	0.116	0.085	0.085
7	0.111	0.114	0.085	0.085
14	0.104	0.111	0.084	0.085
21	0.098	0.107	0.083	0.085
28	0.092	0.104	0.081	0.085
42	0.082	0.099	0.078	0.084

Step 3 results for Clethodim sulfone with GAP300 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.572	-	0.170	-
1	0.028	1.261	0.079	0.135
2	0.000	0.634	0.060	0.108
4	0.000	0.317	0.043	0.082
7	0.000	0.181	0.033	0.064
14	0.000	0.091	0.024	0.046
21	0.000	0.060	0.019	0.038
28	0.000	0.045	0.016	0.033
42	0.000	0.030	0.012	0.027

Step 3 results for Clethodim sulfone with GAP300 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.108		0.088	-
1	0.002	0.632	0.041	0.071
2	0.000	0.318	0.030	0.056
4	0.219	0.159	0.040	0.041
7	0.000	0.107	0.021	0.036
14	0.000	0.054	0.014	0.027
21	0.000	0.036	0.012	0.022
28	0.000	0.027	0.010	0.019
42	0.000	0.018	0.007	0.016

Step 3 results for Clethodim sulfone with GAP384–D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.006		0.010	
1	0.006	0.006	0.010	0.010
2	0.006	0.006	0.010	0.010
4	0.006	0.006	0.010	0.010
7	0.006	0.006	0.010	0.010
14	0.006	0.006	*	0.010
21	0.006	0.006	*	0.010
28	0.006	0.006	*	0.010
42	0.006	0.006	*	0.010

Step 3 results for Clethodim sulfone with GAP384–D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.038	-	0.057	-
1	0.038	0.038	0.057	0.057
2	0.037	0.038	0.057	0.057
4	0.037	0.038	0.057	0.057
7	0.037	0.037	0.057	0.057
14	0.036	0.037	0.057	0.057
21	0.035	0.037	0.056	0.057
28	0.035	0.037	0.056	0.057
42	0.033	0.037	0.055	0.057

Step 3 results for Clethodim sulfone with GAP384–D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.029	-	0.027	-
1	0.028	0.029	0.027	0.027
2	0.028	0.029	0.027	0.027
4	0.026	0.028	0.027	0.027
7	0.023	0.026	0.026	0.027
14	0.018	0.025	0.025	0.027
21	0.014	0.024	0.026	0.027
28	0.013	0.024	0.026	0.026
42	0.023	0.023	0.024	0.026

Step 3 results for Clethodim sulfone with GAP384–R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.151	-	0.108	-
1	0.149	0.150	0.108	0.108
2	0.148	0.149	0.108	0.108
4	0.145	0.148	0.107	0.108
7	0.141	0.146	0.107	0.108
14	0.133	0.142	0.106	0.107
21	0.125	0.138	0.105	0.107
28	0.118	0.134	0.103	0.107
42	0.104	0.126	0.099	0.106

Step 3 results for Clethodim sulfone with GAP384–R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	2.012	-	0.216	-
1	0.036	1.615	0.100	0.172
2	0.000	0.812	0.075	0.137
4	0.000	0.406	0.055	0.104
7	0.000	0.232	0.042	0.081
14	0.000	0.116	0.030	0.059
21	0.000	0.077	0.024	0.048
28	0.000	0.058	0.020	0.042
42	0.000	0.039	0.015	0.034

Step 3 results for Clethodim sulfone with GAP384–R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.414		0.111	-
1	0.003	0.806	0.052	0.090
2	0.000	0.406	0.038	0.070
4	0.277	0.203	0.050	0.052
7	0.000	0.136	0.027	0.045
14	0.000	0.068	0.018	0.038
21	0.000	0.046	0.015	0.028
28	0.000	0.034	0.012	0.024
42	0.000	0.023	0.009	0.020

Step 3 results for Clethodim sulfone with GAP2x192 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.008	-	0.013	-
1	0.008	0.008	*	0.013
2	0.008	0.008	*	0.013
4	0.008	0.008	*	0.013
7	0.008	0.008	*	0.013
14	0.008	0.008	*	0.013
21	0.008	0.008	*	0.013
28	0.008	0.008	*	0.013
42	0.008	0.008	*	0.013

Step 3 results for Clethodim sulfone in with GAP2x192 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.040	-	0.058	-
1	0.040	0.040	0.058	0.058
2	0.040	0.040	0.058	0.058
4	0.040	0.040	0.058	0.058
7	0.040	0.040	0.058	0.058
14	0.039	0.040	0.057	0.058
21	0.038	0.040	0.057	0.058
28	0.037	0.039	0.057	0.058
42	0.035	0.039	0.056	0.057

Step 3 results for Clethodim sulfone with GAP2x192 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.026	-	0.024	-
1	0.025	0.025	0.024	0.024
2	0.024	0.025	0.024	0.024
4	0.023	0.024	0.024	0.024
7	0.021	0.023	0.024	0.024
14	0.017	0.022	0.023	0.024
21	0.014	0.022	0.024	0.024
28	0.013	0.021	0.024	0.024
42	0.020	0.020	0.023	0.024

Step 3 results for Clethodim sulfone with GAP2x192 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.084	-	0.073	-
1	0.083	0.084	0.073	0.073
2	0.082	0.083	0.073	0.073
4	0.081	0.083	0.073	0.073
7	0.079	0.082	0.073	0.073
14	0.074	0.079	0.072	0.073
21	0.070	0.077	0.071	0.073
28	0.080	0.077	0.070	0.073
42	0.073	0.077	0.067	0.072

Step 3 results for Clethodim sulfone with GAP2x192 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	1.677	-	0.155	-
1	0.001	0.934	0.069	0.117
2	0.000	0.467	0.054	0.093
4	0.000	0.234	0.042	0.072
7	0.000	0.134	0.034	0.058
14	0.000	0.067	0.026	0.044
21	0.000	0.046	0.023	0.038
28	0.000	0.062	0.019	0.033
42	0.000	0.043	0.014	0.031

Step 3 results for Clethodim sulfone with GAP2x192 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.714	-	0.057	-
1	0.001	0.407	0.027	0.046
2	0.000	0.205	0.020	0.036
4	0.143	0.103	0.026	0.027
7	0.000	0.069	0.014	0.024
14	0.000	0.035	0.010	0.018
21	0.000	0.023	0.008	0.015
28	0.000	0.017	0.006	0.013
42	0.000	0.012	0.005	0.010

CLETHODIM OXAZOLE SULFONE – STEP3 results

Step 3 results for Clethodim oxazole sulfone with GAP300 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0416		0.206	-
1	0.0416	0.0416	*	0.206
2	0.0416	0.0416	*	0.205
4	0.0416	0.0416	*	0.205
7	0.0416	0.0416	*	0.205
14	0.0415	0.0416	*	0.205
21	0.0414	0.0416	*	0.205
28	0.0415	0.0416	*	0.204
42	0.0416	0.0415	*	0.204

Step 3 results for Clethodim oxazole sulfone with GAP300 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.193	-	0.623	-
1	0.193	0.193	*	0.623
2	0.193	0.193	*	0.623
4	0.192	0.193	*	0.623
7	0.191	0.193	*	0.623
14	0.186	0.192	*	0.622
21	0.181	0.191	*	0.622
28	0.176	0.189	*	0.621
42	0.167	0.186	*	0.618

Step 3 results for Clethodim oxazole sulfone with GAP300 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.124	-	0.228	-
1	0.108	0.114	0.227	0.228
2	0.104	0.111	0.227	0.228
4	0.100	0.106	0.225	0.227
7	0.102	0.104	0.223	0.227
14	0.0977	0.103	0.214	0.225
21	0.0757	0.100	0.206	0.223
28	0.0534	0.0950	0.199	0.220
42	0.0737	0.0801	0.188	0.214

Step 3 results for Clethodim oxazole sulfone with GAP300 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0421	-	0.0746	-
1	0.0415	0.0418	0.0746	0.0746
2	0.0411	0.0416	0.0746	0.0746
4	0.0402	0.0411	0.0746	0.0746
7	0.0391	0.0405	0.0746	0.0746
14	0.0369	0.0393	0.0744	0.0746
21	0.0348	0.0381	0.0741	0.0746
28	0.0331	0.0371	0.0737	0.0745
42	0.0297	0.0352	0.0728	0.0744

Step 3 results for Clethodim oxazole sulfone with GAP300 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.5750	-	0.1290	-
1	0.0115	0.4610	0.0664	0.1070
2	0.0003	0.2320	0.0511	0.0870
4	0.0001	0.1160	0.0390	0.0676
7	0.0000	0.0664	0.0310	0.0542
14	0.0000	0.0332	0.0229	0.0407
21	0.0000	0.0221	0.0191	0.0342
28	0.0000	0.0172	0.0178	0.0305
42	0.0000	0.0115	0.0147	0.0257

Step 3 results for Clethodim oxazole sulfone with GAP300 –R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.6800	-	0.1070	-
1	0.0021	0.3880	0.0517	0.0871
2	0.0004	0.1960	0.0382	0.0689
4	0.2090	0.0980	0.0610	0.0520
7	0.0001	0.0714	0.0307	0.0478
14	0.0000	0.0358	0.0209	0.0366
21	0.0000	0.0238	0.0170	0.0308
28	0.0000	0.0183	0.0157	0.0272
42	0.0000	0.0122	0.0125	0.0229

Step 3 results for Clethodim oxazole sulfone with GAP384–D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0416	-	0.206	
1	0.0416	0.0416	*	0.206
2	0.0416	0.0416	*	0.205
4	0.0416	0.0416	*	0.205
7	0.0416	0.0416	*	0.205
14	0.0415	0.0416	*	0.205
21	0.0414	0.0416	*	0.205
28	0.0415	0.0416	*	0.204
42	0.0416	0.0415	*	0.204

Step 3 results for Clethodim oxazole sulfone with GAP384–D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.193	-	0.623	-
1	0.193	0.193	*	0.623
2	0.193	0.193	*	0.623
4	0.192	0.193	*	0.623
7	0.191	0.193	*	0.623
14	0.186	0.192	*	0.622
21	0.181	0.191	*	0.622
28	0.176	0.189	*	0.621
42	0.167	0.186	*	0.618

Step 3 results for Clethodim oxazole sulfone with GAP384–D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.124	-	0.228	-
1	0.108	0.114	0.227	0.228
2	0.104	0.111	0.227	0.228
4	0.100	0.106	0.225	0.227
7	0.102	0.104	0.223	0.227
14	0.098	0.103	0.214	0.225
21	0.076	0.100	0.206	0.223
28	0.053	0.095	0.199	0.220
42	0.074	0.080	0.188	0.214

Step 3 results for Clethodim oxazole sulfone with GAP384–R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0421	-	0.0746	-
1	0.0415	0.0418	0.0746	0.0746
2	0.0411	0.0416	0.0746	0.0746
4	0.0402	0.0411	0.0746	0.0746
7	0.0391	0.0405	0.0746	0.0746
14	0.0369	0.0393	0.0744	0.0746
21	0.0348	0.0381	0.0741	0.0746
28	0.0331	0.0371	0.0737	0.0745
42	0.0297	0.0352	0.0728	0.0744

Step 3 results for Clethodim oxazole sulfone with GAP384–R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.5750	-	0.1290	-
1	0.0115	0.4610	0.0664	0.1070
2	0.0003	0.2320	0.0511	0.0870
4	0.0001	0.1160	0.0390	0.0676
7	0.0000	0.0664	0.0310	0.0542
14	0.0000	0.0332	0.0229	0.0407
21	0.0000	0.0221	0.0191	0.0342
28	0.0000	0.0172	0.0178	0.0305
42	0.0000	0.0115	0.0147	0.0257

Step 3 results for Clethodim oxazole sulfone with GAP384–R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.6800	-	0.1070	-
1	0.0021	0.3880	0.0517	0.0871
2	0.0004	0.1960	0.0382	0.0689
4	0.2090	0.0980	0.0610	0.0520
7	0.0001	0.0714	0.0307	0.0478
14	0.0000	0.0358	0.0209	0.0366
21	0.0000	0.0238	0.0170	0.0308
28	0.0000	0.0183	0.0157	0.0272
42	0.0000	0.0122	0.0125	0.0229

Step 3 results for Clethodim oxazole sulfone with GAP2x192 –D3 ditch

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0568	-	0.270	-
1	0.0567	0.0567	*	0.269
2	0.0567	0.0567	*	0.269
4	0.0567	0.0567	*	0.269
7	0.0565	0.0567	*	0.269
14	0.0562	0.0567	*	0.269
21	0.0560	0.0566	*	0.268
28	0.0561	0.0566	*	0.268
42	*	0.0565	*	0.266

Step 3 results for Clethodim oxazole sulfone with GAP2x192 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.263	-	0.846	-
1	0.263	0.263	*	0.846
2	0.262	0.263	*	0.846
4	0.261	0.263	*	0.846
7	0.260	0.262	*	0.846
14	0.254	0.261	*	0.845
21	0.247	0.259	*	0.844
28	0.240	0.257	*	0.843
42	0.228	0.253	*	0.840

Step 3 results for Clethodim oxazole sulfone with GAP2x192 –D4 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.164	-	0.311	-
1	0.144	0.152	0.311	0.311
2	0.139	0.147	0.310	0.311
4	0.134	0.141	0.308	0.311
7	0.135	0.138	0.305	0.310
14	0.129	0.137	0.294	0.308
21	0.102	0.133	0.285	0.305
28	0.0745	0.126	0.277	0.302
42	0.100	0.108	0.263	0.295

Step 3 results for Clethodim oxazole sulfone with GAP2x192 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0267	-	0.0597	-
1	0.0263	0.0265	0.0597	0.0597
2	0.0260	0.0263	0.0597	0.0597
4	0.0255	0.0260	0.0596	0.0597
7	0.0248	0.0256	0.0596	0.0597
14	0.0233	0.0248	0.0595	0.0596
21	0.0220	0.0241	0.0593	0.0596
28	0.0246	0.0242	0.0590	0.0596
42	0.0246	0.0240	0.0577	0.0595

Step 3 results for Clethodim oxazole sulfone with GAP2x192 –R1 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.438	-	0.0876	-
1	0.0003	0.292	0.0446	0.0692
2	0.0001	0.147	0.0359	0.0564
4	0.0000	0.0736	0.0290	0.0450
7	0.0000	0.0421	0.0245	0.0374
14	0.0000	0.0210	0.0196	0.0297
21	0.0000	0.0146	0.0216	0.0276
28	0.0000	0.0193	0.0181	0.0256
42	0.0000	0.0143	0.0149	0.0244

Step 3 results for Clethodim oxazole sulfone with GAP2x192–R3 Stream

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.4350	-	0.0705	-
1	0.0014	0.2480	0.0347	0.0578
2	0.0003	0.1250	0.0258	0.0459
4	0.1370	0.0627	0.0410	0.0348
7	0.0001	0.0459	0.0208	0.0321
14	0.0000	0.0234	0.0143	0.0248
21	0.0000	0.0161	0.0116	0.0208
28	0.0000	0.0121	0.0108	0.0185
42	0.0000	0.0083	0.0086	0.0156

CLETHODIM IMINE – STEP3 results

Step 3 results for Clethodim imine with GAP300 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0001	-	0.0003	-
1	0.0001	0.0001	0.0003	0.0003
2	0.0001	0.0001	0.0003	0.0003
4	0.0001	0.0001	0.0003	0.0003
7	0.0001	0.0001	0.0003	0.0003
14	0.0001	0.0001	0.0003	0.0003
21	0.0001	0.0001	0.0003	0.0003
28	0.0001	0.0001	0.0003	0.0003
42	0.0001	0.0001	0.0003	0.0003

Step 3 results for Clethodim imine with GAP300 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.285	-	0.628	-
1	0.277	0.281	0.628	0.628
2	0.270	0.277	0.627	0.628
4	0.258	0.271	0.627	0.628
7	0.243	0.262	0.625	0.627
14	0.211	0.245	0.617	0.627
21	0.184	0.229	0.607	0.625
28	0.166	0.216	0.599	0.623
42	0.135	0.194	0.579	0.618

Step 3 results for Clethodim imine with GAP384–D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0001	-	0.0004	-
1	0.0001	0.0001	0.0004	0.0004
2	0.0001	0.0001	0.0004	0.0004
4	0.0001	0.0001	0.0004	0.0004
7	0.0001	0.0001	0.0004	0.0004
14	0.0001	0.0001	0.0004	0.0004
21	0.0001	0.0001	0.0004	0.0004
28	0.0001	0.0001	0.0004	0.0004
42	0.0001	0.0001	0.0004	0.0004

Step 3 results for Clethodim imine with GAP384–R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.369	-	0.801	-
1	0.358	0.363	0.801	0.801
2	0.349	0.359	0.801	0.801
4	0.334	0.350	0.800	0.801
7	0.315	0.340	0.797	0.801
14	0.274	0.317	0.788	0.800
21	0.238	0.297	0.775	0.798
28	0.215	0.280	0.764	0.795
42	0.174	0.251	0.738	0.789

Step 3 results for Clethodim imine with GAP2x192 –D4 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0001	-	0.0004	-
1	0.0001	0.0001	0.0004	0.0004
2	0.0001	0.0001	0.0004	0.0004
4	0.0001	0.0001	0.0004	0.0004
7	0.0001	0.0001	0.0004	0.0004
14	0.0001	0.0001	0.0004	0.0004
21	0.0001	0.0001	0.0004	0.0004
28	0.0001	0.0001	0.0004	0.0004
42	0.0001	0.0001	*	0.0004

Step 3 results for Clethodim imine with GAP2x192 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.179	-	0.521	-
1	0.174	0.176	0.521	0.521
2	0.169	0.174	0.520	0.521
4	0.162	0.170	0.520	0.521
7	0.152	0.164	0.519	0.520
14	0.132	0.154	0.514	0.520
21	0.115	0.144	0.508	0.519
28	0.126	0.140	0.502	0.517
42	0.134	0.132	0.487	0.515

CLETHODIM IMINE SULFOXIDE - STEP3 results

Step 3 results for Clethodim imine sulfoxide with GAP300 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0001	-	0.0001	-
1	0.0001	0.0001	0.0001	0.0001
2	0.0001	0.0001	0.0001	0.0001
4	0.0001	0.0001	0.0001	0.0001
7	0.0001	0.0001	0.0001	0.0001
14	0.0001	0.0001	0.0001	0.0001
21	0.0001	0.0001	0.0001	0.0001
28	0.0001	0.0001	0.0001	0.0001
42	0.0001	0.0001	0.0001	0.0001

Step 3 results for Clethodim imine sulfoxide with GAP384–R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0001	-	0.0001	-
1	0.0001	0.0001	0.0001	0.0001
2	0.0001	0.0001	0.0001	0.0001
4	0.0001	0.0001	0.0001	0.0001
7	0.0001	0.0001	0.0001	0.0001
14	0.0001	0.0001	0.0001	0.0001
21	0.0001	0.0001	0.0001	0.0001
28	0.0001	0.0001	0.0001	0.0001
42	0.0001	0.0001	0.0001	0.0001

Step 3 results for Clethodim imine sulfoxide with GAP2x192 –R1 Pond

Time after max. peak (d)	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
Global max	0.0001		0.0001	
1	0.0001	0.0001	0.0001	0.0001
2	0.0001	0.0001	0.0001	0.0001
4	0.0001	0.0001	0.0001	0.0001
7	0.0001	0.0001	0.0001	0.0001
14	0.0001	0.0001	0.0001	0.0001
21	0.0001	0.0001	0.0001	0.0001
28	0.0001	0.0001	0.0001	0.0001
42	0.0001	0.0001	0.0001	0.0001

PEC (sediment)

See tables above point 1.5.8

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)

Modelling by FOCUS PEARL 3.3.3 and FOCUS PELMO 3.3.2, calculations, locations: Châteaudun, Hamburg; Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, and Thiva.

For FOCUS PEC_{gw} modelling

Geometric mean DT_{50lab} (20°C, aerobic, moisture corrected):

clethodim: 0.56 d (the correct values to use would be 0.66 d)

clethodim sulfoxide: 7.01 d and mean ff 87.45%

(the correct values to use would be 13.89 d and mean ff 43.54)

clethodim sulfone: 7.97 d and mean ff 87.28% (the correct values to use would be 13.89 d and mean ff 43.54)

clethodim oxazole sulfone: 32 d and mean ff 16.95%

Koc and 1/n used for FOCUS PEC_{gw} modeling:

Arithmetic mean Koc (L/kg) / 1/n

Clethodim: 4 (conservative value agreed in PRAPeR 78) / 0.975

Clethodim sulfoxide: 13 / 0.83

Clethodim sulfone: 11 / 0.79

Clethodim oxazole sulfone: 51 / 1.03

Plant uptake factor: 0.5 (for metabolites a plant uptake factor of 0 should have been used; however, it is expected not to have substantial impact on the groundwater modelling results).

Application rate

Crop: sugar beet

192 g as/ha about BBCH 11-39 (GAP 240 with 20% foliar interception)

115.2 g as/ha at BBCH 31-39 (GAP 384 with 70% foliar interception)

2 x 153.6 g as/ha at BBCH 12-39 with a 21-day interval
(GAP 2x192 with 20% foliar interception)

Data gap identified in PRAPeR 78 for a groundwater assessment for the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

PEC_(gw)

Maximum concentration

FOCUS PELMO 3.3.2
80th percentile annual average:
Clethodim: 0.000 µg/L
Clethodim sulfoxide: 0.021 µg/L
Clethodim sulfone: 0.113 µg/L
Clethodim oxazole sulfone: 0.356 µg/L

PEARL 3.3.3
80th percentile annual average:
Clethodim: 0.000 µg/L
Clethodim sulfoxide: 0.5663 µg/L
Clethodim sulfone: 1.0905 µg/L
Clethodim oxazole sulfone: 0.5264 µg/L

FOCUSPELMO 3.3.2 results: 80th percentile annual average

PELMO - PEC _{gw} (µg/L) GAP 240 BBCH 12-39					
	Scenario	Clethodim	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone
“Northern Europe”	Châteaudun	0.000	0.000	0.020	0.165
	Hamburg	0.000	0.001	0.023	0.225
	Jokioinen	0.000	0.000	0.002	0.130
	Kremsmünster	0.000	0.000	0.009	0.139
	Okehampton	0.000	0.001	0.048	0.199
“Southern Europe”	Piacenza	0.000	0.003	0.039	0.124
	Porto	0.000	0.000	0.000	0.008
	Sevilla	0.000	0.009	0.005	0.028
	Thiva	0.000	0.000	0.000	0.009

PELMO - PECgw (µg/L) GAP 384 BBCH 31-39					
	Scenario	Clethodim	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone
“Northern Europe”	Châteaudun	0.000	0.000	0.002	0.046
	Hamburg	0.000	0.001	0.012	0.116
	Jokioinen	0.000	0.000	0.000	0.030
	Kremsmünster	0.000	0.000	0.004	0.074
	Okehampton	0.000	0.000	0.004	0.091
“Southern Europe”	Piacenza	0.000	0.000	0.007	0.049
	Porto	0.000	0.000	0.000	0.001
	Sevilla	0.000	0.000	0.000	0.004
	Thiva	0.000	0.000	0.000	0.002

PELMO - PECgw (µg/L) GAP 192 BBCH 11-39					
	Scenario	Clethodim	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone
“Northern Europe”	Châteaudun	0.000	0.001	0.048	0.266
	Hamburg	0.000	0.001	0.061	0.356
	Jokioinen	0.000	0.000	0.021	0.207
	Kremsmünster	0.000	0.000	0.031	0.250
	Okehampton	0.000	0.003	0.113	0.328
“Southern Europe”	Piacenza	0.000	0.007	0.092	0.204
	Porto	0.000	0.000	0.000	0.011
	Sevilla	0.000	0.021	0.050	0.102
	Thiva	0.000	0.000	0.000	0.015

PEARL 3.3.3 results: 80th percentile annual average

PEARL - PECgw (µg/L) GAP 240 BBCH 12-39					
	Scenario	Clethodim	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone
“Northern Europe”	Châteaudun	0.0000	0.0082	0.1777	0.3435
	Hamburg	0.0000	0.0033	0.1003	0.3124
	Jokioinen	0.0000	0.0102	0.1227	0.3037
	Kremsmünster	0.0000	0.0076	0.1233	0.2790
	Okehampton	0.0000	0.0075	0.1295	0.2703
“Southern Europe”	Piacenza	0.0000	0.0250	0.2044	0.2239
	Porto	0.0000	0.0000	0.0000	0.0253
	Sevilla	0.0000	0.1745	0.1804	0.1825

	Thiva	0.0000	0.0002	0.0203	0.1471
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PEARL - PECgw (µg/L) GAP 384 BBCH 31-39					
	Scenario	Clethodim	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone
“Northern Europe”	Châteaudun	0.0000	0.0085	0.1436	0.2305
	Hamburg	0.0000	0.0135	0.1867	0.2490
	Jokioinen	0.0000	0.0066	0.0970	0.2200
	Kremsmünster	0.0000	0.0061	0.0988	0.1997
	Okehampton	0.0000	0.0061	0.0802	0.1974
“Southern Europe”	Piacenza	0.0000	0.0081	0.0855	0.1582
	Porto	0.0000	0.0000	0.0000	0.0129
	Sevilla	0.0000	0.0014	0.0112	0.0737
	Thiva	0.0000	0.0018	0.0502	0.1506

PEARL - PECgw (µg/L) GAP 192 BBCH 11-39					
	Scenario	Clethodim	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone
“Northern Europe”	Châteaudun	0.0000	0.0158	0.3252	0.5264
	Hamburg	0.0000	0.0103	0.2636	0.5033
	Jokioinen	0.0000	0.0034	0.2171	0.4927
	Kremsmünster	0.0000	0.0127	0.2396	0.4367
	Okehampton	0.0000	0.0145	0.2910	0.4155
“Southern Europe”	Piacenza	0.0000	0.0597	0.3316	0.3873
	Porto	0.0000	0.0000	0.0000	0.0437
	Sevilla	0.0000	0.5663	1.0905	0.4048
	Thiva	0.0000	0.0007	0.0505	0.2499

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

Direct photolysis in air	NA
Quantum yield of direct photo-transformation	No data
Photochemical oxidative degradation in air	Latitude: no data Season: no data DT ₅₀ : Atkinson calculation for reaction with OH-radical: 0.827 h [Cis-isomer], 0.818 h [Trans-isomer], (1.5x10 ⁶ OH/cm ³) for reaction with ozone: 22.566 h [Cis-isomer], 21.154 h [trans-isomer], (7x10 ¹¹ mol/cm ³)
Volatilization	from plant surfaces: NA from soil: NA

PEC (air)

Method of calculation

Not calculated. Taking into consideration the very low vapour pressure of clethodim: $2.1 \cdot 10^{-6}$ Pa at 20°C, and the Henry's law constant $1.40 \cdot 10^{-7}$ (Pa.m³/mol) at 20°C, respectively, contamination of the air is very unlikely to occur.

For the metabolites the following vapour pressures are available (EPIWIN):

Clethodim sulfoxide: $2.14 \cdot 10^{-12}$ mmHg

Clethodim sulfone: $8.24 \cdot 10^{-13}$ mmHg

Imine sulfoxide: $9.69 \cdot 10^{-11}$ mmHg

Oxazole: $6.24 \cdot 10^{-6}$ mmHg

Oxazole sulfoxide: $3.38 \cdot 10^{-7}$ mmHg

Oxazole sulfone: $1.49 \cdot 10^{-7}$ mmHg

As these values are considered to be low, none of the identified metabolite of clethodim was considered relevant for air and no PEC_{air} was calculated.

PEC_(a)

Maximum concentration

Not calculated.

Residues requiring further assessment (Annex IIA, point 7.3)

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered

Soil:

clethodim, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone, 2-[3-chloroallyloxyimino] butanoic acid (soil photolysis), *trans*-3-chloroacrylic acid (soil photolysis)

Ground water:

provisionally clethodim, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone, 2-[3-chloroallyloxyimino] butanoic acid, *trans*-3-chloroacrylic acid; however, a data gap was identified for the characterization of the chromatographic peak M20 found in a soil metabolism study in order to support the exclusion of the content of this peak from the overall quantification of metabolite clethodim oxazole sulfoxide. In case that this fraction is part (one of the isomers) of clethodim oxazole sulfoxide and the quantitative determination makes the metabolite occurring more than 5% at 2 consecutive time points, then a groundwater assessment would be needed clethodim oxazole sulfoxide.

Surface water:

clethodim, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone

Sediment:

clethodim, clethodim oxazole sulfone, clethodim imine sulfoxide, clethodim imine

Air:

Clethodim

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

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

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

No classification proposed.

Ecotoxicology

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

Acute toxicity to birds

Dietary toxicity to birds

Reproductive toxicity to birds

Acute toxicity to mammals

Reproductive toxicity to mammals

LD ₅₀ >1640 mg/kg bw (bobwhite quail)
LC ₅₀ >851 mg/kg bw/day (mallard duck)
NOEL 17 mg/kg bw/day (bobwhite quail)
LD ₅₀ 1133 g/kg bw (rat)
NOEL 16 mg/kg bw/day (rat, 2-year chronic toxicity and carcinogenicity study)

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

Clethodim						
Toxicity/exposure ratios for birds (Annex IIIA, points 10.3)						
Bird of 300 g bw, DFI 228 g/d (leafy crops)						
Bird of 10 g bw, DFI 10.4 g/d, DWI 2.6 mL/d (insects, drinking water)						
Bird of 100 g bw, DFI 113 g/d (earthworms)						
Bird of 1000 g bw, DFI 206 g/d (fish)						
NOEL 17 mg/kg bw/day						
Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2000; European Commission, 2002).						
Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	route	TER	Annex VI Trigger
0.384	Sugar beet	herbivorous bird	acute	leafy crops	>65	10
0.384	Sugar beet	insectivorous bird	acute	insects	>79	10
0.300	Sugar beet	insectivorous bird	acute	water	>20	10
0.384	Sugar beet	herbivorous bird	short-term	leafy crops	>73	10
0.384	Sugar beet	insectivorous bird	short-term	insects	>73	10
0.384	Sugar beet	herbivorous bird	long-term	leafy crops	2.7	5
0.300	Sugar beet	herbivorous bird	long-term	leafy crops	3.5	5
2x0.192	Sugar beet	herbivorous bird	long-term	leafy crops	3.9	5
0.384	Sugar beet	herbivorous bird	long-term	leafy crops	7.3 ^(A)	5
0.384	Sugar beet	insectivorous bird	long-term	insects	1.5	5
0.3	Sugar beet	insectivorous bird	long-term	insects	1.9	5
2 x 0.192	Sugar beet	insectivorous bird	long-term	insects	2.9	5
0.384	Sugar beet	insectivorous bird	long-term	insects	4.7 ^(B)	5
0.384	Sugar beet	piscivorous bird	long-term	fish	403	5
0.384 soil pH 4.5 K _{oc} 41.5 L/kg	Sugar beet	bird	long-term	earthworms	2.4^(C)	5
0.300 soil pH 4.5 K _{oc} 41.5 L/kg	Sugar beet	bird	long-term	earthworms	3.1^(C)	5
2x0.192 soil pH 4.5 K _{oc} 41.5 L/kg	Sugar beet	bird	long-term	earthworms	4.5^(C)	5
0.384 soil pH 5.5 K _{oc} 41.5 L/kg	Sugar beet	bird	long-term	earthworms	24 ^(C)	5
0.384 soil pH 6.5 K _{oc} 4 L/kg	Sugar beet	bird	long-term	earthworms	23 ^(C)	5

^(A) Refined TER value, based on a DT₅₀ of 3 days and a resulting refined ftwa and MAF of 0.20 and 1.04, respectively.

(B) Refined TER value, based on PD and PT refinement using literature data for the yellow wagtail (PD of 0.764 and 0.236 for large and small insects, respectively).

(C) TER values taking into account pH dependent K_{oc} (in BCFworm) and non-dissociated clethodim fraction at pH > pK_a (see addendum)

Metabolites						
Toxicity/exposure ratios for birds (Annex IIIA, points 10.3)						
Bird of 300 g bw, DFI 228 g/d (leafy crops)						
Bird of 100 g bw, DFI 113 g/d (earthworms)						
Bird of 1000 g bw, DFI 206 g/d (fish)						
Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2000, European Commission, 2002).						
Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	route	TER	Annex VI Trigger
Clethodim sulfoxide (based on toxicity value from parent clethodim)						
0.384	Sugar beet	herbivorous bird	long-term	leafy crops	17	5
0.384	Sugar beet	piscivorous bird	long-term	fish	95	5
0.384	Sugar beet	bird	long-term	earthworms	14	5
0.3	Sugar beet	bird	long-term	earthworms	17	5
Clethodim sulfone (based on toxicity value from parent clethodim)						
0.384	Sugar beet	bird	long-term	earthworms	>25	5
Clethodim oxazole sulfone (based on toxicity value from parent clethodim)						
0.384	Sugar beet	bird	long-term	earthworms	1367	5

Clethodim						
Toxicity/exposure ratios for mammals (Annex IIIA, points 10.3)						
Mammal of 3000 g bw, DFI 832 g/d (leafy crops)						
Mammal of 10 g bw, DFI 14 g/d, DWI 1.6 mL/d (drinking water, earthworms)						
Mammal of 3000 g bw, DFI 390 g/d (fish)						
NOEL: 16 mg a.s./kg bw/d						
Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2000, European Commission, 2002).						
Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	Route	TER	Annex VI Trigger
0.384	sugar beet	herbivorous mammal	acute	leafy crops	122	10
0.300	sugar beet	small mammal	acute	water	24	10
0.384	sugar beet	herbivorous mammal	long-term	leafy crops	7.1	5
0.384	sugar beet	mammal	long-term	fish	601	5
0.384 soil pH 4.5 K _{oc} 41.5 L/kg	sugar beet	mammal	long-term	earthworms	1.7 ^(A)	5
0.300 soil pH 4.5 K _{oc} 41.5 L/kg	sugar beet	mammal	long-term	earthworms	2.3 ^(A)	5
2x0.195 soil pH 4.5 K _{oc} 41.5 L/kg	sugar beet	mammal	long-term	earthworms	3.3 ^(A)	5
0.384 soil pH 5.5	sugar beet	mammal	long-term	earthworms	17 ^(A)	5

K_{oc} 41.5 L/kg						
0.384 soil pH 6.5 K_{oc} 4 L/kg	sugar beet	mammal	long-term	earthworms	17 ^(A)	5

^(A) TER values taking into account pH dependent K_{oc} (in BCFworm) and non-dissociated clethodim fraction at pH > pKa (see addendum)

Metabolites

Toxicity/exposure ratios for **mammals** (Annex IIIA, points 10.3)

Mammal of 3000 g bw, DFI 832 g/d (leafy crops)

Mammal of 10 g bw, DFI 14 g/d, DWI 1.6 mL/d (drinking water, earthworms)

Mammal of 3000 g bw, DFI 390 g/d (fish)

Assessment in agreement with Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC (Working Document Sanco/4145/2000, European Commission, 2002).

Application rate (kg as/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	Route	TER	Annex VI Trigger
Clethodim sulfoxide (based on toxicity value from parent clethodim)						
0.384	sugar beet	mammal	long-term	earthworms	10	5
0.3	sugar beet	mammal	long-term	earthworms	13	5
Clethodim sulfone (based on toxicity value from parent clethodim)						
0.384	sugar beet	mammal	long-term	earthworms	>24	5
Clethodim oxazole sulfone (based on toxicity value from parent clethodim)						
0.384	sugar beet	mammal	long-term	earthworms	1333	5

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.s./l)**
Laboratory tests				
<i>Salmo gairdneri</i>	clethodim	96 h	Mortality, EC ₅₀	25 ^(A)
<i>Oncorhynchus mykiss</i>		21 d	NOEC	3.9 ^(A)
<i>Daphnia magna</i>		48 h	Immobility, EC ₅₀	>100 ^(B)
<i>Daphnia magna</i>		21 d	Reproduction, NOEC	49 ^(B)
<i>Selenastrum capricornutum</i>		72 h	Biomass, growth rate, EC ₅₀	>12 ^(A)
<i>Lemna gibba</i>		14 d	Fronds, EC ₅₀	1.9 ^(C)
<i>Oncorhynchus mykiss</i>	Select 240 EC	96 h	Mortality, EC ₅₀	3.4 ^(B)
<i>Oncorhynchus mykiss</i>	Select + oily adjuvant	21 d	NOEC	0.29 ^(A)
<i>Oncorhynchus mykiss</i>	TM-20016	21 d	NOEC	1.1 ^(B)
<i>Daphnia magna</i>	Select 2 EC	48 h	Immobility, EC ₅₀	5.1 ^(A)
<i>Daphnia magna</i>	Select + oily adjuvant	21 d	Reproduction, NOEC	0.00084 ^(B)
<i>Daphnia magna</i>	TM-20016	21 d	Reproduction, NOEC	0.51 ^(B)
<i>Scenedesmus subspicatus</i>	Select + oily adjuvant	72 h	Biomass, growth rate, EC ₅₀	1.5 ^(A)
<i>Scenedesmus subspicatus</i>	Select 2 EC	72 h	growth rate, EC ₅₀	3.2 ^(A)
<i>Lemna gibba</i>	Select 240 EC + oily adjuvant	14 d	Fronds, EC ₅₀	4.52 ^(B)
<i>Lemna gibba</i>	Select 2 EC	14 d	Fronds, EC ₅₀	69 ^(A)
<i>Desmodesmus subspicatus</i>	clethodim sulfoxide	72 h	Biomass, EC ₅₀	>100 ^(B)
<i>Lemna gibba</i>	clethodim sulfoxide	7 d	Biomass, EC ₅₀	88 ^(B)
<i>Oncorhynchus mykiss</i>	clethodim sulfoxide	96 h	Mortality, EC ₅₀	> 100 ^(B)

<i>Chironomus riparius</i>	clethodim imine	28 d	Emergence, NOEC	10 ^(D)
Microcosm or mesocosm tests				
Not available				

* Formulations Select and Select 2 EC are identical, but differ from Select 240 EC in solvent content.

Select 240 = 240 g clethodim/L. Select and Select 2EC = 256 g clethodim/L. TM-20016 is a 240 g/L clethodim formulation without oily adjuvant.

**endpoint given in bold are used in risk assessment. Since the formulation is more toxic than the active substance by one order of magnitude or more (except for *L. gibba*), the data on the product should be used for risk assessment. This is in line with section 2.5.3 from the aquatic guidance document. Furthermore, endpoints from the formulation studies including the oily adjuvant should be used, since the endpoints with Select with the oily adjuvant are worst case and the GAP as submitted with the dossier contained applications with oily adjuvant only. However, formulated clethodim could also be used without oily adjuvant. Selection of the relevant endpoint should therefore be taken at Member State level, depending on the proposed use.

(A) Based on mean measured concentrations.

(B) Based on analytically confirmed nominal concentrations.

(C) Based on nominal concentrations (analytically confirmed for initial concentrations).

(D) Based on measured initial concentrations.

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

Focus step 1

Crop: sugar beet

Application rate (kg as/ha)	Organism	Test substance	Time-scale	Distance (m)	TER	Annex VI Trigger
0.384	fish	Select 240 EC	96 hours	1	26	100
0.384	Daphnia	Select 2 EC	48 hours	1	39	100
0.384	algae	Select+ oily adjuvant	72 hours	1	11	10
0.3	fish	Select 240 EC	96 hours	1	33	100
0.3	Daphnia	Select 2 EC	48 hours	1	50	100
0.3	algae	Select+ oily adjuvant	72 hours	1	15	10
0.384	Lemna	clethodim	14 days	1	14	10
0.384	fish	Select+ oily adjuvant	21 days	1	2	10
0.384	Daphnia	Select+ oily adjuvant	21 days	1	6E-03	10
0.3	Lemna	clethodim	21 days	1	18	10
0.3	fish	Select+ oily adjuvant	21 days	1	3	10
0.3	Daphnia	Select+ oily adjuvant	21 days	1	8E-03	10

Focus step 2

Crop: sugar beet

Application rate (kg as/ha)	Organism	Test substance	Time-scale	Distance (m)	TER	Annex VI Trigger
0.384	fish	Select 240 EC	96 hours	1	445	100
0.384	Daphnia	Select 2 EC	48 hours	1	668	100
0.3	fish	Select 240 EC	96 hours	1	809	100
0.3	Daphnia	Select 2 EC	48 hours	1	1213	100
0.384	fish	Select+ oily adjuvant	21 days	1	38	10
0.384	Daphnia	Select+ oily	21 days	1	0.11	10

		adjuvant				
0.3	fish	Select+ oily adjuvant	21 days	1	69	10
0.3	Daphnia	Select+ oily adjuvant	21 days	1	0.20	10

Focus step 3 and 4

Crop: sugar beet, treatment: 300 g a.s./ha (N-EU), NOEC Daphnia 0.84 µg a.s./L (Select 240 + oily adjuvant)

Scenario	Relevant water body for sugar beet	PEC max Step3 (µg/L)	TER	Buffer distance between crop and water body (m)	PEC max Step4 (µg/L)	TER
D3 (Vreedepeel)	Ditch	1.57	0.53	30	n.a.	n.a.
D4 (Skousbo)	Pond	0.064	13.1	3.8	0.064	13.1
D4 (Skousbo)	Stream	1.244	0.68	30	0.082	10.2
R1 Weiherbach)	Pond	0.064	13.1	3.8	0.064	13.1
R1 Weiherbach)	Stream	1.091	0.77	30	0.072	11.7
R3 (Bologna)	Stream	1.534	0.55	25 30	0.157 n.a	5.35 n.a

Focus step 3 and 4

Crop: sugar beet, treatment: 384 g a.s./ha (S-EU), NOEC Daphnia 0.84 µg a.s./L (Select 240 + oily adjuvant)

Scenario	Relevant water body for sugar beet	PEC max Step3 (µg/L)	TER	Buffer distance between crop and water body (m)	PEC max Step4 (µg/L)	TER
D3 (Vreedepeel)	Ditch	2.011	0.42	30	n.a.	n.a.
D4 (Skousbo)	Pond	0.081	10.4	3.8	0.081	10.4
D4 (Skousbo)	Stream	1.592	0.53	30	n.a.	n.a.
R1 Weiherbach)	Pond	0.081	10.4	3.8	0.080	10.5
R1 Weiherbach)	Stream	1.396	0.60	30	n.a.	n.a.
R3 (Bologna)	Stream	1.964	0.43	30	n.a.	n.a.

Focus step 3 and 4

Crop: sugar beet, treatment: 2 x 192 g a.s./ha (S-EU), NOEC Daphnia 0.84 µg a.s./L (Select 240 + oily adjuvant)

Scenario	Relevant water body for sugar beet	PEC max Step3 (µg/L)	TER	Buffer distance between crop and water body (m)	PEC max Step4 (µg/L)	TER
D3 (Vreedepeel)	Ditch	0.874	0.96	18	0.081	10.4
D4 (Skousbo)	Pond	0.055	15.3	3.8	0.055	15.3
D4 (Skousbo)	Stream	0.702	1.19	16	0.079	10.6
R1 Weiherbach)	Pond	0.050	16.8	3.8	0.050	16.8
R1 Weiherbach)	Stream	0.601	1.40	14	0.077	10.9
R3 (Bologna)	Stream	0.846	0.99	16 18	0.100 n.a	8.4 n.a

Bioconcentration

Bioconcentration factor (BCF)

Annex VI Trigger for the bioconcentration factor

Clearance time (CT₅₀)

(CT₉₀)

Level of residues (%) in organisms after the 14 day depuration phase

Clethodim: 2.1
1000 for readily biodegradable compounds
4.9 d (allyl-label) and 0.23 d (ring-label)
16 d (allyl-ring) and 0.76 d (ring-label)
≤ 30% after 14 d depuration

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

Acute oral toxicity

Acute contact toxicity

LD ₅₀ >43 µg a.s./bee (Select 240 EC)
LD ₅₀ 55 µg a.s./bee (Select + adjuvant)
LD ₅₀ >51 µg a.s./bee (Select 240 EC)
LD ₅₀ 68 µg a.s./bee (Select + adjuvant)

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

Application rate (g as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
384	Sugar beet	oral contact	<8.9 <7.5	50 50

Field or semi-field tests

Not required

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

Species	Test type and exposure scenario	Test Substance	Dose (g as/ha)	Endpoint	Adverse effect (%)* or L(E)R50 (g a.s./ha)	Annex VI /Escort II Trigger
Laboratory tests						
<i>Aphidius rhopalosiphi</i>	Laboratory, sprayed plants	Select + Adjuvant	9.6 240	mortality/reproduction LR ₅₀ , ER ₅₀	0 / 5 0 / 5 >240 g a.s./ha	50%

<i>Typhlodromus pyri</i>	Extended laboratory ^(A)	Select + Adjuvant	9.6	mortality/reproduction LR ₅₀ , ER ₅₀	82 / 51 <9.6 g a.s./ha	50%
<i>Typhlodromus pyri</i>	Extended laboratory ^(A)	Select + Adjuvant	0.6 1.2 2.4 4.8 9.6	mortality/reproduction LR ₅₀ ER ₅₀	1 / 10 4 / 0.2 16 / 14 73 / 33 100 / n.a. ^(B) 3.6 g a.s./ha >4.8 g a.s./ha	50%
<i>Typhlodromus pyri</i>	Extended laboratory	Select 240 EC	0, 11 and 384	Fresh residues: 4, 7 & 14 d aged:	LR ₅₀ <384 ER ₅₀ >11 LR ₅₀ >384 ER ₅₀ >384	50%
<i>Poecilus cupreus</i>	Laboratory, sand	Select + Adjuvant	256	mortality/food consumption LR ₅₀	3.3 / +3.1 >256 g a.s./ha	50%
<i>Poecilus cupreus</i>	Laboratory, sand	Select 240 EC	221	mortality/food consumption LR ₅₀	3.4 / 10 >221 g a.s./ha	50%
<i>Aleochara bilineata</i>	Laboratory, sand	Select 240 EC	259	parasitic capacity ER ₅₀	2.6 >259 g a.s./ha	50%
<i>Aleochara bilineata</i>	Laboratory, natural soil	Select 240 EC + Adjuvant	386	parasitic capacity ER ₅₀	1.9 >386 g a.s./ha	50%
<i>Chrysoperla carnea</i>	Extended laboratory ^(C)	Select 240 + Adjuvant	384	mortality/reproduction LR ₅₀ , ER ₅₀	2.2 / 19 >384 g a.s./ha	50%

* Effects are adverse effects, i.e. X% effect on mortality means X% more mortality and Y% effect on reproduction means Y% less reproduction compared to control. When effects are favourable for the test organisms, a + sign is used for the sublethal effect percentages and a – sign for mortality effect percentages.

(A) Exposure to dry residues on laboratory treated *Phaseolus vulgaris* leaves.

(B) n.a. = not applicable (insufficient survivors from initial phase to assess reproduction).

(C) Exposure to dry residues in conjunction with esterified rape seed oil (1.0 L/ha) on laboratory treated apple leaves.

Field or semi-field tests
Not provided

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

Acute toxicity

clethodim sulfoxide
LC₅₀ >1000 mg/kg (500 mg a.s./kg^(A))
Select 240 EC
LC₅₀ 129 mg a.s./kg (65 mg a.s./kg^(A))

Reproductive toxicity

clethodim oxazole sulfone
NOEC 10 mg/kg (5 mg a.s./kg^(A))

(A) corrected for organic content of OECD 207 substrate

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

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
0.384	Sugar beet	acute	420	10

(A) TER based on PEC soil for which 70% crop interception was assumed (application at BBCH ~40 in sugar beet)

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

Nitrogen mineralization

Clethodim
Up to 2.741 mg a.s./kg: effects <25%
Select EC 240
Up to 2.7 mg a.s./kg: effects <25% (1 soil)
At 0.53 and 2.7 mg a.s./kg: effects >25% after 28 and 42 days (= end of test) (2nd soil)
Select + Para Sommer(= oily adjuvant)
Up to 1.7 mg a.s./kg: effects <25% (2 soils)^(A).
Clethodim oxazole sulfone
Up to 0.10 mg a.s./kg: effects <25%

Carbon mineralization

Clethodim
Up to 2.741 mg a.s./kg: effects <25%
Select EC 240
Up to 2.7 mg a.s./kg: effects <25% (2 soils).
Select + Para Sommer(= oily adjuvant)
Up to 1.7 mg a.s./kg: effects <25% (2 soils).
Clethodim oxazole sulfone
Up to 0.10 mg a.s./kg: effects <25%

(A) Study not suitable to evaluate effects of metabolites.

Effects on other non-target organisms (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Collembola					
Clethodim oxazole sulfoxide: NOEC 100 mg a.s./kg soil (<i>F. candida</i>) (NOEC 50 mg a.s./kg soil corrected for organic content of OECD 207 substrate)					
Non-target terrestrial plants					
<u>Screening data with Select 2 EC-H and Para Sommer</u>					
Species	treatment	survival (kg a.s./ha)		biomass production (kg a.s./ha)	
		NOEC	ER50	NOEC	ER50
Oat	post-emergence	0.016	0.024	0.0040	0.099
Corn	post-emergence	0.0040	0.0081	0.25	0.25
Onion	post-emergence	0.76	>0.76	0.76	>0.76
Rape	post-emergence	0.76	>0.76	0.063	>0.76
Carrot	post-emergence	0.76	>0.76	0.063	0.23
Red clover	post-emergence	0.76	>0.76	0.76	>0.76

Seedling emergence and vegetative vigour tests with active substance clethodim, metabolites and formulation
Select

	Rate response for seedling emergence	Rate response for vegetative vigor (plant dry weight)
	EC ₅₀ (g a.s./ha)	EC ₅₀ (g a.s./ha)
Ryegrass (<i>L. perenne</i>)		clethodim: 6.7 g a.s./ha clethodim sulfoxide: 25 g a.s./ha clethodim sulfone: 23 g a.s./ha clethodim oxazole sulfone: >320 g a.s./ha
Cockspurr grass (<i>E. crus-galli</i>)		clethodim: 3.4 g a.s./ha clethodim sulfoxide: 16 g a.s./ha clethodim sulfone: 12 g a.s./ha clethodim oxazole sulfone: >320 g a.s./ha
Soybean (<i>Glycine max</i>)	Select: > 0.28 g a.s./ha (all species)	Select: > 0.28 g a.s./ha (all species)
Lettuce (<i>Lactuca sativa</i>)		
Carrot (<i>Daucus carota</i>)		
Tomato (<i>Lycopersicon esculentum</i>)		
Cucumber (<i>Cucumis sativus</i>)		
Cabbage (<i>Brassica oleracea</i>)		
Oat (<i>Avena sativa</i>)	Select: 54 g a.s./ha	Select: 20 g a.s./ha
Perennial ryegrass (<i>Lolium perenne</i>)	Select: 67 g a.s./ha	Select: 6.7 g a.s./ha
Corn (<i>Zea mays</i>)	Select: 25 g a.s./ha	Select: 13 g a.s./ha
Onion (<i>Allium cepa</i>)	Select: > 280 g a.s./ha	Select: > 280 g a.s./ha

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

Respiratory rate

clethodim
EC₅₀ > 95 mg/L
Select H EC24
EC₅₀ 162 mg as/L

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

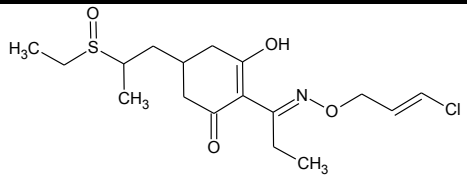
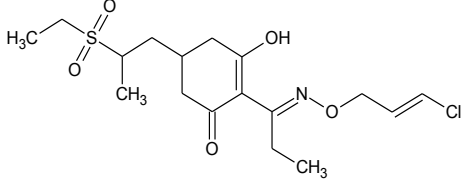
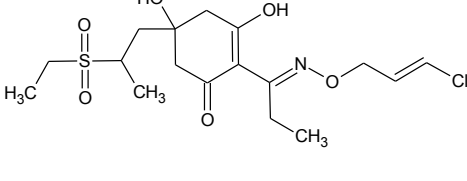
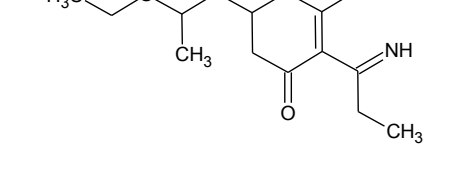
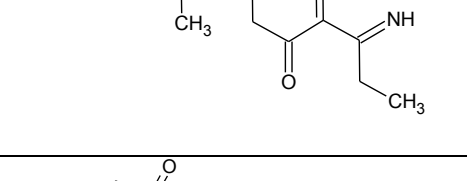
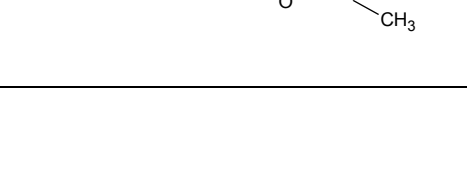
Compartment	
soil	Parent
water	Parent
sediment	Parent
groundwater	Parent
air	Parent

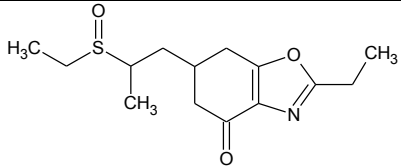
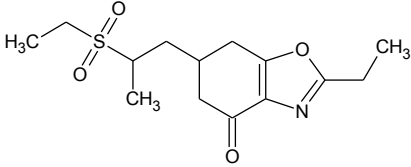
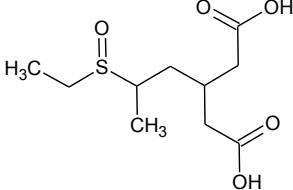
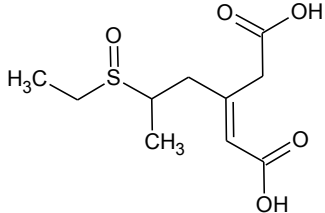
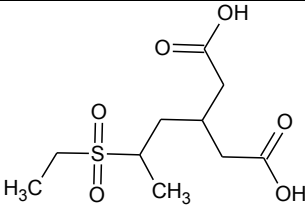
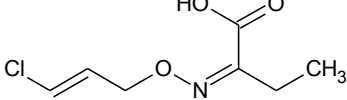
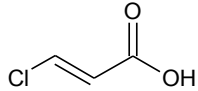
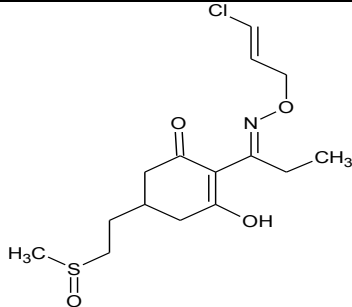
Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data

No classification is proposed

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
clethodim sulfoxide	2-[(<i>EZ</i>)-1-[(<i>E</i>)-3-chloroallyloxyimino]propyl]-5-[(<i>2RS</i>)-2-(ethylsulfinyl)propyl]-3-hydroxycyclohex-2-en-1-one or 2-[(1 <i>EZ</i>)- <i>N</i> -{[(<i>2E</i>)-3-chloro-2-propen-1-yl]oxy}propanimidoyl]-5-[(<i>2RS</i>)-2-(ethylsulfinyl)propyl]-3-hydroxy-2-cyclohexen-1-one	
clethodim sulfone	2-[(<i>EZ</i>)-1-[(<i>E</i>)-3-chloroallyloxyimino]propyl]-5-[(<i>2RS</i>)-2-(ethylsulfonyl)propyl]-3-hydroxycyclohex-2-en-1-one or 2-[(1 <i>EZ</i>)- <i>N</i> -{[(<i>2E</i>)-3-chloro-2-propen-1-yl]oxy}propanimidoyl]-5-[(<i>2RS</i>)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-cyclohexen-1-one	
clethodim 5-OH sulfone	2-[(<i>EZ</i>)-1-[(<i>E</i>)-3-chloroallyloxyimino]propyl]-5-[(<i>2RS</i>)-2-(ethylsulfonyl)propyl]-3,5-dihydroxycyclohex-2-en-1-one or 2-[(1 <i>EZ</i>)- <i>N</i> -{[(<i>2E</i>)-3-chloro-2-propen-1-yl]oxy}propanimidoyl]-5-[(<i>2RS</i>)-2-(ethylsulfonyl)propyl]-3,5-dihydroxy-2-cyclohexen-1-one	
clethodim imine	5-[(<i>2RS</i>)-2-(ethylsulfanyl)propyl]-3-hydroxy-2-(1-iminopropan-1-yl)cyclohex-2-en-1-one or 5-[(<i>2RS</i>)-2-(ethylsulfanyl)propyl]-3-hydroxy-2-propanimidoyl-2-cyclohexen-1-one	
clethodim imine sulfoxide	5-[(<i>2RS</i>)-2-(ethylsulfinyl)propyl]-3-hydroxy-2-(1-iminopropan-1-yl)cyclohex-2-en-1-one or 5-[(<i>2RS</i>)-2-(ethylsulfinyl)propyl]-3-hydroxy-2-propanimidoyl-2-cyclohexen-1-one	
clethodim imine sulfone	5-[(<i>2RS</i>)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-(1-iminopropan-1-yl)cyclohex-2-en-1-one or 5-[(<i>2RS</i>)-2-(ethylsulfonyl)propyl]-3-hydroxy-2-propanimidoyl-2-cyclohexen-1-one	

Code/Trivial name	Chemical name*	Structural formula*
clethodim oxazole sulfoxide	2-ethyl-6-[(2 <i>RS</i>)-2-(ethylsulfinyl)propyl]-6,7-dihydro-1,3-benzoxazol-4(5 <i>H</i>)-one	
clethodim oxazole sulfone	2-ethyl-6-[(2 <i>RS</i>)-2-(ethylsulfonyl)propyl]-6,7-dihydro-1,3-benzoxazol-4(5 <i>H</i>)-one	
M17R	3-[(2 <i>RS</i>)-2-(ethylsulfinyl)propyl]pentanedioic acid	
M15R	(2 <i>EZ</i>)-3-[(2 <i>RS</i>)-2-(ethylsulfinyl)propyl]pent-2-enedioic acid	
M18R	3-[(2 <i>RS</i>)-2-(ethylsulfonyl)propyl]pentanedioic acid	
2-[3-chloroallyloxyimino]butanoic acid (CBA)	(2 <i>EZ</i>)-2-({[(2 <i>E</i>)-3-chloroprop-2-en-1-yl]oxy}imino)butanoic acid	
<i>trans</i> -3-chloroacrylic acid (CAA)	(2 <i>E</i>)-3-chloroprop-2-enoic acid	
S-methyl sulfoxide	2-[(1 <i>E</i>)-N-{{[(2 <i>E</i>)-3-chloroprop-2-en-1-yl]oxy}propanimidoyl]-3-hydroxy-5-[2-(methylsulfinyl)ethyl]cyclohex-2-en-1-one	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

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	emulsifiable concentrate
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

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

NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in ground water
PEC _{sed}	predicted environmental concentration in sediment
PEC _{soil}	predicted environmental concentration in soil
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK _a	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r ²	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t _{1/2}	half-life (define method of estimation)
TER	toxicity exposure ratio
TER _A	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year