

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl¹

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SUMMARY

Commission Regulation (EC) No 737/2007³ (hereinafter referred to as ‘the Regulation’) lays down the procedure for the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Kresoxim-methyl is one of the first group of active substances listed in the Regulation.

In accordance with Article 6 of the Regulation, the notifier BASF SE submitted a dossier on kresoxim-methyl to Belgium and Lithuania, being the designated rapporteur Member State (RMS), and co-rapporteur Member State, respectively. In accordance with Article 10 of the Regulation, Belgium prepared an Assessment Report in consultation with Lithuania, which was submitted to the EFSA and the Commission of the European Communities (hereafter referred to as ‘the Commission’). The Assessment Report was received by the EFSA on 31 March 2010.

In accordance with Article 11 of the Regulation, the EFSA distributed the Assessment Report to Member States and the notifier for comments on 19 April 2010. The EFSA collated and forwarded all comments received to the Commission on 20 May 2010.

In accordance with Article 12, following consideration of the Assessment Report and the comments received, the Commission requested the EFSA to arrange an expert consultation on the Assessment Report as appropriate and deliver its conclusions on kresoxim-methyl.

The conclusions presented in this report were reached on the basis of the evaluation of the representative uses of kresoxim-methyl as a fungicide on cereals, apples, pears and grapes as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

No critical areas of concern were identified in the physical-chemical properties section. Data gaps were identified for the specification and for the products of animal origin method.

The available data in the mammalian toxicology data package were sufficient to derive health based reference values and to perform the risk assessment for operators, workers and bystanders. No data gaps or critical areas of concern were identified.

Based on the metabolism studies conducted on the fruit crops, cereals and root/tuber crop groups, the residue in plant was defined as kresoxim-methyl for monitoring and as sum of kresoxim-methyl, BF 490-2 and BF 490-9 free and conjugated for risk assessment. A conversion factor was proposed for

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³ OJ L169, 29.06.2007, p.10

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grape but additional information is required to derive such a factor for pome fruits. The animal residue definition was proposed for ruminant products only and was defined as BF 490-1 for monitoring and sum of BF 490-1, BF 490-2 and BF 490-9 for risk assessment. No intake concern is expected for the consumers, the highest TMDI being less than 1% of the ADI.

The data available on fate and behaviour in the environment were sufficient to carry out the required environmental exposure assessments at the EU level for the representative uses, with the exception that data were not available to clearly demonstrate that leachate from a pertinent lysimeter study did not contain individual metabolites in annual average concentrations exceeding 0.1 µg/L. In addition, the groundwater exposure related to the late application in grapes and apples was not finalised as no modelling was provided for these application patterns. The potential for groundwater contamination above the parametric drinking water limit of 0.1µg/L consequent to the other representative uses was assessed as low for kresoxim-methyl and the metabolites BF 490-1 (acid of kresoxim-methyl) and BF 490-5 (diacid of kresoxim-methyl).

A low risk was identified for non-target organisms following the representative uses.

KEY WORDS

Kresoxim-methyl, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Commission Regulation (EC) No 737/2007⁴ (hereinafter referred to as ‘the Regulation’) lays down the procedure for the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Kresoxim-methyl is one of the first group of active substances listed in the Regulation.

In accordance with Article 6 of the Regulation, the notifier BASF SE submitted a dossier on kresoxim-methyl to Belgium and Lithuania, being the designated rapporteur Member State (RMS), and co-rapporteur Member State, respectively. In accordance with Article 10 of the Regulation, Belgium prepared an Assessment Report in consultation with Lithuania (Belgium, 2010a), which was submitted to the EFSA and the Commission of the European Communities (hereafter referred to as ‘the Commission’). The Assessment Report was received by the EFSA on 31 March 2010.

In accordance with Article 11 of the Regulation, the EFSA distributed the Assessment Report to Member States and the notifier for comments on 19 April 2010. A 30 day period was provided for commenting. In addition, the EFSA conducted a public consultation on the Assessment Report. The EFSA collated and forwarded all comments received to the Commission on 20 May 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The RMS also provided a response to the comments in column 3.

In accordance with Article 12, following consideration of the Assessment Report and the comments received, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 28 June 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on kresoxim-methyl. The need for expert consultation was considered in a telephone conference between the EFSA, the RMS and the Commission on 5 July 2010. On the basis of the comments received, the notifier’s response to the comments, and the RMS’ subsequent evaluation thereof, it was concluded that consultation with Member State experts was not required.

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 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 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 September 2010.

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

- the comments received,

⁴ OJ L169, 29.06.2007, p.10

- the Reporting Table (5 July 2010),
- the Evaluation Table (18 October 2010),

Given the importance of the Assessment Report including its addendum (compiled version of September 2010 containing all individually submitted addenda; Belgium, 2010b) 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

Kresoxim-methyl is the ISO common name for methyl (*E*)-methoxyimino[α -(*o*-tolylloxy)-*o*-tolyl]acetate (IUPAC).

The representative formulated products for the evaluation were 'BAS 494 04 F' a suspension concentrate (SC) containing 125 g/l kresoxim-methyl and 125 g/l epoxiconazole and 'BAS 490 02 F' a water dispersible granule (WG) containing 500 g/kg kresoxim-methyl.

The representative uses evaluated comprise outdoor foliar spraying against fungi in cereals (wheat, barley, rye and triticale), apples, pears and grapes. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The active substance is manufactured as a technical concentrate (TK) and the active substance range in the TK is 750 g/kg to 1000 g/kg. The calculated dry weight minimum purity is 934 g/kg. It should be noted that the reference source has changed, the original source for the Annex I listing no longer exists. Methanol, methyl chloride and toluene are considered as relevant impurities their maximum levels in the technical material are 5 g/kg, 1 g/kg and 1g/kg respectively. A data gap was identified for quality control data to support the specification levels for impurities Reg. No. 301 189 and Reg. No. 271 246 and therefore the specification should be regarded as provisional

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

It should be noted that the proposed tank mix recommendations are only acceptable with continuous tank agitation.

Methods enabling determination of the content of the relevant impurities in the representative formulated products were not provided because these impurities will not increase on storage, however these may be required at Member State level, pursuant to Art. 4, 1(c) of Council Directive 91/414/EEC.

The method for plants is the multi method DFG S19 GC-MS and there is also a LC-MS/MS method available with ILV, both of these methods analyse for kresoxim-methyl. It should be noted however, the residue definition for processed commodities also includes BF 490-1 which the plant methods don't analyse for. For the residue definition BF 490-1 in products of animal origin a HPLC-UV method is available for muscle, liver and kidney but a confirmatory method and ILV have been identified as data gaps. For fat and milk no methods are available and this is also identified as a data gap. For soil, water and air LC-MS/MS methods are available to analyse kresoxim-methyl and BF 490-1 in soil and water and kresoxim-methyl in air. A method for body fluids and tissues is not required as kresoxim-methyl is not classified as toxic or very toxic.

2. Mammalian toxicity

Kresoxim-methyl has a low acute toxicity potential (rat oral LD₅₀ >5000 mg/kg bw, dermal LD₅₀ >2000 mg/kg bw, LC₅₀ > 5.6 mg/L); it is not a skin or eye irritant, nor a skin sensitiser. After repeated administration the body weight decreases and the liver weight increases: the relevant short-term and long-term toxicity No Observed Adverse Effect Levels (NOAELs) are 146 mg/kg bw/day (90-day study in rats) and 36 mg/kg bw/day (2-year study in rats). Kresoxim-methyl did not show genotoxic potential but it causes liver tumours in rat at the Maximum Tolerated Dose (MTD), likely via a non-genotoxic threshold mechanism. The classification as Carc. Cat. 3 R40 ("Limited evidence of carcinogenic effect") was proposed. Kresoxim-methyl is neither a reproductive nor a developmental toxicant. It is not a neurotoxic agent. The Acceptable Daily Intake (ADI) is 0.4 mg/kg bw/day based

on the NOAEL of the 2-year study in rat, Safety Factor (SF) 100; the Acceptable Operator Exposure Level (AOEL) is 0.9 mg/kg bw/day based on the rat 90-day study NOAEL, considering an oral absorption of 63 % and a SF of 100. Based on the toxicological profile of kresoxim-methyl, an Acute Reference Dose (ARfD) was not allocated. The operator and worker exposure levels for both the water dispersible granule (WG) and suspension concentrate (SC) formulations are below the AOEL even without any Personal Protective Equipment (PPE), as well as the exposure levels of bystanders.

Based on their toxicological profile, the impurities methanol, methyl chloride and toluene should be considered as relevant but of no concern at the levels in the proposed specification.

As for rat metabolites BF 490-1, BF 490-2 and BF 490-9, only metabolite BF 490-1 was slightly more toxic in the acute oral rat study than the parent compound; and it should be classified accordingly (Xn; R22). All other metabolites were not harmful by oral uptake. All investigated metabolites were found to be not mutagenic in the bacterial assays. According to the available information, and considering their structures, it is unlikely that they are more toxic than kresoxim-methyl, and therefore the reference values of the parent are applicable in case a consumer risk assessment is needed.

3. Residues

Metabolism in plants has been investigated on fruit crops (apple, grape), cereals (wheat) and root/tuber crops (sugar beet) using a ¹⁴C labelling on the phenoxy or phenyl ring and/or a ¹³C labelling on the methoxyimino chain. In each crop, the metabolic pathway of kresoxim-methyl was seen to be similar. The parent kresoxim-methyl was the predominant compound of the total residues in all the matrices (55 % to 97 % TRR, except in wheat grain, 17 % TRR), the other metabolites being present in lower proportions, below 10 % TRR. In plants, the metabolism proceeds first by the cleavage of the methyl ester bond to generate the metabolite BF 490-1 (acid of kresoxim-methyl), which can be regarded as an intermediate that undergoes hydroxylation resulting in metabolites BF 490-2 and BF 490-9 with further glucoside conjugations. A similar metabolic profile was observed in the rotational crop study conducted on wheat, carrot, bean and lettuce. Based on these studies the residue definition for monitoring was limited to the parent kresoxim-methyl only. For risk assessment, the residue was defined as the sum of kresoxim-methyl and metabolites BF 490-2 and BF 490-9 free and conjugates. The inclusion of the metabolites BF 490-2 and BF 490-9, observed in limited proportions and levels in the metabolism studies, is supported by the residue trials conducted on grapes, where these metabolites were detected at similar levels to the parent at the PHI of 35 days, and since they are considered of similar toxicity to the parent (see section 2).

Residue trials on apple/pear, grape and cereals conducted over several growing seasons were provided. On grape and cereals, samples were analysed according to the residue definition for risk assessment, for the parent kresoxim-methyl and the metabolites BF 490-2 and BF 490-9 using different analytical methods. However, parent residues were often analysed after hydrolysis as BF 490-1, and the values stated as “kresoxim-methyl” in the Assessment Report in fact represent the sum of the parent and the metabolite BF 490-1. Nevertheless, and considering that BF 490-1 was detected in very low proportions in the plant metabolism studies (more often <3 % TRR), it can be assumed that the residue levels analysed “as BF 490-1”, mainly correspond to the parent residue levels. On pome fruits a limited number of trials were performed in compliance with the critical GAP. However, since the residue levels were below 0.05 mg/kg in numerous additional trials conducted with an exaggerated number of applications (8 to 12), no additional trials are necessary and the MRL was proposed at the LOQ of 0.05 mg/kg. A conversion factor for risk assessment of 1.7 was derived for grapes. No conversion factor is necessary for cereals, the residues in grains being below the LOQ. No data are available for apple/pear and additional information is required to derive a conversion factor for pome fruits.

Kresoxim-methyl was shown to be stable in the standard hydrolysis study under conditions simulating pasteurisation and baking but was almost totally degraded to the acid metabolite (BF 490-1) under sterilisation conditions (71 % TRR). Unfortunately, the possible presence of the metabolite BF 490-1 in the processed commodities could not be confirmed by the processing studies, since samples were

analysed as BF 490-1 after alkaline hydrolysis. Consequently, the actual ratio “parent/BF 490-1” in processed commodities is not known and the residue definition for monitoring in processed commodities is therefore proposed as the sum of parent and BF 490-1. For risk assessment and considering that BF 490-2 and BF 490-9 were detected in significant levels in some processed fractions (wine), and that the presence of BF 490-1 can not be excluded, EFSA proposes to define the residue as “sum kresoxim-methyl, BF 490-1, BF 490-2 and BF 490-9”. The processing studies conducted on apple and grape are not fully appropriate to derive processing factors, since the residue levels of the parent compound in the raw agricultural commodity are not known as the samples were analysed as BF 490-1. However, since BF 490-1 was seen to be present in limited proportions in the metabolism studies performed on primary crops, it can be assumed that the residues analysed in raw agricultural commodity as “BF 490-1” are a correct indicator of the residue levels of the parent compound only.

The representative uses did not trigger any assessment for poultry and the available metabolism study confirms that no individual compound is expected to be present in poultry matrices above 0.001 mg/kg. Therefore a residue definition is proposed for ruminant products only. The goat metabolism study shows kresoxim-methyl to be extensively metabolised to numerous compounds, the parent not being detected in any matrices except fat, but in very low proportions (7 % TRR). The metabolite BF 490-1 appears to be the main compound in muscles (24 % TRR), BF 490-2 the main compound in fat and kidney (24-34 % TRR) and BF 490-9 the major compound in liver and milk (29 and 63 % TRR). However, this metabolic profile is not totally consistent with the results of the feeding study, where BF 490-1 is shown to be present in significantly higher amounts than BF 490-2 and BF 490-9. The very overdosed levels the metabolism study was performed with (850N/280N) may explain these differences. Therefore it is the EFSA proposal to rely on the feeding study where BF 490-1 is the most abundant compound, to define the residue for monitoring as BF 490-1 only. For risk assessment it is proposed to define the residue as sum of BF 490-1, BF 490-2 and BF 490-9. As the ratio “total residues/BF 490-1” is in the range of 1.1 to 1.9 for the different matrices when considering the results of the feeding study, a default conversion factor of 2 is proposed for risk assessment. However, since the transfer in milk is very limited, this conversion factor is not necessary for milk.

The consumer risk assessment using the EFSA PRIMo rev.2 gives intakes of less than 1 % of the ADI. This assessment is not fully finalised since a conversion factor is not available for pome fruits, but this is not a concern, considering the low calculated intake. No acute risk assessment was conducted since the setting of an ARfD was considered not necessary for kresoxim-methyl.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, kresoxim-methyl exhibits very low to low persistence forming the major (>10 % applied radioactivity (AR)) metabolite BF 490-1 (acid of kresoxim-methyl), which exhibited moderate to medium persistence. Small amounts (<5 % AR) of the metabolite BF 490-5 (diacid of kresoxim-methyl) also occurred. Although this low level of formation does not usually trigger further consideration, the exposure concentrations in both surface and groundwater has been assessed for BF 490-5 (see Appendix A).

Mineralisation of the cresyl and phenyl ring radiolabels to carbon dioxide accounted for 19 % (after 90 days) and 37 % AR (after 91 days) respectively. The formation of unextractable residues (not extracted using acetonitrile:water) for the radiolabel placed in the cresyl and phenyl ring accounted for 30 - 48 % (after 90 days) and 37 % (after 91 days) respectively. In anaerobic soil incubations mineralisation was less than 3 % AR after 100 days, while formation of BF 490-1 reached 63 % after 100 days. In the available field soil dissipation studies (spray application to the soil surface on bare soil plots in late spring) the persistency of kresoxim-methyl was very low while that of BF 490-1 was low to moderate. Kresoxim-methyl exhibited medium mobility in soil, whilst BF 490-1 exhibited high to very high mobility.

Neither kresoxim-methyl nor BF 490-1 leached in average concentrations exceeding 0.1 µg/l in the available lysimeter study, which had dose rates and timings pertinent to all representative uses being

assessed. However, leachate from all three lysimeters contained non-identified radioactive residues in annual average concentrations exceeding 0.1 µg/l in all three years of the study. It was not clearly reported whether BF 490-5 was excluded from being a component of this non-identified radioactivity. Two significant peaks were characterised as making up the majority of the unidentified radioactivity in the leachate. Since these peaks were not quantified in the context of annual average concentrations, it cannot be excluded that the leachate contained individual metabolites leached in annual average concentrations exceeding 0.1 µg/l. Consequently a data gap has been identified for quantification of these two unidentified peaks in a way that allows it to be assessed whether the annual average leachate concentrations are less than 0.1 µg/l.

In laboratory incubations in dark aerobic natural sediment water systems, kresoxim-methyl exhibited low persistence, forming the major metabolite BF 490-1 (max. ca. 68 % AR in water and 18 % in sediment, exhibiting high to very high persistence). In these studies the unextractable sediment fraction (not extracted using acetonitrile: water) was the major sink accounting for 12 % AR while mineralisation accounted for 7 - 10 % AR after 100 days. The rate of decline of kresoxim-methyl in a laboratory sterile aqueous photolysis experiment was slow relative to that which occurred in the aerobic sediment water, whereas the decline of the metabolite BF 490-1 was much faster relative to that which had occurred in the aerobic sediment water.

The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC)) were carried out for kresoxim-methyl as well as the metabolites BF 490-1 and BF 490-5 using the FOCUS step 1, step 2 and step 3 approach (version 1.1 of the Steps 1-2 in FOCUS calculator; FOCUS, 2001). For kresoxim-methyl the step 4 calculations⁵ appropriately followed the FOCUS guidance (FOCUS, 2007), with no-spray drift buffer zones implemented for the drainage scenarios (reducing spray drift by maximum 95 %), and combined no-spray buffer zones with vegetative buffer strips (reducing solute flux in run-off by maximum 90 %) being implemented for the run-off scenarios. Risk managers may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS report (FOCUS, 2007) acknowledges that for substances with $K_{Foc} < 2000$ mL/g (such as kresoxim-methyl), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature than is the case for more strongly adsorbed compounds.

The available groundwater exposure assessments were appropriately carried out using FOCUS scenarios (FOCUS, 2000) and the model PEARL 3.3.3 for the active substance kresoxim-methyl and BF 490-1 and BF 490-5. To assess the risk associated with preferential transport through structured soils the Chateaudun scenarios were also simulated using the MACRO model.⁶ For kresoxim-methyl, BF 490-1 and BF 490-5 the potential for groundwater exposure from the representative uses above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios. For grape and apple the modelling results were only provided for the early application (April – May) while those associated with the late application (Apple: July – September; Grape: July – October) were not provided. A data gap was thus identified for an assessment of the groundwater exposure risk for the later application in apples and grapes.

5. Ecotoxicology

The acute, short-term (birds only) and long-term risk for birds and mammals from dietary exposure to kresoxim-methyl was assessed as low for all representative uses based on the guidance document (European Commission, 2002). The long-term risk of kresoxim-methyl for birds and mammals eating contaminated earthworms and fish was assessed as low for all representative uses. Additionally, the risk for birds and mammals drinking contaminated surface water was assessed as low for all uses. The

⁵ Step 3 and 4 simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.

⁶ Simulations with all the models correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.

risk of the plant metabolites of kresoxim-methyl was considered to be covered by the risk assessment of the active substance for both birds and mammals.

Kresoxim-methyl is very toxic to aquatic organisms based on the toxicity data available. The representative formulation was of similar toxicity to aquatic organisms as the technical active substance, based on the content of active substance. TER calculations were based on initial PEC values for FOCUS_{sw} step 3 and step 4 for pome fruit and grapes. For cereals, TER calculations were based on initial PEC values for FOCUS_{sw} step 1 and step 2. Whereas no mitigation measures were required to address the risk for the representative use in cereals, mitigation measures corresponding to no-spray buffer zones of 20 m and 10 m were required to identify a low risk in all scenarios for the representative use in pome fruit and grapes respectively, based on laboratory endpoints. A mesocosm study with multiple applications and measurement of concentrations was provided in order to address the aquatic risk assessment. A NOAEC of 33µg a.s./L was derived based on transient effects on zooplankton. The risk to aquatic organisms was assessed as low for the uses in pome fruits and grapes in all FOCUS_{sw} Step 3 scenarios based on the mesocosm endpoint and an assessment factor of 3. Consequently, mitigation measures were not required in order to address the risk to aquatic organisms. The risk to aquatic organism from the two metabolites BF 490-1 and BF 490-5 was assessed as low based on FOCUS_{sw} Step 1. Kresoxim-methyl had some potential for bioaccumulation in fish however the clearance time was assessed as fast.

The risk to bees, earthworms, soil micro-organisms, non-target plants and biological methods for sewage treatment was assessed as low for all representative uses, based on the data available. The risk to non-target arthropods was assessed as low at tier 1. In addition, this assessment was confirmed by information from extended laboratory tests and several field studies in orchards and grapes.

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
Kresoxim-methyl	Very low to low persistence DT ₅₀ : < 1 days – 3 days (SFO & biphasic, DT ₉₀ : 1.6 – 10.3 days 20 °C, 40 % MWHC soil moisture). (Field dissipation studies: DT ₉₀ < 1 day).	The risk to soil-dwelling organisms was assessed as low.
BF 490-1 (acid of kresoxim-methyl)	Moderate to medium persistence DT ₅₀ : 23 – 86 days (SFO & biphasic, DT ₉₀ : 106 – 287 days, 20 °C, 40-42 % MWHC soil moisture). (Field dissipation studies, single first order DT ₅₀ : 1 – 26 days)	The risk to soil-dwelling organisms was assessed as low.

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
Kresoxim-methyl	Medium mobility K _{foc} 219-372 mL/g	No for cereals. Data gaps for apples and grapes.	Yes	Yes	Yes
BF 490-1	Very high to high mobility K _{foc} 17- 109 mL/g	No for cereals. Data gaps for apples and grapes.	No	Yes (due to the current classification of kresoxim-methyl as R40)	No

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Kresoxim-methyl	Very toxic to aquatic organisms. The risk to aquatic organisms was assessed as low.
BF 490-1	No harmful effects detected on fish, daphnia or algae

6.4. Air

Compound (name and/or code)	Toxicology
Kresoxim-methyl	Not acutely toxic via inhalation

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

- Quality control data for impurities Reg. No. 301 189 and Reg. No. 271 246 to support their proposed levels in the specification (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- A method of analysis with ILV and a confirmatory method if necessary for the matrices fat and milk (relevant for use in cereals, apple and pear; submission date proposed by the notifier: unknown; see section 1).
- Confirmatory method of analysis and ILV for the matrices kidney, liver and muscle (relevant for use in cereals, apple and pear; submission date proposed by the notifier: unknown; see section 1)
- Additional residue data are required for pome fruits in order to derive a conversion factor for risk assessment (relevant for use in apple and pear; submission date proposed by the notifier: unknown; see section 3).
- Quantification of the two unidentified peaks in the leachate from the lysimeter study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- A groundwater exposure risk assessment for the late application in apples/pears (July – September) and grape (July – October) (relevant for later application timings in apples/pears and grapes; submission date proposed by the notifier: unknown; see section 4).

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

- None.

ISSUES THAT COULD NOT BE FINALISED

- The groundwater exposure assessment related to the late application in grapes and apples/pears could not be finalised as groundwater modelling simulations were not provided for this aspect of the representative use.
- Quantification of the two unidentified peaks as annual average concentrations in the lysimeter leachate is necessary in order to assess whether an unidentified metabolite would exceed the 0.1µg/L parametric drinking water limit and thus trigger a groundwater metabolite relevance assessment.

CRITICAL AREAS OF CONCERN

- None.

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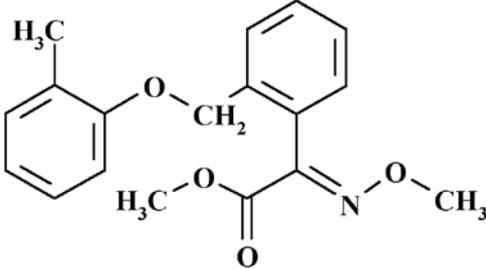
APPENDICES

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

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

Active substance (ISO Common Name) ‡	Kresoxim-methyl
Function (e.g. fungicide)	Fungicide
Rapporteur Member State	Belgium
Co-rapporteur Member State	Lithuania

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	methyl (E)-methoxyimino[α -(<i>o</i> -tolylloxy)- <i>o</i> -tolyl]acetate
Chemical name (CA) ‡	methyl (αE)- α -(methoxyimino)-2-[(2-methylphenoxy)methyl]benzeneacetate
CIPAC No ‡	568
CAS No ‡	143 390-89-0
EC No (EINECS or ELINCS) ‡	not allocated
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	min. 750 g/kg (<u>wet</u> technical grade a.i.) i.e. min. 934 g/kg (dry weight basis; calculated)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Methanol: max. 5 g/kg Methyl chloride: max. 1 g/kg Toluene: max. 1 g/kg
Molecular formula ‡	C ₁₈ H ₁₉ NO ₄
Molecular mass ‡	313.3 u
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	101.6-102.7 °C (99.7 %)
Boiling point (state purity) ‡	not applicable (decomposition before boiling)
Temperature of decomposition (state purity)	310 °C (99.7 %)
Appearance (state purity) ‡	White crystals (99.7 %)
	Off-white, fine powder (wet TGAI, 94.4 %)
Vapour pressure (state temperature, state purity) ‡	$2.3 * 10^{-6}$ Pa (20°C, 99.6 %)
Henry's law constant ‡	$3.6 * 10^{-4}$ Pa m ³ mol ⁻¹
Solubility in water (state temperature, state purity and pH) ‡	2.0 mg/L (20°C, 99.4 %)
	Solubility in water not dependent on pH
Solubility in organic solvents ‡ (state temperature, state purity)	At 20 °C (99.7 %):
	n-heptane: 1.72 g/L
	Toluene: 111 g/L
	Dichloromethane: 939 g/L
	Methanol: 14.9 g/L
	Acetone: 217 g/L
	Ethyl acetate: 123 g/L
Surface tension ‡ (state concentration and temperature, state purity)	72.8 mN/m (90 % saturation concentration, wet TGAI, 94.4 %)
Partition co-efficient ‡ (state temperature, pH and purity)	log P _{ow} = 3.40 (at 25 °C, not dependent on pH, 99.4 %)
Dissociation constant (state purity) ‡	Does not dissociate in the pH range 1 – 13 (99.9 %)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	purity: 99.7% max: 204nm (shoulders: 271 & 277 nm)
	at λ > 290 nm: purity: 99.6% λ _{max} (nm) ε (L.mol ⁻¹ .cm ⁻¹) 292.5 378 302.5 103 312.5 25 320 9 340 1
Flammability ‡ (state purity)	Not highly flammable (95.5 %; 97.8 %); Not self-heating below 400°C (97.8%)
Explosive properties ‡ (state purity)	Not explosive (97.8 %)
Oxidising properties ‡ (state purity)	Not oxidising (97.8 %)

Summary of representative uses evaluated (kresoxim-methyl)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	g as/hL min – max (l)	Water L/ha min-max	g as/ha min-max (l)		
Cereals (wheat, barley, rye, triticale)	Northern & Southern Europe	BAS 494 04 F	F	<i>P. herpotrichoides (Erysiphe graminis)</i> , <i>Septoria, spp.</i> <i>Puccinia spp.</i> <i>(Fusarium spp)</i> , <i>R. secalis</i> <i>P. teres</i>	SC	125 g/L* + 125 g/L**	foliar spray	BBCH 25 - 69	2 max	21 days	31.3-62.5* + 31.3-62.5**	200–400	125* + 125**	35	[1]
Apples, pears	Northern & Southern Europe	BAS 490 02 F (CANDIT)	F	<i>Venturia inequalis</i> , <i>Podosphaera leucotricha</i>	WG	500 g/kg*	Foliar spray	BBCH 53-79	1 - 4	7 – 10 days	6 – 63*	200-1800	100–125*	35	[1], [2] Rate increases with plant growth: 100 + 100 + 125 + 125
Grapes	Northern & Southern Europe	BAS 490 02 F (CANDIT)	F	<i>Guignardia bidwellii</i> <i>Phomopsis viticola</i> <i>Pseudopeziza tracheiphila</i> <i>Unicinula necator</i>	WG	500 g/kg*	Foliar spray	BBCH 19 - 81	1 - 3	8 – 14 days	6 – 100*	150-1600	100–150*	35	[1], [2] Rate increases with plant growth: 100 + 120 + 150

*Kresoxim-methyl

**Epoiconazole

[1] Groundwater exposure assessment for metabolites not finalised due to unidentified radioactivity in lysimeter leachate.

[2] Groundwater exposure assessment was not finalised, the available assessment does not cover the full application period for the horticultural/viticulture practice applied for in respect of the active substance and metabolites.

<p>Note: For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse 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) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypryr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</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) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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Methods of Analysis

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

Technical as (analytical technique)	- CIPAC method 568/TC/M/- (reversed phased HPLC on a RP 18 column using UV-detection at 223 nm and external calibration)
Impurities in technical as (analytical technique)	HPLC-UV; titration; Karl-Fischer; Methyl chloride, methanol, toluene: Headspace GC – FID (standard addition)
Plant protection product (analytical technique)	- <i>WG formulation CANDIT (BAS 490 02 F)</i> : kresoxim-methyl by CIPAC method 568/WG/M/- (HPLC-UV) - <i>SC formulation ALLEGRO (BAS 494 04 F)</i> : Kresoxim-methyl by CIPAC method 568/SC/M/- (HPLC-UV); Epoxiconazole by CIPAC method 609/SC/M/- (GC-FID); Kresoxim-methyl and epoxiconazole by BASF method CF-A 500 (HPLC-UV)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Kresoxim-methyl (BAS 490 F)
Food of animal origin	-No residue definition is proposed for poultry matrices. -BF 490-1 (ruminant matrices, milk)
Soil	Kresoxim-methyl (BAS 490 F); BF 490-1
Water surface	Kresoxim-methyl (BAS 490 F); BF 490-1
drinking/ground	Kresoxim-methyl (BAS 490 F); BF 490-1
Air	Kresoxim-methyl (BAS 490 F)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Multi-residue method DFG S19 (GC-MS): LOQ (BAS 490 F): 0.01 mg/kg (tomato, lemon, wheat grain); LOQ (BAS 490 F): 0.02 mg/kg (rape seed) - BASF method 445/0 (LC-MS/MS): LOQ (BAS 490 F): 0.05 mg/kg (all crop matrix categories); ILV available
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Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

(modified) BASF method 354/2 (HPLC-UV):
LOQ (BF 490-1 and BF 490-9): 0.01 mg/kg (liver, kidney, muscle,

OPEN for milk: method incl. primary validation + ILV + confirmatory method;

OPEN for other ruminant matrices (muscle, liver, kidney): confirmatory method and ILV;

OPEN for fat: method incl. ILV + confirmatory method

Soil (analytical technique and LOQ)

BASF method L0084/01 (LC-MS/MS):
LOQ (BAS 490 F, BF 490-1, BF 490-5): 0.005 mg/kg

Water (analytical technique and LOQ)

BASF method L0156/01 (LC-MS/MS):
LOQ (BAS 490 F, BF 490-1, BF 490-5): 0.03 µg/L (tap water, ground water, surface water)

Air (analytical technique and LOQ)

BASF method L0111/01 (LC-MS/MS):

LOQ (BAS 490 F): 1 µg/m³

Body fluids and tissues (analytical technique and LOQ)

Not required
(kresoxim-methyl is not toxic or very toxic)

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

Active substance (kresoxim-methyl)

RMS/peer review proposal

none

Mammalian toxicology

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Approx. 63% within 48 hours (based on recovery in urine and bile, low dose, rat)
Distribution ‡	Widely distributed.
Potential for accumulation ‡	Negligible
Rate and extent of excretion ‡	Rapid excretion (ca. 90% within 48 hours)
Metabolism in animals ‡	Saturation at high doses (esterolytic detoxification)
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound and BF-490-1 (<i>acid of Kresoxim-methyl</i>)

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral ‡	>5000 mg/kg bw	
Rat LD ₅₀ dermal ‡	>2000 mg/kg bw	
Rat LC ₅₀ inhalation ‡	> 5.6 mg/L	
Skin irritation ‡	Not irritating	
Eye irritation ‡	Not irritating	
Skin sensitisation ‡	Non-sensitiser (Maximisation Test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Decreased body weight; increased liver weight; increased GGT	
Relevant oral NOAEL ‡	146 mg/kg bw/day (90d rat)	
Relevant dermal NOAEL ‡	Not applicable	
Relevant inhalation NOAEL ‡	Not applicable	

Genotoxicity ‡ (Annex IIA, point 5.4)

No genotoxic potential	
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Decreased body weight; increased liver weight	
Relevant NOAEL ‡	36 mg/kg bw/day (2-yr oral, rat)	
Carcinogenicity ‡	Rat liver tumours at the MTD (8000 ppm), considered to arise via a non-genotoxic threshold mechanism. Not oncogenic in mice.	R40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Decreased pup weight gain and delayed development at parentally toxic dose levels	
Relevant parental NOAEL ‡	1000 ppm (100 mg/kg bw/day)	
Relevant reproductive NOAEL ‡	16000 ppm (1500 mg/kg bw/day)	
Relevant offspring NOAEL ‡	1000 ppm (100 mg/kg bw/day)	

Developmental toxicity

Developmental target / critical effect ‡	No developmental toxicity or maternal toxicity observed in either rat or rabbit prenatal toxicity studies up to the limit dose level	
Relevant maternal NOAEL ‡	1000 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat, rabbit:	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No evidence; NOAEL: > 2000 mg/kg bw	
Repeated neurotoxicity ‡	No evidence; NOAEL: > 1180 mg/kg bw/day Systemic NOAEL: 292 mg/kg bw/day	
Delayed neurotoxicity ‡	No data, not necessary	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Kresoxim-Methyl did act as a promotor in rat liver, previously exposed to an initiator, acting above a threshold dose via reversible stimulation of replicative DNA synthesis. The relevant NOAEL is 800 ppm based on meaningful increases of both number and area of GST-P+-liver foci in rats
Studies with metabolite BF-490-1	Acute oral LD ₅₀ : 1090 / 2000mg/kg bw (m / f); Xn; R22 Ames test: negative with and without S-9 mix
Studies with metabolite BF-490-2	Acute oral LD ₅₀ : >5000 mg/kg bw Ames test: negative with and without S-9 mix
Studies with metabolite BF-490-9	Acute oral LD ₅₀ : >5000 mg/kg bw Ames test: negative with and without S-9 mix
Studies with metabolite BF-490-15	Ames test: negative with and without S-9 mix
Studies performed on impurities ‡	none

Medical data ‡ (Annex IIA, point 5.9)

Control of liver function indicators 6-12 months after starting manufacture process: did not reveal any adverse findings
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Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.4 mg/kg bw/day	2-yr oral rat	100
AOEL ‡	0.9 mg/kg bw/day	90-d oral rat, supported by 1 year dog	100 (63% oral absorption)
ARfD ‡	Not allocated	Not necessary	-

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (BAS 490 02F 50 % WG)	Neat formulation: 0.3%	Spray mix: 13%
Formulation (BAS 494 04F 12.5 % SC)	Neat formulation: 6%	Spray mix: 6%

Exposure scenarios (Annex IIIA, point 7.2)

Operator (BAS 490 02F 50 % WG)	<p>German model Tractor high crop: 2.91% of AOEL; Hand-held: 1.34% of AOEL</p> <p>UK POEM Tractor high crop: 29.9% of AOEL; Hand-held: 25% of AOEL</p>
Workers	9% of AOEL (German model)
Bystanders	0.89% of AOEL (Lloyd and Bell)
Operator (BAS 494 04F 12.5 % SC)	<p>German model Tractor low crop: 1.06% of AOEL;</p> <p>UK POEM Tractor low crop: 4.3% of AOEL</p>
Workers	<1% of AOEL
Bystanders	<1% of AOEL (Lloyd and Bell)

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

Human health classification (kresoxim-methyl)	RMS/peer review proposal ; Carc. Cat. 3; Xn, R40 ; the same classification was proposed in the 28th ATP
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Residues

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

Plant groups covered	- Fruit crops (grape, apple) - Cereals (wheat) and - Root/tuber crops (sugar beet)
Rotational crops	Wheat, lettuce, carrot, green bean
Metabolism in rotational crops similar to metabolism in primary crops?	Yes.
Processed commodities	Standard hydrolysis study and processing studies on grape and apple
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Kresoxim-methyl stable under pasteurisation and baking, conditions, but almost totally degraded to the acid metabolite BF 490-1 under pasteurisation (73% TRR)
Plant residue definition for monitoring	Kresoxim-methyl Processed commodities: sum kresoxim-methyl and BF 490-1
Plant residue definition for risk assessment	Sum kresoxim-methyl, BF 490-2 and BF 490-9 free and conjugated, Processed commodities: Sum kresoxim methyl, BF 490-1, BF 490-2 and BF 490-9.
Conversion factor (monitoring to risk assessment)	Grape: 1.7 Cereals: Not necessary Apple/pears: data gap

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

Animals covered	Lactating goat and Laying hen (but not assessed),
Time needed to reach a plateau concentration in milk and eggs	-Milk: plateau reached on day 3 -Eggs: Residue levels increased over the study duration from 0.10 to 0.22 mg/kg equiv. in the high dose group.
Animal residue definition for monitoring	- BF 490-1 (ruminant matrices, milk) - No residue definition proposed for poultry matrices.
Animal residue definition for risk assessment	- Sum of BF 490-1, BF 490-2 and BF 490-9 (ruminant matrices, milk) - No residue definition is proposed for poultry matrices.
Conversion factor (monitoring to risk assessment)	2 for all ruminant matrices except milk (Derived from the ratio "total BF 490-1+BF 490-2+BF 490-9/BF 490-1" observed in the cow feeding study).
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No: Kresoxim-methyl (fat soluble, log K_{ow} : 3.4) but almost totally degraded in goat to BF 490-1 non fat soluble.

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

Confined study (radiolabelled)

Rotational crops metabolism study shows similar metabolic pathway of kresoxim-methyl as for the primary crops.

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

Metabolism and residue studies

- Kresoxim-methyl and glycoside conjugates of BF 490-2 and BF 490-9 stable in grape, apple and apple processed products at -10°C, up to 26 (grape) and 12 (apple) months.
- Kresoxim-methyl, BF 490-2 and BF 490-9 stable up to 24 months at -20°C in wheat grain and dried pea.
- Kresoxim-methyl, BF 490-2 and BF 490-9 stable up to 5 months (wheat, green matter) and 3 months (wheat straw) when stored at -20°C.

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

Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

	Ruminant:	Poultry:	Pig:
Conditions of requirement of feeding studies			
	Yes 0.81/2.07 mg/kg DM/day Dairy/Beef cattle	No	No
	No	No	Not applicable
	Yes	No	Not applicable
Feeding studies: ⁽¹⁾ Residue levels in matrices : Max (BF 490-1) mg/kg in the highest dose group (75N/25N, dairy/beef cattle)			
Muscle	0.01 (BF 490-1)	-	-
Liver	0.04 (BF 490-1)	-	-
Kidney	0.39 (BF 490-1)	-	-
Fat	0.13 (BF 490-1)	-	-
Milk	<0.002(BF 490-9) ⁽²⁾		
Eggs		-	

⁽¹⁾: Feeding rates in the dairy cow study were: 0.23(8N/3N), 0.65 (22N/7N) and 2.19 (75N/25N) mg/kg bw/day.

⁽²⁾: BF 490-1 was not analysed in milk in the feeding study, since it was recovered at trace level in milk (1.6% TRR) in the metabolism study where BF 490-9 was major (63% TRR). As BF 490-9 was not detected in the feeding study (<0.002 mg/kg) at the highest dose rate representing a 75N dose rate for dairy cattle, no residues are expected to be transferred in milk and it was decided per default, to set fort milk, the same residue definition for monitoring and risk assessment as for the other ruminants matrices and to apply a default residue value of 0.01 mg/kg.

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

Crop	Northern Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according representative use	HR (c)	STM (b)
Apples/ Pears	Northern EU	Pear: 0.1 kg a.s./ha, 4 applications., PHI: 35 days: Kresoxim m.: <0.05 mg/kg, not analysed for BF 490-2 and BF 490-9 Overdosed trials on Apples: 0.1 kg/ha, 8 applications., 35 d PHI: Kresoxim m.: 10x <0.05, 0.06	The trials provided on pears were performed at a slightly under dosed seasonal rate of 0.4 kg/ha (maximum seasonal rate: 0.45 kg/ha). Even if the number of trials conducted in compliance with the cGAP is limited, it seems not necessary to request additional trials to propose a MRL of 0.05, since residues were almost below 0.05 mg/kg in the overdosed trials (8 to 12 applications).	0.05*	0.05 [-]	0.05 [-]
	Southern EU	Pear, 0.1 kg a.s./ha, 4 applications, PHI: 35 days: Kresoxim-m.: <0.05, <0.05 BF 490-2: <0.05, <0.05 BF 490-9: 0.07, <0.05 Overdosed trials on Apple: 0.1 kg/ha, 8-12 applications., 28-35 d PHI: Kresoxim m.: 14x <0.05				
Grapes	NE	GAP: 0.15 kg/ha, 3 applic., PHI: 35 days Kresoxim-m.: 0.04, 0.05, <u>0.09</u> , <u>0.11</u> , <u>0.15</u> , <u>0.18</u> , 0.18, 0.27 BF 490-2: 0.03, 0.03, <u>0.02</u> , <u>0.04</u> , <u>0.04</u> , <u>0.04</u> , 0.05, 0.03 BF 490-9: 0.02, 0.02, <u>0.02</u> , <u>0.02</u> , <u>0.03</u> , <u>0.03</u> , 0.05, 0.02	Underlined value refers to residue level at PHI 42 days (since higher than that observed at day 35).	0.5	0.27 [0.32]	0.13 [0.20]
	SE	GAP: 0.15 kg/ha, 3 applic., PHI: 35 days: Kresoxim-m.: <u>0.02</u> , 0.02, 0.03, 0.04, 0.06, 0.06, 0.19, 0.33 BF 490-2: <u>0.02</u> , 0.01, <0.01, <0.01, 0.05, 0.03, 0.03, 0.03 BF 490-9: <u>0.01</u> , 0.01, <0.01, 0.01, 0.02, 0.04, 0.02, 0.03	Values for parent and metabolites are reported in their respective order. Bold: HR as total residues			

[]: Total residues calculated as sum kresoxim-methyl + BF 490-2 + BF 490-9 (no correction for molecular weights, since negligible)

Crop	Northern Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation comments	MRL estimated from trials according representative use	HR (c)	STMR (b)
Wheat	Northern EU	<p>Spring/winter Wheat: 2 applications, 0.125 kg/h, PHI: 35 day:</p> <p>Grain: Kresoxim-m.: 13x <0.05, not analysed for BF 490-2 and BF 490-9</p> <p>Straw: Kresoxim-m.: <0.05, <0.05, 0.06, 0.09, 0.24, 0.36, 0.58, 0.59, 0.65, 0.74, 1.16, 1.51, 2.42 BF 490-2: 0.07, <0.05, 0.05, <0.05, 0.06, 0.16, 0.14, 0.14, 0.10, 0.06, 0.15, 0.65, <0.05 BF 490-9: <0.05, <0.05, 0.07, <0.05, <0.05, 0.30, 0.23, 0.27, 0.19, 0.13, 0.21, 0.44, 0.09</p>	<p>Values for parent and metabolites are reported in the respective order.</p> <p>Bold: HR as total residues</p>	0.10	<0.05 [-] grain 2.42 [2.60] straw	<0.05 [-] grain 0.58 [0.93] straw
	Southern EU	<p>Spring/winter Wheat: 2 applications, 0.125 kg/ha (BBCH 69-PHI: 35 days):</p> <p>Grain: Kresoxim-m: 6x <0.01, 3x <0.01, 0.01, 0.01, 0.02, 0.02, <0.05, 0.06 BF 490-2: 6x <0.01, 3x na, <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 BF 490-9: 6x <0.01, 3x na, <0.01, <0.01, <0.01, <0.01, <0.01, <0.01</p> <p>Straw: Kresoxim-m.: <0.01, 0.04, 0.07, 0.10, 0.10, 0.11, 0.21, 0.22, 0.25, 0.38, 0.45, 0.48, 0.51, 0.52, 1.50 BF 490-2: na, <0.01, 0.01, 0.03, 0.03, 0.03, 0.05, na, 0.06, na, 0.01, <0.01, 0.04, 0.01, 0.04 BF 490-9: na, <0.01, <0.01, <0.01, 0.03, 0.04, 0.05, na, 0.05, na, 0.04, 0.09, 0.04, 0.05, 0.05</p>	<p>Values for parent and metabolites are reported in the respective order.</p> <p>na: not analysed for</p> <p>Bold: HR as total residues</p>	0.10	0.06 [0.06] grain 1.5 [1.59] straw	0.01 [0.03] grain 0.22 [0.34] straw
Rye	Northern EU	<p>Winter rye: 2 applications, 0.125 kg/ha, (BBCH 69-PHI: 35 days):</p> <p>Grain: Kresoxim-m.: <0.05, Not analysed for BF 490-2 and BF 490-9</p> <p>Straw: Kresoxim-m.: <0.05, BF 490-2: 0.06, BF 490-9: 0.12</p>		0.10		

[]: Total residues calculated as sum kresoxim-methyl + BF 490-2 + BF 490-9 (no correction for molecular weights, since negligible)

Crop	Northern Southern Region, field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation comments	MRL estimated from trials according representative use	HR (c)	STMR (b)
Barley	Northern EU	<p>Spring/winter barley: 2 applications, 0.125 kg/h, PHI: 35 day:</p> <p>Grain: Kresoxim-m.: 16x <0.05, not analysed for BF 490-2 and BF 490-9</p> <p>Straw: Kresoxim-m.: 2x <0.05, <0.05, <0.05, 0.07, 0.13, 0.15, 0.26, 0.28, 0.36, 0.52, 0.55, 0.61, 0.63, 0.66, 0.75 BF 490-2: 2x <0.05, <0.05, <0.05, <0.05, 0.08, 0.11, 0.12, <0.05, 0.12, 0.14, 0.09, 0.16, 0.10, 0.18, 0.17 BF 490-9: 2x <0.05, 0.06, 0.06, <0.05, 0.12, 0.10, 0.10, 0.08, 0.07, <0.05, 0.10, <0.05, 0.08, 0.30, 0.09</p>	Values for parent and metabolites reported in the respective order.	0.1	<0.05 [-] grain 0.75 [1.14] straw	<0.05 [-] grain 0.27 [0.45] straw
	Southern EU	<p>Spring/winter barley: 2 applications, 0.125 kg/ha (BBCH 69-PHI: 35 days):</p> <p>Grain: Kresoxim-m.: <0.01, 4x 0.01, 4x 0.01, 0.02, 3x 0.02, 3x 0.03, 0.04, 0.05, 0.08 BF 490-2: na, 4x na, 4x <0.01, na, 3x <0.01, 3x <0.01, <0.01, <0.01, <0.01 BF 490-9: na, 4x na, 4x <0.01, na, 3x <0.01, 3x <0.01, <0.01, <0.01, <0.01</p> <p>Straw: Kresoxim-m.: 0.04, 0.09, 0.09, 0.13, 0.15, 0.17, 0.22, 0.32, 0.36, 0.41, 0.43, 0.43, 0.44, 0.57, 0.87, 0.89, 1.06, 1.24, 2.14 BF 490-2: na, 0.02, 0.01, na, na, 0.04, na, 0.03, 0.03, 0.15, 0.07, 0.05, na, 0.03, 0.03, 0.04, na, 0.03, 0.14 BF 490-9: na, 0.01, 0.01, na, na, 0.05, na, <0.01, 0.07, 0.11, 0.03, 0.05, na, <0.01, 0.02, 0.06, na, 0.06, 0.20</p>	Values for parent and metabolites are reported in the respective order. na: not analysed for	0.1	0.08 [0.10] grain 2.14 [2.48] straw	0.02 [0.04] grain 0.41 [0.53] straw

[]: Total residues calculated as sum kresoxim-methyl + BF 490-2 + BF 490-9 (no correction for molecular weights, since negligible)

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

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

ADI	0.4 mg/kg b.w./day
TMDI (% ADI) according to EFSA PRIMo rev.2A	Highest TMDI 1% ADI (FR All population)
TMDI (% ADI) according to WHO European diet	-
TMDI (% ADI) according to national diets	-
IEDI (WHO European Diet) (% ADI)	-
NEDI (specify diet) (% ADI)	-
Factors included in IEDI and NEDI	MRLs and CF of 1.7 for grape and of 2 for ruminant products (except milk)
ARfD	Not allocated, not necessary
IESTI (% ARfD)	-
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	-

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

Note: Processing studies are not fully appropriate to derive processing factors, since samples analysed as BF 490.1 (sum parent plus BF 490-1). Thus, the parent residue levels in the raw commodities are not known. Nevertheless since BF 490-1 was seen to represent a minor proportion in the metabolism studies (<3% TRR), it can be assumed that the residue level detected in the raw commodity is a correct indicator of the parent residue levels only.

Crop/processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor Mean (values)	Yield factor	
Apple/Juice	4	0.23 (0.10, 0.26, 0.26, 0.31) ^a		
Apple/ Wet pomace	4	1.15^b (0.26, 0.47, 1.06, 2.82) ^{a&b}		
Apple/Sauce	3	0.28 (0.26, 0.26, 0.31) ^a		
Grape/Must cold	4	0.29 (0.18, 0.20, 0.26, 0.53)		
Grape/Must heated	4	0.18 (0.08, 0.16, 0.20, 0.29)		
Grape/wet pomace	4	2.03 (0.86, 1.92, 2.28, 3.06)		
Grape/White wine	2	0.15 (0.11, 0.20)		
Grape/Rosé wine	2	0.18 (0.07, 0.29)		
Grape/Red wine	2	0.18 (0.07, 0.29)		

^a: Processing factor calculated on washed fruits in 3 studies when unwashed value not available or when residue level in washed apple higher than residue level in raw fruit.

^b: Large variability. Highest PF used for animal burden calculation (2.82)

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

Plant products (Residue definition for monitoring: kresoxim-methyl)

- Apple/pear	0.05*
- Grape	0.5
- Cereals (Barley, Wheat, rye and triticale)	0.1

Ruminant products (Residue definition for monitoring: BF 490-1)

- Meat, fat, liver	0.01*
- Kidney	0.02

- Milk

0.01*

Fate and behaviour in the environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

Mineralization after 100 days ‡	Phenyl label 36.7% after 91 d, (n=1) Cresyl label 18.7, 17.2% after 90 d, (n=2)
Non-extractable residues after 100 days ‡	Phenyl label 36.7 after 91 d, (n=1) Cresyl label: 47.6, 30.1% after 90 d, (n=2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	BF 490-1 Max. 65.9 - 83.8 % after 2-3 d 2.5 - 24.9 % after 181-183 d BF490-5 (metabolite of BF 490-1) Max 5 % of applied BF 490-1 in an EU soil on 1 date (hence < 5 % of parent kresoxim-methyl)

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

Anaerobic degradation ‡	
Mineralization after 100 days	Conditions: Cresyl 14C-label/1 soil/0.5 mg as/kg - Nitrogen atmosphere / dark / 40% MWHC 2.6 % mineralisation after 100 d
Non-extractable residues after 100 days	Conditions: Cresyl 14C-label/1 soil/0.5 mg as/kg - Nitrogen atmosphere / dark / 40% MWHC 19.6 % bound residues after 100 d
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	BF 490-1: max. of 83.9 % after 3 d 63.2 % after 100 d
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	In the dark: Kresoxim-methyl: DT50 < 1 d; DT90 < 5 d BF 490-1: plateau level of about 78-80% after 2 days With light: Kresoxim-methyl: DT50 = 0.7 d; DT90 = 2.2 d BF 490-1: DT50 = 8.5 d; DT90 = 28 d No significant photoproducts

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

Laboratory studies ‡

	X ⁷	PH	Temp. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ / DT ₉₀ (d) normalized to 20°C and pF2	St. (χ ²)	St (R ²)	Kinetics
Kresoxim-methyl	Aerobic conditions							
sandy loam (Bruch West) dataset 2	-	7.82	20°C/ 40% MWHC	0.555/1.844	0.457	9.85	-	SFO
sandy loam (Bruch West) dataset 4	-	7.8	20°C/ 40% MWHC	0.475/1.577	0.368	8.48	-	SFO
Geomean (Bruch West)				0.51	0.41			
sandy loam (Holly Springs) dataset 3	-	6.4	20°C/ 75% of 0.33 bar	3.11 */10.32	1.85	10.87	-	FOMC
				1.26	0.87			

*SFO-DT50 back calculated from the bi-phasic; DT₉₀ 10.32/3.32

Metabolite BF 490-1	Aerobic conditions							
Soil type	X ¹	pH (CaCl ₂)	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
sandy loam (Bruch West) dataset 2	-	7.2	20°C/ 40% MWHC	46.2/153.4	0.89	38.1	13.33	SFO
sandy loam (Bruch West) dataset 4	-	7.8	20°C/ 40% MWHC	36.4/120.9	0.90	28.2	7.13	SFO
Geomean (Bruch West)				41	-	32.8 [#]		
sandy loam (Holly Springs) dataset 3 **	-	6.4	20°C/ 75% of 0.33 bar	58.9/195.9	0.94	35.05	8.10	SFO
Sand (Borris) dataset 5 **	-	5.3	20°C/ 40% MWHC	51/169	-	47.4	8.73	SFO
Sandy loam (Langvad) dataset 7 **	-	5.8	20°C/ 40% MWHC	85.7/274.5	-	59.2	4.10	SFO
Sand (Karup) Dataset 6 **	-	4.6	20°C/ 40% MWHC	22.8/287.6	-	5.5 and 117.5 (SFO: fast and slow phases)		DFOP

⁷ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Metabolite BF 490-1	Aerobic conditions							
Soil type	X ¹	pH (CaCl ₂)	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Sand (LUFA 2.1)	-	5.2	20°C/ 41% MWHC	48/159	-	36.6	6.4	SFO
Loam (LUFA 3A)	-	7.3	20°C/ 42% MWHC	36/119	-	23.0	5.0	SFO
Loamy sand (Speyrer Wald)	-	5.7	20°C/ 41% MWHC	77/256	-	54.9	5.2	SFO
Loam (Payette)	-	6.3	20°C/ 41% MWHC	32/106.24	-	27.8	2.7	SFO
Geomean				50,9/167	-	40.8		
Median				49,5/164	-	36.6		

the geometric mean DT50 of the Bruch West soil was included in the calculation of the overall mean recalculated

** BF 490-1 applied as test item.

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X ¹	pH (H ₂ O)	Depth (cm)	DT ₅₀ (d) Actual	DT ₉₀ (d) actual	St. (r ²)	DT ₅₀ (d) Norm.	Method of calculation
For all field trials	-	-	-	-	-	< 1 d	-	-	-

Metabolite BF 490-1	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH (H ₂ O)	Depth (cm)	DT ₅₀ (d) Actual	DT ₉₀ (d) actual	St. % χ ² ***	DT ₅₀ (d) Norm.	Method of calculation *
Sandy silty loam (bare)	Niederhofen	7.2	25	14.1	47.0	17.9	10.8	SFO
Clayey loamy sand (bare)	Birkenheide	5.5	25	7.3	24.2	0.7	4.7	SFO
Sandy loam (bare)	Oberding	7.3	25	37.4	124.1	15	25.5	SFO
Sandy silty loam (bare)	Brockhausen	7.5	25	4.9	16.2	5.8	3.6	SFO
Loamy sand (bare)	New York	5.9	15	12.8	126.7	16.4	11.5**	FOMC**
Silty loam (bare)	Oregon	5.9	15	7.7	50.8	16.9	8.3**	FOMC**
Sandy loam (bare)	California	7.1	30	7.6	25.2	6.7	9.2	SFO
Sandy loam (bare)	Nova Scotia	5.3	15	18.0	59.9	25	12.4	SFO
loam (bare)	Ontario	7.4	30	2.9	53.8	22.4	6.8**	DFOP**

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

Metabolite BF 490-1	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH (H ₂ O)	Depth (cm)	DT ₅₀ (d) Actual	DT ₉₀ (d) actual	St. % χ^2 ***	DT ₅₀ (d) Norm.	Method of calculation*
Sandy loam (bare)	British Columbia	6.1	30	29.8	283.9	5.2	8.1**	DFOP**
Geometric mean							8.8	
median							8.8	

*: method of calculations for the actual DT50 (not normalized).

** : The normalized DT50 (for PEC gw calculations) were calculated according SFO modelling

***: the χ^2 values refer to the DT50 Norm

Metabolite BF 490-5	Aerobic conditions								
Soil type	Location		pH	Depth (cm)	DT ₅₀ (d) actual	St. % χ^2	DT ₅₀ (d) Norm.	Formation fraction	Method of calculation
Loamy sand (bare)	New York	-	5.9	7	-	19.7	3.5	61%	SFO
Silty loam (bare)	Oregon	-	5.9	7	-	12.2	3.7	50%	SFO
Sandy loam (bare)	Nova Scotia	-	5.3	7	-	18.3	3.9	61%	SFO
Sandy loam (bare)	British Columbia	-	6.1	7	-	23.9	1.0	32%	SFO
							geomean = 2.7	Arithmetic mean = 51%	

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

No

Soil accumulation and plateau concentration ‡

Not relevant

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X ¹	pH (CaCl ₂)	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (% χ^2)	Method of calculation
Sandy loam Bruch West	-	7.5	20/	-	0.294/0.978	9.08	SFO
Geometric mean/median							

Metabolite BF 490-1	Anaerobic conditions						
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¹ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Soil type	X ¹	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20°C pF2/10kPa	St. (% χ^2)	Method of calculation
Sandy loam Bruch West	-	7.5	20/	-	0.9251	395.7/>1000	5.73	SFO
Geometric mean/median								

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand Speyer 2.1	0.70	6.1	-	-	2.60	372	0.97
Loamy sand Speyer 2.2	2.29	6.0	-	-	7.74	338	0.99
Sandy loam Speyer 2.3	1.20	6.2	-	-	3.62	301	0.95
Clayey loam Limburgerhof	2.70	7.5	-	-	5.92	219	0.99
Arithmetic mean/median						308	0.975
pH dependence, Yes or No				No			

Metabolite BF 490-1 ‡							
Soil Type	OC %	Soil pH (H ₂ O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam (1)	0.90	6.8	-	-	< 0.1	19.3	(*)
Sandy loam (2)	2.60	6.7	-	-	0.62	24	0.94
Loamy sand	1.00	7.3	-	-	< 0.1	24.16	(*)
Clayey loam	3.27	8.5	-	-	0.55	17	0.91
Clay, Red River Valley	1.80	6.5	-	-	0.7942	44	0.814
Loamy sand, Fuquay-Varina	0.64	5.7	-	-	0.4400	69	0.836
Loam, Savoy	2.61	6.3	-	-	0.8718	33	0.758
Coarse sand, Jyndeved**	1.4	6.23	-	-	0.47	33.6	0.95
Coarse sand, Borris**	1.3	6.05	-	-	0.46	35.4	0.92
Sandy loam, Flakkebjerg**	1.63	6.25	-	-	0.59	36.2	0.96
Coarse sand, Karup**	1.68	5.9	-	-	0.47	28.0	0.94
Loamy clay, Langvad**	1.31	6.95	-	-	0.30	22.9	0.93
Sand, Speyerer Wald	0.7	7.8	-	-	0.2116	30.2	0.912
Loam (NL, PBK)	2.1	7.1	-	-	0.37	17	0.95
Sandy loam (NL, PWK)	1.4	7.3	-	-	0.29	21	0.95
Sand (NL, ORD)	1.3	5.4	-	-	1.08	83	0.93
Sand (NL, OZP)	1.4	6.4	-	-	0.67	48	0.93
Sand (NL, CHD)	3.0	5.4	-	-	3.28	109	0.94
Loamy sand (NL, CHV)	2.8	6.3	-	-	1.77	63	0.94
sand / loamy sand (NL, PHS)	1.9	6.2	-	-	0.51	27	0.95
Sandy loam (NL, MBO)	1.4	6.1	-	-	0.24	17	0.97

Arithmetic mean/median		Median: 30.2	Median = 0.94
		Arithmetic mean = 38.2	Arithmetic mean = 0.92
<p>pH dependence: yes. The Koc - pH - relationship can be described by a sigmoidal curve with a $K_{f,oc}$ under very acid conditions ($K_{f,oc,ac}$) of 1231.2 mL/g and a $K_{f,oc,ba}$ of 23.1 mL/g for basic soils</p>			

*: not analyzed

** : Danish soil classification

Metabolite BF 490-5 ‡							
Soil Type	OC %	Soil pH (0.01 M CaCl ₂)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand, LUFA 2.1	0.68	5.2	-	-	0.034	5.05	0.914
Loamy sand, Speyerer Wald	0.62	5.7	-	-	0.036	5.82	0.933
Sandy loam, Payette Idaho	1.33	6.3	-	-	0.016	1.21	0.792
Loam, LUFA 3A	2.73	7.3	-	-	0.032	1.19	0.776
Arithmetic mean/median					0.030	3.32	0.854
pH dependence (yes or no)			No				

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

Column leaching ‡	Eluation (mm): 200 mm Time period (d): 2 d
	Leachate: 40.2-56.1 % total residues/radioactivity in leachate, as metabolite BF 490-1 25.8-15.5 % total residues/radioactivity retained in top 5 cm
Aged residues leaching ‡	Aged for (d): 30 d Eluation (mm): 200 mm Time period (d): 2 d
	Analysis of soil residues post ageing (soil residues pre-leaching): 49.1 % BF 490-1
	Leachate: 56.7-58.4 % total residues/radioactivity in leachate, as metabolite BF 490-1 30.7-26.1 % total residues/radioactivity retained in top 6 cm
	Aged for (d): 30 d Eluation (mm): 200 mm Time period (d): 2 d

	<p>Leachate:</p> <p>Sand (0.6% OC) 73.1-76.9 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p> <p>Sandy loam (2.1% OC) <0.2-0.8 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p> <p>loamy sand (1.0% OC) 40.8-33.2 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p>
	<p>Aged for (d): 30 d</p> <p>Eluation (mm): 200 mm</p> <p>Time period (d): 2 d</p>
	<p>Leachate:</p> <p>Sandy loam (0.9% OC) 69.2-99.1 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p> <p>Sandy loam (2.6% OC) 2.6-1.6 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p> <p>loamy sand (1.0% OC) 58.8-53.4 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p>
	<p>Aged for (d): 30 d</p> <p>Eluation (mm): 200 mm</p> <p>Time period (d): 2 d</p> <p>Leachate:</p> <p>Sandy loam (0.9% OC) 48.2-41.2 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p> <p>Sandy loam (2.6% OC) 14.7-24.3 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p> <p>Sandy loam (1.3% OC) 62.0-43.0 % total residues/radioactivity in leachate, as a.s. and BF 490-1</p>

Lysimeter/ field leaching studies ‡

<p>Location: Limburgerhof (Germany)</p> <p>Study type : lysimeter</p> <p>Soil properties: loamy sand-sand, pH = 5.7-6.8 , OC= 0.94-0.14% , MWHC = -</p> <p>Dates of application : April-May</p> <p>Crop : /Interception estimated: winter barley and winter wheat (BBCH 30/31 and 49/51), -</p> <p>Number of applications:</p> <p>2 years, 2 applications per year (lysimeter 7)</p> <p>1 year, 2 applications/year (lysimeter 8 and 9)</p> <p>Duration: 3 years</p> <p>Application rate: 300 g/ha/year</p> <p>Average annual rainfall (mm) (years 1, 2, 3): 813.2, 824.5, 874.5 mm</p> <p>Average annual leachate volume (mm): 195.7 to 243.1 mm</p> <p>Individual annual average concentrations :see table below</p> <p>Amount of radioactivity in the soils at the end of the study (lysimeters 7, 8, 9 =)</p>

27.47% AR; 0.1% % AR as a.s., 0.2 % AR as BF 490-1
 33.68% AR; 0.6% % AR as a.s., 0.3 % AR as BF 490-1
 25.58% AR; 0.1% % AR as a.s., 0.2 % AR as BF 490-1

Radioactivity recovered in the leachates of the lysimeters

Period	No.	µg/L ⁽²⁾	% of applied radioactivity ⁽³⁾	a.s. µg/L	BF 490-1 µg/L	Non-identifiable radioactive residues µg/L
1 st year of study 04/1992-04/1993	7	0.518	0.549	< 0.01	0.025	0.426
	8	0.520	0.419	< 0.01	0.040	0.454
	9	0.436	0.362	< 0.01	0.018	0.389
2 nd year of study 04/1993-04/1994	7	0.687	0.326	< 0.01	< 0.012	0.635
	8	0.285	0.251	< 0.01	0.003	0.266
	9	0.355	0.295	< 0.01	0.005	0.333
3 rd year of study 04/1994-04/1995	7	0.396	0.173	< 0.01	< 0.01	0.379
	8	Dismantled	dismantled	-	-	-
	9	0.167	0.142	< 0.01	< 0.01	0.158
Total period of study	7	Mean : 0.537	Sum: 1.048	Mean : < 0.01	Mean : < 0.014	Mean: 0.482
	8	Mean: 0.397	Sum: 0.670	Mean : < 0.01	Mean: 0.021	Mean: 0.356
	9	Mean: 0.318	Sum: 0.798	Mean : < 0.01	Mean : < 0.01	Mean: 0.292

Lysimeter/ field leaching studies ‡

Location: 8 locations in The Netherland
 Study type : field leaching studies
 Not acceptable

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT ₅₀ (d): 1 day Kinetics: SFO
Method of calculation	representative worst case from field studies.
Application data	Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³
	Apples Application rate: 4 appl. of 100, 100 125 and 125 g a.s./ha with an interval of 7 days Interception of 60-70% Time of application (month or season): March to May
	Grapevine Application rate: 3 appl. of 100, 120 and 150 g a.s./ha with an interval of 8 days Interception of 50% Time of application (month or season): March to May
	Winter cereals Application rate: 2 appl. of 125 g a.s./ha with an interval of 21 days Interception of 50 and 70% Time of application (month or season): February to April
	Spring cereals Application rate: 2 appl. of 125 g a.s./ha with an interval of 21 days Interception of 50 and 70% Time of application (month or season): April to July

Apples

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 4 appl.)	Multiple application Time weighted average (after 4 appl.)
Initial	-		0.050	-
Short term 24h	-	-	0.025	0.038
2d	-	-	0.013	0.029
4d	-	-	0.003	0.020
Long term 7d	-	-	< 0.001	0.019
21d	-	-	< 0.001	0.015
28d	-	-	< 0.001	0.013
50d	-	-	< 0.001	0.008
100d	-	-	< 0.001	0.004
Plateau concentration	Not relevant			

grapevines

PEC_(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 3 appl.)	Multiple application Time weighted average (after 3 appl.)
Initial	-		0.100	-
Short term 24h	-	-	0.050	0.075
2d	-	-	0.025	0.059
4d	-	-	0.006	0.039
Long term 7d	-	-	0.001	0.025
21d	-	-	< 0.001	0.022
28d	-	-	< 0.001	0.017
50d	-	-	< 0.001	0.010
100d	-	-	< 0.001	0.005
Plateau concentration	Not relevant			

Winter and spring cereals

PEC_(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 2 appl.)	Multiple application Time weighted average (after 2 appl.)
Initial	-		0.083	-
Short term 24h	-	-	0.042	0.063
2d	-	-	0.021	0.049
4d	-	-	0.005	0.032
Long term 7d	-	-	0.001	0.021
21d	-	-	0.050	0.010
28d	-	-	< 0.001	0.009
50d	-	-	< 0.001	0.005
100d	-	-	< 0.001	0.003
Plateau concentration	Not relevant			

Metabolite BF 490-1
Method of calculation

Molecular weight relative to the parent (BF490-1/ a.s.):
299.3/313.3
DT₅₀ (d): 37.4 days
Kinetics: SFO
representative non-normalized worst case from field studies.

Application data

Maximum occurrence in soil (f_{max,soil}) related to the parent of 84%

Apples

PEC_(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 4 appl.)	Multiple application Time weighted average (after 4 appl.)
Initial	-		0.130	-
Short term	24h	-	0.127	0.128
	2d	-	0.125	0.127
	4d	-	0.120	0.125
Long term	7d	-	0.114	0.122
	28d	-	0.077	0.105
	50d	-	0.051	0.091
	100d	-	0.020	0.068
Plateau concentration	Not relevant			

grapevines

PEC_(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 3 appl.)	Multiple application Time weighted average (after 3 appl.)
Initial	-		0.175	-
Short term	24h	-	0.172	0.174
	2d	-	0.169	0.172
	4d	-	0.163	0.169
Long term	7d	-	0.154	0.164
	28d	-	0.104	0.137
	50d	-	0.069	0.119
	100d	-	0.027	0.087
Plateau concentration	Not relevant			

Winter and spring cereals

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 2 appl.)	Multiple application Time weighted average (after 2 appl.)
Initial	-		0.085	-
Short term 24h	-	-	0.084	0.085
2d	-	-	0.082	0.084
4d	-	-	0.079	0.082
Long term 7d	-	-	0.075	0.080
28d	-	-	0.051	0.067
50d	-	-	0.034	0.062
100d	-	-	0.013	0.047
Plateau concentration	Not relevant			

Metabolite BF 490-5
Method of calculation

Molecular weight relative to the parent (BF490-5/
BF490-1): 329.31/299.3
DT₅₀ (d): 3.9 days
Kinetics: SFO
representative normalized worst case from lab studies.

Application data

formation fraction of 61% (if sequential modelling is
employed)

Apples

PEC_(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 4 appl.)	Multiple application Time weighted average (after 4 appl.)
Initial	-		0.022	-
Short term 24h	-	-	0.022	0.022
2d	-	-	0.021	0.022
4d	-	-	0.018	0.022
Long term 7d	-	-	<0.014	0.021
28d	-	-	0.001	0.017
50d	-	-	< 0.001	0.012
100d	-	-	< 0.001	0.006
Plateau concentration	Not relevant			

grapevines

PEC_(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 3 appl.)	Multiple application Time weighted average (after 3 appl.)
Initial	-		0.034	-
Short term 24h	-	-	0.034	0.034
2d	-	-	0.032	0.034
4d	-	-	0.028	0.033
Long term 7d	-	-	0.021	0.032
28d	-	-	0.001	0.023
50d	-	-	< 0.001	0.015
100d	-	-	< 0.001	0.008
Plateau concentration	Not relevant			

Winter and spring cereals

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual (after 2 appl.)	Multiple application Time weighted average (after 2 appl.)
Initial	-		0.017	-
Short term 24h	-	-	0.017	0.017
2d	-	-	0.016	0.017
4d	-	-	0.014	0.017
Long term 7d	-	-	0.011	0.016
28d	-	-	0.007	0.011
50d	-	-	< 0.001	0.008
100d	-	-	< 0.001	0.004
Plateau concentration	Not relevant			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

pH 5: DT₅₀: 821.8 d at 25 °C (1st order, $\chi^2=0.3\%$)
DT₅₀ Met BF 490-1: ~ 3 % AR (30 d)

pH 7: DT₅₀: 35 d at 25 °C (1st order, $\chi^2=2.2\%$)
DT₅₀ Met BF 490-1: ~ 40 % AR (30 d)

pH 9: DT₅₀: 0.38 d at 25 °C (1st order, $\chi^2=1.7\%$)
DT₅₀ Met BF 490-1: ~ 100 % AR (30 d)

Photolytic degradation of active substance and metabolites above 10 % ‡

DT₅₀ a.s.: 702.2 hours (=29.3 days), continuous irradiation with simulated sunlight
DT₅₀ BF 490-1: 18.2 d, continuous irradiation, in pure water in a Suntest apparatus equipped with a Xenon lamp

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

-

Readily biodegradable ‡
(yes/no)

Kresoxim-methyl and BF-490-1 considered not ready biodegradable.

Degradation in water / sediment

Parent	Distribution (eg max in water 75.6 %AR after 0 d. Max. sed 26.8 % after 1 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole sys.	St. % χ^2	DT ₅₀ -DT ₉₀ Water	St. % χ^2	DT ₅₀ -DT ₉₀ sed	St. % χ^2	Method of calculation
Krempe	7.7	7.1	20	1.26	7.2	-	-	-	-	SFO

Ohlau	7.8	6.3	20	1.36	4.7	-	-	-	-	SFO
Geometric mean/median										

BF-490-1	Distribution (eg max in water 68.3% after 7 d. Max. sed 17.5 % after 14 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole sys.	St. % χ^2	DT ₅₀ -DT ₉₀ Water	St. % χ^2	DT ₅₀ -DT ₉₀ sed	St. % χ^2	Method of calculation
Krempe	7.7	7.1	20	405.7	2.6	-	-	-	-	Simultaneous fit to parent and metabolite
Ohlau	7.8	6.3	20	381.0	3.4	-	-	-	-	
Geometric mean/median										

Mineralization and non extractable residues

Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Krempe	7.7	7.1	7.7 % after 100 d. (end of the study).	11.9 % after 100 d.	11.9 % after 100 d. (end of the study).
Ohlau	7.8	6.3	10.1 % after 100 d. (end of the study).	7.2 % after 100 d.	7.2 % after 100 d. (end of the study).

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

Parent

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: STEPS1-2 in FOCUS version 1.1
Molecular weight (g/mol): 313.3
Water solubility (mg/L): 2
K_{fOC} (L/kg): 308
DT₅₀ soil (d): 1 day (field. In accordance with FOCUS SFO)
DT₅₀ water/sediment system (d): 1.36 (representative worst case from sediment water studies)
DT₅₀ water (d): 1000
DT₅₀ sediment (d): 1.36 (representative worst case from sediment water studies)

Parameters used in FOCUSsw step 3 (if performed)

Version control no.'s of FOCUS software: FOCUS-PRZM version 1.1.1, FOCUS-MACRO version 4.4.2, FOCUS-TOXSWA version 2.2.1 and SWAN version 1.1.4.
Vapour pressure (Pa): 2.3×10^{-6}
K_{fOC} (L/kg): 308
DT₅₀ soil (d): 1 day (field. In accordance with FOCUS SFO)
1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) 0.975

Application rate

Apples
Application rate: 4 appl. of 100, 100 125 and 125 g

a.s./ha with an interval of 7 days Interception of 60-70% Time of application (month or season): March to May
Grapevine Application rate: 3 appl. of 100, 120 and 150 g a.s./ha with an interval of 8 days Interception of 50% Time of application (month or season): March to May
Winter cereals Application rate: 2 appl. of 125 g a.s./ha with an interval of 21 days Interception of 50 and 70% Time of application (month or season): February to April
Spring cereals Application rate: 2 appl. of 125 g a.s./ha with an interval of 21 days Interception of 50 and 70% Time of application (month or season): April to July
Spray drift, Runoff, Drainage

Main routes of entry

Application timing for kresoxim-methyl in apples and grapevines in the relevant scenarios (Step 3 and 4)

Scenario	Water body	Application window*	Application dates according to PAT** #
Apples, BBCH 53-79, early application			
D3 - Vredepeel	Ditch	15 th April - 5 th June (15 th April - 15 th Mai)	20 th April / 4 th May / 17 th May / 24 th May (20 th April)
D4 - Skousbo	pond, stream	20 th April - 10 th June (20 th April - 20 th Mai)	19 th April / 26 th April / 30 th May / 6 th June (19 th April)
D5 - La Jailliere	pond, stream	1 st April - 22 nd Mai (1 st April - 1 st Mai)	8 th April / 22 nd April / 11 th May / 19 th May (8 th April)
R1 - Weiherbach	pond, stream	15 th April - 5 th June (15 th April - 15 th Mai)	26 th April / 8 th May / 15 th May / 31 st May (26 th April)
R2 - Porto	Stream	15 th March - 05 th Mai (15 th March - 14 th April)	21 st March / 30 th March / 22 nd April / 29 th April (22 nd March)
R3 - Bologna	Stream	1 st April - 22 nd Mai (1 st April - 1 st Mai)	4 th April / 11 th April / 22 nd April / 18 th May (4 th April)
R4 - Roujan	Stream	15 th March - 05 th Mai (15 th March - 14 th April)	21 st March / 15 th April / 22 nd April / 29 th April (21 st March)

Application timing for kresoxim-methyl in apples and grapevines in the relevant scenarios (Step 3 and 4)

Scenario	Water body	Application window*	Application dates according to PAT** #
Apples, BBCH 53-79, late application			
D3 - Vredepeel	Ditch	5 th August - 25 th September (26 th August - 25 th September)	18 th Aug. / 26 th Aug. / 5 th Sept. / 12 th Sept. (26 th August)
D4 - Skousbo	pond, stream	5 th August - 25 th September (26 th August - 25 th September)	27 th Aug / 10 th Sept. / 17 th Sept. / 24 th Sept. (27 th August)
D5 - La Jailliere	pond, stream	16 th July - 5 th September (6 th August - 5 th September)	19 th July / 4 th Aug. / 27 th Aug. / 3 rd Sept. (27 th August)
R1 - Weiherbach	pond, stream	5 th August - 25 th September (26 th August - 25 th September)	4 th Aug. / 20 th Aug. / 2 nd Sept. / 17 th Sept. (25 th August)
R2 - Porto	Stream	6 th July - 26 August (27 th July - 26 th August)	21 st July / 28 th July / 4 th Aug. / 11 th Aug. (5 th August)
R3 - Bologna	Stream	21 st July - 10 th September (11 th August - 10 th September)	31 st July / 7 th Aug. / 14 th Aug. / 28 th Aug. (13 th August)
R4 - Roujan	Stream	21 st July - 10 th September (11 th August - 10 th September)	20 th July / 30 th July / 11 th Aug. / 18 th Aug. (11 th August)
Grapevines, BBCH 19-81, early application			
D6 - Thiva	Ditch	15 th February - 2 nd April (15 th February - 17 th March)	27 th February / 14 th March / 25 th March (27 th February)
R1 - Weiherbach	pond, stream	29 th April - 14 th June (29 th April - 29 th Mai)	28 th April / 9 th May / 13 th June (28 th April)
R2 - Porto	Stream	29 th April - 14 th June (29 th April - 29 th Mai)	30 th March / 22 nd April / 30 th April (22 nd April)
R3 - Bologna	Stream	15 th April - 31 st May (15 th April - 15 th May)	14 th April / 22 nd April / 18 th May (14 th April)
R4 - Roujan	Stream	24 th March - 9 th May (24 th March - 23 rd April)	23 rd March / 29 th April / 7 th May (23 rd March)
Grapevines, BBCH 19-81, late application			
D6 - Thiva	Ditch	21 st August - 6 th October (6 th September - 6 th October)	20 th August / 28 th August / 5 th September (5 th September)
R1 - Weiherbach	pond, stream	10 th August - 25 th September (26 th August - 25 th September)	20 th August / 2 nd September / 17 th September (25 th August)
R2 - Porto	stream	11 th July - 26 th August (27 th July - 26 th August)	26 th July / 3 rd August / 11 th August (5 th August)
R3 - Bologna	stream	12 th August - 27 th September (28 th August - 27 th September)	13 th August / 28 th August / 23 rd September (28 th August)
R4 - Roujan	stream	1 st July - 16 th August (17 th July - 16 th August)	25 th July / 2 nd August / 13 th August (25 th July)

* in parenthesis: application window for a single application

** in parenthesis: application date for a single application

Due to a technical error when deriving the Julian days for SWASH input, the dates for the application window were set to one day before the presented dates. This can lead to application dates, which are one day before the start of the application window. This small deviation from the presented approach is negligible under worst-case considerations and will not distort the results.

Scenario	Water body	Application window*	Application dates according to PAT** #
Winter cereals, BBCH 25-69			
D1 - Lanna	ditch, stream	1 st April - 22 nd May (1 st April - 1 st May)	31 st March / 25 th April (31 st March)
D2 - Brimstone	ditch, stream	1 st March - 21 st April (1 st March - 31 st March)	28 th February / 1 st April (28 th February)
D3 - Vredepeel	Ditch	1 st March - 21 st April (1 st March - 31 st March)	29 th February / 4 th April (29 th February)

Scenario	Water body	Application window*	Application dates according to PAT** #
D4 - Skousbo	pond, stream	1 st March - 21 st April (1 st March - 31 st March)	28 th February / 18 th April (28 th February)
D5 - La Jailliere	pond, stream	1 st March - 21 st April (1 st March - 31 st March)	7 th March / 8 th April (7 th March)
D6 - Thiva	Ditch	15 th February - 7 th April (15 th February - 17 th March)	27 th February / 25 th March (27 th February)
R1 - Weiherbach	pond, stream	1 st March - 21 st April (1 st March - 31 st March)	28 th February / 5 th April (28 th February)
R3 - Bologna	stream	15 th February - 7 th April (15 th February - 17 th March)	19 th February / 20 th March (19 th February)
R4 - Roujan	stream	15 th February - 7 th April (15 th February - 17 th March)	2 nd March / 4 th April (2 nd March)
Spring cereals, BBCH 25-69			
D1 - Lanna	ditch, stream	4 th June - 25 th July (4 th June - 4 th July)	17 th June / 8 th July (17 th June)
D3 - Vredepeel	Ditch	1 st May - 21 st June (1 st May - 31 st May)	4 th May / 27 th May (4 th May)
D4 - Skousbo	pond, stream	26 th May - 16 th July (26 th May - 25 th June)	30 th May / 4 th July (30 th May)
D5 - La Jailliere	pond, stream	14 th April - 4 th June (14 th April - 14 th May)	14 th April / 11 th May (14 th April)
R4 - Roujan	stream	14 th April - 4 th June (14 th April - 14 th May)	4 th May / 27 th May (4 th May)

* in parenthesis: application window for a single application

** in parenthesis: application date for a single application

Due to a technical error when deriving the Julian days for SWASH input, the dates for the application window were set to one day before the presented dates. This can lead to application dates, which are one day before the start of the application window. This small deviation from the presented approach is negligible under worst-case considerations and will not distort the results.

Metabolite BF 490-1

Parameters used in FOCUSsw step 1 and 2

Molecular weight:299.3
 Water solubility (mg/L): 90.1
 Soil and water metabolite:
 Kfoc, ba (L/kg): 23.1
 DT₅₀ soil (d): 8.8 days Geometric mean of field studies (n=10, normalized at 20°C and pF2, In accordance with FOCUS SFO)
 DT₅₀ water/sediment system (d): 468.6 (representative worst case from sediment water studies)
 DT₅₀ water (d): 36
 DT₅₀ sediment (d): 1000
 Crop interception (%):See above data on active substance
 Maximum occurrence observed (% molar basis with respect to the parent)
 Water: 81%
 Soil : 84%

Parameters used in FOCUSsw step 3 (if performed)

Not applicable

Application rate

See above data on active substance

Main routes of entry

Spray drift of the parent, Runoff, Drainage

Metabolite BF 490-5

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 329.31
 Water solubility (mg/L): 100
 Soil metabolite:
 Kfoc (L/kg): 3.3
 DT₅₀ soil (d): 2.7 days
 DT₅₀ water/sediment system (d): 1000 *
 DT₅₀ water (d): 1000 *
 DT₅₀ sediment (d): 1000 *
 Maximum occurrence observed 0.01* (% molar basis with respect to the parent)
 4.3% in soil
 (*) worst case default assumptions, this metabolite is not present in w/s studies

Parameters used in FOCUSsw step 3 (if performed)

Not applicable

Application rate

See above data on active substance

Main routes of entry

Runoff, Drainage

PEC_{sw,ini} values (Focus, Step 1 and 2) of Kresoxim-methyl and its metabolites BF 490-1 and BF 490-5 following application of BAS 490 02 F to pomefruit

FOCUS Step		PEC _{sw,ini} [µg/L]		
		Kresoxim-methyl	BF 490-1	BF 490-5
Step 1		41.702	167.495	7.505
Step 2*	Europe North	18.393	25.963	0.052
	Europe South	18.393	28.945	0.101

* Multiple application scenario representing worst-case

Bold letters: worst-case PEC values used for TER calculations

PEC_{sw,ini} values (Focus, Step 1 and 2) of Kresoxim-methyl and its metabolites BF 490-1 and BF 490-5 following application of BAS 490 02 F to grapevine

FOCUS Step		PEC _{sw,ini} [µg/L]		
		Kresoxim-methyl	BF 490-1	BF 490-5
Step 1		39.458²⁾	126.114²⁾	6.751²⁾
Step 2*	Europe North	5.690²⁾	9.411 ²⁾	0.093 ¹⁾
	Europe South	5.690²⁾	12.648 ¹⁾	0.185 ¹⁾

* Multiple application scenario representing worst-case

1) worst-case PEC values resulting from early application

2) worst-case PEC values resulting from late application

Bold letters: worst-case PEC values used for TER calculations

PEC_{sw,ini}, 2 and 7 day PEC_{twa} values (Step 3 and 4 level) of Kresoxim-methyl following application of BAS 490 02 F to pomefruit (early application)

Scenario			PEC _{sw,ini} [µg/L]					
			Step 3 edge of field	Step 4 5 m buffer [#]	Step 4 10 m buffer [#]	Step 4 15 m buffer [#]	Step 4 20 m buffer [#]	Step 4 30 m buffer [#]
D3	ditch	ini	9.699 ¹⁾	7.621 ¹⁾	4.680 ¹⁾	2.105 ¹⁾	1.070 ¹⁾	0.409 ¹⁾
		twa (2 d)	5.019 ²⁾	3.876 ¹⁾	2.380 ¹⁾	1.206 ²⁾	--	--
		twa (7 d)	1.950 ¹⁾ *	1.315 ¹⁾ §	0.717 ²⁾	--	--	--
D4	pond	ini	1.296 ²⁾	1.459 ²⁾	0.815 ²⁾	0.419 ²⁾	0.236 ²⁾	0.057 ¹⁾
		twa (2 d)	--	--	--	--	--	--
		twa (7 d)	1.236 ²⁾	1.391 ²⁾	0.778 ²⁾	--	--	--
	stream	ini	9.393 ¹⁾	8.071 ¹⁾	4.956 ¹⁾	2.230 ¹⁾	1.133 ¹⁾	0.434 ¹⁾
		twa (2 d)	0.551 ¹⁾	--	--	--	--	--
		twa (7 d)	0.194 ¹⁾ *	0.151 ¹⁾ §	0.078 ²⁾	--	--	--
D5	pond	ini	1.325 ²⁾	1.491 ²⁾	0.833 ²⁾	0.428 ²⁾	0.242 ²⁾	0.057 ¹⁾
		twa (2 d)	0.677 [*]	--	--	--	--	--
		twa (7 d)	1.266 ²⁾	1.425 ²⁾	0.796 ²⁾	--	--	--
	stream	ini	9.403 ¹⁾	8.079 ¹⁾	4.962 ¹⁾	2.232 ¹⁾	1.135 ¹⁾	0.434 ¹⁾
		twa (2 d)	0.969 ¹⁾	--	--	--	--	--
		twa (7 d)	0.277 ¹⁾ *	0.216 ¹⁾ §	0.097 ¹⁾ §	--	--	--
R1	pond	ini	1.298 ²⁾	1.461 ²⁾	0.817 ²⁾	0.420 ²⁾	0.237 ²⁾	0.057 ¹⁾
		twa (2 d)	--	--	--	--	--	--
		twa (7 d)	1.228 ²⁾	1.382 ²⁾	0.773 ²⁾	--	--	--
	stream	ini	7.847 ¹⁾	6.743 ¹⁾	4.141 ¹⁾	1.863 ¹⁾	0.947 ¹⁾	0.362 ¹⁾
		twa (2 d)	0.681 ¹⁾	--	--	--	--	--
		twa (7 d)	0.195 ¹⁾	0.167 ¹⁾	0.064 ²⁾	--	--	--
R2	stream	ini	10.396 ¹⁾	8.933 ¹⁾	5.486 ¹⁾	2.468 ¹⁾	1.254 ¹⁾	0.480 ¹⁾
		twa (2 d)	0.443 ¹⁾	--	--	--	--	--
		twa (7 d)	0.127 ¹⁾	0.109 ¹⁾	0.050 ²⁾	--	--	--
R3	stream	ini	11.102 ¹⁾	9.540 ¹⁾	5.858 ¹⁾	2.635 ¹⁾	1.340 ¹⁾	0.512 ¹⁾
		twa (2 d)	1.809 ¹⁾	--	--	--	--	--
		twa (7 d)	0.518 ¹⁾	0.445 ¹⁾	0.216 ²⁾	--	--	--
R4	stream	ini	7.849 ¹⁾	6.745 ¹⁾	4.142 ¹⁾	1.863 ¹⁾	0.947 ¹⁾	0.362 ¹⁾
		twa (2 d)	0.685 ¹⁾	--	--	--	--	--
		twa (7 d)	0.196 ¹⁾	0.191 ²⁾	0.120 ²⁾	--	--	--

1) Worst-case PEC values resulting from single application

2) Worst-case PEC values resulting from four applications

[#] drift and if possible runoff mitigation

* worst-case PEC values resulting from late application in pomefruit

-- not needed for TER calculations

PEC_{sw,ini}, 2 and 7 day PEC_{twa} values (Step 3 and 4 level) of Kresoxim-methyl following application of BAS 490 02 F to grapevine (late application)

			PEC _{sw,ini} [µg/L]		
Scenario			Step 3 - edge of field	Step 4 - 5 m buffer [#]	Step 4 - 10 m buffer [#]
D6	ditch	Ini	2.954 ²⁾	1.774 ²⁾	0.634 ²⁾
		twa (2 d)	--	--	--
		twa (7 d)	2.001 ¹⁾	1.209 ¹⁾	--
R1	pond	Ini	0.186 ²⁾	0.217 ²⁾	0.118 ²⁾
		twa (2 d)	--	--	--
		twa (7 d)	0.176 ²⁾	0.205 ²⁾	--
	stream	Ini	1.888 ¹⁾	1.375 ¹⁾	0.498 ¹⁾
		twa (2 d)	--	--	--
		twa (7 d)	0.058 ¹⁾	0.042 ¹⁾	--
R2	stream	Ini	2.530 ¹⁾	1.844 ¹⁾	0.668 ¹⁾
		twa (2 d)	0.141 ¹⁾	--	--
		twa (7 d)	0.040 ¹⁾	0.029 ¹⁾	--
R3	stream	Ini	2.661 ¹⁾	1.939 ¹⁾	0.702 ¹⁾
		twa (2 d)	--	--	--
		twa (7 d)	0.248 ¹⁾	0.208 ¹⁾	--
R4	stream	Ini	1.888 ¹⁾	1.375 ¹⁾	0.498 ¹⁾
		twa (2 d)	--	--	--
		twa (7 d)	0.135 ²⁾	0.135 ²⁾	--

1) Worst-case PEC values resulting from single application

2) Worst-case PEC values resulting from three applications

[#] drift and if possible runoff mitigation

-- not needed for TER calculations

PEC_{sw,ini} values (Focus, Step 1 and 2) of Kresoxim-methyl and its metabolites BF 490-1 and BF 490-5 following application of BAS 494 04 F to winter and spring cereals

FOCUS Step		PEC _{sw,ini} [µg/L]		
		Kresoxim-methyl	BF 490-1	BF 490-5
Step 1		30.686	66.657	3.750
Step 2*	Europe North	1.158	4.017	0.068
	Europe South	1.158	6.837	0.134

* Multiple application scenario representing worst case # single application scenario represents worst case

Bold letters: worst-case PEC values used for TER calculations

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –
 Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
 Model(s) used: FOCUS-PEARL 3.3.3 and FOCUS-MACRO 4.4.2
 Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva

Kresoxim-methyl
 Geometric mean $DT_{50field}$ 1 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).
 K_{fOC} : arithmetic mean 308 mL/g, $1/n=0.975$.

BF 490-1
 Geometric mean $DT_{50field}$ 8.8 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).
 $K_{f,om,ac}$: 714.2 mL g⁻¹; $K_{f,om,ba}$: 13.4 mL g⁻¹
 $K_{f,oc,ac}$: 1231.2 mL g⁻¹; $K_{f,oc,ba}$: 23.1 mL g⁻¹
 Value of 23.1 mL g⁻¹ used for MACRO calculation
 "fraction transformed" factor from a.s. to BF 490-1 of 0.84

BF 490-5
 Geometric mean or median parent $DT_{50lab/field}$ 2.7 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).
 K_{OC} : parent, arithmetic mean 3.3, $1/n=0.854$.
 "fraction transformed" from BF 490-1 to BF 490-5 of 0.51

Application rate

Apples
 Application rate: 4 appl. of 100, 100 125 and 125 g a.s./ha with an interval of 7 days
 Interception of 60-70%
 Time of application (month or season): March to May

Grapevine
 Application rate: 3 appl. of 100, 120 and 150 g a.s./ha with an interval of 8 days
 Interception of 50%
 Time of application (month or season): March to May

Winter cereals
 Application rate: 2 appl. of 125 g a.s./ha with an interval of 21 days
 Interception of 50 and 70%
 Time of application (month or season): February to April

Spring cereals
 Application rate: 2 appl. of 125 g a.s./ha with an interval of 21 days

Interception of 50 and 70%
Time of application (month or season): April to July

Agricultural use pattern of kresoxim-methyl in BAS 490 02 F applied to apples

Crop	Apples			
Growth stage at first application [BBCH]	53			
Interval [d]	7			
Application rate [g ha ⁻¹]	100	100	125	125
Interception [%]	65	65	70	70
Amount reaching the soil surface [g ha ⁻¹]	35	35	37.5	37.5
Total yearly soil load [g ha ⁻¹]	145			
Application dates				
Scenario				
Châteaudun	1 st April (91)*	8 th April (98)*	15 th April (105)*	22 nd April (112)*
Hamburg	15 th April	22 nd April	29 th April	6 th May
Jokioinen	10 th May	17 th May	24 th May	31 st May
Kremsmünster	15 th April	22 nd April	29 th April	6 th May
Okehampton	25 th March	1 st April	8 th April	15 th April
Piacenza	1 st April	8 th April	15 th April	22 nd April
Porto	15 th March	22 nd March	29 th March	5 th April
Sevilla	15 th March	22 nd March	29 th March	5 th April
Thiva	15 th March	22 nd March	29 th March	5 th April

* Number in parenthesis = Julian day for MACRO

Agricultural use pattern of kresoxim-methyl in BAS 490 02 F applied to grapevines

Crop	Grapevines		
Growth stage at first application [BBCH]	19		
Interval [d]	8		
Application rate [g ha ⁻¹]	100	120	150
Interception [%]	50	50	50
Amount reaching the soil surface [g ha ⁻¹]	50	60	75
Total yearly soil load [g ha ⁻¹]	185		
Application dates			
Scenario			
Châteaudun	15 th April (105)*	23 rd April (113)*	1 st May (121)*
Hamburg	15 th May	23 rd May	31 st May
Kremsmünster	15 th May	23 rd May	31 st May
Piacenza	15 th April	23 rd April	1 st May
Porto	29 th March	6 th April	14 th April
Sevilla	14 th April	22 nd April	30 th April
Thiva	29 th March	6 th April	14 th April

* Number in parenthesis = Julian day for MACRO

Agricultural use pattern of kresoxim-methyl in BAS 494 04 F applied to winter and spring cereals

Crop	Cereals	
Growth stage at first application [BBCH]	25	
Interval [d]	21	
Application rate [g ha ⁻¹]	125	125
Interception [%]	50	70
Amount reaching the soil surface [g ha ⁻¹]	62.5	37.5
Total yearly soil load [g ha ⁻¹]	100	
Application dates		
Scenario	Winter cereals	
Châteaudun	1 st March (60)*	22 nd March (81)*
Hamburg	1 st March	22 nd March
Jokioinen	1 st April	22 nd April
Kremsmünster	1 st March	22 nd March
Okehampton	1 st March	22 nd March
Piacenza	1 st March	22 nd March
Porto	15 th February	8 th March
Sevilla	15 th February	8 th March
Thiva	15 th February	8 th March
Scenario	Spring cereals	
Châteaudun	9 th April (99)*	30 th April (120)*
Hamburg	1 st May	22 nd May
Jokioinen	17 th June	8 th July
Kremsmünster	1 st May	22 nd May
Okehampton	1 st May	22 nd May
Porto	9 th April	30 th April

* Number in parenthesis = Julian day for MACRO

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

PEARL/ Apples	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BF 490-1	BF 490-5
	Chateaudun	< 0.001	0.038	0.013
	Hamburg	< 0.001	< 0.001	0.003
	Jokioinen	< 0.001	< 0.001	0.003
	Kremsmunster	< 0.001	0.024	0.007
	Okehampton	< 0.001	< 0.001	0.001
	Piacenza	< 0.001	0.015	0.012
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	0.010	0.004
	Thiva	< 0.001	0.002	0.001

	Chateaudun (MACRO)	< 0.001	0.011	0.003
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PEARL/ grapevines	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BF 490-1	BF 490-5
	Chateaudun	< 0.001	0.055	0.023
Hamburg	< 0.001	< 0.001	0.003	
Jokioinen	-	-	-	
Kremsmunster	< 0.001	0.020	0.008	
Okehampton	-	-	-	
Piacenza	< 0.001	0.025	0.019	
Porto	< 0.001	< 0.001	< 0.001	
Sevilla	< 0.001	0.012	0.005	
Thiva	< 0.001	0.004	0.002	
Chateaudun (MACRO)	< 0.001	0.054	0.014	

PEARL/ winter cereals	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BF 490-1	BF 490-5
	Chateaudun	< 0.001	0.001	< 0.001
Hamburg	< 0.001	< 0.001	0.001	
Jokioinen	< 0.001	< 0.001	0.001	
Kremsmunster	< 0.001	0.012	0.005	
Okehampton	< 0.001	< 0.001	0.002	
Piacenza	< 0.001	0.004	0.006	
Porto	< 0.001	< 0.001	< 0.001	
Sevilla	< 0.001	< 0.001	< 0.001	
Thiva	< 0.001	< 0.001	< 0.001	
Chateaudun (MACRO)	< 0.001	0.005	0.001	

PEARL/ spring cereals	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			BF 490-1	BF 490-5
	Chateaudun	< 0.001	0.001	< 0.001
	Hamburg	< 0.001	< 0.001	0.001
	Jokioinen	< 0.001	< 0.001	0.006
	Kremsmunster	< 0.001	0.012	0.005
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	-	-	-
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	-	-	-
	Thiva	-	-	-
	Chateaudun (MACRO)	< 0.001	0.002	0.001

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

Direct photolysis in air ‡

Not studied - no data requested

Quantum yield of direct phototransformation

-

Photochemical oxidative degradation in air ‡

DT₅₀ of 0.28 d (12 h day) derived by the Atkinson model (AOPWIN version 1.88). K_{OH} = 38.2 10⁻¹² cm³ molecule⁻¹ s⁻¹

the OH-concentration: was 1.5 x 10⁶ mol cm⁻³

Volatilisation ‡

Not available, not required

Not available, not required

Metabolites

None

PEC (air)

Method of calculation

Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.

PEC_(a)

Maximum concentration

e.g. negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).

Soil: Kresoxim-methyl and BF 490-1
Surface Water: Kresoxim-methyl and BF 490-1
Sediment: Kresoxim-methyl and BF 490-1

Ground water: Kresoxim-methyl and BF 490-1
Air: Kresoxim-methyl

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

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	Several groundwater and surface monitoring studies have been submitted as supporting information. These studies have been performed according to various protocols (locations; years, agricultural practices; national survey – municipal water wells survey – observation of a few fields). It is not always clear whether kresoxim-methyl and/or its metabolite BF-490 have been measured.
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	The few occurrences of kresoxim-methyl and its metabolite in groundwater and surface water are related to local use conditions (pedo-climatic conditions, agricultural practices, point source/diffuse pollution,...). In consequence, the relevance of these studies should be evaluated in the framework of the national authorizations.
	-

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

R53

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
<i>Colinus virginianus</i>	kresoxim-methyl	acute	LD₅₀ > 2150	-
<i>Colinus virginianus</i>	kresoxim-methyl	short-term	LC₅₀ > 1051	LC ₅₀ > 5000
<i>Anas platyrhynchos</i>	kresoxim-methyl	short-term	LC ₅₀ > 2195	LC ₅₀ > 5000
<i>Colinus virginianus</i>	kresoxim-methyl	long-term	NOEC = 51.7	NOEC = 500
Mammals ‡				
rat	kresoxim-methyl	acute	LD₅₀ > 5000	-
rat	kresoxim-methyl	long-term	NOAEL = 100	-
Additional higher tier studies ‡				
Not required.				

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

Crop and application rate: pome fruit (apple, pear) at 1-4 applications x 0.100-0.125 kg a.s./ha

Indicator species/Category ²	Time scale	ETE	TER ¹	Annex VI Trigger ³
Tier 1 (Birds)				
insectivorous	acute	6.76	> 318	10
	short-term	3.77	> 279	10
	long-term	3.77	13.7	5
vermivorous	long-term	0.069	746	5
piscivorous	long-term	0.309	167	5
Higher tier refinement (Birds)				
Not required.				
Tier 1 (Mammals)				
herbivorous	acute	26.6	> 188	10
	long-term	9.32	10.7	5
vermivorous	long-term	0.088	1134	5
piscivorous	long-term	0.191	523	5
Higher tier refinement (Mammals)				
Not required.				

¹ in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

² for cereals indicate if it is early or late crop stage

³ If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Crop and application rate: grapevines at 1-3 applications x 0.100-0.150 kg a.s./ha

Indicator species/Category ²	Time scale	ETE	TER ¹	Annex VI Trigger ³
Tier 1 (Birds)				
insectivorous	acute	8.11	> 265	10
	short-term	4.52	> 232	10
	long-term	4.52	11.4	5
vermivorous	long-term	0.102	509	5
piscivorous	long-term	0.097	532	5
Drinking water consumption	acute	33.7	63.8	10
Higher tier refinement (Birds)				
Not required.				
Tier 1 (Mammals)				
herbivorous	acute	30.1	> 166	10
	long-term	10.2	9.84	5
vermivorous	long-term	0.129	773	5
piscivorous	long-term	0.060	1663	5
Drinking water consumption	acute	19.6	255	10
Higher tier refinement (Mammals)				
Not required.				

¹ in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

² for cereals indicate if it is early or late crop stage

³ If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Crop and application rate: cereals at 2 applications x 0.125 kg a.s./ha

Indicator species/Category ²	Time scale	ETE	TER ¹	Annex VI Trigger ³
Tier 1 (Birds)				
herbivorous	acute	9.37	> 229	10
	short-term	5.14	> 204	10
	long-term	2.72	19.0	5
insectivorous	acute	6.76	> 318	10
	short-term	3.77	> 279	10
	long-term	3.77	13.7	5
vermivorous	long-term	0.046	1119	5
piscivorous	long-term	0.022	2376	5
Higher tier refinement (Birds)				
Not required.				
Tier 1 (Mammals)				
herbivorous	acute	29.61	> 168.9	10
	long-term	8.61	11.6	5

Indicator species/Category ²	Time scale	ETE	TER ¹	Annex VI Trigger ³
insectivorous	acute	1.1	> 4535	10
	long-term	0.40	249	5
vermivorous	long-term	0.059	1700	5
piscivorous	long-term	0.013	7424	5
Higher tier refinement (Mammals)				
Not required				

¹ in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

² for cereals indicate if it is early or late crop stage

³ If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Laboratory tests ‡				
Fish				
<i>Oncorhynchus mykiss</i>	kresoxim-methyl	96 h (static)	Mortality, LC ₅₀	> 150 µg a.s./L (m) < 190 µg a.s./L (m)
<i>Oncorhynchus mykiss</i>	kresoxim-methyl	96 h (flow-through)	Mortality, LC ₅₀	190 µg a.s./L (mm)
<i>Lepomis macrochirus</i>	kresoxim-methyl	96 h (static)	Mortality, LC ₅₀	620 µg a.s./L (m)
<i>Lepomis macrochirus</i>	kresoxim-methyl	96 h (flow-through)	Mortality, LC ₅₀	499 µg a.s./L (mm)
<i>Cyprinus carpio</i>	kresoxim-methyl	96 h (static)	Mortality, LC ₅₀	> 247 µg a.s./L (mm) < 326 µg a.s./L (mm)
<i>Oncorhynchus mykiss</i>	kresoxim-methyl	28 d (flow-through)	Growth NOEC	13 µg a.s./L (mm)
<i>Pimephales promelas</i>	kresoxim-methyl	32 d (flow-through)	Growth NOEC	87 µg a.s./L (mm)
<i>Oncorhynchus mykiss</i>	BF 490-1	96 h (static)	Mortality, LC ₅₀	> 100 mg/L (nom)
<i>Oncorhynchus mykiss</i>	CANDIT	96 h (static)	Mortality, LC ₅₀	0.150 mg/L (0.075 mg a.s./L) (m)
<i>Cyprinus carpio</i>	CANDIT	96 h (static)	Mortality, LC ₅₀	1.946 mg/L (0.97 mg a.s./L) (m)
<i>Oncorhynchus mykiss</i>	CANDIT	28 d (flow-through)	Growth NOEC	0.125 mg/L (0.063 mg a.s./L) (m)
<i>Oncorhynchus mykiss</i>	ALLEGRO	96 h (static)	Mortality, LC ₅₀	1.33 mg/L (m)

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
<i>Oncorhynchus mykiss</i>	ALLEGRO	28 d (flow-through)	Growth NOEC	0.06 mg/L (nom)
Aquatic invertebrate				
<i>Daphnia magna</i>	kresoxim-methyl	48 h (static)	Mortality, EC ₅₀	186 µg a.s./L (nom)
<i>Daphnia magna</i>	kresoxim-methyl	48 h (flow-through)	Mortality, EC ₅₀	332 µg a.s./L (mm)
<i>Daphnia magna</i>	kresoxim-methyl	21 d (semi-static)	Reproduction, NOEC	32 µg a.s./L (nom)
<i>Daphnia magna</i>	kresoxim-methyl	21 d (flow-through)	Reproduction, NOEC	55 µg a.s./L (mm)
<i>Daphnia magna</i>	BF 490-1	48 h (static)	Mortality, EC ₅₀	> 100 mg/L (nom)
<i>Daphnia magna</i>	BF 490-5	48 h (static)	Mortality, EC ₅₀	> 100 mg/L (nom)
<i>Daphnia magna</i>	CANDIT	48 h (static)	Mortality, EC ₅₀	0.289 mg/L (0.14 mg a.s./L) (m)
<i>Daphnia magna</i>	CANDIT	21 d (semi-static)	Reproduction, NOEC	0.112 mg/L (0.056 mg a.s./L) (m)
<i>Daphnia magna</i>	ALLEGRO	48 h (static)	Mortality, EC ₅₀	0.73 mg/L (nom)
<i>Daphnia magna</i>	ALLEGRO	21 d (semi-static)	Reproduction, NOEC	0.125 mg/L (nom)
Sediment dwelling organisms				
Not required.				
Algae				
<i>Ankistrodesmus bibrianus</i>	kresoxim-methyl	72 h (static)	Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	63 µg a.s./L (nom) 250 µg a.s./L (nom)
<i>Selenastrum capricornutum</i>	kresoxim-methyl	5 d (static)	Biomass: E _b C ₅₀	59.4 µg a.s./L (m)
<i>Pseudokirchneriella subcapitata</i>	BF 490-1	72 h (static)	Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	> 500 mg/L (nom) > 500 mg/L (nom)
<i>Pseudokirchneriella subcapitata</i>	CANDIT	72 h (static)	Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	0.040 mg/L (0.02 mg a.s./L) (m) 0.303 mg/L (0.15 mg a.s./L) (m)
<i>Pseudokirchneriella subcapitata</i>	ALLEGRO	72 h (static)	Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	0.299 mg/L (m) > 2.25 mg/L (m)
Higher plant				
Not required.				
Microcosm or mesocosm tests				

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
<p>Mesocosm study conducted with CANDIT, multiple application, duration <i>ca.</i> 6 months. NOEC = 6.6 µg a.s./L (nom) NOAEC = 33 µg a.s./L (nom)</p>				

¹ indicate whether based on nominal (_{nom}) or mean measured concentrations (_{mm}). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)
Aquatic risk assessment for use in pome fruit (1-4 applications of max 0.125 kg a.s./ha)

No calculations performed with FOCUS Step 1 and 2 for the a.s.

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in pome fruit (1-4 x 0.125 kg a.s./ha) based on **FOCUS step 3** calculations (PEC_{max ini} and PEC_{TWA} over 2 days for acute and PEC_{TWA} over 7 days for chronic)

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC _{sw} (µg/L)	TER	Annex VI trigger
D3	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Acute	LC ₅₀ = 190 µg/L	9.699	20	100
D4	Pond (PEC _{ini})				1.296	147	100
	Stream (PEC _{ini})				9.393	20	100
D5	Pond (PEC _{ini})				1.325	143	100
	Stream (PEC _{ini})				9.403	20	100
R1	Pond (PEC _{ini})				1.298	146	100
	Stream (PEC _{ini})				7.847	24	100
R2	Stream (PEC _{ini})				10.396	18	100
R3	Stream (PEC _{ini})				11.102	17	100
R4	Stream (PEC _{ini})				7.849	24	100
D3	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Long-term	NOEC = 13 µg/L	9.699	1.3	10
D4	Pond (PEC _{ini})				1.296	10	10
	Stream (PEC _{ini})				9.393	1.4	10
D5	Pond (PEC _{ini})				1.325	9.8	10
	Stream (PEC _{ini})				9.403	1.4	10
R1	Pond (PEC _{ini})				1.298	10	10
	Stream (PEC _{ini})				7.847	1.7	10
R2	Stream (PEC _{ini})				10.396	1.3	10
R3	Stream (PEC _{ini})				11.102	1.2	10
R4	Stream (PEC _{ini})				7.849	1.7	10
D3	Ditch (PEC _{ini})	<i>Daphnia magna</i>	Acute	EC ₅₀ = 186 µg/L	9.699	19	100
D4	Pond (PEC _{ini})				1.296	144	100
	Stream (PEC _{ini})				9.393	20	100
D5	Pond (PEC _{ini})				1.325	140	100
	Stream (PEC _{ini})				9.403	20	100
R1	Pond (PEC _{ini})				1.298	143	100
	Stream (PEC _{ini})				7.847	24	100
R2	Stream (PEC _{ini})				10.396	18	100

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC _{sw} (µg/L)	TER	Annex VI trigger			
R3	Stream (PEC _{ini})	<i>Daphnia magna</i>	Long-term	NOEC = 32 µg/L	11.102	17	100			
R4	Stream (PEC _{ini})				7.849	24	100			
D3	Ditch (PEC _{ini})				9.699	3.3	10			
D4	Pond (PEC _{ini})				1.296	25	10			
	Stream (PEC _{ini})				9.393	3.4	10			
D5	Pond (PEC _{ini})				1.325	24	10			
	Stream (PEC _{ini})				9.403	3.4	10			
R1	Pond (PEC _{ini})				1.298	25	10			
	Stream (PEC _{ini})				7.847	4.1	10			
R2	Stream (PEC _{ini})				10.396	3.1	10			
R3	Stream (PEC _{ini})				11.102	2.9	10			
R4	Stream (PEC _{ini})				7.849	4.1	10			
D3	Ditch (PEC _{ini})				<i>Ankistrodermus bibraianus</i>	Acute	EC ₅₀ = 63 µg/L	9.699	6.5	10
D4	Pond (PEC _{ini})							1.296	49	10
	Stream (PEC _{ini})	9.393	6.7	10						
D5	Pond (PEC _{ini})	1.325	48	10						
	Stream (PEC _{ini})	9.403	6.7	10						
R1	Pond (PEC _{ini})	1.298	49	10						
	Stream (PEC _{ini})	7.847	8.0	10						
R2	Stream (PEC _{ini})	10.396	6.1	10						
R3	Stream (PEC _{ini})	11.102	5.7	10						
R4	Stream (PEC _{ini})	7.849	8.0	10						

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in pome fruit (1-4 x 0.125 kg a.s./ha) based on **FOCUS step 4** calculations (PEC_{max ini} and PEC_{TWA} over 2 days for acute and PEC_{TWA} over 7 days for chronic)

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC _{sw} (µg/L)	TER	Annex VI trigger
D3	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Acute	LC ₅₀ = 190 µg/L	10	4.680	41	100
					15	2.105	90	
					20	1.070	178	
D4	Pond (PEC _{ini})				--	--	--	100
	Stream (PEC _{ini})				10	4.956	38	
					15	2.230	85	
D5	Pond (PEC _{ini})				20	1.133	168	100
					--	--	--	

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC _{sw} (µg/L)	TER	Annex VI trigger
R1	Stream (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Long-term	NOEC = 13 µg/L	10	4.962	38	100
					15	2.232	85	
					20	1.135	167	
	Pond (PEC _{ini})				--	--	--	
	Stream (PEC _{ini})				10	4.141	46	100
					15	1.863	102	
					20			
R2	Stream (PEC _{ini})				10	5.486	35	100
					15	2.468	77	
					20	1.254	152	
R3	Stream (PEC _{ini})				10	5.858	32	100
					15	2.635	72	
					20	1.340	142	
R4	Stream (PEC _{ini})				10	4.142	46	100
					15	1.863	102	
D3	Ditch (PEC _{ini})	10	4.680	2.8	10			
		15	2.105	6.2				
		20	1.070	12				
D4	Pond (PEC _{ini})	--	--	--				
	Stream (PEC _{ini})	10	4.956	2.6	10			
		15	2.230	5.8				
	20	1.133	11					
D5	Pond (PEC _{ini})	5	1.491	8.7	10			
		10	0.833	16				
	Stream (PEC _{ini})	10	4.962	2.6	10			
	15	2.232	5.8					
	20	1.135	11					
R1	Pond (PEC _{ini})	--	--	--				
	Stream (PEC _{ini})	10	4.141	3.1	10			
		15	1.863	7.0				
	20	0.947	14					
R2	Stream (PEC _{ini})	10	5.486	2.4	10			
		15	2.468	5.3				
		20	1.254	10				
R3	Stream (PEC _{ini})	10	5.858	2.2	10			
		15	2.635	4.9				
		20	1.340	10				
R4	Stream (PEC _{ini})	10	4.142	3.1	10			
		15	1.863	7.0				
		20	0.947	14				
D3	Ditch (PEC _{ini})	<i>Daphnia magna</i>	Acute	EC ₅₀ = 186 µg/L	10	4.680	40	100
					15	2.105	88	
D4	Pond (PEC _{ini})				--	--	--	

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC _{sw} (µg/L)	TER	Annex VI trigger		
	Stream (PEC _{ini})				10	4.956	38	100		
					15	2.230	83			
					20	1.133	164			
D5	Pond (PEC _{ini})				--	--	--			
	Stream (PEC _{ini})				10	4.962	37		100	
R1	Stream (PEC _{ini})				15	2.232	83			
					20	1.135	164			
R2	Pond (PEC _{ini})				--	--	--			
	Stream (PEC _{ini})				10	4.141	45		100	
R3	Stream (PEC _{ini})				15	1.863	100			
					20	1.254	148			
R4	Stream (PEC _{ini})				10	5.486	34	100		
					15	2.468	75			
20	1.254	148								
D3	Stream (PEC _{ini})				10	5.858	32	100		
					15	2.635	71			
20	1.340	139								
R4	Stream (PEC _{ini})				10	4.142	45	100		
					15	1.863	100			
D4	Ditch (PEC _{ini})				5	7.621	4.2		10	
					10	4.680	6.8			
					15	2.105	15			
D5	Pond (PEC _{ini})				--	--	--			
					Stream (PEC _{ini})	5	8.071		4.0	10
						10	4.956		6.5	
15	2.230	14								
D5	Stream (PEC _{ini})				--	--	--			
					Pond (PEC _{ini})	5	8.079		4.0	10
						10	4.962		6.4	
15	2.232	14								
R1	Stream (PEC _{ini})	<i>Daphnia magna</i>	Long-term	NOEC = 32 µg/L	--	--	--	10		
					Pond (PEC _{ini})	5	6.743		4.7	
						10	4.141		7.7	
15	1.863	17								
R2	Stream (PEC _{ini})				5	8.933	3.6	10		
					10	5.486	5.8			
					15	2.468	13			
R3	Stream (PEC _{ini})				5	9.540	3.4	10		
					10	5.858	5.5			
					15	2.635	12			
R4	Stream (PEC _{ini})				5	6.745	4.7	10		
					10	4.142	7.7			
					15	1.863	17			

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC _{sw} (µg/L)	TER	Annex VI trigger
D3	Ditch (PEC _{ini})	<i>Ankistrodermus bibraianus</i>	Acute	EC ₅₀ = 63 µg/L	5 10	7.621 4.680	8.3 13	10
D4	Pond (PEC _{ini})				--	--	--	10
	Stream (PEC _{ini})				5 10	8.071 4.956	7.8 13	10
D5	Pond (PEC _{ini})				--	--	--	10
	Stream (PEC _{ini})				5 10	8.079 4.962	7.8 13	10
R1	Pond (PEC _{ini})				--	--	--	10
	Stream (PEC _{ini})				5 10	6.743 4.141	9.3 15	10
R2	Stream (PEC _{ini})				5 10	8.933 5.486	7.1 11	10
R3	Stream (PEC _{ini})				5 10	9.540 5.858	6.6 11	10
R4	Stream (PEC _{ini})				5 10	6.745 4.142	9.3 15	10

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in pome fruit (1-4 x 0.125 kg a.s./ha) based on **FOCUS step 3** calculations (PEC_{max ini}) and mesocosm endpoint

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC _{sw} (µg/L)	TER	Trigger
D3	Ditch (PEC _{ini})	Mesocosm study	Long-term	NOAEC = 33 µg a.s./L	9.699	3.4	3
D4	Pond (PEC _{ini})				1.296	25.5	3
	Stream (PEC _{ini})				9.393	3.5	3
D5	Pond (PEC _{ini})				1.325	24.9	3
	Stream (PEC _{ini})				9.403	3.5	3
R1	Pond (PEC _{ini})				1.298	25.4	3
	Stream (PEC _{ini})				7.847	4.2	3
R2	Stream (PEC _{ini})				10.396	3.2	3
R3	Stream (PEC _{ini})				11.102	3.0	3
R4	Stream (PEC _{ini})				7.849	4.2	3

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to metabolites BF 490-1 and BF 490-5 in surface water for use in pome fruit (1-4 x 0.125 kg a.s./ha) based on **FOCUS step 1** calculations (PEC_{ini})

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
BF 490-1	<i>Oncorhynchus mykiss</i>	LC ₅₀ > 100 mg/L	Acute	167.495	-	> 597	100

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
	<i>Daphnia magna</i>	EC ₅₀ > 100 mg/L	Acute	167.495	-	> 597	100
	<i>Pseudokirchneriella subcapitata</i>	EC ₅₀ > 500 mg/L	Acute	167.495	-	> 2985	10
BF 490-5	<i>Daphnia magna</i>	EC ₅₀ > 100 mg/L	Acute	7.505	-	> 13324	100

Aquatic risk assessment for use in grapevine (1-3 applications of max 0.150 kg a.s./ha)

No calculations performed with FOCUS Step 1 and 2 for the a.s.

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in grapevine (1-3 x 0.150 kg a.s./ha) based on **FOCUS step 3** calculations (PEC_{max ini} and PEC_{TWA} over 2 days for acute and PEC_{TWA} over 7 days for chronic)

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC _{sw} (µg/L)	TER	Annex VI trigger
D6	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Acute	LC ₅₀ = 190 µg/L	2.954	64	100
R1	Pond (PEC _{ini})				0.186	1 022	100
	Stream (PEC _{ini})				1.888	101	100
R2	Stream (PEC _{ini})				2.530	75	100
R3	Stream (PEC _{ini})				2.661	71	100
R4	Stream (PEC _{ini})				1.888	101	100
D6	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Long-term	NOEC = 13 µg/L	2.954	4.4	10
R1	Pond (PEC _{ini})				0.186	70	10
	Stream (PEC _{ini})				1.888	6.9	10
R2	Stream (PEC _{ini})				2.530	5.1	10
R3	Stream (PEC _{ini})				2.661	4.9	10
R4	Stream (PEC _{ini})				1.888	6.9	10
D6	Ditch (PEC _{ini})	<i>Daphnia magna</i>	Acute	EC ₅₀ = 186 µg/L	2.954	63	100
R1	Pond (PEC _{ini})				0.186	1 000	100
	Stream (PEC _{ini})				1.888	99	100
R2	Stream (PEC _{ini})				2.530	74	100
R3	Stream (PEC _{ini})				2.661	70	100
R4	Stream (PEC _{ini})				1.888	99	100
D6	Ditch (PEC _{ini})	<i>Daphnia magna</i>	Long-term	NOEC = 32 µg/L	2.954	11	10
R1	Pond (PEC _{ini})				0.186	172	10
	Stream (PEC _{ini})				1.888	17	10

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC _{sw} (µg/L)	TER	Annex VI trigger
R2	Stream (PEC _{ini})	<i>Ankistrodermus bibraianus</i>	Acute	EC ₅₀ = 63 µg/L	2.530	13	10
R3	Stream (PEC _{ini})				2.661	12	10
R4	Stream (PEC _{ini})				1.888	17	10
D6	Ditch (PEC _{ini})				2.954	21	10
R1	Pond (PEC _{ini})				0.186	339	10
	Stream (PEC _{ini})				1.888	33	10
R2	Stream (PEC _{ini})				2.530	25	10
R3	Stream (PEC _{ini})				2.661	24	10
R4	Stream (PEC _{ini})	1.888	33	10			

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in grapevine (1-3 x 0.150 kg a.s./ha) based on **FOCUS step 4** calculations (PEC_{max ini} and PEC_{TWA} over 2 days for acute and PEC_{TWA} over 7 days for chronic)

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC _{sw} (µg/L)	TER	Annex VI trigger
D6	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Acute	LC ₅₀ = 190 µg/L	5	1.774	107	100
R1	Pond (PEC _{ini})				--	--	--	100
	Stream (PEC _{ini})				--	--	--	100
R2	Stream (PEC _{ini})				5	1.844	103	100
R3	Stream (PEC _{ini})				5	1.939	98*	100
R4	Stream (PEC _{ini})				--	--	--	100
D6	Ditch (PEC _{ini})	<i>Oncorhynchus mykiss</i>	Long-term	NOEC = 13 µg/L	5	1.774	7.3	10
R1	Pond (PEC _{ini})				10	0.634	21	
	Stream (PEC _{ini})				--	--	--	10
R2	Stream (PEC _{ini})				5	1.375	9.5	10
					10	0.498	26	
R3	Stream (PEC _{ini})				5	1.844	7.0	10
					10	0.668	19	
R4	Stream (PEC _{ini})				5	1.939	6.7	10
		10	0.702	19				
R4	Stream (PEC _{ini})	5	1.375	9.5	10			
		10	0.498	26				
D6	Ditch (PEC _{ini})	<i>Daphnia magna</i>	Acute	EC ₅₀ = 186 µg/L	5	1.774	105	100
R1	Pond (PEC _{ini})				--	--	--	100
	Stream (PEC _{ini})				5	1.375	135	100
R2	Stream (PEC _{ini})				5	1.844	100	100

Scenario	Water body type	Test organism	Time scale	Toxicity end point	Buffer zone distance	PEC _{sw} (µg/L)	TER	Annex VI trigger
R3	Stream (PEC _{ini})				5 10	1.939 0.702	96 265	100
R4	Stream (PEC _{ini})				5	1.375	135	100

* Considering the fast degradation of kresoxim-methyl in water and the short exposure time in streams, the value of 98 appears sufficiently close to the required standard trigger to conclude low risk of unacceptable limits

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in grapevine (1-3 x 0.150 kg a.s./ha) based on **FOCUS step 3** calculations (PEC_{max ini}) and mesocosm endpoint

Scenario	Water body type	Test organism	Time scale	Toxicity end point	PEC _{sw} (µg/L)	TER	Annex VI trigger
D6	Ditch (PEC _{ini})	Mesocosm study	Long-term	NOAEC = 33 µg a.s./L	2.954	11	3
R1	Pond (PEC _{ini})				0.186	177	3
	Stream (PEC _{ini})				1.888	17	3
R2	Stream (PEC _{ini})				2.530	13	3
R3	Stream (PEC _{ini})				2.661	12	3
R4	Stream (PEC _{ini})				1.888	17	3

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to metabolites BF 490-1 and BF 490-5 in surface water for use in grapevine (1-3 x 0.150 kg a.s./ha) based on **FOCUS step 1** calculations (PEC_{ini})

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
BF 490-1	<i>Oncorhynchus mykiss</i>	LC ₅₀ > 100 mg/L	Acute	126.114	-	> 793	100
	<i>Daphnia magna</i>	EC ₅₀ > 100 mg/L	Acute	126.114	-	> 793	100
	<i>Pseudokirchneriella subcapitata</i>	EC ₅₀ > 500 mg/L	Acute	126.114	-	> 3965	10
BF 490-5	<i>Daphnia magna</i>	EC ₅₀ > 100 mg/L	Acute	6.751	-	> 14813	100

Aquatic risk assessment for use in cereals (2 applications of 0.125 kg kresoxim-methyl/ha)

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in cereals (2 x 0.125 kg a.s./ha) based on **FOCUS step 1** calculations (PEC_{ini})

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
kresoxim-methyl	<i>Oncorhynchus mykiss</i>	LC ₅₀ = 190 µg/L	Acute	30.686	-	6.19	100

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
		NOEC = 13 µg/L	Long-term	30.686	-	0.42	10
	<i>Daphnia magna</i>	EC ₅₀ = 186 µg/L	Acute	30.686	-	6.06	100
		NOEC = 32 µg/L	Long-term	30.686	-	1.04	10
	<i>Ankistrodermus bibraianus</i>	EC ₅₀ = 63 µg/L	Acute	30.686	-	2.05	10

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to kresoxim-methyl in surface water for use in cereals (2 x 0.125 kg a.s./ha) based on **FOCUS step 2** calculations (PEC_{ini})

Test substance	Organism	Toxicity end point (µg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
kresoxim-methyl	<i>Oncorhynchus mykiss</i>	LC ₅₀ = 190 µg/L	Acute	1.158	-	164	100
		NOEC = 13 µg/L	Long-term	1.158	-	11	10
	<i>Daphnia magna</i>	EC ₅₀ = 186 µg/L	Acute	1.158	-	161	100
		NOEC = 32 µg/L	Long-term	1.158	-	28	10
	<i>Ankistrodermus bibraianus</i>	EC ₅₀ = 63 µg/L	Acute	1.158	-	54	10

Toxicity Exposure Ratio's (TER's) for aquatic organisms exposed to metabolites BF 490-1 and BF 490-5 in surface water for use in cereals (2 x 0.125 kg a.s./ha) based on **FOCUS step 1** calculations (PEC_{ini})

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC _{ini} (µg/L)	PEC _{twa} (µg/L)	TER	Annex VI Trigger
BF 490-1	<i>Oncorhynchus mykiss</i>	LC ₅₀ > 100 mg/L	Acute	66.657	-	> 1500	100
	<i>Daphnia magna</i>	EC ₅₀ > 100 mg/L	Acute	66.657	-	> 1500	100
	<i>Pseudokirchneriella subcapitata</i>	EC ₅₀ > 500 mg/L	Acute	66.657	-	> 7501	10
BF 490-5	<i>Daphnia magna</i>	EC ₅₀ > 100 mg/L	Acute	6.837	-	> 14626	100

	kresoxim-methyl	BF 490-1	BF 490-5
logP _{O/W}	3.4	< 3	< 3
Bioconcentration factor (BCF) ¹ ‡	220 (whole fish) 430 (viscera) 52 (fillet)		
Annex VI Trigger for the bioconcentration factor	100		
Clearance time (days) (CT ₅₀)	0.37 (days 0-3, whole fish) 3.4 (days 3-10, whole fish) 0.36 (days 0-3, viscera) 3.5 (days 3-10, viscera) 0.21 (days 0-3, fillet) 3.9 (days 3-10, fillet)		
(CT ₉₀)	-		
Level and nature of residues (%) in organisms after the 14 day depuration phase			

¹ only required if log P_{O/W} >3.

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

Test substance	Acute oral toxicity (LD ₅₀ µg/bee)	Acute contact toxicity (LD ₅₀ µg/bee)
kresoxim-methyl ‡	> 110.0 µg a.s./bee	> 100.0 µg a.s./bee
CANDIT	> 230.94 µg/bee	> 200.00 µg/bee
ALLEGRO	> 428.8 µg/bee	> 435.2 µg/bee
Field or semi-field tests		
Not required.		

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

Crop and application rate: pome fruit (apple, pear) at 1-4 applications x 0.100-0.125 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
kresoxim-methyl	oral	< 1.13	50
kresoxim-methyl	contact	< 1.25	50
CANDIT	oral	< 1.08	50
CANDIT	contact	< 1.25	50

Crop and application rate: grapevines at 1-3 applications x 0.100-0.150 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
kresoxim-methyl	oral	< 1.35	50
kresoxim-methyl	contact	< 1.50	50
CANDIT	oral	< 1.30	50
CANDIT	contact	< 1.50	50

Crop and application rate: cereals at 2 applications x 0.125 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
kresoxim-methyl	oral	< 1.13	50
kresoxim-methyl	contact	< 1.25	50
ALLEGRO	oral	< 2.53	50
ALLEGRO	contact	< 2.50	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR ₅₀ g/ha ¹)
<i>Typhlodromus pyri</i> ‡	CANDIT	Mortality	LR₅₀ (7 d) > 900 g/ha
<i>Typhlodromus pyri</i> ‡	ALLEGRO	Mortality	LR₅₀ (7 d) > 3000 mL/ha
<i>Aphidius rhopalosiphi</i> ‡	CANDIT	Mortality	LR₅₀ (48 h) > 900 g/ha
<i>Aphidius rhopalosiphi</i> ‡	ALLEGRO	Mortality	LR₅₀ (48 h) > 3000 mL/ha

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

Crop and application rate: pome fruit (apple, pear) at 1-4 applications x 0.100-0.125 kg a.s./ha

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
CANDIT	<i>Typhlodromus pyri</i>	> 900	< 0.75	< 0.18	2
CANDIT	<i>Aphidius rhopalosiphi</i>	> 900	< 0.75	< 0.18	2

¹ 3 m distance assumed to calculate the drift rate

Crop and application rate: grapevines at 1-3 applications x 0.100-0.150 kg a.s./ha

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
CANDIT	<i>Typhlodromus pyri</i>	> 900	< 0.77	< 0.05	2
CANDIT	<i>Aphidius rhopalosiphi</i>	> 900	< 0.77	< 0.05	2

¹ 3 m distance assumed to calculate the drift rate

Crop and application rate: cereals at 2 applications x 0.125 kg a.s./ha

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
ALLEGRO	<i>Typhlodromus pyri</i>	> 3000	< 0.57	< 0.01	2
ALLEGRO	<i>Aphidius rhopalosiphi</i>	> 3000	< 0.57	< 0.01	2

¹ 1 m distance assumed to calculate the drift rate

Effects of kresoxim-methyl on non-target terrestrial arthropods - All the tests were performed with the formulation CANDIT(*), in order to evaluate the risk of the use of the a.s. in cereals crop

Test species	Test system	Duration of exposure	Results	Hazard Assessment	References
Studies from the Annex II dossier					
<i>Typhlodromus pyri</i>	Lab test	(16 days)	E = 14.91 % (dose: 148 g a.s./ha in 200 L water)	harmless	Kühner Ch., 1993
<i>Trichogramma cacoeciae</i>	Lab test	(7 days)	E = -17.86 % (dose: 150 g a.s./ha in 200 L water)	harmless	Kühner Ch., 1994a
<i>Coccinella septempunctata</i>	Lab test	(40 days)	E = 59.7 % (dose : 150 g a.s./ha in 200 L water)	slightly harmful important reduction of the adults fertility	Kleiner R., 1993a
<i>Poecilus cupreus</i> ¹	Lab test	(14 days)	E = 0 % (dose: 150 g a.s./ha in 400 L water)	harmless	Schlosser E., 1993a
Studies from the Annex III dossier of CANDIT ²					
<i>Typhlodromus pyri</i>	Lab test (different stages)	(2-4 days)	eggs : E = 4.1 % larvae : E = - 3.1 % males : E = 18.8 % females : E = - 3.0 % (dose 0.3 kg formulation/ha in 150 L water)	harmless	Ufer A., 1994b
<i>Coccinella septempunctata</i>	Semi-field test	(40 days)	E = - 23.4 % (dose : 0.3 kg formulation/ha in 300 L water)	harmless	Kleiner R., 1993c
<i>Orius insidiosus</i>	Lab test (second nymph)	(10 days as nymph + 10 days as nymph)	mortality and reproduction : E = 5.5% (dose : 2 appl. of 0.2 kg for-	harmless	Ufer A., 1996b

	stage to adult)	mulation/ha)		
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¹ The study on *Poecilus* was performed with a SC 500 g a.s./L

² Main results of studies submitted in Belgium for the provisional authorisation of CANDIT (apples); no summary available in the DAR

Summary of effects of the formulation CANDIT on non-target terrestrial arthropods (field studies)

Test species	Test system	Results	References
<i>Typhlodromus pyri</i>	apples 4 applications 0.1 kg a.s./ha 1500 L water/ha	E(2 appl.) = -25.1 % E(4 appl.) = -13.3 %	Research Station of Gorseme (1995)
	apples 4 applications 0.2 kg a.s./ha 1500 L water/ha	E(2 appl.) = -20.0 % E(4 appl.) = 10.1 %	
	apples 6 applications 0.1 kg a.s./ha 1500 L water/ha	E(2 appl.) = -15.6 % E(4 appl.) = -26.5 % E(6 appl.) = 33.6 %	
	apples 12 applications 0.1 kg a.s./ha 1500 L water/ha (in association with metiram)	E(9 appl.) = 32.45 % E(12 appl.) = 18.53 % E(60 d after last appl.) = -11.49 %	
<i>Typhlodromus pyri</i>	vines 6 applications 0.073 kg to 0.297 kg a.s./ha 400 L to 1600 L water/ha	E (7 d after last appl.) = - 39 % E (28 d after last appl.) = 22 %	Lipps H.P., 1994
	vines 6 applications 0.074 kg to 0.304 kg a.s./ha 400 L to 1600 L water/ha	E (7 d after last appl.) = - 10 % E (28 d after last appl.) = 35 %	Ipach R., 1994
<i>Typhlodromus pyri</i>	apples 8 applications 0.15 kg a.s./ha 1500 L water/ha	E (7d after last appl.) = 25.3 % E (28 d after last appl.) = 15.8 %	Rohner R., 1994
	apples 8 applications 0.15 kg a.s./ha 1500 L water/ha	E (7 d after last appl.) = 16.8 % E (28d after last appl.) = 54.3 %	Kühner Ch., 1994b

<i>Anthocoris</i> species	pears 5 applications 0.15 kg a.s./ha 1500 L water/ha	E (4 days after last appl. - nymphs) = 40.7 % E (4 days after last appl. - adults) = -2.7 %	Research Station of Gorsem, 1996
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Summary of the formulations CANDIT and ALLEGRO on non-target arthropods : further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) ¹	End point	% effect ²	Trigger value		
<i>Poecilus cupreus</i>	adults	BAS 490 02 F – CANDIT, quartz sand, 14 d	900 g form/ha, initial	Corrected mortality	3.33 %	50 %		
				Reproduction	-0.63 %	50 %		
				LR ₅₀ > 900 g CANDIT/ha (450 g a.s./ha)				
<i>Typhlodromus pyrus</i>	proto-nymphs	BAS 490 02 F – CANDIT, bean leaves, 14 d	150 g form/ha, initial	Corrected mortality	3.1 %	50 %		
				Reproduction	20.1 %	50 %		
				300 g form/ha, initial	Corrected mortality	12.8 %	50 %	
					Reproduction	24.9 %	50 %	
					600 g form/ha, initial	Corrected mortality	7.0 %	50 %
						Reproduction	13.7 %	50 %
900 g form/ha, initial	Corrected mortality	20.5 %	50 %					
	Reproduction	13.6 %	50 %					
1250 g form/ha, initial	Corrected mortality	8.9 %	50 %					
	Reproduction	34.4 %	50 %					
				LR ₅₀ > 1250 g CANDIT/ha (625 g a.s./ha)				
<i>Aphidius rhopalosiphii</i>	adults	BAS 490 02 F – CANDIT, barley plants, 14 d	150 g form/ha, initial	Corrected mortality	3.33 %	50 %		
				Reproduction	-	50 %		
				300 g form/ha, initial	Corrected mortality	0.00 %	50 %	
					Reproduction	-	50 %	
				600 g form/ha, initial	Corrected mortality	0.00 %	50 %	
Reproduction	8.49 %	50 %						
900 g form/ha, initial	Corrected mortality	0.00 %	50 %					
	Reproduction	21.32 %	50 %					
1250 g form/ha, initial	Corrected mortality	0.00 %	50 %					
	Reproduction	42.45 %	50 %					

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) ¹	End point	% effect ²	Trigger value
				LR ₅₀ > 1250 g CANDIT/ha (625 g a.s./ha)		
<i>Coccinella septempunctata</i>	larvae	BAS 490 02 F – CANDIT, apple leaves, 1-3 days until metamorphosis was completed	100 g form/ha, initial	Corrected mortality Reproduction	-2.50 % -13.8 %	50 % 50 %
			240 g form/ha, initial	Corrected mortality Reproduction	-12.50 % -73.1 %	50 % 50 %
			540 g form/ha, initial	Corrected mortality Reproduction	-15.00 % 11.6 %	50 % 50 %
				LR ₅₀ > 540 g CANDIT/ha (270 g a.s./ha)		
<i>Coccinella septempunctata</i>	larvae	BAS 490 02 F – CANDIT, apple leaves, 1-3 days until metamorphosis was completed	600 g form/ha, initial	Corrected mortality Reproduction	0.0 % 11.5 %	50 % 50 %
			900 g form/ha, initial	Corrected mortality Reproduction	10.2 % -3.8 %	50 % 50 %
				LR ₅₀ > 900 g CANDIT/ha (450 g a.s./ha)		

¹ indicate whether initial or aged residues

² Corrected mortality : positive values : adverse effects

Reproduction, food consumption : positive values : reduction; negative values : enhancement

Field or semi-field tests

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 4 times at application rates of 0.20 kg/ha BAS 490 02 F at the 1st and 2nd application and 0.25 kg/ha BAS 490 02 F at the 3rd and 4th application at water volumes of 900 L/ha in an apple orchard in Southern France.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F is applied 4 times at application rates of 0.20 kg/ha BAS 490 02 F in 900 L/ha water for the 1st application, of 0.20 kg/ha BAS 490 02 F in 1000 L/ha water for the 2nd application and 0.25 kg/ha BAS 490 02 F in 1100 L/ha water for the 3rd and 4th application in an apple orchard.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 4 times at application rates of 0.25 kg/ha BAS 490 02 F in 1200 L/ha water in an apple orchard in South West Germany.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 3 times at application rates of 0.30 kg/ha BAS 490 02 F in 600 L/ha water for the 1st application and 0.30 kg/ha in 800 L/ha water for the 2nd and 3rd application in a vineyard in South West Germany.

No unacceptable effects on predatory mite populations (Acari: Phytoseiidae) were observed if BAS 490 02 F was applied 3 times at application rates of 0.30 kg/ha BAS 490 02 F in 800 L/ha water in a vineyard in Southern France.

Summary of effects on predatory mites (*Typhlodromus pyri*) exposed to BAS 49002 F – formulation CANDIT in apple orchards and grapevines

Species	Crop	Maximum application rate [g/ha]	Sampling time ¹⁾	Effects ²⁾ [%]	Reference
predatory mites	Apple orchard	2 x 200 + 2 x 250	7 DAA 1 6 DAA 2 6 DAA 4 27 DAA 4	+4.5 / +27.5 ³⁾ -2.3 / +22.3 ³⁾ +5.6 / +28.3 ³⁾ +2.3 / +25.8 ³⁾	Lehmhus, 2007/1017533
predatory mites	Apple orchard	2 x 200 + 2 x 250	7 DAA 1 6 DAA 2 6 DAA 4 26 DAA 4	-8.2 +0.5 -4.0 -17.4	Lehmhus, 2007/1017531
predatory mites	Apple orchard	4 x 250	8 DAA 1 6 DAA 2 5 DAA 4 26 DAA 4	+13.7 +3.8 +2.9 +10.0	Lehmhus, 2007/1017532 + 2008/1020041 (Amendment)
predatory mites	Grapevine	3 x 300	5 DAA 1 5 DAA 2 8 DAA 3 28 DAA 3	-25.1 +14.1 -31.5 +3.2	Lehmhus, 2007/1017534
predatory mites	Grapevine	3 x 300	8 DAA 1 7 DAA 2 6 DAA 3 31 DAA 3	-0.4 +14.2 +11.3 +2.0	Lehmhus, 2007/1017535 + 2008/1034511 (Amendment)

1) DAA = Days After Application.

2) Effects calculated according to Abbott (1925). Negative values indicate a higher population development compared to the control.

3) Effects calculated according to Henderson-Tilton as the mite population in the different treatment groups was statistically significant different before the 1st application.

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

Test organism	Test substance	Time scale	End point ¹
Earthworms			
<i>Eisenia foetida</i>	kresoxim-methyl ‡	acute 14 days	LC ₅₀ > 937 mg a.s./kg d.w. soil LC _{50 corr} > 469 mg a.s./kg d.w. soil
<i>Eisenia foetida</i>	BF 490-1	acute 14 days	LC₅₀ > 1000 mg/kg d.w. soil
<i>Eisenia foetida</i>	BF 490-5	acute 14 days	LC₅₀ > 1000 mg/kg d.w. soil
<i>Eisenia foetida</i>	CANDIT	acute 14 days	LC ₅₀ = 644 mg/kg d.w. soil LC _{50 corr} = 322 mg/kg d.w. soil (161 mg a.s./kg d.w. soil)
<i>Eisenia foetida</i>	ALLEGRO	acute 14 days	LC ₅₀ > 1000 mg/kg d.w. soil
<i>Eisenia foetida</i>	ALLEGRO	chronic 56 days	NOEC = 11.56 mg/kg
Other soil macro-organisms			
Not required.			
Collembola			
Not required.			
Soil micro-organisms			
Nitrogen mineralisation	BF 490-1	42 days	< 25 % effect at 0.2 and 2.0 mg/kg d.w. soil in sandy loam soil and sandy clay loam soil
	BF 490-5	28 days	< 25 % effect at 0.042 and 0.42 mg/kg d.w. soil in loamy sand soil
	CANDIT	28 days	< 25 % effect at 0.4 and 4.0 mg/kg d.w. soil in clay sand soil and sandy loam soil
	ALLEGRO	28 days	< 25 % effect at 1.33 and 13.33 µL/kg d.w. soil in clay sand soil and sandy loam soil
Carbon mineralisation	BF 490-1	28 days	< 25 % effect at 0.2 and 2.0 mg/kg d.w. soil in sandy loam soil and sandy clay loam soil
	BF 490-5	28 days	< 25 % effect at 0.042 and 0.42 mg/kg d.w. soil in loamy sand soil
	CANDIT	28 days	< 25 % effect at 0.4 and 4.0 mg/kg d.w. soil in clay sand soil and sandy loam soil
	ALLEGRO	28 days	< 25 % effect at 1.33 and 13.33 µL/kg d.w. soil in clay sand soil and sandy loam soil
Field studies ²			
Not required.			

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

² litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate: pome fruit (apple, pear) at 1-4 applications x 0.100-0.125 kg a.s./ha

Test organism	Test substance	Time scale	Initial PECsoil (mg a.s./kg)	TER	Trigger
Earthworms					
<i>Eisenia foetida</i>	kresoxim-methyl ‡	acute	0.050	> 9380	10
<i>Eisenia foetida</i>	BF 490-1	acute	0.130	> 7692	10
<i>Eisenia foetida</i>	BF 490-5	acute	0.022	> 50000	10
<i>Eisenia foetida</i>	CANDIT	acute	0.050	3220	10
Other soil macro-organisms					
Not required.					

Crop and application rate: grapevines at 1-3 applications x 0.100-0.150 kg a.s./ha

Test organism	Test substance	Time scale	Initial PECsoil (mg a.s./kg)	TER	Trigger
Earthworms					
<i>Eisenia foetida</i>	kresoxim-methyl ‡	acute	0.100	> 4690	10
<i>Eisenia foetida</i>	BF 490-1	acute	0.175	> 5714	10
<i>Eisenia foetida</i>	BF 490-5	acute	0.034	> 29412	10
<i>Eisenia foetida</i>	CANDIT	acute	0.100	1610	10
Other soil macro-organisms					
Not required.					

Crop and application rate: cereals at 2 applications x 0.125 kg a.s./ha

Test organism	Test substance	Time scale	Initial PEC _{soil} (mg a.s./kg)	TER	Trigger
Earthworms					
<i>Eisenia foetida</i>	kresoxim-methyl ‡	acute	0.083	> 5651	10
<i>Eisenia foetida</i>	BF 490-1	acute	0.085	> 11765	10
<i>Eisenia foetida</i>	BF 490-5	acute	0.017	> 58824	10
Other soil macro-organisms					
Not required.					

First Tier Toxicity Exposure Ratio's (TER's) for earthworms exposed to the formulation BAS 494 04 F – ALLEGRO

Test species	Time-scale	Endpoint (mg/kg dry soil)	initial PEC _{SOIL} (mg/kg dry soil)*	TER	Annex VI Trigger Value
Kresoxim-methyl as contained in BAS 494 04 F					
<i>Eisenia fetida</i>	long-term	1.3	0.083	15.7	5
Epoxiconazole as contained in BAS 494 04 F					
<i>Eisenia fetida</i>	long-term	1.3	0.128	10.2	5

* initial PEC_{SOIL} calculations are based on application rates of 2 x 0.125 kg kresoxim-methyl/ha and 2 x 0.125 kg epoxiconazole/ha in cereals, 50% and 70% interception, soil layer of 5 cm

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

Crop and application rate: pome fruit (apple, pear) at 1-4 applications x 0.100-0.125 kg a.s./ha

Most sensitive species	Test substance	ER ₅₀ vegetative vigour	ER ₅₀ emergence	Exposure ¹	TER	Trigger
carrot, cabbage, pea, corn, oats, onion	CANDIT	> 900 g/ha	-	159 g/ha	5.65	5

¹ exposure has been estimated based on Ganzelmeier drift data

Crop and application rate: grapevines at 1-3 applications x 0.100-0.150 kg a.s./ha

Most sensitive species	Test substance	ER ₅₀ vegetative vigour	ER ₅₀ emergence	Exposure ¹	TER	Trigger
carrot, cabbage, pea, corn, oats, onion	CANDIT	> 900 g/ha	-	47.6 g/ha	18.9	5

¹ exposure has been estimated based on Ganzelmeier drift data

Crop and application rate: cereals at 2 applications x 0.125 kg a.s./ha

Most sensitive species	Test substance	ER ₅₀ vegetative vigour	ER ₅₀ emergence	Exposure ¹	TER	Trigger
onion, oats, pea, rapeseed, carrot, sunflower	ALLEGRO	> 2000 mL/ha	-	40.5 mL/ha	49.4	5

¹ exposure has been estimated based on Ganzelmeier drift data

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

Not required.

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

Test type/organism	End point
<i>Pseudomonas sp</i>	EC ₅₀ > 1000 mg a.s./L EC ₅₀ > 1000 mg BF 490-1/L

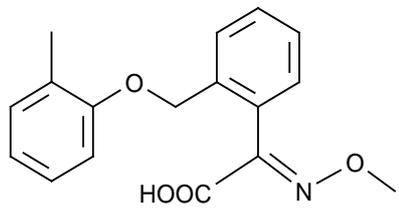
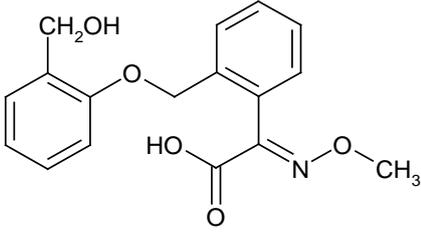
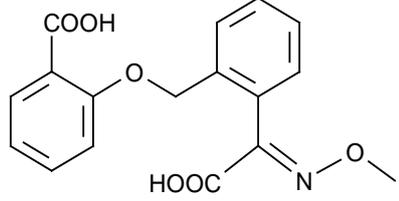
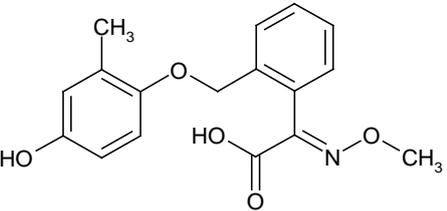
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	kresoxim-methyl, BF 490-1, BF 490-5
water	kresoxim-methyl, BF 490-1, BF 490-5
sediment	-
groundwater	-

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

Active substance	RMS/peer review proposal
	N, R50/53
Preparation	RMS/peer review proposal
	N, R50/53 for CANDIT
	N, R50/53 for ALLEGRO

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
BF 490-1 (acid of kresoxim-methyl)	(<i>E</i>)-methoxyamino(α -(<i>o</i> -tolylloxy)- <i>o</i> -tolyl]acetic acid	
BF 490-2	(2 <i>E</i>)-(2-([2-(hydroxymethyl)phenoxy]methyl]phenyl)(methoxyimino)acetic acid	
BF 490-5 (diacid of kresoxim-methyl)	2-({2-[(<i>E</i>)-carboxy(methoxyimino)methyl]benzyl}oxy)benzoic acid	
BF 490-9	(2 <i>E</i>)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid	

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

ABBREVIATIONS

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

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 – ultra violet
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter-laboratory validation
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
PEC _{twa}	predicted environmental concentration time weighted average
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