CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the United Kingdom, for the pesticide active substance pyroxsulam are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of pyroxsulam as a herbicide on winter wheat, rye and triticale. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

Pyroxsulam, peer review, risk assessment, pesticide, herbicide

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SUMMARY

Pyroxsulam is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC the United Kingdom (hereinafter referred to as the 'RMS') received an application from Dow AgroSciences GmbH for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2007/277/EC.

The RMS provided its initial evaluation of the dossier on pyroxsulam in the Draft Assessment Report (DAR), which was received by the EFSA on 20 March 2008. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR. The peer review was initiated on 27 February 2012 by dispatching the DAR for consultation of the Member States and the applicant Dow AgroSciences GmbH.

Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and environmental fate and behaviour and EFSA should adopt a conclusion on whether pyroxsulam can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

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

No data gaps were identified for the sections identity, physical and chemical properties and analytical methods.

In the mammalian toxicology section a critical area of concern was identified since the technical specification is not supported by the batches used in the toxicological studies. Data gaps were identified to address the toxicological profile of an impurity and the groundwater metabolites 7-OH-XDE-742, PSA and 6-Cl-7-OH-XDE-742.

Based on the available studies, the residue definition for monitoring and risk assessment was proposed as pyroxsulam for the cereal plant group. MRLs were proposed at 0.01* mg/kg for wheat, rye and triticale. No chronic risk was identified for consumers, the highest TMDI being only 0.01% of the ADI.

No data gaps or areas of concern were identified in the residues section.

Sufficient information has been provided to elucidate the fate and behaviour of pyroxsulam in the environment. No data gaps and no critical areas of concern were identified.

Data gaps were identified for further risk assessments for aquatic organisms and soil organisms. The risk to birds and mammals, honeybees, non-target arthropods, non-target terrestrial plants and sewage treatment organisms was concluded to be low for the representative uses of pyroxsulam.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of upto 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC, the United Kingdom (hereinafter referred to as the 'RMS') received an application from Dow AgroSciences GmbH for approval of the active substance pyroxsulam. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2007/277/EC.[6]

The RMS provided its initial evaluation of the dossier on pyroxsulam in the DAR, which was received by the EFSA on 20 March 2008. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of an updated DAR (United Kingdom, 2012). The peer review was initiated on 27 February 2012 by dispatching the DAR to Member States and the applicant Dow AgroSciences GmbH for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 18 June 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant, and that the EFSA

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision 2007/277/EC of 20 April 2007 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pyroxsulam in Annex I to Council Directive 91/414/EEC. OJ No L 116, 4.5.2007, p. 59-61.

should organise an expert consultation in the areas of mammalian toxicology and environmental fate and behaviour.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in March 2013.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on winter wheat, rye and triticale, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (18 June 2012),
- the Evaluation Table (26 March 2013),
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of February 2013 containing all individually submitted addenda (United Kingdom, 2013)) 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

Pyroxsulam is the ISO common name for *N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide (IUPAC).

The representative formulated product for the evaluation was 'GF-1274', a water dispersible granule (WG) containing 75 g/kg pyroxsulam. The formulation contains a safener.

The representative uses evaluated comprise spray applications for control of grasses and broad leaf weeds in winter wheat, winter triticale and winter rye. Full details of the GAPs 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 following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of the active substance is 965 g/kg. No FAO specification exists. The specification is based on industrial scale production. The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of pyroxsulam or the representative formulation. It should be noted that the formulation should not be stored above 40°C. The main data regarding the identity of pyroxsulam and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of pyroxsulam in technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

The modified multi-residue enforcement method DFG S19 with HPLC-MS/MS can be used for the post-registration monitoring of pyroxsulam in food of plant and animal origin with LOQs of 0.01 mg/kg (wheat grain, tomato, orange, oilseed rape, meat, liver, fat, milk and egg).

Residues of pyroxsulam in soil can be monitored with the modified multi-residue enforcement method DFG S19 with HPLC-MS/MS with LOQs of 0.01 mg/kg. Pyroxsulam residues in groundwater and surface water and in air can be monitored by HPLC-MS/MS, with LOQs of 0.05 µg/L and 2.7 µg/m3 respectively. An HPLC-MS/MS method exists for residues in body fluids (blood, urine) with a LOQ of 0.001 mg/L. It should be noted however, that this method is not required as the active substance is not proposed for classification as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004) and SANCO/10597/2003 – rev. 10.1 (European Commission, 2012).

Pyroxsulam was discussed at the Pesticide Peer Review Experts' Teleconference (TC 79) on mammalian toxicology.

The technical specification is not supported by the batches used in the toxicological studies leading to a critical area of concern. This is because further data are needed to support higher levels of an impurity in the proposed technical specification compared to the content in the toxicological studies (data gap).

In rats, pyroxsulam is extensively and rapidly absorbed and excreted. Oral absorption is estimated to be about 75%. Highest systemic levels are found in plasma, liver and kidney. There is no evidence for accumulation. The main metabolic pathway identified is *O*-dealkylation of pyroxsulam to form 2-desmethyl-XDE-742.

Low acute toxicity is observed when pyroxsulam is administered by the oral, dermal and inhalation routes to rats. Slight skin and eye irritation was observed. There was potential for skin sensitisation.

In short-term oral studies with mice and dogs, the critical effects were observed in the liver (increased liver weight in mice and dogs; hypertrophy in dogs). Non-specific critical effects such as reduced body weight gain were observed in rats and dogs. The dog was the most sensitive species. The lowest short-term oral NOAEL is 89 mg/kg bw per d (1-yr dog study).

Pyroxsulam is not genotoxic *in vitro* or *in vivo*.

In long-term studies with mice, the critical effects were observed in the liver (increased liver weight and foci of altered hepatocytes). Non-specific critical effects such as reduced body weight gain were observed in rats. Large granular lymphocyte leukaemia (LGL) in Fisher 344 rats and hepatocellular adenomas and carcinomas in mice were observed. The carcinogenic potential was discussed during the experts' teleconference: with a minority opinion to the contrary (one expert), the majority of experts (two experts) considered that the liver tumours in mice (LGL in Fisher 344 rats was considered not relevant to humans) suggest that classification regarding carcinogenicity[7] would not be required for pyroxsulam. The relevant long-term NOAELs are 100 mg/kg bw per d for both rat and mouse.

Fertility and overall reproductive performance was not impaired; the parental, reproductive and offspring NOAELs are 1000 mg/kg bw per d. In the developmental toxicity studies, there was no evidence of teratogenicity, and the relevant maternal and developmental NOAELs are 1000 mg/kg bw per d for the rat and 300 mg/kg bw per d for the rabbit.

No neurotoxicity findings were noted in a 12-month neurotoxicity study in rats with dietary dose of up to 1000 mg/kg bw per d.

Toxicological studies were provided on two metabolites found in groundwater at levels exceeding 0.1 µg/L according to environmental fate and behaviour models (see section 4). The metabolite referred to as PSA did not show a genotoxic potential in the three *in vitro* studies. A final conclusion on the relevance of the metabolite from a toxicological point of view cannot be drawn because it is unknown whether the metabolite could be acutely toxic or very toxic (data gap). The metabolite referred to as 6-Cl-7-OH-XDE-742 gave a negative response in the Ames test. However, a full *in vitro* genotoxicity data package is needed to conclude on the genotoxic potential of this metabolite (data gap). Regarding the acute toxicity, no further data would be necessary due to the structure similarities with the parent and the lack of structural alerts.

No toxicological studies were submitted for the metabolite referred to as 7-OH-XDE-742 found in groundwater at levels exceeding 0.1 µg/L (see section 4). The experts at TC 79 agreed that genotoxicity could be bridged between the 7-OH-XDE-742 and 6-Cl-7-OH-XDE-742 metabolites. No conclusion could be reached now on the relevance of the 7-OH-XDE-742 metabolite. Final conclusion depends on the genotoxicity testing results with 6-Cl-7-OH-XDE-742 (data gap). Regarding the acute toxicity, no further data would be necessary due to the structure similarities with the parent and the lack of structural alerts.

[7] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

The acceptable daily intake (**ADI**) is 0.9 mg/kg bw per d, based on the NOAEL of 89 mg/kg bw per d found in the 1-y dog study and applying a uncertainty factor of 100. The acceptable operator exposure level (**AOEL**) is 0.7 mg/kg bw per d, based on a overall short-term NOAELs of 90 mg/kg bw per d for dogs and applying a uncertainty factor of 100, with a 75% correction for oral absorption. No acute reference dose (**ARfD**) is proposed for pyroxsulam. The relevant dermal absorption values for 'GF-1274' WG are 10% for both the concentrate and the dilution.

Considering the representative use in winter cereals the estimated operator exposure is below the AOEL (<1% and 4% of the AOEL) even without the use of personal protective equipment according to the German and UK POEM Model respectively. Worker and bystander exposure is below the AOEL (both <1% of the AOEL).

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999) and the recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

Metabolism in plants was investigated in cereals only (wheat), using ^{14}C-pyroxsulam either labelled on the pyridine or triazolopyrimidine ring. Experimental designs were representative of the supported uses. A single application was done at a rate of 37.5 g a.s./ha (2N rate) at growth stage BBCH 30-31 and using a formulation containing a safener at the same ratio as proposed in the commercial product (1:1).

Pyroxsulam was rapidly metabolised, accounting 7 days after application for less than 7% TRR in forage samples. The metabolism involves mainly the desmethylation of pyroxsulam to produce 5-OH-pyroxsulam that undergoes further conjugation reactions. At interim harvest, 51 days after application, 5-OH-XDE-742 free and conjugated accounted for *ca.* 50% TRR in the hay samples (*ca.* 0.05 mg/kg). Additional dealkyled metabolites were identified (7-OH-XDE-742, 5,7-diOH-XDE-742) but in very low amounts, representing individually less than 1% TRR. Metabolites resulting from the cleavage of the molecule at the sulfonamide bond (PSA, ADTP) were also identified, but in very low proportions (0.1% to 1.2% TRR). In mature plants, 92 days after the treatment, TRRs were only 0.03 mg/kg in straw and less than 0.002 mg/kg in grain, and therefore characterisation of the residues was not attempted. Having regard to the low DT_{50} in soil (2 to 16 days at 20°C, laboratory conditions) the confined rotational crop study was limited to a single plant back interval of 30 days. For both labels, TRRs at harvest in potato, lettuce and wheat were almost all below 0.005 mg/kg with a maximum value of 0.036 mg/kg in potato foliage.

Considering the low TRRs observed in straw and grain in the 2N study, it was concluded that no individual component is expected to be present at significant levels in plants at maturity and the residue definition for monitoring and risk assessment was proposed by default as pyroxsulam, for the cereal crop group. The 5-OH-XDE-742 metabolite was not considered in the proposed residue definition having regard to the representative uses, but its contribution to the dietary animal intakes would have to be reconsidered if further uses are envisaged on crops where it could represent a significant part of the residues (e.g. pastures).

Trials on winter wheat conducted in Northern and Southern EU over two growing seasons were provided. Different formulations were used, all containing the safener in a ratio 1:1. In each field trial, the formulation was applied alone and in addition with an adjuvant. Residue levels in grain and straw were all below the LOQ of 0.01 mg/kg, except in 3 trials where residues in straw were in the range of 0.010 to 0.022 mg/kg when the adjuvant was added. These data are supported by the storage stability studies showing pyroxsulam residues to be stable up to six months in water-, oil- and starch-containing matrices, when stored frozen at -20°C. Processing studies were not provided and not required as residues in grain were below the LOQ.

Metabolism studies on goat and poultry were submitted although the animal intakes were calculated to be far below the trigger value of 0.1 mg/kg feed per day. Animals were dosed at *ca.* 10 mg/kg feed per day, representing approximately a 500N and 1250N rate for beef cattle and poultry respectively. In goat, pyroxsulam was extensively excreted in urine and faeces and less that 10% of the administrated radioactivity was recovered in milk and tissues. Residue levels were all below 0.025 mg/kg in all edible matrices and pyroxsulam was identified as the major component in milk (95% TRR) and mostly as conjugates in kidney and liver (40% to 60% TRR). In addition to the parent, 5,7-diOH-XDE-742 was also identified in liver and kidney (<5% TRR) and 7-OH-pyroxsulam in urine and faeces. Excretion was more intensive for poultry where almost 100% of the administered radioactivity was recovered in excreta. TRRs were below 0.01 mg/kg in all edible matrices, except in liver (0.019 mg/kg). Considering the low calculated animal burden, residue definitions and MRLs were not proposed for products of animal origin.

No chronic risk was identified for consumers. Using the EFSA PRIMo model and the MRL of 0.01 mg/kg proposed for wheat and rye, the highest TMDI was calculated to be 0.01% of the ADI (DK child). An acute risk assessment was not conducted as it was concluded that the setting of an ARfD was not necessary for pyroxsulam.

4. Environmental fate and behaviour

The following evaluation of section 4 has been completed having consideration of the following guidance: EFSA PPR (2004), EFSA PPR (2007), European Commission (2002b), FOCUS (2000, 2001, 2006, 2007, 2008 and 2009).

Pyroxsulam was discussed at the Pesticide Peer Review Experts' Teleconference (TC 80) for environmental fate and behaviour in November 2012.

A standard aerobic degradation study under non-sterile laboratory conditions led to pyroxsulam degrading to < 5% applied radioactivity (AR) after 118 days and to the formation of the following major (>10% AR) metabolites: 7-OH-XDE-742 (max 13.7% AR, 3 days after treatment (DAT)), 5-OH-XDE-742 (max 24.4% AR, 3 DAT), 6-Cl-7-OH-XDE-742 (max 26.2% AR, 7 DAT) and pyridine sulfonamide (max 13.2% AR, 29 DAT). Another minor non-transient metabolite, pyridine sulfonic acid (PSA) was 5% AR at two consecutive time points in one soil, triggering a groundwater exposure assessment. Mineralisation of both the pyridine ring and the triazolopyrimidine portion radiolabels to carbon dioxide accounted for 12.9-14.8% AR after 94 days. The formation of non-extracted residues (NER) (non-extracted using acetonitrile:HCl) accounted for 88-94% AR after 100 days. It was therefore considered that pyroxsulam met the criteria in section C, par 2.5.1.1 of Council Directive 97/57/EC[8] (Annex VI) which states that no authorisation shall be given if a substance meets the criteria of less than 5% mineralisation and more than 70% non-extracted residues at 100 days, "unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects in succeeding crops occur and/or there is an unacceptable impact on the environment". Consequently, potential adverse ecotoxicological effects resulting from potential accumulation of the non-extracted residues have been considered further in the ecotoxicology section.

In addition to the two radiolabelled studies a non-radiolabelled aerobic rate of degradation study was also conducted with pyroxsulam on an additional 16 soils. Pyroxsulam exhibits very low to moderate persistence in soil. Metabolite 7-OH-XDE-742 exhibits low to medium persistence, metabolite 5-OH-XDE-742 exhibits low persistence, and pyridine sulfonamide metabolite exhibits moderate to high persistence. For metabolite pyridine sulfonic acid (PSA) no reliable degradation kinetic fit could be obtained and therefore a conservative value of 300 days was considered for groundwater modelling. An additional degradation study for the aerobic soil metabolite 6-Cl-7-OH-XDE-742 in four soils was submitted. This metabolite exhibits moderate persistence. Under anaerobic conditions pyroxsulam was

[8] Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market. OJ No L 265, 27.9.1997, p. 87-109.

degraded at a slower rate than under aerobic conditions. The amount of pyroxsulam in the test system remained constant through the first 30 days of incubation, then began to decline forming the 7-OH-XDE-742 metabolite (max 76.5% AR) and the new metabolite 5,7-diOH-XDE-742 (max 27.3% AR at study end) and NER (25% AR at study end). Degradation of metabolite 5,7-diOH-XDE-742 was investigated further in aerobic soil with direct application of metabolite. However, the resulting single first order (SFO) DT_{50} values derived from this study were considered as not relied on in the risk assessment and the use of the FOMC (First Order Multi-Compartment) DT_{90}/3.32 calculated from the parent applied study were considered appropriate for modelling purposes. The estimated degradation rates for 5,7-diOH-XDE-742 showed that this metabolite exhibits very low to low persistence in soil. A photolytic degradation study showed that in comparison with dark control samples, the presence of light did not enhance the degradation rate of pyroxsulam. No phototransformation products exceeding 10% AR were identified. Pyroxsulam and metabolites 7-OH-XDE-742 and 6-Cl-7-OH-XDE-742 exhibited very high to high mobility in soil. 5-OH-XDE-742 exhibited very high mobility, pyridine sulfonamide exhibited very high to medium mobility and 5,7-diOH-XDE-742 exhibits high to low mobility. For the pyridine sulfonic acid no adsorption values could be determined and therefore a conservative K_{oc} value of 1 mL/g, in combination with a FOCUS default 1/n value of 1.0, was considered for modelling purposes. Pyroxsulam and metabolites 5-OH-XDE-742, 7-OH-XDE-742, 6-Cl-7-OH-XDE-742 and 5,7-diOH-XDE-742 appear to demonstrate pH dependence of adsorption, with lower adsorption at higher pH. It was considered appropriate to use adsorption values in modelling which reflect this pH dependence. It was concluded that the adsorption to soil of pyridine sulfonamide was not pH dependent.

The PEC (Predicted environmental concentrations) in soil covering the representative uses assessed, can be found in Appendix A,

In laboratory incubations in two dark aerobic natural sediment water systems pyroxsulam exhibited moderate persistence, with less than 1% AR as carbon dioxide at the study end. The unextractable sediment fraction (not extracted by acetonitrile) was a sink for the pyrimidine ring and triazolopyrimidine ^{14}C radiolabels, accounting for 32.8%-73.1% AR at the study end. Pyroxsulam dissipated relatively quickly from the water phase into the sediment (max 19.8% AR), forming two metabolites at concentrations > 10% AR. 7-OH-XDE-742 was formed at 33% AR in the water phase and 26% AR in sediment, with a total system peak of 58% AR. This metabolite exhibited moderate persistence in the total system. The metabolite ATSA was formed in the water phase at a peak of 9.6% AR and exhibited moderate to medium persistence. In laboratory sterile aqueous photolysis experiments pyroxsulam exhibited low persistence, forming the major transformation products pyridine sulfinic acid (max 79.2% AR) and ADTP (max 39.8% AR). The necessary surface water and sediment exposure assessments (PEC calculations) were carried out for parent pyroxsulam, the major aerobic soil metabolites 5-OH-XDE-742, 7-OH-XDE-742, 6-Cl-7-OH-XDE-742 and pyridine sulfonamide, for the anaerobic metabolite 5,7-diOH-XDE-742, for the sediment/water metabolite ATSA and for the photolysis products pyridine sulfinic acid and ADTP. The FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator) was used for all the compounds and for the active substance pyroxsulam FOCUS Step 3 calculations were performed using SWASH v 3.1, incorporating MACRO 4.3b, PRZM 3.2b and TOXSWA 2.1.3.

The predicted environmental concentrations for pyroxsulam and its metabolites in shallow groundwater following application to winter cereals have been calculated using the FOCUS PELMO (v 3.3.2) and FOCUS PEARL (v 3.3.3) leaching models. Metabolites 7-OH-XDE-742, 6-Cl-7-OH-XDE-742, 5,7-diOH-XDE-742, pyridine sulfonamide and PSA were modelled separately as direct applications to soil after correcting for the maximum percent observed in soil and molecular weight. The experts agreed in the TC 80 that the combination with DT_{50} derived from SFO Top Down fit and metabolite maximum percentage formed used in FOCUS groundwater modelling was appropriate for all the metabolites except metabolite 5-OH-XDE-742. For this metabolite, where reliable formation fractions were derived, the assessment was properly based on a SFO-SFO parent pyroxsulam + 5-OH-XDE-742 model scheme. Following the request of the TC 80 fate experts, a new groundwater modelling assuming a plant uptake factor of 0 for the metabolites was submitted (Addendum 2; United

Kingdom, 2013). For pyroxsulam, 5-OH-XDE-742, 5-7-diOH-XDE-742 and pyridine sulfonamide, PECgw were predicted to be < 0.1 µg/L in both models for all 9 FOCUS scenarios and for the 6 applications dates simulated over October to March. For 7-OH-XDE-742, there is only one exceedence of 0.1 µg/L (0.123 µg/L in Piacenza scenario with PELMO model). Metabolite 6-Cl-7-OH-XDE-742 exceeded 0.1 µg/L in 5 out of 9 scenarios, with a maximum PECgw value of 0.413 µg/L (Piacenza scenario, October application, PELMO model). PECgw for metabolite Pyridine sulfonic acid (PSA) were predicted to be > 0.1 µg/L (max 0.523 µg/L) for both models, all scenarios and application dates. It should be noted that insufficient information was provided for metabolites PSA, 6-Cl-7-OH-XDE-742 and 7-OH-XDE-742 to conclude on their toxicological profile, and data gaps were identified (see section 2).

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

5. Ecotoxicology

The following documents were considered for the risk assessments: European Commission 2002a and 2002b, SETAC (2001), and EFSA (2009).

The risk to birds and mammals, to honeybees, to non-target arthropods and to sewage treatment organisms was concluded to be low for the representative uses of pyroxsulam.

The available data indicated that pyroxsulam might be classified as very toxic to aquatic organisms[9]. Appropriate risk assessments were available for the parent pyroxsulam and the relevant soil and aquatic metabolites for aquatic organisms. The risk in relation to the soil and surface water metabolites was assessed as low. With regard to pyroxsulam, high risk was indicated for 3 out of the 9 modelled scenarios (FOCUS step 3). No further assessments or assessments considering risk mitigation (i.e. FOCUS step 4) were available. Therefore a data gap was identified for further risk assessments for aquatic organisms for situations represented by the 3 relevant FOCUS surface water scenarios (D1, D2, R3). Risk assessments were also available for the metabolites for which the PECgw was estimated to be above the level of 0.1 µg/L. On the basis of these assessments, a high risk to aquatic organisms from the groundwater metabolite PSA (if groundwater was to return to the surface and become surface water) could not be excluded for some FOCUS groundwater scenarios. Therefore a data gap was identified for further risk assessments for aquatic organisms for situations represented by the relevant FOCUS groundwater scenarios (Chateaudun, Hamburg, Jokioinen, Sevilla and Thiva). It is noted that the assessments for the PSA metabolite are considered to be worst case.

A large data set for soil organisms (earthworms, collembolan and soil microorganisms) was available for the parent pyroxsulam and its aerobic soil metabolites. Although some uncertainties for some of these endpoints were noted (see Appendix A), a low risk to soil macro- and microorganisms was concluded based on these data. No risk assessment was available for the major anaerobic soil metabolite 5,7-diOH-XDE-742. Therefore a data gap was identified for this metabolite to address the risk to soil organisms. However it is noted that the formation of this metabolite is expected only in prolonged anaerobic conditions and this metabolite exhibited very low to low persistence in soil (see section 4). Therefore, even if 5,7-diOH-XDE-742 was toxic to soil organisms, it is considered unlikely to pose a long-term risk to soil organisms. The persistence trigger for the non-extractable soil residues (mineralisation rate < 5% in conjunction with bound residue formation > 70% after 100 days) had been breached for some laboratory soils. Therefore further assessments for soil organisms (including non-target terrestrial plants) were available, which included a tailor-made laboratory study on collembolan. Risk assessments using the endpoints of this collembolan study were also available, however a low risk to non-extractable soil residues could not be concluded on the basis of these assessments alone (see Appendix A). However, considering all the available information for soil

[9] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

organisms (i.e. toxicity data and risk assessments) along with the available assessments on the fate and behaviour of the non-extractable soil residues, a low risk for non-target soil organisms, including collembolan, could be concluded for the non-extractable soil residues.

With regard to non-target terrestrial plants, appropriate data and risk assessments were available for the parent pyroxsulam and relevant information (i.e. screening tests) for the soil metabolites. On the basis of these assessments a low risk was concluded to non-target terrestrial plants provided that risk mitigation that corresponds to a 5 metre no-spray buffer zone is used. With regard to the risk from non-extractable soil residues, a low risk could be concluded on the basis of the assessments described above.

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
pyroxsulam	very low to moderate persistence Single first-order DT_{50} 0.8-15.2 days (20ºC, pF2 soil moisture)	The risk to soil organisms was assessed as low.
5-OH-XDE-742	low persistence Single first-order DT_{50} 2.4-4.4 days (20ºC pF 2 soil moisture	The risk to soil organisms was assessed as low.
7-OH-XDE-742	low to medium persistence Single first-order DT_{50} 4.0-79.0 days (20ºC pF 2 soil moisture	The risk to soil organisms was assessed as low.
6-Cl-7-OH-XDE-742	moderate persistence Single first-order DT_{50} 16.2-47.3 days (20ºC pF 2 soil moisture	The risk to soil organisms was assessed as low.
pyridine sulfonamide	moderate to high persistence Single first-order DT_{50} 51-154 days (20ºC pF 2 soil moisture	The risk to soil organisms was assessed as low.
5,7-diOH-XDE-742 (anaerobic conditions)	very low to low persistence FOMC DT_{50} 0.9-4.5 days (20ºC, pF2 soil moisture)	Data gap.

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
Pyroxsulam	very high to high mobility K_{Foc} 7.1-53.3 mL/g	No	Yes	Yes	Yes
5-OH-XDE-742	very high mobility K_{doc} 2-22 mL/g	No	No (considerably less than the parent)	No data, assessment not triggered.	The risk to aquatic organisms was assessed as low.
7-OH-XDE-742	very high to high mobility K_{doc} 20-108 mL/g	0.1 µg/L exceeded in only 1 out of 9 scenarios (0.123 µg/L in Piacenza scenario with PELMO model)	No (considerably less than the parent)	Further data are required. (No toxicological studies)	The risk to aquatic organisms was assessed as low.
6-Cl-7-OH-XDE-742	very high to high mobility K_{doc} 14-81 mL/g	0.1 µg/L exceeded in 5 out of 9 scenarios (max PECgw value of 0.413 µg/L in Piacenza scenario, October application, PELMO model)	No (considerably less than the parent)	Further data are required. (Bacterial reverse mutation test = negative)	The risk to aquatic organisms was assessed as low.
pyridine sulfonamide	very high to medium mobility K_{Foc} 23.7-161.7 mL/g	No	No (considerably less than the parent)	No data, assessment not triggered.	The risk to aquatic organisms was assessed as low.
5,7-diOH-XDE-742 (anaerobic conditions)	high to low mobility K_{doc} 53-557 mL/g	No	No (considerably less than the parent)	No data, assessment not triggered.	The risk to aquatic organisms was assessed as low.

PSA (minor non transient metabolite)	No data available. Proposed K_{oc} of 1 mL/g, FOCUS default 1/n of 1.0 for modelling purposes	Yes: PECgw > 0.1 µg/L in 9 out of 9 scenarios for both (FOCUS PEARL and FOCUS PELMO) models and all application rates (max 0.523 µg/L)	No (considerably less than the parent)	Further data are required. (Bacterial reverse mutation test = negative *In vitro* cytogenetics test = negative *In vitro* mammalian cell gene mutation test = negative)	Data gap

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Pyroxsulam	High risk to aquatic organisms was assessed for 3 out of 9 FOCUS SW scenarios.
5-OH-XDE-742 (from soil)	The risk to aquatic organisms was assessed as low.
7-OH-XDE-742	The risk to aquatic organisms was assessed as low.
6-Cl-7-OH-XDE-742 (from soil)	The risk to aquatic organisms was assessed as low.
pyridine sulfonamide (from soil)	The risk to aquatic organisms was assessed as low.
5,7-diOH-XDE-742 ((from soil, anaerobic conditions)	The risk to aquatic organisms was assessed as low.
ATSA (water phase)	The risk to aquatic organisms was assessed as low.
pyridine sulfinic acid (aqueous photolysis)	The risk to aquatic organisms was assessed as low.
ADTP (aqueous photolysis)	The risk to aquatic organisms was assessed as low.

6.4. Air

Compound (name and/or code)	Toxicology
pyroxsulam	Not acutely toxic. Rat LC50 > 5.12 mg/L; 4 hours

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Information to address the toxicological relevance (i.e. acute oral toxicity) of the groundwater metabolite PSA (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Information to address the toxicological relevance (i.e. a full *in vitro* genotoxicity package) of the groundwater metabolite 6-Cl-7-OH-XDE-742 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Information to address the toxicological relevance (i.e. genotoxic potential) of the groundwater metabolite 7-OH-XDE-742 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Information to address the toxicological relevance (i.e. genotoxic potential) of impurity number 3 in table C.1.3 of Volume 4 of the DAR (January 2012) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Further risk assessments are necessary for aquatic organisms for situations represented by D1, D2 and R3 FOCUS surface water scenarios (relevant for all representative uses evaluated for situations represented by D1, D2 and R3 FOCUS surface water scenarios; submission date proposed by the applicant: unknown; see section 5).
- Further risk assessments are necessary for aquatic organisms for situations represented by Chateaudun, Hamburg, Jokioinen, Sevilla and Thiva FOCUS groundwater scenarios for the metabolite PSA (relevant for all representative uses evaluated for situations represented by Chateaudun, Hamburg, Jokioinen, Sevilla and Thiva FOCUS groundwater scenarios; submission date proposed by the applicant: unknown; see section 5).
- Further risk assessments are necessary for soil organisms for the metabolite 5,7-diOH-XDE-742 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

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

- On the basis of the risk assessments, a low risk was concluded to non-target terrestrial plants provided that risk mitigation measures that correspond to a 5 metre no-spray buffer zone are considered.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The assessment of the relevance of metabolites found in groundwater exceeding 0.1 µg/L could not be finalised due to the lack of sufficient data to conclude on the relevance from a toxicological point of view (hazard assessment).

2. The risk assessment for aquatic organisms could not be finalised for situations represented by Chateaudun, Hamburg, Jokioinen, Sevilla and Thiva FOCUS groundwater scenarios for the metabolite PSA.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

3. The technical specification is not supported by the batches used in the toxicological studies.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

All columns are also grey as the technical material specification proposed was not comparable to the material used in the testing that was used to derive the toxicological reference values.

Representative use		**Winter wheat**	**Winter rye**	**Winter triticale**
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial vertebrates	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified			
	Assessment not finalised			
Risk to aquatic organisms	Risk identified	3 out of 9 FOCUS SW scenarios for the a.s.	3 out of 9 FOCUS SW scenarios for the a.s.	3 out of 9 FOCUS SW scenarios for the a.s.
	Assessment not finalised	X[2]	X[2]	X[2]
Groundwater	Legal parametric value breached			

exposure active substance	Assessment not finalised			
Groundwater exposure metabolites	Legal parametric value breached			
	Parametric value of 10µg/L[(a)] breached			
	Assessment not finalised	X[1]	X[1]	X[1]
Comments/Remarks				

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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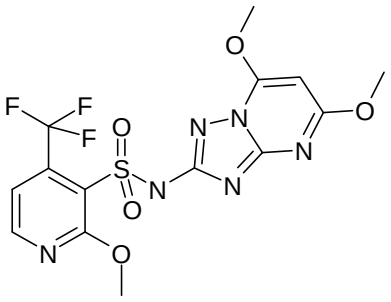
APPENDICES

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

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

Active substance (ISO Common Name) ‡	Pyroxsulam
Function (*e.g.* fungicide)	Herbicide
Rapporteur Member State	United Kingdom
Co-rapporteur Member State	Not applicable

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide
Chemical name (CA) ‡	*N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide
CIPAC No ‡	793
CAS No ‡	422556-08-9
EC No (EINECS or ELINCS) ‡	Not available
FAO Specification (including year of publication) ‡	There is currently no FAO specification
Minimum purity of the active substance as manufactured ‡	965 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	open
Molecular formula ‡	$C_{14}H_{13}F_3N_6O_5S$
Molecular mass ‡	434.4 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	208.3 °C (99.3% pure)
Boiling point (state purity) ‡	Decomposes before boiling (99.3% pure)
Temperature of decomposition (state purity)	213 °C (99.3% pure)
Appearance (state purity) ‡	White crystalline solid (99.3% pure) Off-white powder (98.0% technical)
Vapour pressure (state temperature, state purity) ‡	< 1 x 10^{-7} Pa at 20 °C (99.3% pure)
Henry's law constant ‡	6.94 x 10^{-7} Pa m^3 mol^{-1} at 20°C
Solubility in water (state temperature, state purity and pH) ‡	0.0164 g/L at 20 °C (pH 4) (99.3% pure) 3.20 g/L at 20 °C (pH 7) 13.7 g/L at 20 °C (pH 9)
Solubility in organic solvents ‡ (state temperature, state purity)	At 20°C, 99.3% pure Solvent — solubility (g/l) Heptane — <1 1-octanol — 0.0730 Xylene — 0.0352 1,2-dichloroethane — 3.94 Methanol — 1.01 Acetone — 2.79 ethyl acetate — 2.17
Surface tension ‡ (state concentration and temperature, state purity)	62.3 mN/m at 20 °C (0.01 % solution) 63.0 mN/m at 20 °C (1.0 % solution)
Partition co-efficient ‡ (state temperature, pH and purity)	At 20 ºC, purity 99.3% pure pH 4 buffer soln, logPow = 1.08 ± 0.01 pH 7 buffer soln, logPow = -1.01 ± 0.05 pH 9 buffer soln, logPow = -1.60 ± 0.12
Dissociation constant (state purity) ‡	At 20 ºC pk_a = 4.67 ± 0.01
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	100% pure Unbuffered (neutral) solution: λmax 297 nm; ε = 8000 $L.mol^{-1}.cm^{-1}$ Acidic solution : λmax 297 nm, ε = 7600 $L.mol^{-1}.cm^{-1}$ Basic solution λmax 292 nm, ε = 11100 $L.mol^{-1}.cm^{-1}$
Flammability ‡ (state purity)	Not highly flammable (98% technical as manufactured)
Explosive properties ‡ (state purity)	Not explosive
Oxidising properties ‡ (state purity)	Not oxidising

Summary of representative uses evaluated (*pyroxsulam*)*

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	g as/hL min-max (l)	Water L/ha min-max	g as/ha min-max (l)		
Winter wheat, Winter triticale, Winter rye	**N & S Europe**	**GF-1274**	**F**	**Grasses & broad leaf weeds**	**WG**	**75 g/kg**	**Tractor mounted spray**	**BBCH 11-39 Autumn/ Spring**	**One per year**	**NA**	**4–18.75**	**100 - 300**	**12-18.75**	**NA**	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV Identity verified using HPLC-MS/MS
Impurities in technical as (analytical technique)	HPLC-UV GC-FID
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		pyroxsulam
Food of animal origin		Not proposed, not required
Soil		pyroxsulam
Water	surface	pyroxsulam
	drinking/ground	pyroxsulam
Air		pyroxsulam
Body fluids and tisssues		pyroxsulam

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S19, HPLC-MS/MS, LOQ 0.01 mg/kg (tomato, orange, wheat grain and oilseed rape)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S19, HPLC-MS/MS, LOQ 0.01 mg/kg (meat, liver, fat, milk, egg)
Soil (analytical technique and LOQ)	DFG S19, HPLC-MS/MS, LOQ 0.01 mg/kg
Water (analytical technique and LOQ)	DAS GRM 05.19, HPLC-MS/MS, LOQ 0.05 µg/L (drinking, ground and surface water)
Air (analytical technique and LOQ)	P 738 G, HPLC-MS/MS, LOQ 2.7 µg/m^3 (Method submitted although vapour pressure of pure pyroxsulam <10^{-7} hPa and is therefore not necessary)

Body fluids and tissues (analytical technique and LOQ)	DFG S19, HPLC-MS/MS, LOQ 0.001 mg/L (blood, urine) Body tissue: covered by method for food of animal origin (As pyroxsulam is not classified as toxic or very toxic then a method is not required).

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

	RMS/peer review proposal
Pyroxsulam	Unclassified with regard to physical/chemical data

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	**Rat**: Rapid (Tmax <1h); about 75% based on urinary (57-61%) and biliary (17%) excretion within 48 h at 10 mg/kg bw **Mouse**: about 60% based on urinary excretion within 72h (biliary excretion not investigated) at 10 & 100 mg/kg bw
Distribution ‡	**Rat**: Of limited tissues investigated, highest systemic levels (at Cmax and ½ Cmax) in plasma, liver and kidney. **Mouse**: Of limited tissues investigated, highest systemic levels (at 72h) in liver
Potential for accumulation ‡	**Rat**: No evidence for accumulation based on ADME study . **Mouse**: No evidence at realistic exposure levels, but slow elimination from the liver at 1000 mg/kg bw (not measured in rats) will favour accumulation on repeated extreme exposures
Rate and extent of excretion ‡	**Rat**: rapid and extensive (at least 96 %) within 48 h; at 10 mg/kg bw, urine (60 %), faeces (c.50%), bile (17%) **Mouse**: rapid and extensive (100 %) within 48h; at 10 mg/kg bw, urine (60 %), faeces (40%)
Metabolism in animals ‡	**Rat:** Limited metabolism. Parent was main component in urine and faeces. 2-desmethyl-XDE-742 (*ca* 15% of administered dose of 10mg/kg bw) only metabolite identified **Mouse**: not investigated
Toxicologically relevant compounds ‡ (animals and plants)	**Rat**: Parent compound and 2-desmethyl-XDE-742 **Mouse**: Parent compound and metabolite(s)
Toxicologically relevant compounds ‡ (environment)	Further data are required.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2,000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2,000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.12 mg/l 4h (nose-only)	
Skin irritation ‡	Slightly irritating (no classification proposed)	
Eye irritation ‡	Slightly irritating (no classification proposed)	
Skin sensitisation ‡	Sensitiser (M and K maximisation)	R43

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Hepatotoxicity (increased liver weight in mice and dogs; hypertrophy in dogs) Reduced body weight gain in rats and dogs	
Relevant oral NOAEL ‡	90-day rat : 100 mg/kg per d 90-day mouse: 100 mg/kg per d 90-day dog: 91 mg/kg per d 1-year dog: 89 mg/kg per d	
Relevant dermal NOAEL ‡	2-week range-finding study: 1000 mg/kg per d	
Relevant inhalation NOAEL ‡	No data available- not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Pyroxsulam is not genotoxic *in vitro* or *in vivo*	

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

Target/critical effect ‡	Hepatotoxicity (mice), reduced body weight gain (rats)	
Relevant NOAEL ‡	2-year rat: 100 mg/kg per d 18-month mouse: 100 mg/kg per d	
Carcinogenicity ‡	Large granular lymphocyte leukaemia-in Fisher 344 rats Hepatocellular adenoma and carcinoma in male CD-1 mice.	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No adverse effect observed	
Relevant parental NOAEL ‡	1000 mg/kg per d	
Relevant reproductive NOAEL ‡	1000 mg/kg per d	
Relevant offspring NOAEL ‡	1000 mg/kg per d	

Developmental toxicity

Developmental target / critical effect ‡	Rat: No substance related developmental effect	

	Rabbit: No substance related developmental effect	
Relevant maternal NOAEL ‡	Rat: 1000 mg/kg per d Rabbit: 300 mg/kg per d	
Relevant developmental NOAEL ‡	Rat: 1000 mg/kg per d Rabbit: 300 mg/kg per d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available- not required	
Repeated neurotoxicity ‡	12-month rat: no neurotoxicity NOAEL 1000 mg/kg per d No concern from other studies	
Delayed neurotoxicity ‡	No data available- not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available- not required
Studies performed on metabolites or impurities ‡	An Ames study with pyroxsulam spiked with an additional amount of an impurity gave a negative result. PSA (pyridine sulfonic acid) metabolite of pyroxsulam was negative in 3 *in vitro* genotoxicity assays. Pyridine sulfonamide metabolite of pyroxsulam was negative in 3 *in vitro* genotoxicity assays. 6-Cl-7-OH –XDE-742 was negative in an Ames test.

Medical data ‡ (Annex IIA, point 5.9)

No adverse effects reported in manufacturing personnel (apart from one case of suspected skin sensitivity), or in other persons, associated with exposure to pyroxsulam.

Summary (Annex IIA, point 5.10)	Value	Study	Uncertainty factor
ADI ‡	0.9 mg/kg per d	1-year dog	100
AOEL ‡	0.7 mg/kg per d	90-day dog and 1-year dog	100 (correction for 75% oral absorption)
ARfD ‡	Not allocated- not necessary		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation ('GF-237', 25g/l EC, penoxsulam (surrogate))	10% for concentrate and 1:735 dilution, based on *in vivo* rat data.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	For unprotected operators: German model: Pyroxsulam - <1% of AOEL UK POEM: Pyroxsulam – 4% of AOEL
Workers	Based on the German worker re-entry model: <1% of AOEL
Bystanders	Based on a simulated bystander exposure study for field crop sprayers: <1% of AOEL

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

Substance classified	pyroxsulam
Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	No harmonised classification and labelling
Peer review proposal*	Under Council Directive 67/548/EEC[10] Xi R43 May cause sensitisation by skin contact Under Regulation (EC) No 1272/2008)[11]

[10] OJ No 196, 16.08.1967, p. 001-0098
[11] OJ No L 353, 31.12.2008, p. 0001-1355

H317 May cause an allergic skin reaction

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Residues

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

Plant groups covered	Cereals (wheat)
Rotational crops	Wheat, lettuce and potato
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided, not required (residues in cereal grain <0.01 mg/kg)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-
Plant residue definition for monitoring	Pyroxsulam
Plant residue definition for risk assessment	Pyroxsulam
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Lactating goat, laying hen
Time needed to reach a plateau concentration in milk and eggs	5 days
Animal residue definition for monitoring	Not discussed, not proposed (not required considering the representative uses)
Animal residue definition for risk assessment	Not discussed, not proposed (not required considering the representative uses)
Conversion factor (monitoring to risk assessment)	N/A
Metabolism in rat and ruminant similar (yes/no)	-
Fat soluble residue: (yes/no)	Not discussed

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

Wheat, lettuce and potatoes	At plant-back of 30 days, all individual extractable residues were <0.008 mg/kg. No residues expected in raw commodities from cereal small grains, leafy vegetables, or root crops planted 30 DAT with pyroxsulam at application rates up to 18 g/ha (maximum rate)

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

Crop	Pyroxsulam residues stable for at least 6 months when stored at -20°C in: - high water content matrices (spinach, tomato, wheat forage) - high starch content matrices: (wheat grain, potato tuber) - high oil content matrices (soybean) - dry matrices (wheat straw).

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis)	No	No	No
Potential for accumulation (yes/no):	-	-	-
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	-	-	-
	Feeding studies (Not provided, not required)		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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

Crop	Northern Southern Region, Field or glasshouse	**Trials results relevant to the representative uses** (a)	**Recommendation/ comments**	**MRL** estimated from trials according to representative use	**HR** (c)	**STMR** (b)
Winter wheat	Northern EU	**Formulations without adjuvant** Grain: 8x <0.01 Straw: 8x <0.01 **Formulations with adjuvant** (methylated rapeseed oil) Grain: 8x <0.01 Straw: 8x <0.01	MRL of 0.01 mg/kg derived for wheat grain, extrapolated to triticale and rye.	0.01*	<0.01	<0.01
	Southern EU	**Formulations without adjuvant** Grain: 8x <0.01 Straw: 8x <0.01 **Formulations with adjuvant** (methylated rapeseed oil) Grain: 8x <0.01 Straw: 5x <0.01, 0.01, 0.011, 0.022	See above	0.01*	<0.01	<0.01

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 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	**0.9 mg/kg bw per day**
TMDI (% ADI) according to EFSA PRIMo model	Highest TMDI: 0.01% ADI (DK child) (Based on MRL of 0.01 mg/kg for rye and wheat)
TMDI (% ADI) according to UK National diets:	< 0.1% (all sub-populations)
IEDI (WHO European Diet) (% ADI)	N/A
NEDI (specify diet) (% ADI)	N/A
Factors included in IEDI and NEDI	N/A
ARfD	**Not allocated**
IESTI (% ARfD)	N/A
NESTI (% ARfD) according to national (to be specified) large portion consumption data	N/A
Factors included in IESTI and NESTI	N/A

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

Processing studies were not required and have not been conducted as pyroxsulam residues in wheat grain were below the limit of quantification of the analytical method (<0.01 mg/kg)

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

Wheat, triticale and rye grain	0.01* mg/kg

The proposed MRL is based on the LOQ of the analytical method.

Fate and behaviour in the environment

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

Mineralization after 100 days ‡	1.5-12.9% AR after 94-100 d, [^{14}C-pyroxsulam]-PY label (n^{12}= 8). 3.7-14.8% AR after 94-100 d, [^{14}C-pyroxsulam]-TP label (n = 8) Sterile conditions: 0.5% after 92 d (n = 1)
Non-extractable residues after 100 days ‡	31.5 - 88.4% AR after 94-100 d, [^{14}C-pyroxsulam]-PY label (n = 8). 35.3. - 94.1*% AR after 94-100 d, [^{14}C-pyroxsulam]-TP label (n = 8) Sterile conditions: 10.0% after 92 d (n = 1) *The highest NER of 94% in the aerobic soil degradation, which used a rate of 0.033 mg/kg, translates to an NER concentration of 0.031 mg equiv/kg
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	PSA: 0.9-5.9 % (max. values) at 14-118 d (n = 8) 7-OH-XDE-742: 2.5-13.7 % (max. values) at 1-14 d (n = 8) 5-OH-XDE-742: 1.8-24.4 % (max. values) at 3-114 d (n = 8) 6-Cl-7-OH-XDE-742: 0.8-26.2 % (max. values) at 7-63 d (n = 8) Pyridine sulfonamide: 1.9-13.2% (max values) at 29-118 days (n = 8) [^{14}C-TP] & [^{14}C-PY] labels

[12] n corresponds to the number of soils.

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

Anaerobic degradation ‡	
Mineralization after 100 days	0.2% AR after 120 d, [^{14}C-pyroxsulam]-PY label (n = 1). 0.1% AR after 120 d, [^{14}C-pyroxsulam]-TP label (n = 1). Sterile conditions: 1 % after 124 d (n= 1)
Non-extractable residues after 100 days	26.5% AR after 120 d, [^{14}C-pyroxsulam]-PY label (n = 1). 24.9% AR after 120 d, [^{14}C-pyroxsulam]-TP label (n = 1).
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	7-OH-XDE-742: 76.5 % (max. value) at 58 d [^{14}C-pyroxsulam]-TP label (n = 1). 5,7-di-OH-XDE-742 : 27.3 % (max. value) at 126 d [^{14}C-pyroxsulam]-PY label (n = 1).
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	5-OH-XDE-742: 9.4 % (max. value) at 10 d (mean of two labels) (n = 1). 7-OH-XDE-742: 11.5 % (max. value) at 10 d (mean of two labels) (n = 1). [^{14}C-TP] & [^{14}C-PY] labels

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type (US classification)	X[13]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (before normalisation)	DT_{50} (d) 20°C pF2/10kPa	Chi^2 % error	Method of calculation
Sandy clay loam (Charentilly)[a]		6.2	20 °C / 40 %	3.6/12.1 (PY label) 4.0/13.3 (TP label)	3.3 days (mean of two radio-labels)	5.6	SFO
Sandy loam (LUFA 3A)[a]		7.8	20 °C / 40 %	2.0/6.8 (PY label) 2.0/6.8 (TP label)	1.6 days (mean of two radio-labels)	7.4	SFO
Sand (Borstel)[a]		5.7	20 °C / 40 %	10.1/33.5 (PY label) 10.0/33.1 (TP label)	10 days (mean of two radio-labels)	3.6	SFO
Sandy loam (Bruch West)[a]		7.9	20 °C / 40 %	2.7/8.8 (PY label) 2.8/9.4 (TP label)	2.4 days (mean of two radio-labels)	11	SFO
Sandy clay loam (LUFA 3A)[b]		7.5	20 °C / 40 %	2.1/6.8	1.7 days (mean of two radio-labels)	11.0	SFO
Loamy sand (Bruch West)[b]		6.2	20 °C / 40 %	5.0/16.8	5.1 days(mean of two radio-labels)	6.8	SFO
Loamy sand (Borstel)[b]		5.5	20 °C / 40 %	14.6/48.4	13 days (mean of two radio-labels)	3.9	SFO excluding day 4
Loam (Charentilly)[b]		5.6	20 °C / 40 %	3.7/12.4	3.1 days(mean of two radio-labels)	7.7	SFO
Sandy loam (Commerce)		6.6	20 °C / 40 %	16.7/55.4	15.2 days	3.9	SFO

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

Loamy sand (LUFA 2.1)		5.0	20 °C / 40 %	9.0/29.9	9 days	2.8	SFO
Sandy loam (LUFA 5M)		7.3	20 °C / 40 %	1.6/5.2	1.5 days	2.4	SFO
Loamy sand (Site I)		7.4	20 °C / 40 %	1.3/4.3	1.3 days	6.4	SFO
Sandy loam (Site D)		5.4	20 °C / 40 %	3.6/12.0	3.6 days	10.8	SFO
Sandy loam (Site G1)		6.6	20 °C / 40 %	1.0/3.3	1 days	1.7	SFO
Sandy loam (Manning)		7.2	20 °C / 40 %	3.0/10.1	3 days	4.7	SFO
Clay loam (Site 1)		7.3	20 °C / 40 %	0.8/2.6	0.8 days	1.6	SFO
Sandy loam (Site 7)		5.1	20 °C / 40 %	2.4/8.1	2.4 days	2.4	SFO
Sandy loam (Site 6)		6.6	20 °C / 40 %	7.1/23.7	6 days	6.2	SFO
Sandy loam (Site 9)		7.1	20 °C / 40 %	3.9/12.9	3.9 days	4.9	SFO
Sandy clay loam (Regent)		7.5	20 °C / 40 %	1.6/5.2	1.6 days	4.2	SFO
Sandy clay loam (Elstow)		5.3	20 °C / 40 %	12.2/40.6	12.2 days	5.7	SFO
Loamy sand (Ottobiano)		4.8	20 °C / 40 %	2.4/8.1	1.8 days	7.5	SFO
Clay loam (Greggio)		4.6	20 °C / 40 %	4.4/14.6	4.2 days	9.7	SFO
Sandy loam (Spreyerer Wald)		5.7	20 °C / 40 %	2.8/9.2	2.8 days	6.3	SFO
Geometric mean				3.5/11.6	3.3		3.3
Median				3.3/11.1	3.1		3.1

[a] Yoder 2006a study [b] Yoder 2007 study
Geometric mean DT50 of 3.3 days based on applicant values used in FOCUS modelling

Pyroxsulam	Aerobic conditions - lower temperature					
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	St. (r^2)	Method of calculation

Sandy clay loam (Charentilly)[a]		6.2	10°C /40%	14	0.975	SFO

7-OH-XDE-742	Aerobic conditions (Max formed 13.7%AR, 3 DAT)							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} (d) (before normalisation)	f. f. k_{dp}/k_f	DT_{50} (d)* 20°C pF2/10kPa	Chi^2 % error	Method of calculation
Sandy clay loam (Charentilly)[a]		6.2	20 °C / 40 %	38	-	33	28.3	Excel Solver, top down 3-133 days
Sand (Borstel)[a]		5.7	20 °C / 40 %	79		79	1.9	Excel Solver, top down 14-133 days
Loamy sand (Borstel)[b]		5.5	20 °C / 40 %	72		64	15.6	Excel Solver, top down 14-118 days
Sandy loam (Bruch West)[a]		7.9	20 °C / 40 %	4.4		4	15	Excel Solver, top down 3-63d
Loamy sand (Bruch West)[b]		6.2	20 °C / 40 %	34		34	14.3	ModelMaker, top down excluding d29
Geometric mean					-	30		

* kinetic re-analysis with ModelMaker SFO Top Down Fit, corrected to pF2.
Geometric mean DT50 of 25 days (20°C, pF2, SFO Top Down Fit) used in FOCUS modelling
For sandy clay loam (Charentilly)[b] soil metabolite 7-OH-XDE-742 was <10%AR

5-OH-XDE-742	Aerobic conditions (Max formed 24.4%AR, 4 DAT)							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} (d) (before normalisation)	f. f. k_{dp}/k_f	DT_{50} (d)* 20°C pF2/10kPa	Chi^2 % error	Method of calculation
Sandy loam (LUFA 3A)[a]		7.8	20°C/40%	3.4	0.49	2.7	12.8	SFO-SFO
Sandy clay loam (LUFA 3A)[b]		7.5	20°C/40%	5.3	0.353	4.4	5.8	SFO-SFO 0-63d data
Sandy loam (Bruch West)[a]		7.9	20°C/40%	2.7	0.278	2.4	14.3	SFO-SFO
Geometric mean/median						3.1		
* kinetic re-analysis with ModelMaker SFO-SFO Fit with parent, corrected to pF2. Geometric mean DT50 of 3.1 days (20°C, pF2, SFO-SFO Fit) based on applicant values used in FOCUS modelling Poor fit was obtained for sandy clay loam (Charentilly)[a] and no reliable DT50 could be derived.								

6-Cl-7-OH-XDE-742	Aerobic conditions (metabolite formed in parent study, values used in FOCUS modelling. Max formed 26.2%AR, 7 DAT)							
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	Chi^2 % error	Method of calculation
Sandy clay loam Charentilly[a]		6.2	20°C/40%	28	-	24.2	8.9	Excel Solver, top down, SFO 7-133d
Sandy loam Bruch West[a]		7.9	20°C/40%	18		16.2	5.7	Excel Solver, top down, SFO 7-63 days
Loamy sand Borstel[b]		5.5	20°C/40%	53		47.3	16.6	ModelMaker, top down, SFO 29-118 days
Clay Loam Charentilly[b]		5.6	20°C/40%	53		44.7	34.8	ModelMaker, top down, SFO 7-133d***
Geometric mean				50.7		30		
* Kinetic re-analysis with ModelMaker SFO Top Down Fit, corrected to pF2. ** insufficient data points *** included as conservative approach, as not dissimilar to other DT50s and to exclude it only reduces geometric mean to 26 days.								
	Aerobic conditions (metabolite applied as starting material; values <u>not</u> used in FOCUS modelling assuming substance applied directly)							

Sandy clay loam LUFA 3A		7.5	20°C/40%	9.9/33	-	8.2	6.6	Modelmaker SFO
Sandy loam Bruch west		6.2	20°C/40%	22/73	-	22	15.7	Modelmaker SFO
Sandy loam Borstel		5.5	20°C/40%	16/55	-	14	10.4	Modelmaker SFO
Clay loam Charentilly		5.6	20°C/40%	3.6/12	-	3	8.9	Modelmaker SFO
Geometric mean				10.9/35.5		9.4		

Pyridine sulfonamide	Aerobic conditions (metabolite formed in parent study). (Max 13.2%AR, 29 DAT)							
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. (r^2)	Method of calculation
Loamy sand		6.2	20°C/40%	93.4/310.4		93.4*	1.0	ModelMaker, top down
Loam		5.6	20°C/40%	183#/607		154	0.524	ModelMaker, top down
*based on only 2 data points insufficient to be considered reliable								
Geometric mean/median			Not appropriate					
	Aerobic conditions (metabolite applied as test material, used in FOCUS modelling)							
Soil type	X^1	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	K (d)	DT_{50} (d) 20°C pF2/10kPa	Chi^2 % error	Method of calculation
sandy loam (Bruch West)		5.4	20°C/40%	143/475		143	2.2	SFO
clay loam (LUFA 3A)		7.5	20°C/40%	66/220		51	5.3	SFO
clay loam (Charentilly)		5.4	20°C/40%	130/431		109	5.1	SFO
loamy sand (Borstel)		5.4	20°C/40%	60/199		57	3.2	SFO
Geometric mean				93/308		82#		

[#] Conservative use of the dissipation DT50 of 183 days (from parent applied study) instead of the geometric mean DT50 of 82 days (from the metabolite applied study) was checked and did not significantly alter the PECsw concentrations. Also the maximum PECgw concentration was 0.004 µg/l in PELMO (Piacenza, 1st Oct), assuming the geometric mean DT50 soil of 82 d (n=4, soil treated with metabolite). As this was two orders of magnitude below the 0.1 µg/l limit, it is not expected that use of a dissipation DT50 of 183 days will result in a PECgw concentration > 0.1 µg/l. This was checked and confirmed by the RMS; use of 183 days with plant uptake of 0.5 or 0 both gave PECgw concentrations below 0.1 µg/l for 1st Oct, Piacenza in PELMO model.

PSA	Aerobic conditions (Max formed 5.9%AR, 29 DAT)							
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	Chi^2 % error	Method of calculation
Sandy clay loam (Charentilly)[a]		6.2	20°C/40%	41/136		35.5*	9.3	Excel Solver, top down
Geometric mean/median			* based on only 3 data points, insufficient to be reliable. (<10% AR, reached max.5.9%AR in this 1 soil) . Applicant used a default DT50 of 300 days as a conservative estimate in FOCUS modelling .					

5,7-diOH-XDE-742	Aerobic conditions (metabolite applied as starting material; geometric mean DT50 used in FOCUS modelling)							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	K (d)	DT_{50} (d) 20°C pF2/10kPa *	Chi^2 % error	Method of calculation
Loamy sand (Borstel)		6.8	20°C/40 %	0.4/1.5	1.5	-	25.2	SFO
Loamy sand (Limburgerhof)		7.1	20°C/40 %	0.58/1.9	1.2	-	16.6	SFO
Loam (Charentilly)		6.1	20°C/40 %	0.34/1.1	2.05	-	28.4	SFO
Sandy clay loam (LUFA 3A)		7.9	20°C/40 %	0.23/0.8	2.96	-	18.9	SFO
Above SFO values not relied on in the risk assessment. See FOMC DT90/3.32 values below.								
Soil type	X[1]	pH	t. °C / % MWHC	FOMC DT_{50}/ DT_{90} (d)	alpha beta	DT_{50} (d) 20°C pF2/10kPa *	Chi^2 % error	Method of calculation
Loamy sand (Borstel)		6.8	20°C/40 %	0.19/15	0.382 0.037	4.5	3.6	FOMC DT90/3.32

Loamy sand (Limburgerhof)		7.1	20°C/40 %	0.37/8	0.584 0.163	2.4	2.5	FOMC DT90/3.32
Loam (Charentilly)		6.1	20°C/40 %	0.1/9	0.372 0.018	2.7	5.9	FOMC DT90/3.32
Sandy clay loam (Lufa 3A)		7.9	20°C/40 %	0.14/3	0.605 0.067	0.9	6.2	FOMC DT90/3.32
Geometric mean				0.18/8		2.3		
Median				0.17/8.5				

* = no correction conducted, moisture at 10kPa not reported, but RMS has verified using FOCUS default values that correction for soil moisture would not significantly alter these results.

Field studies: No studies submitted, none required.

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration (non-extracted residue) ‡	Modelling of non-extracted residue accumulation presented. Three compartment model in ModelMaker. Flows from extracted residue compartment to non-extracted residue and to CO_2 compartments by either SFO, FOMC or DFOP. Flow from non-extracted residue to CO_2 by SFO. Accumulation factors predicted to be 1.47 – 6.54x parent initial concentration (expressed as parent equivalents). Accumulated PEC_{soil} value of 0.164 mg equiv. pyroxsulam / kg soil based on distribution of non-extractable residue in top 5 cm of soil with 0% crop interception. Refined to **0.123 mg/kg** taking into account 25% crop interception.

Laboratory studies ‡

Pyroxsulam	Anaerobic conditions							
Soil type	X[14]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)		DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy clay loam		6.2	20 °C /100 %	47/85		47		SFO after 30 day lag phase
	Soil photolysis							
Silty clay loam		6.2	25˚C/75% of 1/3 bar	Dark control degraded faster than illuminated samples; true photolysis rate could not be calculated.				
7-OH-XDE-742	Anaerobic conditions (max. formed 61.7%AR, 78 DAT)							
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. (r^2)	Method of calculation
Sandy clay loam		6.2	20 °C /100 %	60/198		60	0	SFO
5,7-di OH-XDE-742	Anaerobic conditions; not calculable, peak at end of study. (max. 27.3%AR, 126 DAT)							
Sandy clay loam		6.2	20 °C /100 %	n.c.		n.c.	-	-

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Pyroxsulam ‡							
Soil Type	OC %	Soil pH	Kd (ml/g)	Koc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
M650	3.7	5.4	1.550-2.095	41.89-56.63	1.55	41.9	0.96
M661	1.3	5.7	0.505-0.740	38.88-56.94	0.69	53.1	1.03
M646	2.7	5.9	0.889-1.604	32.93-59.42	1.03	38.1	0.93
M641	0.9	6.2	0.420-0.555	46.69-61.69	0.48	53.3	1.00
M660	1.7	6.3	0.223-0.552	22.34-55.19	0.24	24.0	0.90
M649	3.8	7.6	0.200-0.475	5.25-12.51	0.27	7.1	0.98
M644	0.8	7.7	0.157-0.671	19.67-83.86	0.19	23.8	0.94
M642	2.5	7.8	0.252-0.388	10.08-15.54	0.25	10.0	0.95
M645	1.3	7.8	0.047-0.318	3.62-24.47	0.33	25.4	1.25
M662	2.5	7.9	0.145-0.276	5.80-11.04	0.16	6.4	0.93
Arithmetic mean/median (not applicable for modelling due to pH dependence)					0.52/0.30	28.3/24.7	0.99/0.955
pH dependence, Yes or No			Yes; sorption of pyroxsulam increases as soil pH decreases. Proposed end points for modelling: <pH 7, Koc 42, 1/n 0.96; >pH 7, Koc 15, 1/n 1.01.				

5-OH-XDE-742							
Soil Type	OC %	Soil pH	Kd (ml/g)	Koc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
Charentilly	1.0	6.3	0.156	16			
LUFA 3A	2.5	7.8	0.073	3			
Borstel	1.3	5.7	0.322	22			
Bruch West	2.5	7.9	0.053	2			
Arithmetic mean (not applicable for modelling due to pH dependence)			0.151	11			
pH dependence (yes or no)			Yes. Proposed end points for modelling: <pH 7, Koc 19,; >pH 7, Koc 2.5, FOCUS default 1/n 1.0				

7-OH-XDE-742							
Soil Type	OC %	Soil pH	Kd (ml/g)	Koc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
Charentilly	1.0	6.3	0.877	88			
LUFA 3A	2.5	7.8	0.823	33			
Borstel	1.3	5.7	1.408	108			
Bruch West	2.5	7.9	0.502	20			
Arithmetic mean (not applicable for modelling due to pH dependence)			0.903	62			
pH dependence (yes or no)			Yes. Proposed end points for modelling: <pH 7, Koc 98, 1/n 0.9; >pH 7, Koc 27, FOCUS default 1/n 1.0.				

6-Cl-7-OH-XDE-742							
Soil Type	OC %	Soil pH	Kd (ml/g)	Koc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
Charentilly	1.0	6.3	0.473	47			
LUFA 3A	2.5	7.8	0.404	16			
Borstel	1.3	5.7	1.057	81			
Bruch West	2.5	7.9	0.35	14			
Arithmetic mean (not applicable for modelling due to pH dependence)			0.571	40			
pH dependence (yes or no)			Yes. Proposed end points for modelling: <pH 7, Koc 64,; >pH 7, Koc 15, FOCUS default 1/n 1.0				

5,7-diOH-XDE-742							
Soil Type	OC %	Soil pH	Kd (ml/g)	Koc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
Charentilly	1.0	6.3	5.572	557			
LUFA 3A	2.5	7.8	1.333	53			
Borstel	1.3	5.7	5.923	456			
Bruch West	2.5	7.9	1.396	56			
Arithmetic mean (not applicable for modelling due to pH dependence)			3.556	280			
pH dependence (yes or no)			Yes. Proposed end points for modelling: <pH 7, Koc 507,; >pH 7, Koc 55,. FOCUS default 1/n 1.0				

Pyridine sulfonic acid (PSA)							
Soil Type	OC %	Soil pH	Kd (ml/g)	Koc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
Charentilly	1.0	6.3	<LOD	<LOD			
LUFA 3A	2.5	7.8	<LOD	<LOD			
Borstel	1.3	5.7	<LOD	<LOD			
Bruch West	2.5	7.9	<LOD	<LOD			
Arithmetic mean/median							
pH dependence (yes or no)			No. Propose Koc of 1 ml/g, FOCUS default 1/n 1.0 for modelling purposes.				

Pyridine sulfonamide							
Soil Type	OC %	Soil pH	Kd (ml/g)	Kdoc (ml/g)	Kf (ml/g)	Kfoc (ml/g)	1/n
Bruch West	0.6	5.4	1.44	240	0.97	161.7	0.93
LUFA 3A	1.9	7.5	0.78	41	0.45	23.7	0.85
Charentilly	1.0	5.4	0.90	90	0.41	41.0	0.80
Borstel	1.1	5.5	0.89	81	0.41	37.3	0.80
Arithmetic mean			0.87	94.25	0.56	65.9	0.845
pH dependence (yes or no)			No. Propose Kfoc 65.9 ml/g and 1/n 0.845 for modelling purposes.				

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

Column leaching ‡	Not submitted, not required
Aged residues leaching ‡	Not submitted, not required

Lysimeter/ field leaching studies ‡	Not submitted, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 17 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies.
Application data	Crop: wheat Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm^3 % plant interception: 0% Number of applications: 1 Application rate: 18.75 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.025		-	
Short term 24h			-	-
2d	0.023	0.024	-	-
4d	0.021	0.023	-	-
Long term 7d			-	-
28d	0.008	0.015	-	-
50d	0.003	0.011	-	-
100d	0.000	0.006	-	-

Plateau concentration	-

7-OH-XDE-742	Molecular weight relative to the parent: 420.3/434.4 Application rate assumed: 2.49 g as/ha (assumed 7-OH-XDE-742 is formed at a maximum of 13.7 % of the applied dose). Maximum PECsoil: 0.003 mg/kg (Assuming 35.9% AR at 10°C and 25% crop interception max. PECsoil: 0.007 mg/kg)

5-OH-XDE-742	Molecular weight relative to the parent: 420.3/434.4 Application rate assumed: 4.37 g as/ha (assumed 5-OH-XDE-742 is formed at a maximum of 24.1 % of the applied dose). Maximum PECsoil: 0.006 mg/kg

6-Cl-7-OH-XDE-742	Molecular weight relative to the parent: 454.8/434.4 Application rate assumed: 5.14 g as/ha (assumed 6-Cl-7-OH-XDE-742 is formed at a maximum of 26.2 % of the applied dose). Maximum PECsoil: 0.007 mg/kg
5,7-di-OH-XDE-742	Anaerobic soil metabolite. Only formed at >10% at last time point (126 d). Unlikely prolonged anaerobic conditions will occur for that length of time in practice. Likely to be a transient metabolite rapidly degraded. Molecular weight relative to the parent: 406/420 Application rate assumed: 4.9119 g/ha (based on 27.3% of (18.75 g /ha x 0.96), with 25% interception). Maximum PECsoil: 0.005 mg/kg
Pyridine sulfonamide See explanation below relating to use of different crop interception factors (required for refined Ecotox assessment)	Molecular weight relative to the parent: 256.2/434.4 Application rate assumed: 1.54 g as/ha (assumed pyridine sulfonamide is formed at a maximum of 13.2 % of the applied dose). Maximum PECsoil: 0% interception - 0.002 mg/kg 25% interception (GS 11-19) – 0.00146 mg/kg 50% interception (GS 20-29) – 0.00097 mg/kg 70% interception (GS 30-39) – 0.00058 mg/kg

Ecotoxicological risk assessment for pyridine sulfonamide with collembola fails using the PECsoil calculated above. This PECsoil value was calculated assuming no crop interception. It is thus justifiable to include crop interception in the PECsoil calculation as the plant protection product is only recommended for use post-crop emergence. Recommended timing in the autumn is from BBCH GS 11 – beginning of tillering; this range would attract a crop interception value of 25%. Use in the spring is recommended from mid-tillering until BBCH GS 39, and would thus attract crop interception values of 50% for growth stages from GS 20-29, and 70% for GS 30-39.

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: hydrolytically stable (no degradation after 32 days)
	pH 7: hydrolytically stable (no degradation after 32 days)
	pH 9: hydrolytically stable (no degradation after 32 days)

Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : 0.83 days Natural light, 40°N; DT_{50} 4.1 days Pyridine sulfinic acid, DT_{50}: 32 days, 79.2 %AR (3.8 DAT) ADTP, DT_{50}: 41 days, 39.8 %AR (3.8 DAT) Estimated DT_{50} at 50°N (summer) 3.6 days
Quantum yield of direct phototransformation in water at □ > 290 nm	4.41×10^{-1} (no units specified in study)
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Pyroxsulam	Distribution (max in water 78.1 % after 7 d (TP label). Max. sed 19.8% AR (PY-label) after 33 d; French system)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
River Roding, UK	8.3	7.3	20	24-78 d	0.982	21-68 d	0.965	14-48 d	2 data pts only	SFO
Haut Languedoc, France	8.1	4.8	20	12-40	0.925	11-35	0.934	21-69 d	0.255	SFO
Geometric mean/median										

7-OH-XDE-742	Distribution (max in water 32.7% AR (PY-label) after 17 d.; French system. Max. sed 25.8 % AR (PY-label) after 17 d; French system).									
Water / sediment system	pH water phase	pH sed	t. °C	Dissipation DT_{50}-DT_{90} whole sys.	St. (r^2)	Dissipation DT_{50}-DT_{90} water	r^2	Dissipation DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
River Roding, UK	8.3	7.3	20	16-52	0.993	18-59	0.981	10-32	0.973	SFO
Haut Languedoc, France	8.1	4.8	20	42-141	0.925	51-168	0.797	n/a	-	SFO
Geometric mean/median										

ATSA	Distribution (max in water 9.6% AR (PY-label) after 54 d.; French system. Max. sed 5.3% AR (TP-label); French system after 75 d)									
Water / sediment system	pH water phase	pH sed	t. °C	Dissipation DT_{50}-DT_{90} whole sys.	St. (r^2)	Dissipation DT_{50}-DT_{90} water	r^2	Dissipation DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
River Roding, UK	8.3	7.3	20	71-237	2 data pts only	n/a		n/a		SFO
Haut Languedoc, France	8.1	4.8	20	22-73	0.570	n/a		n/a		SFO
Geometric mean/median										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization	Non-extractable residues in sed.	Non-extractable residues in sed.
River Roding, UK	8.3	7.3	2.0% after 101 d. (end of the study).	TP R.label: Max 73.1 % after 101 d PY R.label: Max 66.2 % after 54 d	TP R.label: Max 73.1 % after 101 d. (end of the study). PY R.label: Max 65.3 % after 101 d. (end of the study).
Haut Languedoc, France	8.1	4.8	0.8% after 101 d. (end of the study).	TP R.label: Max 32.8 % after 101 d PY R.label: Max 42.3 % after 101 d	TP R.label: Max 32.8 % after 101 d. (end of the study). PY R.label: Max 42.3 % after 101 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: FOCUS surface water tools and scenarios STEPS 1-2 in FOCUS v1.1 Molecular weight (g/mol): 434 Water solubility (mg/L): 3200 K_{OC} (L/kg): 15 1/n of 1.01 [Koc and 1/n from soil of pH >7, considered a conservative worst case for leaching.] DT_{50} soil (d): 3.3 days (Geometric mean, Lab. In accordance with FOCUS SFO, pF2) DT_{50} water/sediment system (d): 24 (representative worst case from sediment water studies) DT_{50} water (d): 24 DT_{50} sediment (d): 1000 [In accordance with latest Generic Guidance for FOCUS Surface Water Scenarios (v.1.1), for compounds with Koc < 100mL/g the whole system DT50 was used for the water phase and a default of 1000 days was used for the sediment phase. The longest dissipation DT50 (whole system) of 24 days was used for the water compartment when this was originally evaluated, instead of the geometric mean DT50 of 17 days. As this was conservative and as initial PECsw concentrations were used in the ecotoxicological risk assessment (i.e. degradation rate irrelevant), this was not recalculated with geometric mean DT50 of 17 d]. Crop interception (%): 25
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v3.1, MACRO v4.3b, PRZM 3.2b, TOXSWA v2.1.3 Vapour pressure: 1 x 10^{-7} Koc: 15 1/n: 1.01 Q10 factor : 2.58
Application rate	Crop: wheat Crop interception: 25% Number of applications: 1 Interval (d): n/a Application rate: 18.75 g as/ha Application window: FOCUS emergence date + 14 days; 30 day window.
Main route of entry	At STEP 3: Global maximum PECsw concentrations in D3 ditch, D5 stream, R1 pond were attributable to spray drift.

For remaining 11 scenarios, peak concentration is associated with drainage/run-off/erosion.

Three highest PECsw concentrations overall occurred in D2 Ditch (1.531 µg/l), R3 stream (1.083 µg/l) and D2 stream (0.958 µg/l) were driven by drainage/run-off/erosion events.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	6.30		0.92	
	24 h	6.12	6.21	0.92	0.92
	2 d	5.94	6.12	0.89	0.91
	4 d	5.61	5.95	0.84	0.89
	7 d	5.14	5.70	0.77	0.85
	14 d	4.20	5.18	0.63	0.78
	21 d	3.43	4.72	0.51	0.71
	28 d	2.80	4.32	0.42	0.65
	42 d	1.87	3.65	0.28	0.55

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.14	---	0.17	---
	24 h	1.11	1.13	0.17	0.17
	2 d	1.08	1.11	0.16	0.17
	4 d	1.02	1.08	0.15	0.16
	7 d	0.94	1.04	0.14	0.16
	14 d	0.77	0.94	0.12	0.14
	21 d	0.63	0.86	0.09	0.13
	28 d	0.52	0.79	0.08	0.12
	42 d	0.35	0.67	0.05	0.10
Southern EU	0 h	0.95		0.14	
	24 h	0.92	0.93	0.14	0.14
	2 d	0.89	0.92	0.13	0.14
	4 d	0.84	0.89	0.13	0.13
	7 d	0.77	0.86	0.12	0.13
	14 d	0.63	0.78	0.10	0.12
	21 d	0.52	0.71	0.08	0.11
	28 d	0.43	0.65	0.06	0.10
	42 d	0.29	0.55	0.04	0.08

Step 3 PECsw for Pyroxsulam

Scenario	**Water body**	**App Date**	**Global Max**	**TWA 1d**	**TWA 2d**	**TWA 4d**	**TWA 7d**	**TWA 14d**	**TWA 21d**	**TWA 28d**	**TWA 42d**
D1	ditch	23 Oct	**0.816**	0.812	0.807	0.792	0.759	0.661	0.573	0.550	0.478
D1	stream	23 Oct	**0.810**	0.695	0.505	0.503	0.478	0.403	0.344	0.333	0.291
D2	ditch	28 Nov	**1.531**	1.167	1.136	0.963	0.879	0.729	0.603	0.523	0.390
D2	stream	28 Nov	**0.958**	0.675	0.656	0.553	0.512	0.425	0.352	0.304	0.226
D3	ditch	10 Dec	**0.119**	0.078	0.043	0.022	0.012	0.006	0.004	0.003	0.002
D4	pond	26 Oct	**0.115**	0.115	0.114	0.114	0.114	0.112	0.110	0.107	0.102
D4	stream	26 Oct	**0.152**	0.140	0.134	0.130	0.118	0.099	0.086	0.074	0.054
D5	pond	27 Nov	**0.032**	0.032	0.032	0.032	0.032	0.031	0.030	0.029	0.028
D5	stream	27 Nov	**0.111**	0.043	0.022	0.018	0.017	0.015	0.013	0.012	0.012
D6	ditch	30 Dec	**0.145**	0.115	0.091	0.065	0.045	0.029	0.023	0.020	0.016
R1	pond	27 Nov	**0.004**	0.004	0.004	0.004	0.004	0.004	0.004	0.003	0.003
R1	stream	27 Nov	**0.166**	0.016	0.008	0.004	0.002	0.002	0.001	0.001	0.001
R3	stream	5 Dec	**1.083**	0.558	0.280	0.140	0.080	0.042	0.029	0.022	0.015
R4	stream	10 Dec	**0.158**	0.082	0.048	0.024	0.014	0.008	0.005	0.004	0.003

5-OH-XDE-742 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 420 Water solubility (mg/L): n/a Soil or water metabolite: soil Koc (L/kg): 2.5 (pH>7) DT_{50} soil (d): 3.1 days (Lab. In accordance with FOCUS SFO) DT50 water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent): 24 Water: 0.1 Sediment: 0.1
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	-
Main routes of entry	-

7-OH-XDE-742 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 420 Water solubility (mg/L): n/a Soil or water metabolite: soil and water Koc (L/kg): 27 (pH>7) DT_{50} soil (d): 30 days (Lab. Geometric mean SFO Top Down Fit from parent applied study, corrected to 20°C and pF2) DT50 water/sediment system (d): 42 DT_{50} water (d): 42 DT_{50} sediment (d): 1000 Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent): 14 Water/Sediment: 58 ---------- As a precautionary measure, the higher formation of this metabolite (35.9% AR) observed in laboratory soil (Charentilly) at 10°C was taken into account. The corresponding soil DT50 of 19.7 days (Top Down method) from this soil and temperature was used to calculate STEP 1 and 2 PECsw.
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	-
Main routes of entry	-

6-Cl-7-OH-XDE-742 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 455 Water solubility (mg/L): n/a Soil or water metabolite: soil Koc (L/kg): 15 (pH >7) DT_{50} soil (d): 30 days (Lab. In accordance with FOCUS SFO Geometric mean Top Down Fit from parent applied study) DT50 water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent): 26 Water: 0.1 Sediment: 0.1
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	-
Main routes of entry	-

ATSA Parameters used in FOCUSsw step 1 and 2	Molecular weight: 338 Water solubility (mg/L): n/a Soil or water metabolite: photolysis/water Koc (L/kg): 1 DT_{50} soil (d): 1000 days (default) DT50 water/sediment system (d): 1000 DT_{50} water (d): 71 DT_{50} sediment (d): 1000 Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent): Soil: 0.1 Water/Sediment: 13
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	-
Main routes of entry	-

5-7-di OH-XDE-742 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 406 Water solubility (mg/L): n/a Soil or water metabolite: anaerobic soil Koc (L/kg): 55 DT_{50} soil (d): 2.3 days (Lab. Pseudo SFO, FOMC DT90/3.32 - direct application to soil) DT50 water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent): 27 (anaerobic) Water: 0.1 Sediment: 0.1
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	-
Main routes of entry	-

Pyridine sulfonamide Parameters used in FOCUSsw step 1 and 2	Molecular weight: 256 Water solubility (mg/L): n/a Soil or water metabolite: soil DT_{50} soil (d): 82 days (Lab. In accordance with FOCUS SFO geometric mean from direct application) DT50 water/sediment system (d): 1000 DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Crop interception (%): 25 Maximum occurrence observed (% molar basis with respect to the parent): 13 Water: 0.1 Sediment: 0.1
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: Step 3 not performed Kom/Koc: 1/n: Metabolite kinetically generated in simulation (no): Formation fraction in soil (k_{dp}/k_f): n/a
Application rate	Crop: wheat Number of applications: 1 Interval (d): n/a Application rate(s): 1.1 g as/ha Depth of water body: 30 cm Application window: as per parent
Main routes of entry	

Metabolite	PECsw (µg/L)			PECsed (µg/kg)		
	Step 1	Step 2 North Oct-Feb	Step 2 South Oct-Feb	Step 1	Step 2 North Oct-Feb	Step 2 South Oct-Feb
5-OH-XDE-742	1.45	0.22	0.18	0.04	0.01	0.00
7-OH-XDE-742 (20°C)	0.91	0.37	0.31	0.24	0.10	0.08
7-OH-XDE-742 (10°C)	2.19	0.77	0.21	0.58	0.63	0.17
6-Cl-7-OH-XDE-742	1.67	0.57	0.46	0.25	0.09	0.07
Pyridine sulfonamide	0.44	0.16	0.13	0.29	0.11	0.08
5,7-diOH-XDE-742	1.47	0.17	0.13	0.81	0.09	0.07
ATSA	0.02	0.02	0.02	< 0.01	< 0.01	< 0.01
Aqueous Photolysis Metabolites:-						
ADTP*	1.13	0.20	0.17	-	-	-
pyridine sulfinic acid*	2.76	0.50	0.42	-	-	-

*calculated from maximum formation values * Koc/Kom input values corresponding to pH ≥ 7.0 used.

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUSgw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PEARL 3.3.3 and PELMO 3.3.2 (for the active substance pyroxsulam). Following PRAPeR teleconference 80, (29 November 2012): The groundwater modelling was repeated for the metabolites, using crop uptake of 0 instead of 0.5. The latest versions of the models (PEARL v4.4.4 and PELMO v.4.4.3) were also used. Scenarios (list of names): Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva. Crop: winter cereals Geometric mean parent DT_{50lab} 3.3 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: pH ≥ 7.0 = 15, pH ≤ 7.0 = 42; $^1/_n$= pH ≥ 7.0 = 1.01, pH ≤ 7.0 = 0.96. Application rate: 18.75 g/ha. No. of applications: 1 Time of application (1st Oct-1st Mar) Metabolites: Due to lack of kinetic analysis metabolites (except 5-OH-XDE-742) modelled as individual directly applied substances. Application rate calculated from peak formation from parent. **5-OH-XDE-742** DT_{50lab} 3.1 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: pH ≥ 7.0 = 2.5, pH ≤ 7.0 = 19; $^1/_n$= 1.0. Formation fraction: 0.374 (Modelled SFO-SFO Fit with parent, and shortest parent DT50 2.2d) No. of applications: 1 Time of application (1st Oct-1st Mar) **7-OH-XDE-742** DT_{50lab} 30 d (geometric mean DT50 after normalisation to 10kPa or pF2 and 20 °C with Q10 of 2.58, Top Down method of calculation). K_{OC}: pH ≥ 7.0 = 27, pH ≤ 7.0 = 98; $^1/_n$= 1.0. Application rate: 1.86 g/ha. No. of applications: 1 Time of application (1st Oct-1st Mar)

6-Cl-7-OH-XDE-742

DT_{50lab} 30 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).
K_{OC}: pH ≥ 7.0 = 15, pH ≤ 7.0 = 64; $^1/_n$= 1.0.

Application rate: 3.86 g/ha.
No. of applications: 1
Time of application (1st Oct-1st Mar)

5-7-diOH-XDE-742

DT_{50lab} 2.3 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).
K_{OC}: pH ≥ 7.0 = 55, pH ≤ 7.0 = 507; $^1/_n$= 1.0.

Application rate: 3.59 g/ha.
No. of applications: 1
Time of application (1st Oct-1st Mar)

Pyridine sulfonic acid (PSA)

DT_{50lab} 300 d (conservative default).
K_{OC}: pH ≥ 7.0 = 1, pH ≤ 7.0 = 1; $^1/_n$= 1.0.

Application rate: 0.49 g/ha.
No. of applications: 1
Time of application (1st Oct-1st Mar)

Pyridine sulfonamide

DT_{50lab} 82 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).
K_{OC}: 66; $^1/_n$= 0.85.

Application rate: 1.09 g/ha.
No. of applications: 1
Time of application (1st Oct-1st Mar)

Pyroxsulam

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun*	8.0	< 0.001	0.001	0.001	< 0.001	< 0.001	< 0.001
	Hamburg	6.4	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	6.2	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster*	7.7	0.003	0.006	0.007	0.002	< 0.001	< 0.001
	Okehampton	5.8	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza*	7.0	0.015	0.038	0.043	0.060	0.022	0.012
	Porto	4.9	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla*	7.3	< 0.001	< 0.001	0.002	< 0.001	< 0.001	< 0.001
	Thiva*	7.7	< 0.001	0.002	0.003	0.003	< 0.001	< 0.001
PEARL	Chateaudun*	8.0	0.001	0.002	0.002	< 0.001	< 0.001	< 0.001
	Hamburg	6.4	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	6.2	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster*	7.7	0.003	0.006	0.005	0.002	< 0.001	< 0.001
	Okehampton	5.8	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza*	7.0	0.017	0.021	0.019	0.017	0.003	< 0.001
	Porto	4.9	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla*	7.3	< 0.001	0.002	0.003	< 0.001	< 0.001	< 0.001
	Thiva*	7.7	0.002	0.010	0.002	0.001	< 0.001	< 0.001

* Koc/Kom input values corresponding to pH ≥ 7.0 used

From ADDENDUM 2 - Following PRAPeR teleconference 80, (29 November 2012)

The groundwater modelling was repeated for the metabolites, using crop uptake of 0 instead of 0.5. The latest versions of the models (PEARL v4.4.4 and PELMO v.4.4.3) were also used. The results are presented below.

5-OH-XDE-742

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun*	8.0	0.003	0.005	0.007	0.001	<0.001	<0.001
	Hamburg	6.4	0.007	0.016	0.013	0.004	0.001	<0.001
	Jokioinen	6.2	0.012	0.014	0.003	<0.001	<0.001	<0.001
	Kremsmünster*	7.7	0.015	0.036	0.028	0.008	0.003	0.002
	Okehampton	5.8	0.004	0.009	0.007	0.002	0.001	<0.001
	Piacenza*	7.0	0.045	0.065	0.060	0.047	<0.001	0.003
	Porto	4.9	0.002	0.011	0.028	0.015	0.004	<0.001
	Sevilla*	7.3	0.001	0.020	0.007	0.001	<0.001	<0.001
	Thiva*	7.7	0.002	0.024	0.005	0.005	<0.001	<0.001
PEARL	Chateaudun*	8.0	0.002	0.003	0.004	<0.001	<0.001	<0.001
	Hamburg	6.4	0.005	0.006	0.004	<0.001	<0.001	<0.001
	Jokioinen	6.2	0.003	0.004	<0.001	<0.001	<0.001	<0.001
	Kremsmünster*	7.7	0.006	0.012	0.008	0.002	<0.001	<0.001
	Okehampton	5.8	0.002	0.004	0.003	<0.001	<0.001	<0.001
	Piacenza*	7.0	0.016	0.018	0.013	0.007	0.001	<0.001
	Porto	4.9	0.001	0.003	0.007	0.002	<0.001	<0.001
	Sevilla*	7.3	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

	Thiva*	7.7	<0.001	0.006	<0.001	0.005	<0.001	<0.001

* Koc/Kom input values corresponding to pH ≥ 7.0 used

7-OH-XDE-742

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun*	8.0	0.040	0.037	0.034	0.026	0.022	0.017
	Hamburg	6.4	0.015	0.015	0.013	0.010	0.006	0.006
	Jokioinen	6.2	0.007	0.006	0.005	0.004	0.004	0.003
	Kremsmünster*	7.7	0.080	0.082	0.075	0.070	0.057	0.049
	Okehampton	5.8	0.014	0.014	0.014	0.011	0.009	0.008
	Piacenza*	7.0	**0.123**	0.099	0.078	0.066	0.035	0.033
	Porto	4.9	0.016	0.016	0.015	0.010	0.007	0.003
	Sevilla*	7.3	0.027	0.036	0.014	0.003	0.002	0.002
	Thiva*	7.7	0.045	0.047	0.023	0.012	0.007	0.003
PEARL	Chateaudun*	8.0	0.042	0.037	0.036	0.029	0.024	0.018
	Hamburg	6.4	0.012	0.011	0.011	0.008	0.006	0.006
	Jokioinen	6.2	0.005	0.004	0.003	0.003	0.002	0.002
	Kremsmünster*	7.7	0.061	0.063	0.015	0.051	0.042	0.038
	Okehampton	5.8	0.012	0.012	0.012	0.009	0.007	0.006
	Piacenza*	7.0	0.082	0.064	0.011	0.037	0.031	0.024
	Porto	4.9	0.009	0.010	0.009	0.005	0.004	0.002
	Sevilla*	7.3	0.009	0.009	<0.001	0.001	0.002	0.002
	Thiva*	7.7	0.033	0.035	0.005	0.013	0.010	0.005

* Koc/Kom input values corresponding to pH ≥ 7.0 used.

6-Cl-7-OH-XDE-742

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun*	8.0	**0.155**	**0.133**	**0.130**	0.098	0.086	0.068
	Hamburg	6.4	0.078	0.081	0.073	0.052	0.040	0.036
	Jokioinen	6.2	0.048	0.043	0.036	0.030	0.026	0.024
	Kremsmünster*	7.7	**0.267**	**0.277**	**0.255**	**0.232**	**0.185**	**0.159**
	Okehampton	5.8	0.074	0.074	0.066	0.054	0.043	0.039
	Piacenza*	7.0	**0.413**	**0.328**	**0.273**	**0.238**	**0.136**	**0.114**
	Porto	4.9	0.084	0.075	0.067	0.044	0.030	0.015
	Sevilla*	7.3	**0.116**	**0.159**	0.063	0.012	0.009	0.006
	Thiva*	7.7	**0.191**	**0.184**	**0.184**	0.057	0.024	0.014
PEARL	Chateaudun*	8.0	**0.159**	**0.147**	**0.145**	**0.114**	0.089	0.076
	Hamburg	6.4	0.070	0.066	0.055	0.042	0.033	0.032
	Jokioinen	6.2	0.036	0.031	0.026	0.024	0.019	0.017
	Kremsmünster*	7.7	**0.210**	**0.225**	**0.211**	**0.180**	**0.152**	**0.132**
	Okehampton	5.8	0.062	0.064	0.054	0.041	0.035	0.034
	Piacenza*	7.0	**0.265**	**0.244**	**0.157**	**0.131**	0.099	0.081
	Porto	4.9	0.053	0.056	0.044	0.030	0.020	0.010
	Sevilla*	7.3	0.046	0.045	0.009	0.006	0.008	0.006
	Thiva*	7.7	**0.153**	**0.138**	0.083	0.056	0.043	0.025

Pyridine sulfonamide

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun	8.0	0.000	0.000	0.000	0.000	0.000	0.000
	Hamburg	6.4	0.004	0.004	0.004	0.004	0.003	0.003
	Jokioinen	6.2	0.001	0.001	0.001	0.001	0.001	0.001
	Kremsmünster	7.7	0.003	0.003	0.003	0.003	0.002	0.002
	Okehampton	5.8	0.005	0.005	0.004	0.004	0.004	0.003
	Piacenza	7.0	0.003	0.003	0.002	0.002	0.002	0.002
	Porto	4.9	0.004	0.004	0.003	0.002	0.002	0.002
	Sevilla	7.3	0.000	0.000	0.000	0.000	0.000	0.000
	Thiva	7.7	0.000	0.000	0.000	0.000	0.000	0.000
PEARL	Chateaudun	8.0	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	6.4	0.004	0.003	0.003	0.002	0.003	0.002
	Jokioinen	6.2	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	7.7	0.002	0.002	0.002	0.002	0.002	0.002
	Okehampton	5.8	0.004	0.004	0.004	0.003	0.003	0.003
	Piacenza	7.0	0.003	0.002	0.002	0.001	0.001	0.001
	Porto	4.9	0.002	0.002	0.002	0.001	<0.001	<0.001
	Sevilla	7.3	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	7.7	<0.001	0.0001	<0.001	<0.001	<0.001	<0.001

Pyridine sulfonic acid

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun	8.0	**0.331**	**0.339**	**0.343**	**0.337**	**0.332**	**0.326**
	Hamburg	6.4	**0.226**	**0.228**	**0.236**	**0.229**	**0.238**	**0.249**
	Jokioinen	6.2	**0.330**	**0.322**	**0.338**	**0.358**	**0.353**	**0.352**
	Kremsmünster	7.7	**0.162**	**0.170**	**0.170**	**0.178**	**0.174**	**0.172**
	Okehampton	5.8	**0.135**	**0.136**	**0.127**	**0.117**	**0.129**	**0.130**
	Piacenza	7.0	**0.210**	**0.200**	**0.226**	**0.231**	**0.233**	**0.234**
	Porto	4.9	**0.136**	**0.141**	**0.125**	**0.115**	**0.122**	**0.122**
	Sevilla	7.3	**0.226**	**0.233**	**0.214**	**0.178**	**0.165**	**0.163**
	Thiva	7.7	**0.330**	**0.311**	**0.286**	**0.283**	**0.270**	**0.250**
PEARL	Chateaudun	8.0	**0.355**	**0.352**	**0.352**	**0.332**	**0.333**	**0.330**
	Hamburg	6.4	**0.291**	**0.260**	**0.236**	**0.224**	**0.229**	**0.234**
	Jokioinen	6.2	**0.401**	**0.407**	**0.420**	**0.404**	**0.394**	**0.384**
	Kremsmünster	7.7	**0.133**	**0.145**	**0.133**	**0.138**	**0.142**	**0.141**
	Okehampton	5.8	**0.133**	**0.133**	**0.123**	**0.125**	**0.133**	**0.134**
	Piacenza	7.0	**0.206**	**0.218**	**0.210**	**0.206**	**0.208**	**0.203**
	Porto	4.9	**0.143**	**0.124**	**0.123**	**0.115**	**0.119**	**0.125**
	Sevilla	7.3	**0.285**	**0.273**	**0.253**	**0.221**	**0.222**	**0.224**
	Thiva	7.7	**0.522**	**0.523**	**0.471**	**0.465**	**0.448**	**0.426**

5-7-diOH-XDE-742

Model	Scenario	Soil pH	Application Date					
			1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun*	8.0	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	6.4	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokioinen	6.2	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster*	7.7	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	5.8	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza*	7.0	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	4.9	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla*	7.3	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva*	7.7	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
PEARL	Chateaudun*	8.0	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	6.4	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokioinen	6.2	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster*	7.7	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	5.8	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza*	7.0	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	4.9	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla*	7.3	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva*	7.7	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

* Koc/Kom input values corresponding to pH ≥ 7.0 used.

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	active substance: 0.441
Photochemical oxidative degradation in air ‡	DT_{50} of 2.149 hours derived by the Atkinson model (version 1.91). OH (12 h) concentration assumed = 1.5 x 10^6 radicals/cm^3
Volatilisation ‡	Not submitted, not required
	Not submitted, not required
Metabolites	Not submitted, not required

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	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Parent pyroxsulam, 7-OH-XDE-742, 5-OH-XDE-742, 6-Cl-7-OH-XDE-742, pyridine sulfonamide and (anaerobic metabolite) 5,7-diOH-XDE-742 Surface Water: Parent pyroxsulam and 7-OH-XDE-742, 5-OH-XDE-742, 6-Cl-7-OH-XDE-742, pyridine sulfonamide, 5,7-diOH-XDE-742, ATSA, pyridine sulfinic acid and ADTP Sediment: Parent pyroxsulam and 7-OH-XDE-742 Ground water: Parent pyroxsulam and 7-OH-XDE-742, 5-OH-XDE-742, 6-Cl-7-OH-XDE- 742, 5,7-diOH-XDE-742, pyridine sulfonamide and PSA (pyridine sulfonic acid) Air: Parent pyroxsulam

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

Soil (indicate location and type of study)	New active substance, none available
Surface water (indicate location and type of study)	New active substance, none available
Ground water (indicate location and type of study)	New active substance, none available
Air (indicate location and type of study)	New active substance, none available

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

Not readily biodegradable. See Ecotoxicology Section 'Classification and proposed labelling': Pyroxsulam is proposed as a candidate for R50/53 risk phrase, 'Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment'.

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				
Colinus virginianus *Anas platyrhynchos*	a.s.	Acute	>2000	N A
Colinus virginianus	a.s.	Short-term	> 988	> 5000
Anas platyrhynchos	a.s.	Long-term	46.3	500
Mammals				
Rat	a.s.	Acute	> 2000	N A
Rat	Preparation ('GF-1274')	Acute	> 390	N A
Rat	a.s.	Long-term endpoint for EFSA (2009)	89*	N A
Additional higher tier studies				
None submitted				

N A – not available
* Based on the endpoint used for the derivation of the ADI.

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

Crop and application rate: Winter cereals BBCH GS 11-39. One application of 18.75 g a.s./ha

Indicator species/Category	Time scale	DDD	TER	Annex VI Trigger
Screening step (Birds)				
Small insectivorous bird (early and late cereals)	Acute	2.9775	> 671.7	10
Small insectivorous bird (early and late cereals)	Long-term	0.64	72.3	5
Screening step (Mammals)				
Small herbivorous mammal	Acute	2.22	> 176	10
Small herbivorous mammal (early cereals)	Long term	0.48	185	5

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity
Laboratory tests				
Fish				
O mykiss.	a.s.	96 hr (static)	LC50	> 87mg a.s./L mm
P promelas	a.s.	40-day (flow-through)	NOEC	10.1 mg a.s./L mm
O mykiss	Preparation 'GF-1274'	96 hr (semi-static)	Mortality, LC_{50}	75 mg 'GF-1274'/L 5.9 mg pyroxsulam/L (4.4-7.9) n
O mykiss	7-OH-XDE-742	96 hr (static)	Mortality, LC_{50}	> 120 mg metab./L mm
O mykiss	ATSA	96 h (static)	Mortality, LC_{50}	>119 mg metabl/L mm
**O mykiss*	Pyridine sulfonamide	96 h (static)	Mortality LC50	>8.7mg metab/L mm
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	EC_{50}	>100 mg a.s./L mm
Daphnia magna	a.s.	21 d (static renewal)	Reproduction, NOEC	10.4 mg a.s./L mm
Daphnia magna	Preparation 'GF-1274'	48 h (static)	EC_{50}	>100 mg 'GF-1274'/L > 7.7 mg pyroxsulam/L n
Daphnia magna	7-OH-XDE-742	48 h (static)	EC_{50}	99 mg metab./L mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity
Daphnia magna	ATSA	48 h (static)	EC50	> 121 mg metab./L mm
**Daphnia magna*	Pyridine sulfonamide	48 h (static)	EC50	10.0 mg metab/L mm
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static) Spiked water	NOEC	100 mg a.s./L n
Chironomus riparius	7-OH –XDE-742	28 d (static) Spiked water	NOEC	30 mg metab./L n
**Chironomus riparius*	Pyridine sulfonamide	28 d (static) Spiked water	NOEC	10.0 mg metab/L n
Algae				
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.111 0.924 mm
Anabaena flos- aquae	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	22 41 mm
Skeletonema costatum	a.s.	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	14.4 59.0 mm
Navicula pelliculosa	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	5.8 6.9 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity
Pseudokirchneriella subcapitata *(formerly known as* Selenastrum capricornutum*) (green algae)*	Preparation 'GF-1274'	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Biomass: E_bC_{50} Growth rate: E_rC_{50}	4.9 n 37 mi mg 'GF-1274'/L 0.35 n 2.7 mi mg pyroxsulam/L
Pseudokirchneriella subcapitata *(formerly known as* Selenastrum capricornutum*) (green algae)*	7-OH-XDE-742	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	50 65 mg metab./L mm
Pseudokirchneriella subcapitata *(formerly known as* Selenastrum capricornutum*) (green algae)*	ATSA	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	16.8 42.8 mg metab./L mm
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	Pyridine sulfinic acid	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>97 >97 mg metab./L mm
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	5-OH-XDE-742	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	57 >80 mg metab./L mm
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	6-Cl-7-OH – XDE-742	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	69 mg metab/L 85 (72 h) mg metab./L mm
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	ADTP	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	>92 mg metab/L > 92 mg metab/L mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	5,7-Di-OH-XDE-742	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	56 mg metab/L 60 mg metab/L mm
Pseudokirchneriella subcapitata (formerly known as *Selenastrum capricornutum*) (green algae)	Pyridine sulfonamide	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 114 mg metab/L mm
Higher plant				
Lemna gibba	a.s.	7 d (static)	EC_{50} frond number	0.00257 mm
Lemna gibba	Preparation 'GF-1274'/L	7 d (static renewal)	Fronds,E_bC50 Based on frond no.	0.0241 mg 'GF-1274'/L 0.0016 mg pyroxsulam/L n
Lemna gibba	7-OH-XDE-742	7 d (static renewal)	Frond density Frond growth rate Frond biomass	1.8 4.0 2.1 mg metab./L mm
Lemna gibba	ATSA	7 d (static renewal)	Frond density Frond growth rate Frond biomass	>120 >120 >120 mg metab./L mm
Lemna gibba	pyridine sulfinic acid	7 d (static renewal)	Frond density Frond growth rate Frond biomass	>110 >110 >110 mg metab./L mm
Lemna gibba	5-OH-XDE-742	7 d (static renewal)	Frond density Frond growth rate Frond biomass	5.7 7.4 6.6 mg metab./L mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity
Lemna gibba	6-Cl-7-OH-XDE-742	7 d (static renewal)	Frond density Frond growth rate Frond biomass	29 46 35 mg metab./L mm
Lemna gibba	ADTP	7 d (static renewal)	Frond density Frond growth rate Frond biomass	>93 >93 >93 mg metab./L mm
Lemna gibba	5,7-Di-OH - XDE-742	7 d (static renewal)	Frond density Frond growth rate Frond biomass	>95 >95 >95 mg metab./L mm
Lemna gibba	Pyridine sulfonamide	7 d (static renewal)	Frond density Frond growth rate Frond biomass	> 114 mg metab./L mm
Microcosm or mesocosm tests				
None submitted or required				

n= nominal concentration
mm = mean measured concentration
mi = measured initial
* *Please note that the endpoint is modelled and it is assumed that the endpoint is ten times more toxic than the parent.*

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

FOCUS Step 1

Winter cereals, one application /crop at 250 g product/ha = 18.75 g pyroxsulam/ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg pyroxsulam/L	TER	Annex VI Trigger
GF-1274	Fish *O mykiss*	5.9 pyroxsulam	Acute	0.0063	937	100
a.s.	Fish *P promelas*	10.1	Chronic	0.0063	1603	10
GF-1274	Aquatic invertebrates *D magna*	> 7.7 pyroxsulam	Acute	0.0063	>1222	100

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg pyroxsulam/L	TER	Annex VI Trigger
a.s.	Aquatic invertebrates *D magna*	10.4	Chronic	0.0063	1651	10
a.s.	Algae	E_bC50 0.11	Growth	0.0063	17.6	10
a.s.	Higher plants *Lemna gibba*	0.00257	Growth	0.0063	**0.43**	10
GF-1274	Higher plants *Lemna gibba*	E_bC50 0.00257	Growth	0.0063	**0.41**	10
a.s.	Sediment-dwelling organisms	100 mg/L	Chronic	0.0063	15873	10

FOCUS Step 2

Winter cereals, one application /crop at 250 g product/ha = 18.75 g pyroxsulam/ha

Test substance	N/S[1]	Organism	Toxicity endpoint (mg/L)	Time scale	PEC_i	TER	Annex VI Trigger
a.s.	N	Higher plants	EbC50 0.00257 mg a.s./L	Chronic	0.00114 mg a.s./L	**2.2**	10
a.s.	S	Higher plants	EbC50 0.00257 mg a.s./L	Chronic	0.00095 mg a.s./L	**2.7**	10

[1] N = northern Europe S = southern Europe

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

Winter cereals, one application /crop at 250 g product/ha = 18.75 g pyroxsulam/ha

Test substance	Scenario	Water body type	Test organism	Toxicity endpoint (mg/L)	PEC (mg/L)	TER	Annex VI trigger
pyroxsulam	D1	Ditch	Higher plants *Lemna gibba*	0.00257	0.000816	**3.1**	10
pyroxsulam	D1	Stream	Higher	0.00257	0.00081	**3.2**	10

Test substance	Scenario	Water body type	Test organism	Toxicity endpoint (mg/L)	PEC (mg/L)	TER	Annex VI trigger
			plants *Lemna gibba*				
pyroxsulam	D2	Ditch	Higher plants *Lemna gibba*	0.00257	0.00153	**1.7**	10
pyroxsulam	D2	Stream	Higher plants *Lemna gibba*	0.00257	0.000958	**2.7**	10
pyroxsulam	D3	Ditch	Higher plants *Lemna gibba*	0.00257	0.000119	22	10
pyroxsulam	D4	Pond	Higher plants *Lemna gibba*	0.00257	0.000115	22	10
pyroxsulam	D4	Stream	Higher plants *Lemna gibba*	0.00257	0.000152	17	10
pyroxsulam	D 5	Pond	Higher plants *Lemna gibba*	0.00257	0.000032	80	10
pyroxsulam	D5	Stream	Higher plants *Lemna gibba*	0.00257	0.000111	23	10
pyroxsulam	D6	Ditch	Higher plants *Lemna gibba*	0.00257	0.000145	18	10
pyroxsulam	R1	Pond	Higher plants *Lemna gibba*	0.00257	0.000004	642	10
pyroxsulam	R1	Stream	Higher plants *Lemna gibba*	0.00257	0.000166	15	10
pyroxsulam	R3	Stream	Higher plants *Lemna gibba*	0.00257	0.00108	**2.4**	10
pyroxsulam	R4	Stream	Higher plants *Lemna gibba*	0.00257	0.000158	16	10

Toxicity exposure ratios for aquatic organisms and metabolites

FOCUS Step 1

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	TER	Annex VI Trigger
7-OH metabolite	Fish *Oncorhynchus mykiss*	> 120	96 h	0.00219	54795	100
7-OH metabolite	Invertebrates *Daphnia magna*	> 99	48 h	0.00219	45205	100
7-OH metabolite	Sediment dweller *Chironomus riparius*	30	28 d	0.00219	13698	100
7-OH metabolite	Algae *Pseudokirch-neriella subcapitata*	50	72 h	0.00219	22381	10
7-OH metabolite	Aquatic higher plants *Lemna gibba*	1.8	7 d	0.00219	822	10
ATSA	Fish *Oncorhynchus mykiss*	> 119	96 h	0.00002	>5950000	100
ATSA	Invertebrates *Daphnia magna*	> 121	48 h	0.00002	>6050000	100
ATSA	Algae *Pseudokirch-neriella subcapitata*	16.8	72 h	0.00002	>840000	10
ATSA	Aquatic higher plants *Lemna gibba*	> 120	7 d	0.00002	>6000000	10
pyridine sulfinic acid	Algae *Pseudokirch-neriella subcapitata*	>97	72 h	0.00276	>35145	10
pyridine sulfinic acid	Aquatic higher plants *Lemna gibba*	> 110	7 d	0.00276	>39855	10
5 OH metabolite	Algae *Pseudokirch-neriella subcapitata*	57	72 h	0.00145	39310	10
5 OH metabolite	Aquatic higher plants *Lemna gibba*	5.7	7 d	0.00145	3931	10
6-Cl-7-OH metabolite	Algae *Pseudokirch-neriella subcapitata*	69	72 h	0.00167	41317	10

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	TER	Annex VI Trigger
6-Cl-7-OH metabolite	Aquatic higher plants *Lemna gibba*	29	7 d	0.00167	17365	10
ADTP	Algae *Pseudokirch-neriella subcapitata*	>92	72 h	0.00113	>81416	10
ADTP	Aquatic higher plants *Lemna gibba*	> 93	7 d	0.00113	>82301	10
5,7-di-OH—XDE-742	Algae *Pseudokirch-neriella subcapitata*	56	72 h	0.00147	38095	10
5,7-di-OH—XDE-742	Aquatic higher plants *Lemna gibba*	> 95	7 d	0.00147	>64626	10
pyridine sulfonamide	Algae *Pseudokirch-neriella subcapitata*	>114	72 h	0.00044	>259091	10
pyridine sulfonamide	Aquatic higher plants *Lemna gibba*	>114	7 d	0.00044	>259091	10

Toxicity exposure ratios for aquatic organisms

Groundwater returning to surface water

Organism	Time scale	Estimated toxicity endpoint[1] (mg/L)	PEC_{GW} (mg/L)	TER	Trigger
Metabolite PSA					
Algae *Pseudokirch-neriella subcapitata*	Acute 72 h	0.011	0.000523	21	10
Aquatic higher plants *Lemna gibba*	Acute 7 d	0.000257	0.000523	**0.49**	10
Aquatic higher plants *Lemna gibba*	Acute 7 d	0.000257	0.0000523[2]	**4.9**	10

[1]Toxicity of metabolite PSA assumed to be ten times greater than the parent
[2] Assumed tenfold dilution factor when groundwater returns to surface water
TER values in **bold** are less than the trigger value

Groundwater returning to surface water

Model	Scenario	Regulatory Acceptable Concentration for metabolite PSA (aquatic plants)[1] µg/L	RAC for metabolite PSA multiplied by dilution factor of 10 (aquatic plants)[1, 2] µg/L	Groundwater PEC value[3] µg/L					
				Application Date					
				1st Oct	1st Nov	1st Dec	1st Jan	1st Feb	1st Mar
PELMO	Chateaudun	0.0257	0.257	**0.331**	**0.339**	**0.343**	**0.337**	**0.332**	**0.326**
	Hamburg	0.0257	0.257	0.226	0.228	0.236	0.229	0.238	0.249
	Jokioinen	0.0257	0.257	**0.330**	**0.322**	**0.338**	**0.358**	**0.353**	**0.352**
	Kremsmünster	0.0257	0.257	0.162	0.170	0.170	0.178	0.174	0.172
	Okehampton	0.0257	0.257	0.135	0.136	0.127	0.117	0.129	0.130
	Piacenza	0.0257	0.257	0.210	0.200	0.226	0.231	0.233	0.234
	Porto	0.0257	0.257	0.136	0.141	0.125	0.115	0.122	0.122
	Sevilla	0.0257	0.257	0.226	0.233	0.214	0.178	0.165	0.163
	Thiva	0.0257	0.257	**0.330**	**0.311**	**0.286**	**0.283**	**0.270**	**0.250**
	Risk assessment outcome			**3/9 scenarios exceed RAC with dilution factor**					
PEARL	Chateaudun	0.0257	0.257	**0.355**	**0.352**	**0.352**	**0.332**	**0.333**	**0.330**
	Hamburg	0.0257	0.257	**0.291**	**0.260**	0.236	0.224	0.229	0.234
	Jokioinen	0.0257	0.257	**0.401**	**0.407**	**0.420**	**0.404**	**0.394**	**0.384**
	Kremsmünster	0.0257	0.257	0.133	0.145	0.133	0.138	0.142	0.141
	Okehampton	0.0257	0.257	0.133	0.133	0.123	0.125	0.133	0.134
	Piacenza	0.0257	0.257	0.206	0.218	0.210	0.206	0.208	0.203
	Porto	0.0257	0.257	0.143	0.124	0.123	0.115	0.119	0.125
	Sevilla	0.0257	0.257	**0.285**	0.273	0.253	0.221	0.222	0.224
	Thiva	0.0257	0.257	**0.522**	**0.523**	**0.471**	**0.465**	**0.448**	**0.426**
	Risk assessment outcome			**5/9 scenarios exceed RAC with dilution factor**					

[1] RAC: toxicity endpoint divided by the trigger value of 10. For metabolite PSA, this value is the estimated from the EC_{50} (frond number) for aquatic plants (2.57 µg/L) for the parent substance divided by 10 (estimated EC_{50} for metabolite PSA = 0.257 µg/L). RAC for metabolite PSA = 0.0257 µg/L

[2] In order to compare the RAC for metabolite PSA to the groundwater PEC values, the dilution factor was applied to RAC value.

[3] Values highlighted in **bold** exceed the RAC multiplied by the dilution factor of 10

Bioconcentration

The log K_{ow} for pyroxsulam is 1.08 at pH 4, - 1.01 at pH 7 and – 1.60 at pH 9. i.e. < 3 so, there is no requirement for a bio-accumulation study.

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
a.s.	> 107.4	> 100
Preparation ('GF-1274')	> 104	> 104
Field or semi-field tests: Not available - Not required.		

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

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	oral	< 0.17	50
a.s.	contact	< 0.19	50
Preparation	oral	< 0.18	50
Preparation	contact	< 0.18	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 pyroxsulam/ha)**
Typhlodromus pyri	'GF-1274'	Mortality	> 37.5
Aphidius rhopalosiphi	'GF-1274'	Mortality	> 37.5

Test substance	**Species**	**Effect (LR_{50} g/ha)**	**HQ in-field**	**HQ off-field (1 m)**	**Trigger**
'GF-1274'	*Typhlodromus pyri*	> 37.5	< 0.5	< 0.014	2
'GF-1274'	*Aphidius rhopalosiphi*	> 37.5	< 0.5	< 0.014	2

Further laboratory and extended laboratory studies Not available - Not required
Field or semi-field tests Not available - Not required

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
Earthworms			
Eisenia foetida	a.s.	Acute 14 days	LC_{50} > 10000 mg a.s./kg d.w.soil
Eisenia foetida	Preparation 'GF-1274'	Acute 14 days	LC_{50} > 1000 mg 'GF-1274'/Kg d.w.soil (> 78 mg a.s./kg d.w.soil)

Test organism	Test substance	Time scale	End point
Eisenia foetida	Preparation 'GF-1274'	Chronic 56 days	NOEC 13.7 mg 'GF-1274'/Kg soil (1.07 mg pyroxsulam/Kg soil)[1]
Eisenia foetida	7-OH metabolite of pyroxsulam	Acute 14 days	LC50 > 1000 mg 7-OH metabolite of pyroxsulam
Eisenia foetida	7-OH metabolite of pyroxsulam	Chronic 56 days	NOEC 0.068 mg 7-OH metabolite of pyroxsulam /Kg soil
Eisenia foetida	5-OH metabolite of pyroxsulam	Acute 14 days	LC50 > 1000 mg 5-OH metabolite of pyroxsulam
Eisenia foetida	5-OH metabolite of pyroxsulam	Chronic 56 days	NOEC 0.107 mg 5-OH metabolite of pyroxsulam /Kg soil [2]
Eisenia foetida	6-Cl-7-OH metabolite of pyroxsulam	Acute 14 days	LC50 > 1000 mg 6-Cl-7-OH metabolite of pyroxsulam
Eisenia foetida	6-Cl-7-OH metabolite of pyroxsulam	Chronic 56 days	NOEC 0.130 mg 6-Cl-7-OH metabolite of pyroxsulam /Kg soil
Eisenia foetida	Pyridine sulfonamide	Acute 14 days	LC50 >1000 mg pyridine sulfonamide/Kg soil
Eisenia foetida	Pyridine sulfonamide	Chronic 56 days	NOEC 0.038 mg pyridine sulfonamide/Kg soil
Other soil macro-organisms			
Folsomia candida	7-OH-XDE-742	28 d	NOEC 0.0680 mg/Kg
Folsomia candida	6-Cl-7-OH-XDE-742	28 d	NOEC 0.136 mg/Kg
Folsomia candida	Pyridine sulfonamide	28 d	NOEC 0.038 mg/Kg
Folsomia candida	NER	28 d	NOEC 0.238 mg/Kg based on initial concentration of bound residues NOEC 0.661 mg/Kg based on final concentration of bound residues NOEC 0.391 mg/Kg based on average exposure concentration[3]
Soil micro-organisms			
Nitrogen mineralisation	'GF-1274'	28 days	< 25% effect at ≥ 0.125 mg a.s./kg d.w.soil (≥ 93.75 mg a.s/ha)
Carbon mineralisation	'GF-1274'	28 day	< 25% effect at ≥ 0.125 mg a.s./kg d.w.soil (≥ 93.75 mg a.s/ha)

Test organism	Test substance	Time scale	End point
Field studies			
Not required			

[1]: the endpoint bears some uncertainty, since the number of juveniles was statistically different form the control in lower concentrations

[2]: modelled toxicity endpoint, assuming that the metabolite is 10 more toxic than the active substance. The endpoint was derived from the study where the number of juveniles was statistically different form the control in lower concentrations (see footnote No. 1)

[3]: It was considered that the study was not ideal (includes some uncertainty) regarding the design and in the conduct (i.e. the number of control juveniles), however it provides valuable information for the risk assessment for NER

Toxicity/exposure ratios for soil organisms

Crop and application rate: Winter cereals BBCH GS 11-39. One application of 18.75 g a.s./ha

Test organism	**Test substance**	**Time scale**	**Soil PEC[1]**	**TER**	**Trigger**
Earthworms					
Eisenia foetida	Pyroxsulam	Acute 14 days	0.025 (assuming 0% inter-ception)	> 400000	10
Eisenia foetida	'GF-1274'	Acute 14 days	0.025	> 3120	10
Eisenia foetida	'GF-1274'	Chronic 56 days	0.025	42.8	5
Eisenia foetida	7-OH metabolite of pyroxsulam	Acute 14 days	0.003	>333333	10
Eisenia foetida	7-OH metabolite of pyroxsulam	Chronic 56 days	0.003	23	5
Eisenia foetida	5-OH metabolite of pyroxsulam	Acute 14 days	0.006	>166667	10
Eisenia foetida	5-OH metabolite of pyroxsulam	Chronic 56 days	0.006	18	5
Eisenia foetida	6-Cl-7-OH metabolite of pyroxsulam	Acute 14 days	0.007	>142857	10
Eisenia foetida	6-Cl-7-OH metabolite of pyroxsulam	Chronic 56 days	0.007	18.6	5
Eisenia foetida	Pyridine sulfonamide	Acute 14 days	0.002	>500000	10
Eisenia foetida	Pyridine sulfonamide	Chronic 56 days	0.002	19	5
Folsomia candida	7-OH-XDE-742	28 d	0.003	20	5
Folsomia candida	6-Cl-7-OH-XDE-742	28 d	0.007	19.4	5

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Folsomia candida	Pyridine sulfonamide	28 d	0.002	19	5

[1] worst case PEC soil was used except for as indicated for pyridine sulfonamide.

Risk assessment (TER) for Collembola exposed to non-extractable residues taking into account different levels of crop interception and different NOECs

	Interception			
BBCH growth stage (cereals)	00-09	10-19	20-29	30-39
	0%	25%	50%	70%
Unextracted residue (pyroxsulam equivalents) PECsoil accumulated values representing repeated annual use	0.164 mg/kg	0.123 mg/kg	0.082 mg/kg	0.050 mg/kg
NOEC of 0.238 mg/kg assuming initial concentration of bound residues	1.4	1.9	2.9	4.7
NOEC 0.661 mg/kg assuming final concentration of bound residues	4	5.4	8.1	13.2
28 day AEEC[1] NOEC 0.391 mg/kg	2.4	3.2	4.8	7.8

[1] average effect exposure concentration (28 days)

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g product/ha) emergence	ER_{50} (g product/ha) vegetative vigour	Exposure (g product/ha)	TER Pre-emergence	TER Vegetative vigour	Trigger
B. vulgaris	'GF-1274'	16.39		6.93 at 1m	2.3		5
B. vulgaris	'GF-1274'	16.39		1.425 at 5m	11.50		5
L. perenne	'GF-1274'		14.86	6.93 at 1m		2.14	5
L. perenne	'GF-1274'		14.86	1.425 at 5m		10.43	5

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

None submitted

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

Test type/organism	end point
Activated sludge	EC50 > 1000 mg pyroxsulam/L

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

Compartment	
soil	Parent pyroxsulam, 7-OH-XDE-742, 5-OH-XDE-742, 6-Cl-XDE-742, pyridine sulfonamide and 5,7-diOH-XDE-742
surface water	Parent pyroxsulam, 7-OH-XDE-742, 5-OH-XDE-742, 6-Cl-7-OH-XDE-742, pyridine sulfonamide, 5,7-diOH-XDE-742, ATSA, pyridine sulfinic acid and ADTP
sediment	Parent pyroxsulam and 7-OH-XDE-742
groundwater	PSA (pyridine sulfonic acid)

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

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 or Regulation (EU) No 188/2011 are not formal proposals.

RMS proposal

Pyroxsulam:-

Hazard symbol:		Dangerous for the environment
Risk phrases:	R 50/53	Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment
Safety phrases:	S60	This material and its container must be disposed of as hazardous waste
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets

Justification for the proposals:		
Risk phrases:	R 50/53	EC 50 for algae and aquatic higher plants < 1 mg/L
Safety phrases:	S60/61	Recommended for substances that may cause effects in the environment

Provisional hazard classification of the active substance for environmental effects according to Regulation (EC) 1272/2008

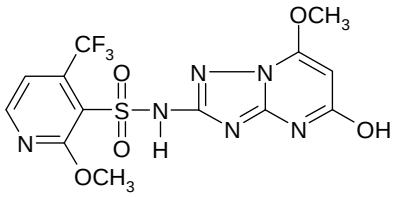
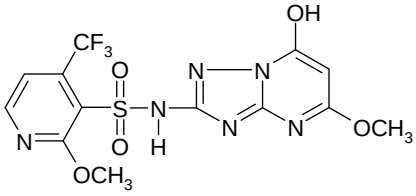
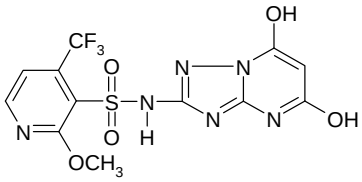
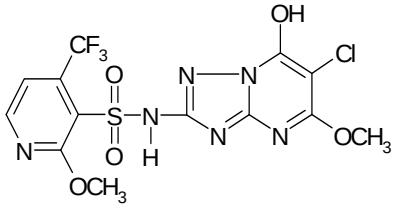
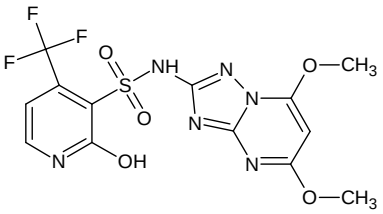
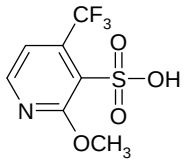
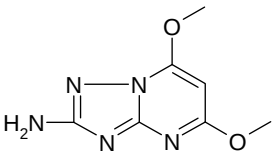
The most sensitive species to the **active substance** is *Lemna gibba*. Therefore, on the basis of the data on *Lemna gibba* pyroxsulam should receive the following classification and labelling:

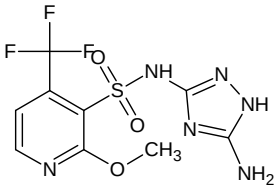
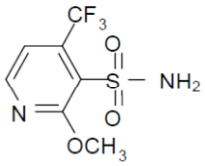
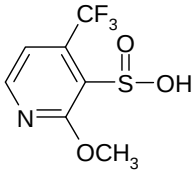
Pictogram	GHS09
Signal word	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects (chronic category 1).
M-factor	100 (acute/chronic)
Precautionary statements	P273 Avoid release to the environment P391 Collect spillage P501 Dispose of contents/ container to ... (in accordance with local/ regional/ national/ international regulation (to be specified))

Justification for classification according to Regulation (EC) 1272/2008

H410	Required as pyroxsulam is a 'chronic category 1', as defined by: i) 7-day EC50 for *Lemna* <0.1 mg/L; 7-day *Lemna* NOEC <0.1 mg/L iii) substance not 'readily biodegradable' (ref. Section B.8.4.3 of Volume 3 DAR).
M-factor of 100	Relevant pyroxsulam toxicity endpoint (*Lemna* EC_{50}) between 0.01 and 0.001 mg a.s. /L. Chronic *Lemna* NOEC ≤ 0.001 and 0.0001 mg a.s./L.
GHS09 Pictogram	Required for 'chronic category 1' substance
Signal word 'Warning'	Required for 'chronic category 1' substance
P273, P 391, P 501	Required for 'chronic category 1' substance

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
5-OH-pyroxsulam **5-OH-XDE-742**	*N*-(5-hydroxy-7-methoxy[1,2,4] triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide	
7-OH-pyroxsulam **7-OH-XDE-742**	*N*-(7-hydroxy-5-methoxy[1,2,4] triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide	
5,7-OH-pyroxsulam **5,7-diOH-XDE-742**	*N*-(5,7-dihydroxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide	
6-Cl-7-OH-pyroxsulam **6-Cl-7-OH-XDE-742**	*N*-(6-chloro-7-hydroxy-5-methoxy [1,2,4] triazolo[1,5-*a*]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl) pyridine -3-sulfonamide	
2-desmethyl-XDE-742	*N*-(5,7-dimethoxy[1,2,4]triazolo[1,5-*a*]pyrimidin-2-yl)-2-oxo-4-(trifluoromethyl)-1,2-dihydro-3-pyridinesulfonamide	
PSA	2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonic acid	
ADTP	5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-amine	

ATSA	*N*-(5-amino-1*H*-1,2,4-triazol-3-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide	
Pyridine sulfonamide	2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide (IUPAC)	
Pyridine sulfinic acid	2-methoxy-4-(trifluoromethyl)pyridine-3-sulfinic acid (IUPAC) 3-pyridinesulfinic acid, 2-methoxy-3-trifluoromethyl (CAS)	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
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 Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DFG	Deutshe Forschungsgemeinschaft method
DK	Denmark
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
FID	flame ionisation detector
FIR	Food intake rate
FOB	functional observation battery

FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	First order multi-compartment
g	gram
GAP	good agricultural practice
GC-FID	gas chromatography with flame ionisation detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
hL	hectolitre
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LGL	large granular lymphocyte leukaemia
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
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NER	non-extracted residues
NESTI	national estimated short-term intake
ng	nanogram
nm	nanometer

NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
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
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