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| **REGISTRATION REPORT**  Part B  Section 9  Ecotoxicology  Detailed summary of the risk assessment |
| Product code: -  Product name(s): **ULTRACENT 460 EC**  Chemical active substance(s):  Prothioconazole, 160 g/L Spiroxamine, 300 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: XXXX  Submission date: August 2023, update December 2023  / July 2024 /October 2024  Evaluation date: October 2024  MS Finalisation date: February 2025 |

Version history

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| When | What |
| August 2023 | First submission – application according to Article 33 in connection with Article 34 of Regulation (EC) No. 1107/2009 with reference to unprotected data of the product INPUT 460 EC authorized in Poland |
| December 2023 | The dossier was updated to include available information on the unprotected data of the reference product INPUT 460 EC (R-61/2011). |
| July 2024 | The dossier was updated based on comments from the evaluating entity |
| October 2024 | Update of the aquatic risk assessment based on zRMS request |
| October 2024 | zRMS finalized evaluation |

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# Ecotoxicology (KCP 10)

This application is submitted by XXXX to Poland for the first authorization of ULTRACENT 460 EC. ULTRACENT 460 EC is an emulsifiable concentrate containing 160 g/L prothioconazole and 300 g/L spiroxamine and is used as a fungicide in cereals. This application is based on the comparability with the reference product INPUT 460 EC of the authorization holder Bayer AG.

The application submitted herewith also relies on Article 34, in the form of an article 33 application. In the authorization procedure applied for herewith, Poland acts as zonal rapporteur member state (zRMS). There are no other concerned member states. Reference is made to the unprotected data and dossier submitted for INPUT 460 EC (R-61/2011, authorization holder Bayer AG) in Poland. Hence, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009. Additionally, data demonstrating the efficacy of the product as well as new studies on its physical-chemical properties is submitted in support of the application for authorization of ULTRACENT 460 EC.

The requested uses for ULTRACENT 460 EC are covered by those of the Polish reference product INPUT 460 EC. Formulation related data requirements are met by access to data previously submitted to the ministry for the identical and similar product INPUT 460 EC, reference to published data, and citing access to both Polish and EU review data now out of protection. The formulation of ULTRACENT 460 EC is supposed to be identical to that previously approved for INPUT 460 EC. For this reason, all formulation related data submitted by the original authorization holder for INUT 460 EC and held by the Polish ministry are cited as unprotected data in support of this current application. ~~Therefore, except for the additionally submitted studies performed with ULTRACENT 460 EC, no new data nor risk assessment are required and thus are not presented in the current dossier.~~

This application refers to data and risk assessments performed in accordance with the Uniform Principles of Regulation (EC) No. 1107/2009 provided for the product INPUT 460 EC.

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| **Review Comments:**  This is the application for registration plant protection product according to Article 33 of Regulation 1107/2009 based on unprotected data for compositionally comparable formulation (acc. Art. 34 of Reg. 1107/2009). ULTRACENT 460 EC is an emulsifiable concentrate containing 160 g/L prothioconazole and 300 g/L spiroxamine and is used as a fungicide in cereals.  Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.  One of the representative formulated product for the EU evaluation of spiroxamine was Input, an EC formulation containing 160 g/L prothioconazole and 300 g/L spiroxamine. The representative uses evaluated were applications in wheat, triticale, rye, barley and oats with the Input 460 EC formulation.  From ecotoxicological perspective ULTRACENT 460 EC is considered equivalent to Input 460 EC. Thus data evaluated at EU level for Input can be used to evaluate this product. |

## Critical GAP and overall conclusions

Table 9.1‑1: Table of critical GAPs

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| Use-No. \* | Member state(s) | Crop and/or situation  (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I \*\* | Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI  (days) | Remarks:  e.g. g saf­ener/ syner­gist per ha | Conclusion | | | | | |  |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product/ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min/max | Birds | Mammals | Aquatic organisms | Bees | Non-target arthropdsarthropods | Soil organisms | Non-target plants |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | | | | | | | |
| 1 | PL | Wheat (winter) | F | Eyespot (PSDCHE), Fusarium sp. (FUSASP), powdery mildew (ERYSGR) | Foliar spray | BBCH 30-31 | 1. 1 2. 1 | - | 1. 0.75 2. 0.75 | 1. 0.12 kg prothioconazole/ha + 0.225 kg spiroxamine/ha 2. 0.12 kg prothioconazole/ha + 0.225 kg spiroxamine/ha | 200-400 | 35 |  | A | A | R | A | A | A | A |
| 2 | PL | Wheat (winter) | F | Eyespot (PSDCHE), Fusarium sp. (FUSASP), powdery mildew (ERYSGR) | Foliar spray | BBCH 31-37 | 1. 1 2. 1 | - | 1. 1.0 2. 1.0 | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | A | A | R | A | A | A | A |
| 3 | PL | Wheat (winter and spring) | F | Rust species (PUCCSP),  Brown rust (PUCCRE)  Powdery mildew (ERYSGR)  Septoria leaf spot(SEPTTR)  Glume blotch (LEPTNO)  Tan spot(PYRNTR) | Foliar spray | BBCH 30-59 | 1. 1 2. 1 | - | 1. 1.0 2. 1.0 | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | A | A | R | A | A | A | A |
| 4 | PL | Barley (winter and spring) | F | Eyespot (PSDCHE)  Brown rust (PUCCHD)  Powdery mildew (ERYSGR)  Rhynchosporium (RHYNSE)  Net blotch (PYRNTE)  Fusarium stem blight(FUSASP*)* | Foliar spray | BBCH 30-51 | 1. 1 2. 1 | - | 1. 1.0 2. 1.0 | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | A | A | R | A | A | A | A |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

|  |  |
| --- | --- |
| A | Acceptable, Safe use |
| R | Further refinement and/or risk mitigation measures required |
| C | To be confirmed by cMS |
| N | No safe use |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| **Remarks**  **table:** | (1) Numeration necessary to allow references  (2) Use official codes/nomenclatures of EU  (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)  (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named  (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated |  | (7) Growth stage at first and 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  (8) The maximum number of application possible under practical conditions of use must be provided  (9) Minimum interval (in days) between applications of the same product.  (10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products  (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  (13) PHI - minimum pre-harvest interval  (14) Remarks may include: Extent of use/economic importance/restrictions |

### Overall conclusions

#### Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC~~.

***Birds***

A risk assessment for birds ~~mammals~~ was conducted according to the “Guidance Document on Risk Assessment for Birds and Mammals” (EFSA Journal 2009; 7(12):1438). In the tiered risk assessment, an acceptable risk from the use of ULTRACENT 460 EC according to the GAP was demonstrated for birds.

***Mammals***

A risk assessment for mammals was conducted according to the “Guidance Document on Risk Assessment for Birds and Mammals” (EFSA Journal 2009; 7(12):1438). In the tiered risk assessment, an acceptable risk from the use of ULTRACENT 460 EC according to the GAP was demonstrated for mammals.

#### Effects on aquatic organisms (KCP 10.2)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

~~The risk assessment demonstrates that no significant risk to the aquatic organisms is present for the central zone relevant scenarios for the zRMS following the intended GAP use of ULTRACENT 460 EC in cereals (winter and spring) when following mitigation measures are taken into consideration.~~

|  |  |
| --- | --- |
| ~~Winter Cereals: 1.0 L/ha, BBCH 30-59~~ | ~~10 m vegetative buffer zone~~ |
| ~~Spring Cereals: 1.0 L/ha, BBCH 30-59~~ | ~~10 m no spray buffer zone~~ |
|  |  |
| **Review Comments**:  According to Polish national requirements given on the website of the Ministry of Agriculture and Rural Development, for each crop the appropriate for Poland scenarios must be included (for surface water: D3, D4, R1). Due to the lack of R1 scenarios for spring cereals, the winter cereals for this scenario are use as surrogate crop.  The calculated PEC/RAC ratios indicate an acceptable risk for all groups of aquatic organisms with following mitigation measures:  To protect aquatic organisms respect 20 m unsprayed, vegetated buffer zone to surface water bodies. | |

#### Effect on bees (KCP 10.3.1)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The hazard quotient for toxicity against ULTRACENT 460 EC is less than 50, indicating that the GAP use of product poses no unacceptable risk to the bees.

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| **Review Comments:**  The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).  The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible risk associated with the exposure of beesto ULTRACENT 460 EC.  No studies on chronic effects of the formulation to adult bees or to larvae were provided in the risk assessment to bees, although this is a data requirement set by the Commission Regulation (EU) 284/2013. The deficiencies should be addressed before the new EFSA guidance becomes applicable. |

#### Effects on arthropods other than bees (KCP 10.3.2)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The risk of ULTRACENT 460 EC was demonstrated to be acceptable if the product is applied according to the intended GAP use.

#### Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The TER calculations demonstrates that no unacceptable exposure of soil macro-organisms is to be expected and no unacceptable effects from the GAP use of ULTRACENT 460 EC to earthworms and other non-target soil organisms is to be expected.

#### Effects on non-target terrestrial plants (KCP 10.6)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

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| **Review Comments:**  Based on the results of studies for both active substances, no herbicidal effect of ULTRACENT 460 EC is expected. |

#### Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Not relevant.

### Grouping of intended uses for risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1‑2: Critical use pattern of ULTRACENT 460 EC grouped according to application rate and crop group

| Grouping according to crop group and application timing | | | |
| --- | --- | --- | --- |
| Group | Intended uses | Application rate | Application timing |
| 1 | winter / spring cereals  (use 1-4) | Prothioconazole: 1 x 160 g a.i./ha  Spiroxamine: 1 x 300 g a.i./ha | Spring |

### Consideration of metabolites

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of ULTRACENT 460 EC is indicated in the table.

Table 9.1‑3 Metabolites of Prothioconazole

| Metabolite | Chemical structure | Molar mass | Maximum occurrence in compartments | Risk assessment required? |
| --- | --- | --- | --- | --- |
| Prothioconazole-S-methyl  (M01) |  | 358.8 g/mol | Soil: 14.6 % | PECgw  PECsoil |
| Prothioconazole-desthio  (M04) |  | 312.2 g/mol | Soil: 57.1 %  Water: 32.2 %  Sediment: 26.9 % | PECgw  PECsoil  PECsw |
| 1, 2, 4-triazole  (M13) |  | 69.065 g/mol | Water/Sediment: 32.7 % | PECsw |

Table 9.1‑4 Metabolites of Spiroxamine

| Metabolite | Chemical structure | Molar mass | Maximum occurrence in compartments | Risk assessment required? |
| --- | --- | --- | --- | --- |
| M01  (KWG 4168-desethyl) |  | 269.4 | Soil: 8.8 % (field > 10 %)  W/S system: < 10 % | PECsoil  PECgw  PECsw/sed |
| M02  (KWG 4168-despropyl) |  | 255.4 | Soil: 45 %  W/S system: 5.8 % | PECsoil  PECgw  PECsw/sed |
| M03  (KWG 4168-N-oxide) |  | 313.5 | Soil: 7.9 %  Water: 11.3 %  Sediment: 1.5 % | PECsoil  PECgw  PECsw/sed |
| M06  (KWG 4168-acid) |  | 327.5 | Water: 31.3 % | PECsw/sed |

## Effects on birds (KCP 10.1.1)

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Avian toxicity studies have been carried out with prothioconazole and spiroxamine and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of ULTRACENT 460 EC were not evaluated as part of the EU assessment of prothioconazole or of spiroxamine.

However, the provision of further data on the formulation ULTRACENT 460 EC is not considered essential, since it can be extrapolated from active substance data.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Laboratory studies** | | | | |
| **Toxicity** | **Tested substance** | **Species** | **Toxicity endpoint** | **Study information** |
| **Acute oral** | Input 460 EC | *-* | LD50 = 1637 mg/kg b.w. | LD50 value (met. extrapolation) |
| spiroxamine | *Bobwhite quail* | LD50 = 565 mg/kg b.w.. | ~~Spiroxamine 7584/VI/97-Final 12.5.99~~  ~~EFSA Journal 2010;8(10)1719~~ |
| prothioconazole | *Bobwhite quail* | LD50 > 2000 mg a.s./kg b.w. | ~~Prothioconazole EFSA SC - Final 12 07.2007~~ |
| JAU 6476-desthio | *Bobwhite quail* | LD50 > 2000 mg a.s./kg b.w./day | ~~Prothioconazole EFSA SC - Final 12 07.2007~~ |
| **Food, short-term** | spiroxamine | *Bobwhite quail* | LC50 > 357,4 mg a.s./kg  b.w./day (5000ppm) | ~~Spiroxamine 7584/VI/97-Final 12.5.99~~ |
| prothioconazole | *Bobwhite quail* | LC50 > 1413 mg a.s./kg  b.w./day  (5000 mg a.s./kg. food) | ~~Prothioconazole EFSA SC - Final 12 07.2007~~ |
| JAU 6476-desthio | *Bobwhite quail* | LC50 > 4090 mg/kg food (cal. LD50 = 614 kg b.w./day) | ~~Prothioconazole EFSA SC - Final 12 07.2007~~ |
| **Reproduction** | spiroxamine | *Bobwhite quail* | NOAEL = 5 mg a.s./kg  b.w./day  NOEC=30 ppm | ~~Spiroxamine 7584/VI/97-Final 12.5.99~~ |
| NOEL = 2.02 mg/kg bw/day  NOAEL = 5.4 mg/kg bw/day | ~~EFSA Journal 2010;8(10)1719~~ |
| prothioconazole | *Mallard duck* | NOEL = 78 mg a.s./kg b.w./day (700 mg/kg | ~~Prothioconazole EFSA SC - Final 12 07.2007~~ |
| JAU 6476-desthio | *Bobwhite quail* | NOEC > 173 mg/kg food  (calc. NOEL = 14,8 mg/ kg  b.w./day) | ~~Prothioconazole EFSA SC - Final 12 07.2007~~ |

|  |
| --- |
| **Review Comments:**  The endpoints for prothioconazole were taken from EFSA scientific report (2007) 106, 1-98 and for spiroxamine were taken from EFSA Journal 2010;8(10):1719. |

|  |  |
| --- | --- |
| **~~Cage or field trials~~** | ~~The risk assessment carried out showed that cage or field trials are not necessary~~ |
| **~~Secondary poisoning tests~~** | ~~the risk assessment for secondary poisoning is set out in the section below~~ |

#### Justification for new endpoints

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Risk assessment has been conducted with the endpoints taken from studies that have previously been EU-evaluated.

|  |
| --- |
| **Review Comments:**  One of the representative formulated product for the EU evaluation of spiroxamine was Input, an EC formulation containing 160 g/L prothioconazole and 300 g/L spiroxamine. The representative uses evaluated were applications in wheat, triticale, rye, barley and oats with the Input formulation.  From ecotoxicological perspective ULTRACENT 460 EC is considered equivalent to Input. Thus data evaluated at EU level for Input can be used to evaluate this product. |

### Risk assessment for spray applications

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~An acute risk assessment for birds was carried out based on the toxicity of the formulation of Input 460 EC, and a short-term and long-term risk assessment was carried out based on the results of tests on the active substances: spiroxamine and prothioconazole. An acute, short-term and long-term risk assessment was also carried out for the ecotoxicologically relevant metabolite of prothioconazole: JAU 6476 - desthio. No acute risk assessment has been carried out for the active substance due to the fact that it has been carried out at EU level for more adverse exposure scenarios than those resulting from the proposed use of the product in Poland. The risk assessment submitted by the applicant was carried out for two applications of the product on cereals at a dose of 1.25 l/ha, assuming an interval of at least 3 weeks between sprays. Because the assessment was carried out for a worse bird exposure scenario than the proposed use of Input 460 EC in Poland, it was accepted by the Institute, as it covers the risk assessment for birds to be carried out for the uses proposed in the instructions for use of the product.~~

~~The proposed scope and mode of application of the product indicated that the main route of exposure for birds is the potential for them to ingest treated plants and insects. As the product is intended for use on cereals in their early and late growth stages, the focus was on assessing the risk to large herbivorous birds and insectivorous birds as the most vulnerable indicator species for the proposed use range.~~

~~Acute risk~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: Input 460 EC~~  ~~- Number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of 0.985 g/cm3)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~LD~~~~50~~ ~~= 1637 mg/kg b.w. (estimated value)~~ | | | | |  | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 142 1 1 1~~ | | | | | ~~93.7 17 10~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 52 1 1 1~~ | | | | | ~~67.6 24 10~~ | | |
| ~~insectivorous bird (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 52 1 1 1~~ | | | | | ~~67.6 24 10~~ | | |
|  | | | | |  | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: JAU 6476-desthio~~  ~~- Number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of product with a density of 0.985 g/cm3)~~  ~~- amount of JAU 6476-desthio: 0.2 kg/ha (0.18kg/ha after consideration of the molar conversion factor of 0.907)~~  ~~- crop and growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 (Bobwhite quail) > 2000 mg/kg b.w.~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 - 1 1 1~~ | | | | | ~~1.64 1220 10~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 52 1 1 1~~ | | | | | ~~10.8 >185 10~~ | | |
| ~~insectivorous bird (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 52 1 1 1~~ | | | | | ~~10.8 >185 10~~ | | |

~~The TER toxic exposure factors exceed the limit value of 10. This means that the risk to birds from acute exposure to Input 460 EC is acceptable.~~

~~Short-term risk~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: prothioconazole~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.2 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 (Bobwhite quail) = 1413 mg/kg b.w./day~~ | | | | |  | | |
| **~~FIR/b.w.~~** | **~~RUD (90percentile [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 76 1 1 1~~ | | | | | ~~8.23 >172 10~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 >234 10~~ | | |
| |  |  | | --- | --- | | ~~insectivorous bird (small insects) (late phase of cereal growth)~~ |  | | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 >234 10~~ | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: spiroxamine~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.375 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 (Bobwhite quail) > 357,4 mg/kg b.w./day~~ | | | | |  | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percenile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 76 1 1 1~~ | | | | | ~~>357.4 >23 10~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~>357.4 >32 10~~ | | |
| ~~insectivorous bird (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~>357.4 >32 10~~ | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: JAU 6476-desthio~~  ~~- number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of product with a density of 0.985 g/cm3)~~  ~~- amount of JAU 6476-desthio: (0.18kg/ha after taking into account a molar conversion factor of 0.907)~~  ~~- crop and growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 (Bobwhite quail) = 614 mg/kg b.w./day~~ | | | | |  | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 - 1 1 1~~ | | | | | ~~1.10 558 10~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 102 10~~ | | |
| ~~insectivorous bird (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 102 10~~ | | |

~~The TERst toxic exposure factors exceed the limit value of 10. This means that the risk from short-term exposure of birds to Input 460 EC is acceptable.~~

~~Long-term risk~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: prothioconazole~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.2 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOEL (Bobwhite quail) = 78 mg/kg b.w../day~~ | | | | |  | | |
| **~~FIR/b.w..~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 76 1 1 1~~ | | | | | ~~4.36 18 5~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 13 5~~ | | |
| ~~ptak owadożerny (małe owady) (późna faza wzrostu zbóż)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 13 5~~ | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: spiroxamine~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.375 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOAEL (Bobwhite quail) = 5 mg/kg b.w../day~~ | | | | |  | | |
| **~~FIR/b.w..~~** | **~~RUD (90 percentile) [mg-kg~~~~-1~~~~-ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 76 1 1 1~~ | | | | | ~~8.18 0.66 5~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~11.3 0.48 5~~ | | |
| ~~insectivorous bird (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~11.3 0.48 5~~ | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: JAU 6476-desthio~~  ~~- number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of product with a density of 0.985 g/cm3)~~  ~~- amount of JAU 6476-desthio: (0.18kg/ha after taking into account a molar conversion factor of 0.907)~~  ~~- crop and growth stage: early and late cereals~~ | | | | | | | |
| ~~NOEL (Bobwhite quail) > 14.8 mg/kg b.w../day~~ | | | | |  | | |
| **~~FIR/b.w..~~** | **~~RUD (90 percentile) [mg-kg~~~~-1~~~~-ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.44 - 1 1 1~~ | | | | | ~~0.243 61 5~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 2.5 5~~ | | |
| ~~insectivorous bird (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~1.04 29 1 1 1~~ | | | | | ~~6.03 2.5 5~~ | | |

~~The TERlt toxic exposure factors do not exceed the limit value for spiroxamine and the JAU 6476-desthio metabolite. This means that the risk from long-term exposure of birds to Input 460 EC needed to be refined.~~

~~Refinement of the risk assessment of long-term exposure of birds to the product~~

~~conducted for spiroxamine and the metabolite JAU 6476-desthio~~

~~In refining the risk to herbivorous birds, data on residues of spiroxamine in green parts of cereal plants and data to adjust PT values were used.~~

~~Residue data were obtained from trials conducted on wheat and barley crops. The tests were carried out by spraying the product twice at a single dose of 1.25 l/ha. The determined initial spiroxamine concentration averaged 5.3 mg a.s. in 1 kg of fresh plant material (studies from the residue section: O.Heinemann, K. Elke; report no. RA-2092/00 and no. RA-2096/00). This value was used to refine the exposure of birds to the product.~~

~~At the first level of risk assessment, it was assumed that the birds receive all their food from the treated area, so the PT was set as 1. This type of assumption, which is appropriate for a first-tier assessment, generally overestimates the exposure of birds to the product. PT is defined as the portion of food/diet received on the treated crop. Based on literature data on studies of the residence time of geese (a standard indicator species in risk assessment) in different crops and their feeding preferences, it was shown that the actual time geese could spend in cereal crops ranged from 4 to 18 % of the total foraging time (Mooij, 1998). Pastures and other green areas proved to be more attractive to geese (Bauer & Glutz von Blotzheim, 1968). Therefore, it must be concluded that the portion of green parts of cereal plants consumed is much lower than assumed in the first stage of the assessment and represents no more than 18% of the total diet. According to the Guidance Document on Risk Assessment for Birds and Mammals SANCO/4245/2000, it is assumed that time spent in the natural habitat can be an indicator to measure the food received. On this basis, the PT value could be reduced. The risk refinement for insectivorous birds was done based on the literature data used for the risk assessment (Crocker et al. 1996) showing the actual possibility of exposure of different bird species in the agricultural environment. A First Tier Risk Assessment was carried out based on standard body weight and diet data for the indicator bird species shrew. The habitat of the shrew has been well described in the literature (Cramp, 1998). These data do not indicate that the shrew is the dominant species that forages in cereal crops. For the Polish area, as indicated in many publications (Christensen et al. 1996; Middleton & Chitty, 1997), the bird species that is most common in cereal crops is the partridge. It can therefore be thought that the risk calculated based on standard assumptions of bird exposure has been overestimated. A refinement of the risk to insectivorous birds based on assumptions of daily food intake and partridge body weight was therefore performed. This approach can be considered acceptable. In addition, an important factor was the use of the RUD value for large insects instead of the RUD value for small insects, which was used in the first stage of the assessment. This approach was reasonable due to the fact that the insects consumed by the partridge mostly belong to the soil arthropod group (Christensen et al., 1996). The mobility of the birds and their associated diurnal movement which results in a significantly lower food intake from the sprayed field centre was also taken into account. It was also shown that in the partridge's daily food intake, 70% is plant food and only 30% insects. All of the above factors allowed the ETE exposure values to be significantly reduced and the TERlt limit of 5 to be reached.~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: spiroxamine~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.375 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOAEL (Bobwhite quail) = 5 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w. /d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous bird (early phase of cereal growth)~~ | | | | | | | |
| ~~0.44 - 1 0.18 1 0.22 25 5~~ | | | | | | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | | | | |
| ~~0.76 29 1 33% 70% 0.14 8.6 5~~ | | | | | | | |
| ~~herbivorous bird that feeds on plant shoots (partridge - Perdix perdix)~~ | | | | | | | |
| ~~0.76 29 1 33% 30% 11.3 8.6 5~~ | | | | | | | |

~~The long-term risk assessment for the metabolite JAU 6476-desthio carried out at the first level was based on the assumption of a maximum amount of the metabolite and did not take into account the degradation time. Taking into account the rate of degradation in plant material with DT50 =3.2 days, determined taking into account 1st order kinetics, the theoretically estimated ETE exposure was reduced from 6.03 to 1.31 mg/kg b.w./bird/day.~~

|  |  |  |
| --- | --- | --- |
| ~~Exposure scenario: JAU 6476-desthio~~  ~~- number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of product with a density of 0.985 g/cm3)~~  ~~- amount of JAU 6476-desthio: (0.18kg/ha after taking into account a molar conversion factor of 0.907)~~  ~~- crop and growth stage: early and late cereals~~ | | |
| ~~NOEL (Bobwhite quail) > 14.8 mg/kg b.w./day~~ | | |
| **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~1.31~~ | ~~11.3~~ | ~~5~~ |

~~As a result of the refinement of the long-term risk, the TERllt toxic exposure factors for both spiroxamine and the prothioconazole metabolite JAU6476-desthio exceed the limit value. This means that the risk from long-term exposure of birds to Input 460 EC is acceptable.~~

~~Risk to earthworm-eating birds~~

~~Input 460EC may be applied at a time when there is little plant coverage of the soil. Consequently, part of the application rate will enter the soil. The Log Pow of the active substance prothioconazole is 3.82, of the metabolites JAU 6476- desthio and JAU S-methyl >3 which means that the substance can be accumulated in the soil and consequently in earthworms. Also, the log Pow for spiroxamine at high soil pH values is above 3. These results indicated the need to assess secondary poisoning for earthworm-feeding birds.~~

~~The following assumptions were made for the assessment:~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~substance~~** | **~~prothioconazole~~** | **~~JAU6476-desthio~~** | **~~JAU S-methyl~~** | **~~spiroxamine~~** |
| **~~Pow~~** | ~~6600~~ | ~~1100~~ | ~~15488~~ | ~~10000~~ |
| **~~Foc~~~~\*~~** | ~~assumed: 0.02~~ | ~~assumed: 0.02~~ | ~~assumed: 0.02~~ | ~~assumed: 0.02~~ |
| **~~Koc~~~~\*\*~~** | ~~1765 ml/g~~ | ~~575.4 ml/g~~ | ~~2556 ml/g~~ | ~~659 ml/g~~ |
| **~~BCF~~~~earthworm~~** | ~~1.89~~ | ~~1.03~~ | ~~3.05~~ | ~~7.65~~ |

~~\* foc - soil organic carbon content (0.02 constant value)~~

~~\*\* Koc - sorption coefficient~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~substance~~** | **~~prothioconazole~~** | **~~JAU6476-desthio~~** | **~~JAU S-methyl~~** | **~~spiroxamine~~** |
| **~~21 d-twa PECsoil~~**  **~~(mg/kg soil)~~** | ~~0.00052~~ | ~~0.06482~~ | ~~0.01705~~ | ~~0.25422~~ |
| **~~PECearthworm\*~~** | ~~0.00098~~ | ~~0.06676~~ | ~~0.05200~~ | ~~1.9447~~ |
| **~~FIR/w.c.~~** | ~~1.1~~ | ~~1.1~~ | ~~1.1~~ | ~~1.1~~ |
| **~~ETE earthworm~~** | ~~0.00108~~ | ~~0.07344~~ | ~~0.05720~~ | ~~2.139~~ |
| **~~NOEL/NOAEL~~**  **~~(mg/kg b.w./bird/day~~** | ~~78~~ | ~~14.8~~ | ~~78~~ | ~~5.4~~ |
| **~~TERlt~~** | ~~72222~~ | ~~202~~ | ~~1364~~ | ~~2.5~~ |
| **~~Limit value TERlt~~** | ~~5~~ | ~~5~~ | ~~5~~ | ~~5~~ |

~~\* PEC earthworms = PECs \* BCF~~

~~The toxic exposure factors for the active substance prothioconazole and its metabolites, calculated for long-term exposure of earthworm-eating birds, exceed the limit value. The TERlt factor calculated for spiroxamine did not exceed the limit value. This means that the risk in this area needed to be refined. The first level assessment of the long-term risk for birds feeding on earthworms was based on the assumption that the indicator bird species feeding on earthworms is the blackbird (Guidance Document on Risk Assessment for Birds and Mammals SANCO/4245/2000). However, based on available literature data, the blackbird may only spend 1.5% of its time in cereal crops during the application period, as its main habitat is woodland with dense undergrowth. This information may be evidence of a reduction in PT, the portion of food coming from cereal crops.~~

|  |  |
| --- | --- |
| **~~substance~~** | **~~spiroxamine~~** |
| **~~21 d-twa PECsoil (mg/kg soil)~~** | ~~0.25422~~ |
| **~~BCF~~** | ~~7.65~~ |
| **~~PECearthworm~~~~\*~~** | ~~1.9447~~ |
| **~~FIR/w.c.~~** | ~~1.1~~ |
| **~~PT~~** | ~~1.5 %~~ |
| **~~ETE~~ ~~earthworm~~** | ~~0.0321~~ |
| **~~NOEL/NOAEL (mg/kg b.w./bird/day)~~** | ~~5.4~~ |
| **~~TERlt~~** | ~~168~~ |
| **~~Limit value TERlt~~** | ~~5~~ |

~~\* PEC earthworms = PECs \* BCF~~

~~The toxic exposure factor calculated for the long-term exposure of earthworm-eating birds to the active substance spiroxamine exceeds the limit value. This means that the risk in this range is acceptable.~~

~~Risk to fish-eating birds~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~substance~~** | **~~prothioconazole~~** | **~~JAU6476-desthio~~** | **~~JAU S-methyl~~** | **~~spiroxamine~~** |
| **~~Max PECwater~~** | ~~0.00168~~ | ~~0.0079~~ | ~~0.00173~~ | ~~0.0031~~ |
| **~~BCFfish~~** | ~~18.8~~ | ~~45~~ | ~~75 (oszacowana)~~ | ~~79~~ |
| **~~PECfish\*~~** | ~~0.0316~~ | ~~0.0356~~ | ~~0.1278~~ | ~~0.2449~~ |
| **~~FIR/b.w.~~** | ~~0.21~~ | ~~0.21~~ | ~~0.21~~ | ~~0.21~~ |
| **~~ETE fish~~** | ~~0.00664~~ | ~~0.00748~~ | ~~0.02726~~ | ~~0.05143~~ |
| **~~NOEL/NOAEL~~**  **~~(mg/kg b.w./bird/day)~~** | ~~78~~ | ~~14.8~~ | ~~78~~ | ~~5.4~~ |
| **~~TERlt~~** | ~~111747~~ | ~~1977~~ | ~~2861~~ | ~~105~~ |
| **~~Limit value TERlt~~** | ~~5~~ | ~~5~~ | ~~5~~ | ~~5~~ |

~~\* PECfish = PEC~~~~s~~ ~~x BCFfish~~

~~The toxic exposure factors for the active substances and metabolites of prothioconazole, calculated for the long-term exposure of earthworm-eating birds, exceed the limit value. This means that the risk in this range is acceptable.~~

#### First-tier assessment (screening/generic focal species)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2‑1: Prothioconazole: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | Cereals | | | | |
| Active substance/product | Prothioconazole | | | | |
| Application rate (g/ha) | 1 × 160 | | | | |
| Acute toxicity (mg/kg bw) | >2000 / >1413\* | | | | |
| TER criterion | 10 | | | | |
| **Screening Step** | | | | | |
| Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Small omnivorous bird | | 158.8 | 1.0 | 25.41 | >78.7 / >55.6 |
| **Screening Step** | | | | | |
| Reprod. toxicity (mg/kg bw/d) | 78 | | | | |
| TER criterion | 5 | | | | |
| Indicator/generic focal species | | SV90 | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Small omnivorous bird | | 64.8 | 0.53 | 5.50 | 14.2 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio, m: multiple. TER values shown in bold fall below the relevant trigger.

\*lowest available endpoint (dietary toxicity)

Table 9.2‑2: JAU 6476-desthio: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | | | | | |
| Active substance/product | | JAU 6476-desthio | | | | | | | | |
| Application rate (g/ha) | | 1 × 145.1\* | | | | | | | | |
| Acute toxicity (mg/kg bw) | | >2000 / >297(worst-case, based on short-term dietary data) | | | | | | | | |
| TER criterion | | 10 | | | | | | | | |
| **Screening Step** | | | | | | | | | | |
| Indicator/generic focal species | | | SV90 | MAF90 | | | DDD90  (mg/kg bw/d) | | TERa | |
| Small omnivorous bird | | | 158.8 | 1.0 | | | 23.04 | | >86.8 / >12.9 | |
| **Screening Step** | | | | | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 14.8 | | | | | | | | |
| TER criterion | | 5 | | | | | | | | |
| Indicator/generic focal species | | | SV90 | MAFm × TWA | | | DDDm  (mg/kg bw/d) | | TERlt | |
| Small omnivorous bird | | | 64.8 | 0.53 | | | 4.98 | | 3.0 | |
| **1st Tier Reproductive Risk Assessment** | | | | | | | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | | | SVm | MAFm × TWA | | DDDm  (mg/kg bw/d) | | TERlt |
| BBCH 30 - 39 | Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods | | | | 5.4 | 0.53 | | 0.4 | | 35.6 |
| BBCH ≥ 40 | Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods | | | | 3.3 | 0.53 | | 0.3 | | 58.3 |
| Cereals Late season – Seed heads | Small granivorous/insectivorous bird “bunting” Grains/ear 100% cereal seeds | | | | 12.5 | 0.53 | | 0.96 | | 15.4 |

\*Application rate based on the application rate of parent substance considering the molar ratio

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio, m: multiple. TER values shown in bold fall below the relevant trigger.

Table 9.2‑3: Spiroxamine: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | | | | | |
| Active substance/product | | Spiroxamine | | | | | | | | |
| Application rate (g/ha) | | 1 × 300 | | | | | | | | |
| Acute toxicity (mg/kg bw) | | 565 | | | | | | | | |
| TER criterion | | 10 | | | | | | | | |
| **Screening Step** | | | | | | | | | | |
| Indicator/generic focal species | | | SV90 | MAF90 | | | DDD90  (mg/kg bw/d) | | TERa | |
| Small omnivorous bird | | | 158.8 | 1.0 | | | 47.64 | | 11.9 | |
| **Screening Step** | | | | | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 2.02 | | | | | | | | |
| TER criterion | | 5 | | | | | | | | |
| Indicator/generic focal species | | | SV90 | MAFm × TWA | | | DDDm  (mg/kg bw/d) | | TERlt | |
| Small omnivorous bird | | | 64.8 | 0.53 | | | 10.30 | | 0.2 | |
| **1st Tier Reproductive Risk Assessment** | | | | | | | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | | | SVm | MAFm × TWA | | DDDm  (mg/kg bw/d) | | TERlt |
| BBCH 30 – 39 | Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods | | | | 5.4 | 0.53 | | 0.9 | | **2.4** |
| BBCH ≥ 40 | Small omnivorous bird “lark” Combination (invertebrates with interception) 25% crop leaves 25% weed seeds 50% ground arthropods | | | | 3.3 | 0.53 | | 0.5 | | **3.8** |
| Cereals Late season – Seed heads | Small granivorous/insectivorous bird “bunting” Grains/ear 100% cereal seeds | | | | 12.5 | 0.53 | | 2.0 | | **1.0** |

\*Application rate based on the application rate of parent substance considering the molar ratio

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio, m: multiple. TER values shown in bold fall below the relevant trigger.

An acceptable risk to prothioconazole and its metabolite JAU 6476-desthio has been demonstrated using Tier 1 assessment. No acceptable risk for spiroxamine could be demonstrated using Tier 1 for reproductive risk assessment. A higher-tier risk assessment is demonstrated in the following.

#### Higher-tier risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The following parameters were refined taking the EFSA Conclusion on Spiroxamine (EFSA Journal 2010;8(10)1719) into consideration.

* Ecologically relevant endpoint NOAEL of 5.4 mg a.i./kg bw/d for higher Tier risk assessment
* The Food Intake Rate and Body weight (FIR/bw) for the focal species “woodlark” (FIR/bw crop leaves = 1.06, weed seeds = 0.23, ground arthropods = 0.7)
* Mean RUD for plants and seeds (RUD = 11.7 mg/kg) and mean RUD for arthropods (RUD = 5.1 mg/kg)
* The ftwa for focal species “woodlark” (crop leaves = 0.332, weed seeds = 0.332, ground arthropods = 0.21
* Refinement of PT for “woodlark” (PT = 0.5 for every category)

According to the EFSA Journal 2010;8(10)1719, a NOAEL of 5.40 mg/kg bw/d can be used for higher tier risk assessment since the effects observed at LOEL level were not adverse and would therefore not impose any impact on population level as mentioned in the Spiroxamine DAR[[1]](#footnote-1).

Food intake rate is taken from the DAR[[2]](#footnote-2) where the diet composition of skylark in early spring was recorded to be mainly plant matter and seeds, but also animal matter and a mean diet composition was assumed to be comprising of 25 % foliage, 25% weed seeds and 50 % ground arthropods. In addition, a mean body weight of 37.2 g for the female skylark has been cited as well.

For yellowhammer an FIR/bw was taken as 0.88 based on EFSA conclusion on spiroxamine[[3]](#footnote-3).

For insectivorous birds an RUD of 5.1 has been used as proposed by SANCO/4145/2000 for large ground dwelling insects and the refinement of RUD for plants and seeds is based on 4 residue trials of spiroxamine in barley as referred in DAR2.

The measured averaged half-life of 3.4 days in barley has been used for spiroxamine as an ftwa refinement (Temple & Palmer 1998). A twa-factor of 0.21 calculated for an averaging time of 14 days determined on a soil dwelling arthropod has been taken from the DAR[[4]](#footnote-4).

Based on observational data, a PT of 0.5 has been defined for woodlarks based on the assumption that birds will only take up to 50 % of their feed within the treated area2 and a PT of 0.4 was taken for yellowhammer.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Review Comments:**  Taking into account the EU agreed steps of refinement (refined reproduction endpoint, refined residue dissipation, deposition factor), for reasons of transparency in the assessment, the relevant parts of DAR are presented below. It should be noted that application rate of spiroxamine evaluated at EU level was 2x375 g a.s./ha.  ***Refinement for birds exposed to Spiroxamine following application of Prothioconazole + Spiroxamine EC 460 in cereals***  *Large herbivorous birds:*   * ***Measured residues of Spiroxamine***   *The tier 1 risk assessment is based on concentrations in feed that have been estimated from the use pattern in combination with a generic RUD value. To refine the risk assessment it is appropriate to replace these generic values for the concentration in feed by measured values from residue trials conducted on young barley plants (ref. KIIIA2 10.1.7/05: Loehrwald & Schmeer, 2008), which have been referenced by Thomas, 2008 (see ref. KIIIA2 10.1.7/04).*  *A total of 4 trials have been conducted in barley. The mean initial residue concentrations after the 1st and 2nd application of 375 g Spiroxamine/ha were 15.75 mg/kg (DALT -14) and 11.7 mg/kg (DALT 0) green material, respectively. The mean initial residues value after the second application can be used in the refined risk assessment for herbivores to replace the term “application rate x RUD”. An additional MAF is considered not necessary.*   * ***Refinement of ftwa***   *Residues in plant food sources within the treated area will decline depending upon the half-life of the active substances, and thus also the risk to animals will decline. For these calculations, the measured averaged half-life for Spiroxamine of 3.4 days in barley is used (see ref. 10.1.7/04). This leads to the following adjustment of ftwa:*  *Table B.9.1‑47: Refinement of ftwa*   |  |  | | --- | --- | | ***Compound*** | ***Spiroxamine*** | | *Matrix* | *Barley* | | *DT50 (days)* | *3.4* | | *Averaging time (days)* | *14* | | *twa-factor* | *0.3302* |  * ***Species of concern***   *Surveys have been conducted to evaluate the focal species in cereal fields. Data are available from Germany, Poland, France and Italy (XXXX et al., 2006, see ref. KIIIA2 10.1.7/06), as well as from Andalusia (XXXX, 2006, see ref. KIIIA2 10.1.7/07).*  *All these surveys indicated that the theoretical indicator species “goose” cannot be considered as one of the focal species. There are only medium-sized omnivores, which were regularly recorded, and these are quail and/or partridge. In the refined risk assessment the quail is considered as the most relevant species.*  *Another bird species, the lark, is also reported by XXXX et al. (see ref. KIIIA2 10.1.7/06) and XXXX (see ref. KIIIA2 10.1.7/07) as small omnivore focal species. XXXX (2007, see ref. KIIIA2 10.1.7/08) monitored the bird abundance in winter cereals fields in spring and summer, and found the skylark as one of the focal species. This information is supported by a survey conducted in cereal fields in spring in Germany (XXXX, 2008, see ref. KIIIA2 10.1.7/14). The extent to which skylarks use cereal fields as foraging habitat in early spring was evaluated. At the time the study was conducted, the majority of the winter cereal fields was in tillering stages up to early stem elongation (BBCH 21-32) whilst the spring cereals were freshly sown (BBCH 00-10). Birds feeding exclusively on seeds are not considered in this risk assessment.*   * ***Portion of diet obtained from the treated area (PT)***   *For long-term exposure, it can be generally assumed that birds will take up only 50 % of their feed within treated areas. Available data and experience supports the facts that mobile bird species will use different food sources within a region.*  *Moreover, the main home range of the generic indicator species ‘goose’ is continuous open greenland. The goose does not spend its whole feeding time within cereal fields; times spent in arable crop areas are recorded as 18 % (Anser fabalis) or 4 % (Anser albifrons) (Mooij 1998,*  *ref. KIIIA2 10.1.2/02). This is a worst-case assumption for winter time, as in many Middle-European countries the geese stay over winter only.*  *In early and late spring time, when most of the fungicide applications are conducted, geese will most likely feed on pasture, greenland and coastal marches. To address the behaviour of the goose, the PT is set at 0.18. Another survey is available to determine the PT for quail in cereal crops (XXXX, 2007, see ref. KIIIA2 10.1.7/08). For quail (Coturnix coturnix) a potential foraging time of 64.27 % is recorded. Therefore the PT is set at 0.65. Based on the survey conducted by XXXX (see ref. KIIIA2 10.1.7/14), the PT for the skylark (Alauda arvensis) was calculated as 0.45 for winter cereal fields in spring.*   * ***Portion of different food types in the diet (PD)***   *For quail**a diet composition of about 15 % of seeds (mainly non cereals), 10 % of other plant material and 75 % of arthropods is recorded (XXXX, 2007, see ref. KIIIA2 10.1.7/08). For the risk assessment purpose, the plant material is summed up as 25 % herbage, representing the available food source within the field at the relevant growth stages of the crop. Based on the survey conducted by XXXX (see ref. KIIIA2 10.1.7/14), the diet composition for the skylark in early spring was recorded to be mainly plants matter and seeds, but also animal matter. However, the food composition of the skylark clearly depends on the availability of food sources (XXXX, 1978, ref. KIIIA2 10.1.2/13). A mean diet composition can be assumed to comprise 25 % foliage, 25 % weed seeds and 50 % ground arthropods.*   * ***Food intake rate (FIR)***   *Quail have a body weight of about 100 g (XXXX, 2002, ref. KIIIA2 10.1.2/04). For the female skylark, a mean body weight of 37.2 g is cited by XXXX (1993, ref. KIIIA2 10.1.2/14). According to procedure as given in the Terrestrial Guidance Document, the food intake rate is calculated as follows:*  *Table B.9.1‑48: Calculation of refined FIR*   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | ***Species*** | ***Body weight (g)*** | ***DEE*** | | ***Food characteristic*** | | | ***Assimilation effic.*** | | ***FIR (fresh material) (g/day)*** | ***FIR/bw*** | | ***equation*** | ***DEE (kJ/d)*** | ***Food type*** | ***Energy (kJ/g dry wt)*** | ***Moisture (%)*** | ***Food type*** | ***%*** | | *Quail* | *100* | *other birds* | *166.49* | *grasses, cereal shoots* | *18.0* | *76.4* | *Animal (Gall)* | *42* | *93.32* | *0.93* | | *arthropods* | *21.9* | *70.5* | *Animal (Gall)* | *70* | *36.81* | *0.37* | | *Lark* | *37.2* | *passeriformes* | *127.8* | *grasses, cereal shoots* | *18.0* | *76.4* | *Seeds (Pass)* | *76* | *39.59* | *1.06* | | *weed seeds* | *21.0* | *11.9* | *Animal (Pass)* | *80* | *8.63* | *0.23* | | *arthropods* | *21.9* | *70.5* | *Seeds (Pass)* | *76* | *26.03* | *0.70* |   *Arthropod diet*  *The refinement for the RUD and ftwa of quail and lark feeding on the part of arthropods in the diet, is presented in detail in the next chapter for insectivorous birds.*  *Table B.9.1‑49: Refined TERLT calculations for herbivorous/omnivorous birds, application of spiroxamine in cereals*   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | ***Species*** | ***Food item*** | ***Toxicity [mg/kg bw/d]*** | ***Exposure*** | | | | | | | | | ***TER*** | | ***FIR/bw*** | ***RUD*** | ***Appl. Rate [kg/ha]*** | ***Measured residues [mg/kg]*** | | ***ftwa*** | ***PT*** | ***PD*** | ***ETE [mg/kg bw/d]*** | | ***Herbivorous birds*** | | | | | | | | | | | | | | *Goose* | *Grass, cereals* | *5.40* | *0.44* | *-* | *-* | | *11.7* | *0.332* | *0.18* | *1* | *0.306* | ***18*** | | ***Omnivorous birds*** | | | | | | | | | | | | | | *Quail* | *Plant material* | *5.40* | *0.93* | *-* | *-* | | *11.7* | *0.3302* | *0.65* | *0.25* | *0.584* | ***8.23*** | | *arthropods* | *0.37* | *5.1* | *0.375* | | *-* | *0.21* | *0.65* | *0.75* | *0.072* | |  | *∑ ETE* | | | | | | | | *0.656* | | *Lark* | *Plant material* | *5.40* | *1.06* | *-* | *-* | | *11.7* | *0.3302* | *0.45* | *0.25* | *0.461* | ***8.65*** | | *Weed seeds* | *0.23* | *-* | *-* | | *11.7a* | *0.3302a* | *0.45* | *0.25* | *0.100* | | *arthropods* | *0.70* | *5.1* | *0.375* | | *-* | *0.21* | *0.45* | *0.50* | *0.063* | |  | *∑ ETE* | | | | | | | | *0.624* |   *a as a replacement it is assumed that weed plants/seeds will be exposed to the same scenario as the young cereal plants; it is also assumed that the decline of Spiroxamine on weeds will be the same as on the cereal crop plants*  *Insectivorous birds:*   * ***Species of concern***   *According to the provisions of the EU Guidance Document the Tier 1 risk assessment for insectivorous birds in cereals is based on a small songbird like the wren (Troglodytes troglodytes).*  *However, the wren cannot be considered particularly field relevant for the use of the product in cereals. Cramp (1998, ref. KIIIA2 10.1.2/05) described the habitat preference of the wren as a wide variety of low cover and foraging opportunities, including herb and field layers of plant growth (within or outside woodland), crops and aquatic vegetation, fallen trees and branches or heaps of brash, hedgerows, gardens, parks, and shrubberies. It is attracted to earthen banks, stone walls, outhouses and other free-standing structures, and natural crags, fissures, sea cliffs, and other faces or slopes providing cavities, crevices, and interstices which can be profitably explored or used for roosting or nesting. In a multi-annual study conducted in the years 1982-1984 on the habitat requirements of birds on farmland in south-western Germany (XXXX, 1989, ref. KIIIA2 10.1.2/06), wrens were recorded 66 times in total per year from which 21 records were made in spring and summer. Most wrens were recorded foraging in forests (average 63.7 %), hedgerows (9.7 %), trees (9.7 %) and small forbs (5.6 %). During spring and summer, no wrens were observed foraging in arable fields (average 0 %).*  *This choice of the yellow wagtail as ecologically relevant insectivorous species for the refined risk assessment is based on generic literature. For cereals, the yellow wagtail (Motacilla flava) is considered as a relevant exclusively insectivorous indicator species. This species makes use of cereal fields in northern Germany in May and June/July (XXXX, 1997, ref. KIIIA2 10.1.2/07) and in Switzerland (XXXX 1994, ref. KIIIA2 10.1.2/08) as a breeding habitat. The yellow wagtail is also reported as small insectivorous focal species in the surveys conducted in Germany, Poland, France and Italy (XXXX et al., 2006, see ref. KIIIA2 10.1.7/06), as well as from Andalusia (XXXX, 2006, see ref. KIIIA2 10.1.7/07).*   * ***Food intake rate (FIR)***   *Yellow wagtails have a body weight of about 17 g (XXXX, 2002, ref. KIIIA2 10.1.2/09). The average daily food intake was estimated to amount 73.7 kJ/day according to XXXX et al. 2002, (ref. KIIIA2 10.1.2/10) based on a body weight of 17.0 g. Arthropods contain on the average 21.9 kJ/g dry weight and consist of 70.5 % water. Therefore arthropods contain 6.5 kJ/g fresh weight. A yellow wagtail using 73.7 kJ/day will eat 11.4 g arthropods per day. Adjusting this figure for assimilation efficiency (76 % for a passerine bird) this results in an average daily food intake of a yellow wagtail of 15 g arthropods per day. Related to the average body weight the FIR/bw will be 0.88.*  *Table B.9.1‑50: Calculation of refined FIR*   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | ***Species*** | ***Body weight (g)*** | ***DEE*** | | ***Food characteristic*** | | | ***Assimilation effic.*** | | ***FIR (fresh material) (g/day)*** | ***FIR/bw*** | | ***equation*** | ***DEE (kJ/d)*** | ***Food type*** | ***Energy (kJ/g dry wt)*** | ***Moisture (%)*** | ***Food type*** | ***%*** | | *Yellow Wagtail* | *17* | *Passerines* | *73.65* | *arthropods* | *21.9* | *70.5* | *Animal (pass)* | *76* | *15.000* | *0.88* |  * ***Portion of diet obtained from the treated area (PT)***   *For long-term exposure, it can be generally assumed that birds will take up only 50 % of their feed within treated areas. Available data and experience supports the facts that mobile bird species will use different food sources within a region.*  *The portion of time spend foraging within a treated cereal field is set at 0.4, based on data from a study of XXXX, 2005 (see ref. KIIIA2 10.1.7/09). XXXX investigated the portion of time that yellow wagtails spend in different habitats. Dominating habitats at the study area were potato fields and winter cereal fields.*  *This observation can be explained by the peculiar biology of the species since for foraging, the species prefers areas devoid of vegetation or characterised by short vegetation such as lawns, short-grazed pastures or mown meadows (XXXX 1984, ref. KIIIA2 10.1.2/11). The preference for yellow wagtails to feed in areas of short vegetation (e.g. pasture) or bare soil is in accordance with the main foraging behaviour of the species, i.e. picking arthropods from the ground or fly-catching arthropods (XXXX and XXXX 1984 and XXXX 1977, ref. KIIIA2 10.1.2/12). Commonly parent wagtails have to cover a distance of several hundreds of meters between nesting and foraging habitat (XXXX 1984).*  *As mentioned above, the available literature and most recent telemetry data (Wolf 2005, ref. KIIIA2 10.1.7/09) indicate that the mean active time spent in arable crops would be clearly below the default value of 1.0. For refinement it is therefore assumed that yellow wagtails will obtain about 60 % of their diet outside the treated areas (PT = 0.4). This value is considered to be a conservative estimate regarding the long-term exposure.*   * ***Refinement of Portion of diet (PD)***   *The Yellow wagtail is primarily an insectivorous bird but also feeds on other epigaeic invertebrates (e.g. spiders). Its foraging behaviour is well known and comprises mainly three techniques: picking (picks items from the ground while walking), run-picking (quick darting run at prey, picking it up either from the ground or as it takes off), and fly-catching (makes short flight from the ground or perch, catching the prey in mid-air). Only occasionally the Yellow wagtail collects insects from plants in hovering flight (Cramp 1998, Birds of the western Palaearctic. CD-rom version). Based on these foraging techniques the Yellow wagtail can be expected to feed on a mixed arthropod diet mainly comprising of insects that at least partly dwell on or visit the ground.*  *A targeted study into the prey spectrum of Yellow wagtails on arable land has been conducted by XXXX (2005). According to his results the Yellow wagtails foraged on Dipteran, Coleoptera, Aphidoidea, Hymenoptera and Aranea, and targeted specimen larger than the respective average size. Based on these results it is considered conservative to assume that the typical diet of Yellow wagtails from arable fields consists of 50 % large and 50 % small insects, taken equally from the foliage and from the ground. In the refined risk assessment a for the Yellow Wagtail a PD of 50 % of large, ground dwelling invertebrates plus a PD of 50 % for small, foliage dwelling invertebrates will be considered.*   * ***Refinement of RUD***   *The default RUD value for insectivorous birds is given in the Guidance Document as 29 mg/kg for chronic exposure of the standard indicator species. Taking into account different insectivorous bird species feeding on small and large insects in different habitats, the RUD value can be refined.*  *A review carried out by Barber et al. (2005, see ref. KIIIA2 10.1.7/10), recommends a median RUD-value of 9.5 for leaf dwellers in all crops and all pesticides. A median RUD of 6.7 is recommended for ground dwelling arthropods at early growth stages of cereals.*  *An RUD of 9.5 for leaf dwelling arthropods at long-term exposure is also confirmed and recommended by BVL (Germany), as published in the Bekanntmachung Nr. 06/02/26 in Bundesanzeiger Nr. 43, page 2255, dated March 02 2007.*  *Therefore, significant additional margins of safety are included when using the RUDs of 29 (for small, foliage dwelling invertebrates) and 5.1 (large, ground dwelling invertebrates).*   * ***Refinement of ftwa***   *A generic ftwa value of 0.75**is accepted by BVL (Germany), as published in the Bekanntmachung Nr. 06/02/26 in Bundesanzeiger Nr. 43, page 2255, dated March 02, 2007, representing the generic dissipation of a compound on arthropod populations. This is based on an assumed half life of 24 days. This value is used in the refined risk assessment for Prothioconazole-desthio. Schmitzer and others (2006/2007; see ref. KIIIA2 10.1.7/11, KIIIA2 10.1.7/12, KIIIA2 10.1.7/13) report a half-life for Spiroxamine on arthropods (dissipation) of 3.38 days (first order).*  *A twa-factor of 0.21 is calculated for an averaging time of 14 days. This value, determined on a soil dwelling arthropod, is considered relevant for the risk assessment in general. In cereals, the birds do not feed exclusively within the crop canopy, but also on the ground. As a consequence different arthropod species can be taken up.*  *Table B.9.1‑52: Refined TER LT calculations for insectivorous birds, application of spiroxamine in cereals*   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | ***Species*** | ***Food item*** | ***Toxicity [mg/kg bw/d]*** | ***Exposure*** | | | | | | | ***TER*** | | ***FIR/bw*** | ***RUD*** | ***Appl. Rate [kg/ha]*** | ***ftwa*** | ***PT*** | ***PD*** | ***ETE [mg/kg bw/d]*** | | ***insectivorous birds exposed to spiroxamine*** | | | | | | | | | | | | *Yellow Wagtail* | *foliage dwelling*  *invertebrates* | *5.40* | *0.88* | *29* | *0.375* | *0.21* | *0.4* | *0.5* | *0.40* | ***11.5*** | | *Ground dwelling* | *0.88* | *5.1* | *0.375* | *0.21* | *0.4* | *0.5* | *0.07* | |  | *∑ ETE* | | | | | | *0.47* |   *After refinement of risk assessment parameters all TERlt values were calculated to be above the Annex VI trigger of concern of 5 for long term exposure, indicating low risk to birds from the use of both lead formulations Spiroxamine EC500 and Proticionazole+Spiroxamine EC 460, respectively, under practical conditions. Thus, a further risk refinement for birds is not considered necessary*.  **zRMS comments:** On the basis of a number of field trials, assessed and accepted at EU level, an acceptable risk to birds has been demonstrated. |

Table 9.2‑4: Spiroxamine: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Representative species** | **FIR/BW** | **Diet of generic focal species in crop (%)** | **PD** | **PT** | **Deposition factor** | **Mean RUD** | **Ftwa** | **Chronic**  **MAF** | **Daily dietary dose (mg/kg bw/day)** | **TERlt** |
| BBCH 30-39 | Woodlark (*Lullula arborea*) | 1.06 | Crop leaves | 0.25 | 0.5 | 0.5 | 11.7 | 0.33 | 1.0 | 0.08 |  |
| 0.23 | Weed seeds | 0.25 | 0.5 | 0.5 | 11.7 | 0.33 | 1.0 | 0.02 |
| 0.7 | Ground arthropods | 0.50 | 0.5 | 0.5 | 5.1 | 0.21 | 1.0 | 0.03 |
|  | | | | | | | | 0.12 | 44.2 |
| BBCH > 40 | Woodlark  (*Lullula arborea*) | 1.06 | Crop leaves | 0.25 | 0.5 | 0.5 | 11.7 | 0.33 | 1.0 | 0.08 |  |
| 0.23 | Weed seeds | 0.25 | 0.5 | 0.5 | 11.7 | 0.33 | 1.0 | 0.02 |
| 0.7 | Ground arthropods | 0.50 | 0.5 | 0.5 | 5.1 | 0.21 | 1.0 | 0.03 |
|  | | | | | | | | 0.12 | 44.4 |
| Late season-Seed heads | Yellowhammer  (*Emberiza citronella*) | 0.88 | cereal seeds | 0.5 | 0.4 | 0.5 | 15 | 0.53 | 1.0 | 0.2 | 25.7 |

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger (unacceptable risk)

Based on the presented higher tier risk assessment it can be concluded that the risk assessment for woodlarks and yellowhammer is acceptable based on the intended GAP use of ULTRACENT 460 EC.

#### Combined toxicity

According to EFSA Journal 2009; 7(12): 1438 combined effects of several toxicants must be specifically considered in the risk assessment when it is obvious that such exposure situations will occur for animals.

For the assessment of acute effects (mortality), a surrogate LD50 can be calculated. The EFSA Guidance Document indicates that the following equation should be used for deriving a surrogate LD50 for a mixture of active substances with known toxicity assuming dose additivity:

where:

X (a.i.i) = fraction of active substance (i) in the formulation mixture

LD50 (a.i.i) = acute toxicity for the active substance (i)

Measured endpoints should only be replaced by modelled endpoints if a significant change of the predicted toxicity is expected. This may be the case if one toxicant may contribute to more than 90 % of the toxicity of the mixture. The toxicity may be compared on basis of artificial “toxicity per fraction” quotients. These values have no biological relevance, but are calculated for comparison only according to the equations below. In case the quotient for one single toxicant deviates from the quotient for the mixture by less than 10 % it is assumed to contribute to more than 90 % of the toxicity of the mixture, while other components of the mixture will only have a marginal impact on the predicted risk. Consequently, the risk assessment is required solely for the most toxic active substance. Otherwise, the predicted LD50 (mix) should be used in the risk assessment.

tox per fraction (a.i.) = LD50 (a.i.i) / X (a.i.i)

tox per fraction (mix) = LD50 (mix) / Σi X (a.i.i)

The LD50 of the mix is summarized in the table below.

Table 9.2‑5: Acute LD50 for the mixture of active substances

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test  substance | Concentration of a.i. in ULTRACENT 460 EC [g/L] | Fraction of a.i. in the formulation mixture A | Acute toxicity endpoint  [mg/kg bw] | Fraction of active  substance/LD50 a.i. | LD50 mix  [mg/kg bw] |
| Prothioconazole | 160 | 0.348 | > 2000 | 0.000175 | **753** |
| Spiroxamine | 300 | 0.652 | 565 | 0.00115 |
| Total | 460 | 1 | - | - |

**A** Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

Table 9.2‑6: Comparison of the measured and predicted endpoints for ULTRACENT 460 EC using the acute toxicity data for birds

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Active substance** | **LD50 [mg a.i./kg bw]** | **X (a.i.) in the mixturea** | **Tox per fraction a.i. b** | **Deviation  [%]c** | **Endpoint used for risk assessment** |
| **LD50 (mix)** | 753 | 1 | 753 | - | LD50 (mix) 753 mg a.i./ kg bw/d |
| Prothioconazole | >2000 | 0.348 | 5750 | 86.9 |
| Spiroxamine | 565 | 0.652 | 866 | 13.09 |
| a Conc. of a.i./Σ conc. prothioconazole+spiroxamine  b Endpoint a.i./X (a.i.)  c((Tox. Fraction a.i. –Tox. Fraction mix)/Tox. Fraction a.i.) x 100  a.i.=active substance  mix= predicted mixture toxicity | | | | | |

Since the quotient for none of the active substances deviates from the quotient for the mixture by less than 10 %, LD50 mixture is the relevant endpoint, and it can not be concluded that one of the active substances contributes to more than 90 % of the toxicity of the mixture. Since the deviation for spiroxamine is slightly over 10 % and due to the significantly lower endpoint, the risk assessment is covered by spiroxamine.

Table 9.2‑7: Long-term toxicity for the mixture of active substances

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test  substance | Concentration of a.i. in ULTRACENT 460 EC [g/L] | Fraction of a.i. in the formulation mixture A | Long-term toxicity endpoint  [mg/kg bw/d] | Fraction of active  substance/NOEL a.i. | NOEL mix  [mg/kg bw/d] |
| Prothioconazole | 160 | 0.348 | 78 | 0.00446 | 8.0 |
| Spiroxamine | 300 | 0.652 | 5.4 | 0.121 |
| Total | 460 | 1 | - | - |

**A** Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

Table 9.2‑8: Comparison of the measured and predicted endpoints for ULTRACENT 460 EC using the chronic toxicity data for birds

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Active substance** | **NOEL [mg a.i./kg bw/d]** | **X (a.i.) in the mixturea** | **Tox per fraction a.i. b** | **Deviation  [%]c** | **Endpoint used for risk assessment** |
| **NOEL (mix)** | 8.0 | 1 | 8.0 | - | NOEL spiroxamine 5.4 mg a.i./ kg bw/d |
| Prothioconazole | 78.0 | 0.348 | 224.3 | 96.4 |
| Spiroxamine | 5.4 | 0.652 | 8.3 | 3.56 |
| a Conc. of a.i./Σ conc. prothioconazole+spiroxamine  b Endpoint a.i./X (a.i.)  c((Tox. Fraction a.i. –Tox. Fraction mix)/Tox. Fraction a.i.) x 100  a.i.=active substance  mix= predicted mixture toxicity | | | | | |

The deviation between the tox per fraction of spiroxamine and mixture is < 10 %. Thus, spiroxamine does contribute to more than 90 % of the toxicity of ULTRACENT 460 EC and can be regarded as the chronic toxicity driver. Therefore, the risk assessment has to be calculated with spiroxamine alone. However, for the sake of completeness, the acute and chronic risk assessment for both the active substances is presented in Chapter 9.2.2.1.

|  |
| --- |
| **Review Comments:**  The risk assessment (combined toxicity) submitted by the Applicant has been accepted. |

#### Drinking water exposure

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf*. Appendix K of EFSA/2009/1438).

Leaf scenario

Since ULTRACENT 460 EC is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a Koc of 1765, prothioconazole belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for birds from all other intended uses in groups 2, 3 and 4 (see 9.1.2).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 160  ~~(160 \* MAF 1.0)~~ |  |  |
| Acute toxicity (mg/kg bw) = | >2000 />1413 | quotient = | <0.08 <0.11 |
| Reprod. toxicity (mg/kg bw/d) = | 78 | quotient = | 2.05 |

With a Koc of 575.4, JAU 6476-desthio belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for birds from all other intended uses in groups 2, 3 and 4 (see 9.1.2).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 145.1  ~~(145.1 \* MAF 1.0)~~ |  |  |
| Acute toxicity (mg/kg bw) = | >2000 / >297 | quotient = | <0.07 <0.5 |
| Reprod. toxicity (mg/kg bw/d) = | 14.8 | quotient = | 9.80 |

With a Koc of 2415, spiroxamine belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for birds from all other intended uses in groups 2, 3 and 4 (see 9.1.2).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 300  ~~(300 \* MAF 1.0)~~ |  |  |
| Acute toxicity (mg/kg bw) = | 565 | quotient = | 0.53 |
| Reprod. toxicity (mg/kg bw/d) = | 5.4 | quotient = | 55.56 |

The quotients of prothioconazole, JAU6476-deshtio and spiroxamine are well below the relevant trigger of 3000 and therefore no unacceptable risk due to the uptake of contaminated drinking water has been demonstrated.

#### Effects of secondary poisoning

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The log Pow of prothioconazole, JAU 6476-desthio and spiroxamine amount to 3.82, 3.04 and 5.08, respectively and thus exceeds the trigger of 3.

A risk assessment for effects of secondary poisoning is required and presented for prothioconazole, JAU 6476-deshtio and spiroxamine in the following.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for birds from all other intended uses (see 9.1.2).

Table 9.2‑9: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | Prothioconazole | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 0.008 | From Part B8, section 8.7.2.1 |
| log Pow / Pow | 3.82 / 6606.93 | EFSA scientific report (2007) 106, 1-98 |
| Koc | 1765 | Mean |
| foc | 0.02 | Default |
| BCFworm | 2.27 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.02 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.0191 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | 78 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 4091.02 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Table 9.2‑10: Assessment of the risk for earthworm-eating birds due to exposure to JAU 6476-desthio via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | JAU 6476-desthio | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 0.020 | From Part B8, section 8.7.2.1 |
| log Pow / Pow | 3.04 / 1096.47 | EFSA scientific report (2007) 106, 1-98 |
| Koc | 575.4 | Mean |
| foc | 0.02 | Default |
| BCFworm | 1.22 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.02 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.0255 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | 14.8 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 579.41 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Table 9.2‑11: Assessment of the risk for earthworm-eating birds due to exposure to spiroxamine via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | Spiroxamine | comments |
| --- | --- | --- |
| PECsoil ~~(twa = 21 d)~~ (mg/kg soil) | ~~0.072~~ 0.082 | From Part B8, section 8.7.2.2 PECaccu. |
| log Pow / Pow | ~~2.98 / 954.99~~ 10000 | EFSA scientific report 2010;8(10)1719 |
| Koc | 2415 | Mean |
| foc | 0.02 | Default |
| BCFworm | ~~0.25~~ 2.5 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | ~~0.02~~ 0.205 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | ~~0.0193~~ 0.215 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | 5.4 | EFSA scientific report 2010;8(10)1719 |
| TERlt | ~~280.49~~ 25.1 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water for aquatic organisms as a limit value for admissible concentrations of prothioconazole, JAU 6476-desthio and spiroxamine in water.

Table 9.2‑12: Assessment of the risk for fish-eating birds due to exposure to prothioconazole via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

| Parameter | Prothioconazole | comments |
| --- | --- | --- |
| PECsw (twa = 21 d) (mg/L) | 0.00315 | From Part B8, Section 8.9.2.1, Step 1 |
| BCFfish | 19.7 | EFSA scientific report (2007) 106, 1-98 |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 0.062 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.01 | DDD = PECfish × 0.159 |
| NOEL (mg/kg bw/d) | 78 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 7905 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Table 9.2‑13: Assessment of the risk for fish-eating birds due to exposure to JAU 6476-desthio via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

| Parameter | JAU 6476-desthio | comments |
| --- | --- | --- |
| PECsw (twa = 21 d) (mg/L) | 0.02453 | From Part B8, Section 8.9.2.1, Step 1 |
| BCFfish | 65 | EFSA scientific report (2007) 106, 1-98 |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 1.5947 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.2536 | DDD = PECfish × 0.159 |
| NOEL (mg/kg bw/d) | 14.8 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 58.4 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Table 9.2‑14: Assessment of the risk for fish-eating birds due to exposure to spiroxamine via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

| Parameter | Spiroxamine | comments |
| --- | --- | --- |
| PECsw (twa = 21 d) (mg/L) | 0.02191 | From Part B8, Section 8.9.2.2, Step 1 |
| BCFfish | 87 | EFSA scientific report 2010;8(10)1719 |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 1.906 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.3031 | DDD = PECfish × 0.159 |
| NOEL (mg/kg bw/d) | 2.02 | EFSA scientific report 2010;8(10)1719 |
| TERlt | 6.66 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

#### Biomagnification in terrestrial food chains

Not relevant.

### Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

### Overall conclusions

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

A risk assessment for mammals was conducted according to the “Guidance Document on Risk Assessment for Birds and Mammals” (EFSA Journal 2009; 7(12):1438). In the tiered risk assessment, an acceptable risk from the use of ULTRACENT 460 EC according to the GAP was demonstrated for birds.

|  |
| --- |
| **Review Comments:**  The acute and chronic risks of ULTRACENT 460 EC to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with active ingredients, relevant metabolite, and maximum residues occurring on food items. Furthermore, for spiroxamine, the EU agreed steps of refinement (refined reproduction endpoint, refined residue dissipation, deposition factor) were taken to account.  All TER values exceed the relevant triggers indicating that ULTRACENT 460 ECdoes not pose an unacceptable risk to birds following applications according to recommended use pattern.  Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low. |

## Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Toxicity (Annex IA, point 7.1)** | | | | |
| **Study type** | **Tested substance** | **Species** | **Toxicity endpoint** | **Information on study** |
| **Acute oral toxicity** | Input 460 EC | Rat | LD50 = 750 mg/kg b.w. | XXXX F.(2002);  Nr 31560 – study accepts toxicology |
| spiroxamine | Mouse | LD50 = 460 mg/kg b.w. | ~~Spiroxamine 7584/VI/97-Final 12.5.99~~ |
| prothioconazole | Rat | LD50 > 6200 mg/kg b.w./day | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| JAU 6476-desthio | Mouse | LD50 = 2235 mg/kg b.w. |
| **Long-term toxicity** | Prothioconazole | Rat | NOELp = 9.7 mg/kg b.w./day NOELr = 95.6 mg/kg b.w./day |
| JAU 6476 - desthio | Rat | NOEL = 10 mg/kg b.w./day |
| Spiroxamine | Rat | NOEC = ~~30 pp~~ 300ppm  NOEC = 80 ppm | ~~Spiroxamine 7584/VI/97-Final 12.5.99~~ |
| NOEL = 22.2 mg/kg bw/day  NOEL = 9.19 mg/kg bw/day | EFSA Journal 2010;8(10)1719 |

|  |
| --- |
| **Review Comments:**  The endpoints for prothioconazole were taken from EFSA scientific report (2007) 106, 1-98 and for spiroxamine were taken from EFSA Journal 2010;8(10):1719. |

#### Justification for new endpoints

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Risk assessment conducted with the endpoints taken from studies have previously been EU-evaluated.

### Risk assessment for spray applications

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The acute risk assessment for mammals, as for birds, was based on the results of the toxicity studies of Input 460 EC, and the long-term risk assessment was based on the results of the individual active substances. An acute and long-term risk assessment was also carried out for two metabolites of prothioconazole considered ecotoxicologically relevant. The risk assessment submitted by the applicant was carried out for two applications of the product in cereals at a dose of 1.25 l/ha, assuming an interval of at least three weeks between sprays. As this assessment was carried out for a worse scenario than the proposed use of Input 460 EC in Poland, it covers the risk assessment for other terrestrial vertebrates that would need to be carried out for the uses proposed in the product label. The assessment was endorsed by the Institute.~~

~~The proposed scope and use of the product indicated that the main route of mammalian exposure is the potential for mammalian ingestion of treated plants and insects. As the product is intended for use on cereals in their early and late growth stages, the focus was on the risk assessment for small herbivorous mammals and insectivorous mammals as the most vulnerable indicator species for the proposed scope of use.~~

~~Acute risk~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: Input 460 EC~~  ~~- Number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of 0.985 g/cm3)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 = 750 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous mammal (early phase of cereal growth)~~ | | | | | | | |
| ~~1.39 142 111 197.38 3.1 10~~ | | | | | | | |
| ~~insectivorous mammal (small insects) (late phase of cereal growth)~~ | | | | | | | |
| ~~0.63 14 111 11 68 10~~ | | | | | | | |

~~As the TERa factor for herbivorous mammals did not exceed the cut-off value, the risk from acute exposure to Input 460 EC needed to be refined. In order to demonstrate the actual exposure of birds to the product, the spiroxamine concentration value determined from tests on 12 wheat and barley samples was used instead of the standard RUD value to calculate the ETE. The maximum spiroxamine concentration determined immediately after the second spray was 11 mg/kg green plant parts, corresponding to 36 mg formulation 460 EC/kg green plant parts (study from residue section: O.Heinemann, K. Elke; report no. RA-2092/00; 2001)~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: Input 460 EC~~  ~~- Number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of 0.985 g/cm3)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 = 750 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~concentration 460 EC mg/kg~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~large herbivorous mammal (early phase of cereal growth)~~ | | | | | | | |
| ~~1.39 36 111 50 15 10~~ | | | | | | | |

~~The toxic exposure factor calculated taking into account the actual residue values is 15 and exceeds the limit value.~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: JAU 6476-desthio~~  ~~- Number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of agent with a density of 0.985 g/cm3)~~  ~~- amount of JAU 6476-desthio: 0.2 kg/ha~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~LD50 = 2235 mg/kg b.w.~~ | | | | |  | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~Small herbivorous mammal (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.39 - 111~~ | | | | | ~~5.2 430 10~~ | | |
| ~~insectivorous bird (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.63 14 111~~ | | | | | ~~1.8 1242 10~~ | | |
| ~~insectivorous mammal (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~0.63 14 111~~ | | | | | ~~1.8 1242 10~~ | | |

~~The TER toxic exposure factors are above the limit value. This means that the risk to birds from acute exposure to Input 460 EC is acceptable.~~

~~Long-term risk~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: prothioconazole~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.2 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOEL reprod = 95.6 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg·kg~~~~-1~~~~·ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~Small herbivorous mammal (early phase of cereal growth)~~ | | | | | | | |
| ~~1.39 76 111 13.8 6.9 5~~ | | | | | | | |
| ~~insectivorous mammal (small insects) (early and late phase of cereal growth)~~ | | | | | | | |
| ~~0.63 5.1 111 0.643 149 5~~ | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: JAU 6476-desthio~~  ~~- Number of applications x dosage: 2 x 1.25 l/ha (1.23 kg/ha of agent with a density of 0.985 g/cm3)~~  ~~- amount of JAU 6476-desthio: 0.2 kg/ha~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOEL~~ ~~reprod.=~~ ~~10 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg-kg~~~~-1~~~~-ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TER~~~~a~~** | **~~Limit value~~** |
| ~~Small herbivorous mammal (early phase of cereal growth)~~ | | | | |  | | |
| ~~1.39 - 1 1 1~~ | | | | | ~~0.76 13 5~~ | | |
| ~~insectivorous mammal (small insects) (early phase of cereal growth)~~ | | | | |  | | |
| ~~0.63 5.1 1 1 1~~ | | | | | ~~0.52 19 5~~ | | |
| ~~insectivorous mammal (small insects) (late phase of cereal growth)~~ | | | | |  | | |
| ~~10.63 29 1 1 1~~ | | | | | ~~0.52 19 5~~ | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: spiroxamine~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.375 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOAEL = 9.19 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~RUD (90 percentile) [mg-kg~~~~-1~~~~-ha~~~~-1~~~~]~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~herbivorous mammal (early phase of cereal growth)~~ | | | | | | | |
| ~~1.39 76 1 1 1 25.8 0.36 5~~ | | | | | | | |
| ~~insectivorous mammal (small insects) (early and late phase of cereal growth)~~ | | | | | | | |
| ~~0.63 5.1 1 1 1 1.20 7.6 5~~ | | | | | | | |

~~The TERlt factor for spiroxamine, calculated for herbivorous mammals at the first level of assessment, did not exceed the limit value, so the risk assessment needed to be refined. Considering DT50 =7 days, it must be concluded that spiroxamine residues in plant parts decrease over time. A weighted average value calculated over a period of four weeks showed that residues after this time period represent 34% of the initial spiroxamine concentration in the plant material. In addition, the study showed that in plant parts of wheat and barley, spiroxamine residues amounted to 5.3 mg/kg of plant material ( DAR-spiroxamine). Due to the fact that the long-term risk assessment was performed without taking into account the dynamics of decomposition of the active substance, it can be concluded that the TERlt value was overestimated. In addition, a food uptake rate assumed for a standard indicator species such as the mouse was used for the first-stage assessment. However, an analysis of a number of publications presented by the applicant indicates that there has been a significant reduction in the mouse population in cereal crops as a result of cultivation activities (Ryszkowski et al, 1973; Truszkowski, 1982; Adamczewska-Andrzejewska, 1981; Butet,A; Leroux, B.A., 2001; Gorman , M. L.; Reynoldas, P., 1993). It appears that the species more commonly found in cereal crops is the hare (Homolka, 1982; Schneider, 1978; Chapuis, J.L., 1990. The theoretically estimated exposure was therefore calculated using data specific to the hare, i.e. a body weight of 3000g and an FIR/ w.c. of 0.28.~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Exposure scenario: spiroxamine~~  ~~- number of applications x dose: 2 x 1.25 l/ha (0.375 kg a.s./ha)~~  ~~- crop and plant growth stage: early and late cereals~~ | | | | | | | |
| ~~NOAEL = 9.19 mg/kg b.w./day~~ | | | | | | | |
| **~~FIR/b.w.~~** | **~~Concentration a.s. mg/kg~~** | **~~AV~~** | **~~PT~~** | **~~PD~~** | **~~ETE\*~~**  **~~mg/kg/b.w./d~~** | **~~TERa~~** | **~~Limit value~~** |
| ~~large herbivorous mammal (early phase of cereal growth)~~ | | | | | | | |
| ~~0.28 5.3 1 1 1 50 16 5~~ | | | | | | | |

~~\*ETE calculated for Ffwa = 0.53~~

~~The toxic exposure factor for spiroxamine, as determined for long-term exposure of terrestrial vertebrates other than birds, exceeds the limit value. This means that the risk in this range is acceptable.~~

~~Risk to earthworm-eating vertebrates other than birds~~

~~Input 460EC can be applied at a time when there is little plant coverage of the soil. Consequently, part of the application rate will enter the soil. The Log Pow of the active substance prothioconazole is 3.82, of the metabolites JAU 6476- desthio and JAU S-methyl >3 which means that the substance can be accumulated in the soil and consequently in earthworms. Also, the log Pow for spiroxamine at high soil pH values is above 3. Therefore, it was necessary to carry out a risk assessment for terrestrial vertebrates other than birds that feed on earthworms.~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~substance~~** | **~~prothioconazole~~** | **~~JAU6476-desthio~~** | **~~JAU S-methyl~~** | **~~spiroxamine~~** |
| **~~21 d-twa PECsoil (mg/kg soil)~~** | ~~0.00052~~ | ~~0.06482~~ | ~~0.01705~~ | ~~0.25422~~ |
| **~~PEC~~~~earthworm~~~~\*~~** | ~~0.00098~~ | ~~0.06676~~ | ~~0.05200~~ | ~~1.9447~~ |
| **~~FIR/w.c.~~** | ~~1.4~~ | ~~1.4~~ | ~~1.4~~ | ~~1.4~~ |
| **~~BCF~~ ~~earthworm~~** | ~~1.89~~ | ~~1.03~~ | ~~3.05~~ | ~~7.65~~ |
| **~~PEC~~~~earthworm~~ ~~mg/kg~~** | ~~0.00098~~ | ~~0.06676~~ | ~~0.05200~~ | ~~1.94478~~ |
| **~~ETE~~ ~~earthworm~~~~mg/kg b.w.~~** | ~~0.00137~~ | ~~0.09346~~ | ~~0.07280~~ | ~~2.723~~ |
| [**~~NOEL~~~~re~~~~p~~~~r~~~~.mg/kg~~**](http://NOELrepr.mg/kgw.c./ptaka) **~~b.w./bird~~** | ~~95.6~~ | ~~10~~ | ~~95.6 9s.a.)~~ | ~~9.19~~ |
| **~~TERlt~~** | ~~99781~~ | ~~107~~ | ~~1313~~ | ~~3.37~~ |
| **~~Limit value TERlt~~** | ~~5~~ | ~~5~~ | ~~5~~ | ~~5~~ |

~~Due to the non-exceedance of the TERlt limit value for spiroxamine, the risk was refined by showing that the actual exposure of terrestrial vertebrates to this substance is significantly lower than the value of the theoretically estimated exposure that was used for the first level of assessment. This is due to the fact that, based on literature data, the mammals (shrews) for which the risk assessment was carried out feed on farmland to a limited extent, as their typical habitat is forest edges, wet meadows, shrub clumps in meadows and marshes, hedgerows, allotments. The calculated new TERlt value is 6.7 and exceeds the limit.~~

~~Risk to other fish-eating terrestrial vertebrates~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~substance~~** | **~~prothioconazole~~** | **~~JAU6476-desthio~~** | **~~JAU S-methyl~~** | **~~spiroxamine~~** |
| **~~Max. PECwater(mg/l)~~** | ~~0.00168~~ | ~~0.00079~~ | ~~0.00173~~ | ~~0.0031~~ |
| **~~PECfish~~** | ~~0.00098~~ | ~~0.06676~~ | ~~0.05200~~ | ~~1.9447~~ |
| **~~FIR/b.w.~~** | ~~0.13~~ | ~~0.13~~ | ~~0.13~~ | ~~0.13~~ |
| **~~BCFfish~~** | ~~18.8~~ | ~~45~~ | ~~75 oszac.~~ | ~~0.2449~~ |
| **~~ETE earthworm mg/kg b.w.~~** | ~~0.00137~~ | ~~0.09346~~ | ~~0.07280~~ | ~~2.723~~ |
| [**~~NOELrepr.mg/kg~~**](http://NOELrepr.mg/kgw.c./ptaka) **~~b.w./bird~~** | ~~95.6~~ | ~~10~~ | ~~95.6 9s.a.)~~ | ~~9.19~~ |
| **~~TERlt~~** | ~~2360~~ | ~~2160~~ | ~~5667~~ | ~~289~~ |
| **~~Limit value TERlt~~** | ~~5~~ | ~~5~~ | ~~5~~ | ~~5~~ |

~~The TERlt long-term toxic exposure factors for terrestrial vertebrates other than birds are above the limit value. This means that the risk in this range is acceptable.~~

~~Furthermore, it should be mentioned that the risk assessment included in the DAR for spiroxamine carried out for two applications on cereals at a single dose of 0.75 kg a.s./kg (in Poland 1 x 0.3 kg a.s./ha is proposed) did not show unacceptable effects on birds and other terrestrial vertebrates.~~

~~Also, the risk assessment carried out for prothioconazole, contained in the DAR for prothioconazole, for a twofold dose of 2 x 0.2 kg a.s.a./ha (in Poland 1 x 0.16 kg a.s.a./ha is proposed) showed no unacceptable effects on birds and other terrestrial vertebrates.~~

~~The risk assessment carried out for birds and other terrestrial vertebrates indicates that Input 460 EC meets the requirements set out in Part C of Annex 3 to the Ordinance of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

#### First-tier assessment (screening/generic focal species)

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3‑1: Prothioconazole: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | Cereals | | | | | | |
| Active substance/product | Prothioconazole | | | | | | |
| Application rate (g/ha) | 1 × 160 | | | | | | |
| Acute toxicity (mg/kg bw) | >6200 | | | | | | |
| TER criterion | 10 | | | | | | |
| **Screening Step** | | | | | | | |
| Indicator/generic focal species | SV90 | | MAF90 | | DDD90  (mg/kg bw/d) | | TERa |
| Small herbivorous mammal | 118.4 | | 1.0 | | 18.94 | | 327.3 |
| **Screening Step** | | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | 95.6 | | | | | | |
| TER criterion | 5 | | | | | | |
| Indicator/generic focal species | SVm | MAFm × TWA | | DDDm  (mg/kg bw/d) | | TERlt | |
| Small herbivorous mammal | 48.3 | 0.53 | | 4.10 | | 23.34 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio, m: multiple. TER values shown in bold fall below the relevant trigger.

Table 9.3‑2: JAU 6476-desthio: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | | | | | | | | |
| Active substance/product | | JAU 6476-desthio | | | | | | | | | | | |
| Application rate (g/ha) | | 1 × 145.1\* | | | | | | | | | | | |
| Acute toxicity (mg/kg bw) | | 2235 | | | | | | | | | | | |
| TER criterion | | 10 | | | | | | | | | | | |
| **Screening Step** | | | | | | | | | | | | | |
| Indicator/generic focal species | | | SV90 | | MAF90 | | | | DDD90  (mg/kg bw/d) | | | TERa | |
| Small herbivorous mammal | | | 118.4 | | 1.0 | | | | 17.18 | | | 130.1 | |
| **Screening Step** | | | | | | | | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 10 | | | | | | | | | | | |
| TER criterion | | 5 | | | | | | | | | | | |
| Indicator/generic focal species | | | SVm | MAFm × TWA | | | | DDDm  (mg/kg bw/d) | | | TERlt | | |
| Small herbivorous mammal | | | 48.3 | 0.53 | | | | 3.71 | | | **2.69** | | |
| **1st Tier Reproductive Risk Assessment** | | | | | | | | | | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | | | | SVm | MAFm × TWA | | | DDDm  (mg/kg bw/d) | | | TERlt |
| BBCH ≥ 20 | Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods | | | | | 1.9 | 0.53 | | | 0.1 | | | 68.4 |
| BBCH 30 - 39 | Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods | | | | | 3.9 | 0.53 | | | 0.3 | | | 33.3 |
| BBCH ≥ 40 | Small herbivorous mammal "vole Grass + cereals 100% grass | | | | | 21.7 | 0.53 | | | 1.7 | | | 6.0 |
| BBCH ≥ 40 | Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods | | | | | 2.3 | 0.53 | | | 0.2 | | | 56.5 |

\*Application rate based on the application rate of parent substance considering the molar ratio

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio, m: multiple. TER values shown in bold fall below the relevant trigger.

Table 9.3‑3: Spiroxamine: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | | | | | | | | |
| Active substance/product | | Spiroxamine | | | | | | | | | | | |
| Application rate (g/ha) | | 1 × 300 | | | | | | | | | | | |
| Acute toxicity (mg/kg bw) | | 460 | | | | | | | | | | | |
| TER criterion | | 10 | | | | | | | | | | | |
| **Screening Step** | | | | | | | | | | | | | |
| Indicator/generic focal species | | | SV90 | | MAF90 | | | | DDD90  (mg/kg bw/d) | | | TERa | |
| Small herbivorous mammal | | | 118.4 | | 1.0 | | | | 35.52 | | | 13.0 | |
| **Screening Step** | | | | | | | | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 9.19 | | | | | | | | | | | |
| TER criterion | | 5 | | | | | | | | | | | |
| Indicator/generic focal species | | | SVm | MAFm × TWA | | | | DDDm  (mg/kg bw/d) | | | TERlt | | |
| Small herbivorous mammal | | | 48.3 | 0.53 | | | | 7.68 | | | **1.20** | | |
| **1st Tier Reproductive Risk Assessment** | | | | | | | | | | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | | | | SVm | MAFm × TWA | | | DDDm  (mg/kg bw/d) | | | TERlt |
| BBCH ≥ 20 | Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods | | | | | 1.9 | 0.53 | | | 0.3 | | | 30.4 |
| BBCH 30 - 39 | Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods | | | | | 3.9 | 0.53 | | | 0.6 | | | 14.8 |
| BBCH ≥ 40 | Small herbivorous mammal "vole Grass + cereals 100% grass | | | | | 21.7 | 0.53 | | | 3.5 | | | **2.7** |
| BBCH ≥ 40 | Small omnivorous mammal “mouse” Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods | | | | | 2.3 | 0.53 | | | 0.4 | | | 25.1 |

\*Application rate based on the application rate of parent substance considering the molar ratio

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio, m: multiple. TER values shown in bold fall below the relevant trigger.

An acceptable risk to prothioconazole and its metabolite JAU 6476-desthio has been demonstrated using Tier 1 assessment. No acceptable risk for spiroxamine could be demonstrated using Tier 1 for reproductive risk assessment for small herbivorous mammal vole. A higher-tier risk assessment is demonstrated in the following.

#### Higher-tier risk assessment

The following parameters were refined taking the EFSA Conclusion on Spiroxamine (EFSA Journal 2010;8(10)1719) into consideration.

* Mean RUD for plants and seeds (mean RUD = 11.7 mg/kg)
* ftwa for the focal species “common vole” (ftwa = 0.3302)

**Review comment:**

Currently fTWA is calculated for 21 days, thus correct value is 0.23, but in the risk assessment the value of 0.3302 is used (the worst case value, accepted at EU level for spiroxamine).

* PT value for the focal species “common vole” (PT = 0.64)
* Refinement of the toxicological endpoint (NOAEL = 22.2 mg/kg/ bw/day)

All the above mentioned refinements have been taken from the EFSA conclusion[[5]](#footnote-5) on spiroxamine and their details can be found in the respective DAR Volume 3, Annex B9.

Table 9.3‑4: Spiroxamine: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of ULTRACENT 460 EC in Cereals

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | | | | |
| Active substance/product | | Spiroxamine | | | | | | | |
| Application rate (g/ha) | | 1 × 300 | | | | | | | |
| Reproductive toxicity [mg/kg bw/d] | | ~~9.19~~ 22.2 | | | | | | | |
| TER criterion | | 5 | | | | | | | |
| Focal species | Food category,  % in diet | | FIR/bw | RUDmean  [mg/kg food] | ~~DF~~ | ~~MAF~~~~mean~~ ~~x~~ ftwa | PT | DDD  [mg/kg bw/d] | TERLT |
| Common vole  (*Microtus arvalis*) | Grass, 100% | | ~~1.33~~  1.39\* | 11.7 | ~~0.3~~ | ~~1 x~~ 0.3302 | 0.64 | ~~0.3~~ 3.5 | ~~31.1~~  6.5 |

\*FIR/bw taken from DAR, for consistency of assessment

The refined risk assessment demonstrates an acceptable long-term/reproductive risk for the intended GAP use of ULTRACENT 460 EC.

#### Combined toxicity

According to EFSA Journal 2009; 7(12): 1438 combined effects of several toxicants must be specifically considered in the risk assessment when it is obvious that such exposure situations will occur for animals.

For the assessment of acute effects (mortality), a surrogate LD50 can be calculated. The LD50 of the mixture is summarised in the tables below.

Table 9.3‑5: Acute LD50 for the mixture of active substances

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test  substance | Concentration of a.i. in ULTRACNET 460 EC [g/L] | Fraction of a.i. in the formulation mixture A | Acute toxicity endpoint  [mg/kg bw/d] | Fraction of active  substance/LD50 a.i. | LD50 mix  [mg/kg bw/d] |
| Prothioconazole | 160 | 0.348 | > 6200 | 0.00006 | **678** |
| Spiroxamine | 300 | 0.652 | 460 | 0.00142 |
| Total | 460 | 1 | - | - |

**A** Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

Table 9.3‑6: Comparison of the measured and predicted endpoints for ULTRACENT 460 EC using the acute toxicity data for mammals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Active substance** | **LD50 [mg a.i./kg bw/d]** | **X (a.i.) in the mixturea** | **Tox per fraction a.i. b** | **Deviation  [%]c** | **Endpoint used for risk assessment** |
| **LD50 (mix)** | 678 | 1 | 678 | - | LD50 (spiroxamine) 460 mg a.i./ kg bw/d |
| Prothioconazole | > 6200 | 0.348 | 17825 | 96.2 |
| Spiroxamine | 460 | 0.652 | 705 | 3.81 |
| a Conc. of a.i./Σ conc. prothioconazole+spiroxamine  b Endpoint a.i./X (a.i.)  c((Tox. Fraction a.i. –Tox. Fraction mix)/Tox. Fraction a.i.) x 100  a.i.=active substance  mix= predicted mixture toxicity | | | | | |

The deviation between the tox per fraction of spiroxamine and mixture is < 10 %. Thus, spiroxamine does contribute to more than 90 % of the toxicity of ULTRACENT 460 EC and can be regarded as the toxicity driver. Therefore, the risk assessment has to be calculated with spiroxamine alone. However, for the sake of completeness, the acute and chronic risk assessment for both the active substances is presented in Chapter 9.3.2.1.

Table 9.3‑7: Long-term toxicity for the mixture of active substances

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test  substance | Concentration of a.i. in ULTRACNET 460 EC [g/L] | Fraction of a.i. in the formulation mixture A | Long-term toxicity endpoint  [mg/kg bw] | Fraction of active  substance/NOEL a.i. | NOEL mix  [mg/kg bw/d] |
| Prothioconazole | 160 | 0.348 | 95.6 | 0.00364 | **13.4** |
| Spiroxamine | 300 | 0.652 | 9.19 | 0.07097 |
| Total | 460 | 1 | - | - |

**A** Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

Table 9.3‑8: Comparison of the measured and predicted endpoints for ULTRACENT 460 EC using the chronic toxicity data for mammals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Active substance** | **NOEL [mg a.i./kg bw/d]** | **X (a.i.) in the mixturea** | **Tox per fraction a.i. b** | **Deviation  [%]c** | **Endpoint used for risk assessment** |
| **NOEL (mix)** | 13.4 | 1 | 13.4 | - | NOEL (spiroxamine) 9.19 mg a.i./ kg bw/d |
| Prothioconazole | 95.6 | 0.348 | 274.9 | 95.1 |
| Spiroxamine | 9.2 | 0.652 | 14.1 | 4.88 |
| a Conc. of a.i./Σ conc. prothioconazole+spiroxamine  b Endpoint a.i./X (a.i.)  c((Tox. Fraction a.i. –Tox. Fraction mix)/Tox. Fraction a.i.) x 100  a.i.=active substance  mix= predicted mixture toxicity | | | | | |

The deviation between the tox per fraction of spiroxamine and mixture is < 10 %. Thus, spiroxamine does contribute to more than 90 % of the toxicity of ULTRACENT 460 EC and can be regarded as the chronic toxicity driver. Therefore, the risk assessment has to be calculated with spiroxamine alone. However, for the sake of completeness, the acute and chronic risk assessment for both the active substances is presented in Chapter 9.3.2.1.

|  |
| --- |
| **Review Comments:**  The risk assessment (combined toxicity) submitted by the Applicant has been accepted. |

#### Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf*. Appendix K of EFSA/2009/1438).

#### Effects of secondary poisoning

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The log Pow of prothioconazole, JAU 6476-desthio and spiroxamine amount to 3.82, 3.04 and 5.08, respectively and thus exceeds the trigger of 3.

A risk assessment for effects of secondary poisoning is required and presented for prothioconazole, JAU 6476-deshtio and spiroxamine in the following.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for mammals from all other intended uses (see 9.1.2).

Table 9.3‑9: Assessment of the risk for earthworm-eating mammals due to exposure to Prothioconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | Prothioconazole | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 0.008 | From Part B8, section 8.7.2.1 |
| log Pow / Pow | 3.82 / 6606.93 | EFSA scientific report (2007) 106, 1-98 |
| Koc | 1765 | Mean |
| foc | 0.02 | Default |
| BCFworm | 2.27 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.02 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.0232 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 95.6 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 4113.15 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger.

Table 9.3‑10: Assessment of the risk for earthworm-eating mammals due to exposure to JAU 6476-desthio via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | JAU 6476-deshtio | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 0.020 | From Part B8, section 8.7.2.1 |
| log Pow / Pow | 3.04 / 1096.47 | EFSA scientific report (2007) 106, 1-98 |
| Koc | 575.4 | Mean |
| foc | 0.02 | Default |
| BCFworm | 1.22 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.02 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.0311 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 10 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 321.15 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger.

Table 9.3‑11: Assessment of the risk for earthworm-eating mammals due to exposure to spiroxamine via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | Spiroxamine | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | ~~0.072~~ 0.082 | From Part B8, section 8.7.2.2 PECaccu |
| log Pow / Pow | ~~2.98 / 954.99~~ 10000 | EFSA scientific report 2010;8(10)1719 |
| Koc | 2415 | Mean |
| foc | 0.02 | Default |
| BCFworm | ~~0.25~~ 2.5 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | ~~0.02~~ 0.205 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | ~~0.0235~~ 2.624 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | ~~9.19~~ 22.2 | EFSA scientific report 2010;8(10)1719 |
| TERlt | ~~391.58~~ 8.46 | NOAEL/DDD |

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water as a limit value for admissible concentrations of prothioconazole, JAU 6476-desthio and spiroxamine in water.

Table 9.3‑12: Assessment of the risk for fish-eating mammals due to exposure to prothioconazole via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

|  |  |  |
| --- | --- | --- |
| Parameter | Prothioconazole | comments |
| PECsw (twa = 21 d) (mg/L) | 0.00315 | From Part B8, Section 8.9.2.1 |
| BCFfish | 19.7 | EFSA scientific report (2007) 106, 1-98 |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 0.062 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.0047 | DDD = PECfish × 0.142 |
| NOEL (mg/kg bw/d) | 95.6 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | >1000 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Table 9.3‑13: Assessment of the risk for fish-eating mammals due to exposure to JAU 6476-desthio via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

|  |  |  |
| --- | --- | --- |
| Parameter | JAU 6476-desthio | comments |
| PECsw (twa = 21 d) (mg/L) | 0.02453 | From Part B8, Section 8.9.2.1 |
| BCFfish | 65 | EFSA scientific report (2007) 106, 1-98 |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 1.59 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.226 | DDD = PECfish × 0.142 |
| NOEL (mg/kg bw/d) | 10 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 44.17 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

Table 9.3‑14: Assessment of the risk for fish-eating mammals due to exposure to spiroxamine via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

|  |  |  |
| --- | --- | --- |
| Parameter | Spiroxamine | comments |
| PECsw (twa = 21 d) (mg/L) | 0.02191 | From Part B8, Section 8.9.2.2 |
| BCFfish | 87 | EFSA scientific report (2007) 106, 1-98 |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 1.906 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.2707 | DDD = PECfish × 0.142 |
| NOEL (mg/kg bw/d) | 9.19 | EFSA scientific report (2007) 106, 1-98 |
| TERlt | 33.95 | NOEL/DDD |

TER values shown in bold fall below the relevant trigger

#### Biomagnification in terrestrial food chains

Not relevant.

### Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

### Overall conclusions

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

A risk assessment for mammals was conducted according to the “Guidance Document on Risk Assessment for Birds and Mammals” (EFSA Journal 2009; 7(12):1438). In the tiered risk assessment, an acceptable risk from the use of ULTRACENT 460 EC according to the GAP was demonstrated for mammals.

|  |
| --- |
| **Review Comments:**  The acute and chronic risks of ULTRACENT 460 EC to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with active ingredients, relevant metabolite, and maximum residues occurring on food items. Furthermore, for spiroxamine, the EU agreed steps of refinement (refined reproduction endpoint, refined residue dissipation, PT value) were taken to account.  All TER values exceed the relevant triggers indicating that ULTRACENT 460 ECdoes not pose an unacceptable risk to mammals following applications according to recommended use pattern.  Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low. |

## Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

## Effects on aquatic organisms (KCP 10.2)

|  |
| --- |
| **Review Comments:**  One of the representative formulated product for the EU evaluation of spiroxamine was Input an EC formulation containing 160 g/L prothioconazole and 300 g/L spiroxamine. The representative uses evaluated were applications in wheat, triticale, rye, barley and oats with the Input formulation.  From ecotoxicological perspective ULTRACENT 460 EC is considered equivalent to Input. Thus data evaluated at EU level for Input can be used to evaluate this product. |

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

Studies on the toxicity to aquatic organisms have been carried out with prothioconazole and spiroxamine and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of ULTRACENT 460 EC were not evaluated as part of the EU assessment of prothioconazole or of spiroxamine.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Laboratory studies | | | | |
| **Species** | **Study type** | **Tested substance** | **Toxicity endpoint** | **Information on study** |
| **Acute toxicity** | | | | |
| *Oncorhynchus mykiss* | 96h, staticstatic | **Input 460 EC Input 460 EC** | LC50 = 6.57mg/l |  |
| GLP, accepted sudy |
| *Daphnia magna* | 48h, staticic | EC50 = 6.3 mg/l | Dogerloh, M.;Sommer, H. (2002); DOM 22017; GLP, accepted study |
| *Selenstrum capricornutum* | 72h, static | ErC50 = 0.16 mg/l | Batscher R. (2002); Nr 841378;  GLP, accepted study |
| *Lemna gibba* | 7d, semi-static | ErC50 = 0.057 mg/l | Batscher R. (2002): Nr  841376; GLP, accepted study |
| *~~Lepomis macrochirus~~* | ~~96h, static~~ | ~~spiroxamine~~ | ~~LC50 = 7.13 mg/l~~ | ~~Spiroxamine~~  ~~7584/VI/Final 22.5.99~~ |
| *~~Daphnia magna~~* | ~~48h, static~~ | ~~spiroxamine~~ | ~~EC50 = 6.1 mg/l~~ | ~~Spiroxamine~~  ~~7584/VI/Final 22.5.99~~ |
| *~~Selenstrum subspicatus~~* | ~~72h, static~~ | ~~spiroxamine~~ | ~~EbC50 = 0.003 mg/l~~ | ~~Spiroxamine~~  ~~7584/VI/Final 22.5.99~~ |
| *~~Oncorhynchus mykiss~~* | ~~96h, static~~ | ~~prothioconazole~~ | ~~LC50 = 1.83 mg/l~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| *~~Daphnia magna~~* | ~~48h, static~~ | ~~prothioconazole~~ | ~~EC50 = 1.3 mg/l~~ |
| *~~Pseudokirchneriella subcapitata~~* | ~~72h, static~~ | ~~prothioconazole~~ | ~~ErC50 = 1.10 mg/l EbC50 = 2.18 mg/l~~ |
| *~~Oncorhynchus mykiss~~* | ~~96h, static~~ | ~~JAU 6476-desthio~~ | ~~LC50 = 6.63 mg b.w. /l~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| *~~Daphnia magna~~* | ~~48h, static~~ | ~~EC50 = 10 mg b.w. /l~~ |
| *~~Selenstrum subspicatus~~* | ~~72h, static~~ | ~~ErC50 = 0.55 mg b.w. /l~~ |
| *~~Oncorhynchus mykiss~~* | ~~96h, semi-static~~ | ~~JAU 6476-S-methyl~~ | ~~LC50 = 1.8~~ [~~b.w. mg/l~~](http://cz.m.mg/l) |
| *~~Daphnia magna~~* | ~~48h, static~~ | ~~EC50 = 2.8 mg b.w. /l~~ |
| *~~Selenstrum subspicatus~~* | ~~72h, static~~ | ~~ErC50 = 47.4 mg b.w. /l EbC50 = 3.77~~ [~~b.w. mg/l~~](http://cz.m.mg/l) |
| *~~Oncorhynchus mykiss~~* | ~~96h, static~~ | ~~1,2,4-Triazole~~ | ~~LC50 = 498 mg b.w. /l~~ |
| *~~Daphnia magna~~* | ~~24h, static~~ | ~~EC50 = 900 mg b.w. /l~~ |
| *~~Selenstrum subspicatus~~* | ~~72h, static~~ | ~~EbC50 = 14 mg b.w. /l~~ |
| ~~Long-term toxicity~~ | | | | |
| *~~Oncorhynchus mykiss~~* | ~~97d ELS, flow-through~~ | ~~prothioconazole~~ | ~~NOEC = 0.308 mg/l~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| *~~Daphnia magna~~* | ~~21d, static~~ | ~~prothioconazole~~ | ~~NOEC = 0.56 mg/~~ |
| *~~Pseudokichneriella subcapitata~~* | ~~72h, static~~ | ~~prothioconazole~~ | ~~EbC50 = 1.10 mg/l ErC50 = 2.18 mg/l~~ |
| *~~Chironomus riparius~~* | ~~long-term~~ | ~~prothioconazole~~ | ~~NOEC = 2.0 mg/l~~ |
| *~~Oncorhynchus mykiss~~* | ~~96d ELS, flow-through~~ | ~~JAU 6476-~~ | ~~desthio~~  ~~NOEC = 3.34 mg b.w. /l~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| *~~Daphnia magna~~* | ~~21d, static~~ | ~~JAU 6476-desthio~~ | ~~NOEC = 0.1 mg b.w. /l~~ |
| *~~Scenedesmus~~* | ~~72h, static~~ | ~~JAU 6476- desthio~~ | ~~EbC50 = 0.073 mg b.w./l ErC50 = 0.55 mg b.w. /l~~ |
| *~~Chironomus riparius~~* | ~~28d, static~~ | ~~JAU 6476­desthio~~ | ~~EC15 = 2.0 mg b.w./l~~ |  |
| *~~Oncorhynchus mykiss~~* | ~~28d, static~~ | ~~1,2,4-Triazole~~ | ~~NOE~~~~r~~~~C > 3.2 mg b.w./l~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| *~~Pseudokichneriella subcapitata~~* | ~~72h, static~~ | ~~1,2,4-Triazole~~ | ~~EbC50 = 8.2 mg b.w./l ErC50 = 22.5 mg b.w./l~~ |
| *~~Oncorhynchus mykiss~~* | ~~93dn ELS, flow-through.~~ | ~~Spiroxamine~~ | ~~LC50 = 0.014 mg /l~~ | ~~Spiroxamine~~  ~~7584/VI/Final 22.5.99~~ |
| *~~Daphnia magna~~* | ~~21d, static~~ | ~~spiroxamine~~ | ~~NOEC = 0.1 mg /l~~ | ~~Spiroxamine~~  ~~7584/VI/Final 22.5.99~~ |
| *~~Chironomus riparius~~* | ~~28d, static~~ | ~~spiroxamine~~ | ~~EC15 = 3.2 mg /l~~ | ~~Spiroxamine~~  ~~7584/VI/Final 22.5.99~~ |

|  |  |
| --- | --- |
| ~~Extended laboratory studies, studies of microcosm and mesocosm~~ | ~~No additional tests were needed due to the clarification of the risk based on laboratory tests~~ |

Endpoints and effect values relevant for the risk assessment for aquatic organisms – spiroxamine and relevant metabolites

| Species | Substance | Exposure  System | Results [mg/L] | Reference |
| --- | --- | --- | --- | --- |
| *Danio rerio* | Spiroxamine | 96 h, s | LC50 = 2.41 nom | EFSA Journal 2010;8(10):1719 |
| *Danio rerio* | 230 d (FLC), f | EC10 = 0.002 nom |
| *Onchrohynchus mykiss* | 93 d (ELS), f | NOEC = 0.014 nom |
| *Daphnia magna* | 48 h, f | EC50 = 3.0 mm | EFSA Journal 2010;8(10):1719 |
| *Daphnia magna* | 21 d, f | NOEC = 0.034 nom |
| *Chironomus riparius* | 28 d, spiked water | EC15 = 5.6 nom 1 |
| *Skeletonema costatum* | 96 h, s | EbC50 = 0.0013 im  ErC50 = 0.0063 im |
| *Desmodesmus subspicatus* | 72 h, s | EbC50 = 0.0032 im  ErC50 = 0.12 im |
| *Lemna gibba* | 14 d, s | 7 d-ErC50 = 6.78 mm  7 d-EyC50 = 3.02 mm |
| *Daphnia magna* | KWG 4168-N-oxide (M03) | 48 h, s | EC50 > 100 nom |
| *Desmodesmus subspicatus* | KWG 4168-N-oxide (M03) | 72 h, s | EbC50 = 9.98 nom  ErC50 = 31.68 nom |
| *Desmodesmus subspicatus* | KWG 4168-N-desethyl (M01) | 72 h, s | EbC50 = 0.133 nom  ErC50 = 0.737 nom |
| *Desmodesmus subspicatus* | KWG 4168-acid (M06) | 72 h, s | EbC50 > 3.2 nom  ErC50 > 3.2 nom |
| Higher-tier studies (micro- or mesocosm studies) | | | | |
| Mesocosm | Mesocosm tests: Preparation Spiroxamine EC 500, 3 applications, 7 day interval, 84 d after treatment, static.  Effects on phytoplankton, zooplankton, macrophytes:  NOAEAC (3 x) = 9.3 μg a.i./L nom (measured initial), only for use in spring with 3 applications with 7 day interval.  NOEC (3x) = 1.0 μg a.i./L nom (measured initial) | | | EFSA Journal 2010;8(10):1719 |

s: static, f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

1A NOEC was stated in the EFSA Conclusion for Spiroxamine. In the original report the reported endpoint is the EC15 value

Endpoints and effect values relevant for the risk assessment for aquatic organisms – prothioconazole and relevant metabolites.

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Oncorhynchus mykiss | Prothioconazole | acute | LC50 = 1.83 mg a.s/L | EFSA Scientific Report (2007) 106, |
| Lepomis macrochirus | Prothioconazole | acute | LC50= 4.59 mg a.s/L | EFSA Scientific Report (2007) 106, |
| Cyprinus carpio | Prothioconazole | acute | LC50= 6.91 mg a.s./L | EFSA Scientific Report (2007) 106, |
| Oncorhynchus mykriss | Prothioconazole | chronic | NOEC= 0.308 mg a.s./L | EFSA Scientific Report (2007) 106, |
| Daphnia magna | Prothioconazole | Acute | EC50= 1.3 mg a.s/L | EFSA Scientific Report (2007) 106, |
| Daphnia Magna | Prothioconazole | Chronic | NOEC= 0.56 mg a.s./L | EFSA Scientific Report (2007) 106, |
| Pseudokirchneriella subcapitata | Prothioconazole | Sub-chronic | 72h ErC50 = 2.18 mg a.s./L  72h EbC50 = 1.10 mg a.s./L | EFSA Scientific Report (2007) 106, |
| Chironomus riparius | Prothioconazole | Chronic | NOEC= 9.14 mg a.s/L | EFSA Scientific Report (2007) 106, |
| Oncorhynchus mykiss | Prothioconazole-desthio | Acute | LC50= 6.63 mg p.m/L | EFSA Scientific Report (2007) 106, |
| Leuciscus idus melanotus | Prothioconazole-desthio | Acute | LC50= 13.2 mg p.m/L | EFSA Scientific Report (2007) 106, |
| Oncorhychus mykiss | Prothioconazole-desthio | Chronic | NOEC= 3.34 µg p.m./L | EFSA Scientific Report (2007) 106, |
| Daphnia magna | Prothioconazole-desthio | Acute | EC50 > 10 mg p.m./L | EFSA Scientific Report (2007) 106, |
| Daphnia magna | Prothioconazole-desthio | Chronic | NOEC= 0.10 mg p.m./L | EFSA Scientific Report (2007) 106, |
| Scenedesmus subspicatus | Prothioconazole-desthio | Sub-chronic | EbC50= 0.073 mg p.m./L  ErC50= 0.55 mg p.m./L | EFSA Scientific Report (2007) 106, |
| Chironomus riparius | Prothioconazole-desthio | Chronic | NOEC= 2.0 mg p.m./L | EFSA Scientific Report (2007) 106, |
| Oncorhychus mykiss | 1,2,4-triazole | Acute | LC50= 498 mg p.m/L | EFSA Scientific Report (2007) 106, |
| Oncorhychus mykiss | 1,2,4-triazole | Chronic | NOErC= 3.2 mg a.s./L | EFSA Scientific Report (2007) 106, |
| Dpahnia magna | 1,2,4-triazole | Acute | EC50= 900 mg p.m./L | EFSA Scientific Report (2007) 106, |
| *Daphnia magna* | 1, 2, 4-triazole | 48h | EC50 > 100 mg pm/L | EU agreed endpoints derived from PRAPeR 13, 2007 (on triazole metabolites) |
| Pseudokirchneriella subcapitata | 1,2,4-triazole | Sub-chronic | EbC50= 8.2 mg p.m./L  ErC50= 22.5 mg p.m./L | EFSA Scientific Report (2007) 106, |
| Higher-tier studies (micro- or mesocosm studies) | | | | |
|  | | | | |

#### Justification for new endpoints

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~In accordance with Commission Directive 2007/21/EC of 10 April 2007 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, for the inclusion of spiroxamine as active substance, Member States must take particular account of the effects on aquatic organisms when taking decisions under the uniform principles and ensure that the conditions of authorization provide for appropriate risk mitigation measures where necessary.~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **~~Organism~~** | **~~Tested substance~~** | **~~Toxicity endpoint (mg/l)~~** | **~~max PECsw (µg/l) Step 3~~** | **~~TER~~** | **~~Limit value~~** |
| **~~Acute risk~~** | | | | | |
| *~~Oncorhynchus mykiss~~* | ~~Input 460 EC~~ | ~~LC50 = 6.57~~ | ~~6.33~~ | ~~1037~~ | ~~100~~ |
| *~~Daphnia magna~~* | ~~Input 460 EC~~ | ~~EC50 = 6.3~~ | ~~6.33~~ | ~~995~~ | ~~100~~ |
| *~~Selenastrum subspicatrus~~* | ~~Input 460 EC~~ | ~~ErC50 = 0.16~~ | ~~6.33~~ | ~~25~~ | ~~10~~ |
| *~~Lemna gibba~~* | ~~Input 460 EC~~ | ~~ErC50 = 0.057~~ | ~~6.33~~ | ~~9~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~JAU 6476-desthio~~ | ~~LC50 = 6.63~~ | ~~0.0455~~ | ~~139120~~ | ~~100~~ |
| *~~Daphnia magna~~* | ~~JAU 6476-desthio~~ | ~~LC50 > 10~~ | ~~0.0455~~ | ~~219780~~ | ~~100~~ |
| *~~Selenastrum subspicatrus~~* | ~~JAU 6476-desthio~~ | ~~ErC50 = 0.55~~ | ~~0.0455~~ | ~~12088~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~JAU 6476-S-methyl~~ | ~~LC50 = 1.8~~ | ~~0.0898~~ | ~~20044~~ | ~~100~~ |
| *~~Daphnia magna~~* | ~~JAU 6476-S-methyl~~ | ~~EC50 = 2.8~~ | ~~0.0898~~ | ~~31180~~ | ~~100~~ |
| *~~Selenastrum subspicatrus~~* | ~~JAU 6476-S-methyl~~ | ~~EbC50 = 47.4~~ | ~~0.0898~~ | ~~527839~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~1.2.4-triazole~~ | ~~LC50 = 498~~ | ~~0.0625~~ | ~~7968~~ | ~~100~~ |
| *~~Daphnia magna~~* | ~~1.2.4-triazole~~ | ~~EbC50 = 900~~ | ~~0.0625~~ | ~~14400~~ | ~~100~~ |
| *~~Selenastrum subspicatrus~~* | ~~1.2.4-triazole~~ | ~~LC50 = 14~~ | ~~0.0625~~ | ~~256~~ | ~~10~~ |
| **~~Long-term risk~~** | | | | | |
| *~~Oncorhynchus mykiss~~* | ~~spiroxamine~~ | ~~NOEC = 0.014~~ | ~~1.566~~ | ~~8.9~~ | ~~10~~ |
| *~~Daphnia magna~~* | ~~spiroxamine~~ | ~~NOEC = 0.1~~ | ~~1.566~~ | ~~63.8~~ | ~~10~~ |
| *~~Chironomus riparius~~* | ~~spiroxamine~~ | ~~EC15 = 3.2~~ | ~~1.566~~ | ~~2 043~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~prothioconazole~~ | ~~NOEC = 0.308~~ | ~~0.838~~ | ~~368~~ | ~~10~~ |
| *~~Daphnia magna~~* | ~~prothioconazole~~ | ~~NOEC = 0.56~~ | ~~0.838~~ | ~~668~~ | ~~10~~ |
| *~~Pseudokichneriella subcapitata~~* | ~~prothioconazole~~ | ~~EbC50 = 1.10 ErC50 = 2.18~~ | ~~0.838~~ | ~~1313~~  ~~2601~~ | ~~10~~ |
| *~~Chironomus riparius~~* | ~~prothioconazole~~ | ~~NOEC = 2.0~~ | ~~0.838~~ | ~~2386~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~JAU 6476-desthio~~ | ~~NOEC = 3.34~~ | ~~0.0455~~ | ~~7406~~ | ~~10~~ |
| *~~Daphnia magna~~* | ~~JAU 6476-desthio~~ | ~~NOEC = 0.1~~ | ~~0.0455~~ | ~~2197~~ | ~~10~~ |
| *~~Scenedesmus subspicatus~~* | ~~JAU 6476-desthio~~ | ~~EbC50 = 0.073 ErC50 = 0.55~~ | ~~0.0455~~ | ~~1604~~  ~~10879~~ | ~~10~~ |
| *~~Chironomus riparius~~* | ~~JAU 6476-desthio~~ | ~~EC15 = 2.0~~ | ~~0.0455~~ | ~~36764~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~1.2.4-triazole~~ | ~~NOE~~~~r~~~~C > 3.2~~ | ~~0.0625~~ | ~~51200~~ | ~~10~~ |
| *~~Daphnia magna~~* | ~~1.2.4-triazole~~ | ~~EbC50 = 8.2 ErC50 = 22.5~~ | ~~0.0625~~ | ~~131200~~  ~~360000~~ | ~~10~~ |

~~It was not necessary to carry out a risk assessment for the metabolite JAU 6476-S-methyl as it was not considered to be relevant in the aquatic environment in the fate and behaviour section.~~

~~TERa acute toxic exposure factors for aquatic organisms, except aquatic plants, exceed the limit value. The long-term toxic exposure factors TERlt for aquatic organisms, except TERlt for fish, exceed the limit value.~~

~~Risk refinement was therefore carried out only for those groups of organisms for which the toxic exposure factors did not reach the limit value. A TER was calculated using the values of predicted environmental concentrations in surface water calculated in step 4, for a 20 m buffer zone. We were limited to calculating the PEC for the 20 m zone, due to the fact that, according to the plant protection legislation, products can be applied at least 20 m away from water bodies and watercourses.~~

~~Risk assessment for the 20 m buffer zone~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **~~Organism~~** | **~~Tested substance~~** | **~~Toxicity endpoint (mg/l)~~** | **~~max PECsw (µg/l) Step 3~~** | **~~TER~~** | **~~Limit value~~** |
| *~~Lemna gibba~~* | ~~Input 460 EC~~ | ~~ErC50 = 0.057~~ | ~~0.470~~ | ~~121~~ | ~~10~~ |
| *~~Oncorhynchus mykiss~~* | ~~Spiroxamine~~ | ~~NOEC = 0.014~~ | ~~0.157~~ | ~~89~~ | ~~10~~ |

~~A risk assessment carried out assuming the maximum predicted environmental concentration in surface water showed that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839), provided that it is applied at a distance of 20 m from water bodies and watercourses.~~

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PECSW) and toxicity endpoint for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

#### Prothioconazole

**From these, it is obvious that the AUC from exposure during mesocosm study is several orders of magnitude higher compared to the** predicted exposure profiles of FOCUS SWASH. Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 calculations for the use of ULTRACENT 460 EC in cereals

| Group |  | Fish acute | | Fish prolonged | | | Inverteb. acute | | | Inverteb. prolonged | | Algae | Sed. dwell. prolonged | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | | *O. mykiss* | | | *Daphnia magna* | | | *D. magna* | | *Pseudokirchneriella subcapitata* | *Chironomus riparius* | |
| Endpoint |  | LC50 | | NOEC | | | EC50 | | | NOEC | | ErC50 | NOEC | |
| (µg/L) |  | 1830 | | 308 | | | 1300 | | | 560 | | 2180 | 9140 | |
| AF |  | 100 | | 10 | | | 100 | | | 10 | | 10 | 10 | |
| RAC (µg/L) |  | 18.3 | | 30.8 | | | 13 | | | 56 | | 218 | 914 | |
| FOCUS Scenario | PEC gl-max (µg/L) |  | |  | | |  | | |  | |  |  | |
| Step 1 |  |  |  | |  |  | |  |  | |  | | |  |
|  | 17.376 | 0.95 | | 0.56 | | | 1.34 | | | 0.31 | | 0.08 | 0.02 | |
| Step 2 |  |  |  | |  |  | |  |  | |  | | |  |
| N-Europe  (Oct-Feb) | 2.4396 | 0.13 | | 0.08 | | | 0.19 | | | 0.04 | | 0.01 | 0.00 | |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

#### Metabolites of prothioconazole

Table 9.5‑2: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for JAU 6476-desthio for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in winter cereals (early application)

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | *O. mykiss* | *Daphnia magna* | *D. magna* | *Scenedesmus*  *subspicatus* | *Chironomus riparius* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | NOEC |
| (µg/L) |  | 6630 | 3.34 | 10000 | 100 | 550 | 2000 |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | 66.3 | 0.334 | 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |
| **Step 1** | | | | | | | |
|  | 24.89 | 0.38 | **74.52** | 0.25 | **2.49** | 0.45 | 0.12 |
| **Step 2** | | | | | | | |
| N-Europe  (Oct-Feb) | 7.3576 | 0.11 | **22.03** | 0.07 | 0.74 | 0.13 | 0.04 |
| **Step 3** | | | | | | | |
| D1\_Ditch | 0.4385 | 0.01 | **1.31** | 0.00 | 0.04 | 0.01 | 0.00 |
| D1\_Stream | 0.2743 | 0.00 | 0.82 | 0.00 | 0.03 | 0.00 | 0.00 |
| D2\_Ditch | 0.6921 | 0.01 | **2.07** | 0.01 | 0.07 | 0.01 | 0.00 |
| D2\_Stream | 0.432 | 0.01 | **1.29** | 0.00 | 0.04 | 0.01 | 0.00 |
| D3\_Ditch | 0.03215 | 0.00 | 0.10 | 0.00 | 0.00 | 0.00 | 0.00 |
| D4\_Pond | 0.02176 | 0.00 | 0.07 | 0.00 | 0.00 | 0.00 | 0.00 |
| D4\_Stream | 0.07115 | 0.00 | 0.21 | 0.00 | 0.01 | 0.00 | 0.00 |
| D5\_Pond | 0.008038 | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 |
| D5\_Stream | 0.0371 | 0.00 | 0.11 | 0.00 | 0.00 | 0.00 | 0.00 |
| D6\_Ditch | 0.06983 | 0.00 | 0.21 | 0.00 | 0.01 | 0.00 | 0.00 |
| R1\_Pond | 0.04409 | 0.00 | 0.13 | 0.00 | 0.00 | 0.00 | 0.00 |
| R1\_Stream | 0.2862 | 0.00 | 0.86 | 0.00 | 0.03 | 0.01 | 0.00 |
| R3\_Stream | 0.4031 | 0.01 | **1.21** | 0.00 | 0.04 | 0.01 | 0.00 |
| R4\_Stream | 0.6523 | 0.01 | **1.95** | 0.01 | 0.07 | 0.01 | 0.00 |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5‑3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for JAU 6476-desthio for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in winter cereals (late application)

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | *O. mykiss* | *Daphnia magna* | *D. magna* | *Scenedesmus*  *subspicatus* | *Chironomus riparius* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | NOEC |
| (µg/L) |  | 6630 | 3.34 | 10000 | 100 | 550 | 2000 |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | 66.3 | 0.334 | 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |
| **Step 1** | | | | | | | |
|  | 24.89 | 0.38 | **74.52** | 0.25 | **2.49** | 0.45 | 0.12 |
| **Step 2** | | | | | | | |
| N-Europe  (Oct-Feb) | 7.3576 | 0.11 | **22.03** | 0.07 | 0.74 | 0.13 | 0.04 |
| **Step 3** | | | | | | | |
| D1\_Ditch | 0.2845 | 0.00 | 0.85 | 0.00 | 0.03 | 0.01 | 0.00 |
| D1\_Stream | 0.1787 | 0.00 | 0.54 | 0.00 | 0.02 | 0.00 | 0.00 |
| D2\_Ditch | 0.5905 | 0.01 | **1.77** | 0.01 | 0.06 | 0.01 | 0.00 |
| D2\_Stream | 0.3744 | 0.01 | **1.12** | 0.00 | 0.04 | 0.01 | 0.00 |
| D3\_Ditch | 0.07629 | 0.00 | 0.23 | 0.00 | 0.01 | 0.00 | 0.00 |
| D4\_Pond | 0.01557 | 0.00 | 0.05 | 0.00 | 0.00 | 0.00 | 0.00 |
| D4\_Stream | 0.05044 | 0.00 | 0.15 | 0.00 | 0.01 | 0.00 | 0.00 |
| D5\_Pond | 0.008242 | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 |
| D5\_Stream | 0.03928 | 0.00 | 0.12 | 0.00 | 0.00 | 0.00 | 0.00 |
| D6\_Ditch | 0.06983 | 0.00 | 0.21 | 0.00 | 0.01 | 0.00 | 0.00 |
| R1\_Pond | 0.06352 | 0.00 | 0.19 | 0.00 | 0.01 | 0.00 | 0.00 |
| R1\_Stream | 0.3674 | 0.01 | **1.10** | 0.00 | 0.04 | 0.01 | 0.00 |
| R3\_Stream | 0.3498 | 0.01 | **1.05** | 0.00 | 0.03 | 0.01 | 0.00 |
| R4\_Stream | 0.3471 | 0.01 | **1.04** | 0.00 | 0.03 | 0.01 | 0.00 |
| **Step 4 (10 m vegetative buffer zone)** | | | | | | | |
| ~~D1\_Ditch~~ | ~~0.2845~~ | ~~0.00~~ | ~~0.85~~ | ~~0.00~~ | ~~0.03~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D1\_Stream~~ | ~~0.1787~~ | ~~0.00~~ | ~~0.54~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ | ~~0.00~~ |
| D2\_Ditch | 0.5905 | 0.01 | **1.77** | 0.01 | 0.06 | 0.01 | 0.00 |
| D2\_Stream | 0.3744 | 0.01 | **1.12** | 0.00 | 0.04 | 0.01 | 0.00 |
| ~~D3\_Ditch~~ | ~~0.01094~~ | ~~0.00~~ | ~~0.03~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ |
| ~~D4\_Pond~~ | ~~0.01472~~ | ~~0.00~~ | ~~0.04~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~0.05044~~ | ~~0.00~~ | ~~0.15~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.005425~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~0.02115~~ | ~~0.00~~ | ~~0.06~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ |
| ~~D6\_Ditch~~ | ~~0.06983~~ | ~~0.00~~ | ~~0.21~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ | ~~0.00~~ |
| ~~R1\_Pond~~ | ~~0.02664~~ | ~~0.00~~ | ~~0.08~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ | ~~0.00~~ |
| R1\_Stream | 0.1668 | 0.00 | 0.50 | 0.00 | 0.02 | 0.00 | 0.00 |
| R3\_Stream | 0.1573 | 0.00 | 0.47 | 0.00 | 0.02 | 0.00 | 0.00 |
| R4\_Stream | 0.157 | 0.00 | 0.47 | 0.00 | 0.02 | 0.00 | 0.00 |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5‑4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for JAU 6476-desthio for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in spring cereals (early application)

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | *O. mykiss* | *Daphnia magna* | *D. magna* | *Scenedesmus*  *subspicatus* | *Chironomus riparius* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | NOEC |
| (µg/L) |  | 6630 | 3.34 | 10000 | 100 | 550 | 2000 |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | 66.3 | 0.334 | 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |
| **Step 1** | | | | | | | |
|  | 24.89 | 0.38 | **74.52** | 0.25 | **2.49** | 0.45 | 0.12 |
| **Step 2** | | | | | | | |
| N-Europe  (Oct-Feb) | 7.3576 | 0.11 | **22.03** | 0.07 | 0.74 | 0.13 | 0.04 |
| **Step 3** | | | | | | | |
| D1\_Ditch | 0.4407 | 0.01 | **1.32** | 0.00 | 0.04 | 0.01 | 0.00 |
| D1\_Stream | 0.2753 | 0.00 | 0.82 | 0.00 | 0.03 | 0.01 | 0.00 |
| D3\_Ditch | 0.0621 | 0.00 | 0.19 | 0.00 | 0.01 | 0.00 | 0.00 |
| D4\_Pond | 0.02115 | 0.00 | 0.06 | 0.00 | 0.00 | 0.00 | 0.00 |
| D4\_Stream | 0.06802 | 0.00 | 0.20 | 0.00 | 0.01 | 0.00 | 0.00 |
| D5\_Pond | 0.008147 | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 |
| D5\_Stream | 0.03906 | 0.00 | 0.12 | 0.00 | 0.00 | 0.00 | 0.00 |
| R4\_Stream | 0.3675 | 0.01 | **1.10** | 0.00 | 0.04 | 0.01 | 0.00 |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5‑5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 1,2,4-triazole for each organism group based on FOCUS Steps 1 calculations for the use of ULTRACENT 460 EC in cereals

| Group |  | Fish acute | Fish prolonged | | Inverteb. acute | Algae |
| --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | *O. mykiss* | | *Daphnia magna* | *Pseudokirchneriella subcapitata* |
| Endpoint |  | LC50 | NOErC | | EC50 | ErC50 |
| (µg/L) |  | 49800 | 3200 | | ~~900000~~ 100000 | 22500 |
| AF |  | 100 | 10 | | 100 | 10 |
| RAC (µg/L) |  | 498 | 320 | | ~~9000~~  1000 | 2250 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  | |  |  |
| **Step 1** | | | | | | |
|  | 3.664 | 0.01 | | 0.01 | 0.00 | 0.00 |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

#### Spiroxamine

Table 9.5‑6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Spiroxamine for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in winter cereals (early application)

| ~~Group~~ |  | ~~Fish acute~~ | ~~Fish prolonged~~ | ~~Inverteb. acute~~ | ~~Inverteb. prolonged~~ | ~~Sed. dwell. prolonged~~ |
| --- | --- | --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Lepomis macrochirus~~* | *~~O. mykiss~~* | *~~Daphnia magna~~* | *~~D. magna~~* | *~~Chironomus riparius~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~NOEC~~ | ~~EC~~~~15~~ |
| ~~(µg/L)~~ |  | ~~7130~~ | ~~14~~ | ~~6100~~ | ~~100~~ | ~~3200~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ | ~~100~~ | ~~10~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~71.3~~ | ~~1.4~~ | ~~61~~ | ~~10~~ | ~~320~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |  |  |
| ~~Step 1~~ |  | | | | | |
|  | ~~26.4557~~ | ~~0.37~~ | **~~18.90~~** | ~~0.43~~ | **~~2.65~~** | ~~0.08~~ |
| ~~Step 2~~ |  | | | | | |
| ~~N-Europe~~  ~~(Oct-Feb)~~ | ~~9.4404~~ | ~~0.13~~ | **~~6.74~~** | ~~0.15~~ | ~~0.94~~ | ~~0.03~~ |
| **~~Step 3~~** | | | | | | |
| ~~D1\_Ditch~~ | ~~1.897~~ | ~~0.03~~ | **~~1.36~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D1\_Stream~~ | ~~1.475~~ | ~~0.02~~ | **~~1.05~~** | ~~0.02~~ | ~~0.15~~ | ~~0.00~~ |
| ~~D2\_Ditch~~ | ~~1.908~~ | ~~0.03~~ | **~~1.36~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D2\_Stream~~ | ~~1.621~~ | ~~0.02~~ | **~~1.16~~** | ~~0.03~~ | ~~0.16~~ | ~~0.01~~ |
| ~~D3\_Ditch~~ | ~~1.89~~ | ~~0.03~~ | **~~1.35~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D4\_Pond~~ | ~~0.0649~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~1.397~~ | ~~0.02~~ | ~~1.00~~ | ~~0.02~~ | ~~0.14~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.06491~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~1.508~~ | ~~0.02~~ | **~~1.08~~** | ~~0.02~~ | ~~0.15~~ | ~~0.00~~ |
| ~~D6\_Ditch~~ | ~~1.868~~ | ~~0.03~~ | **~~1.33~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~R1\_Pond~~ | ~~0.06494~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~R1\_Stream~~ | ~~1.245~~ | ~~0.02~~ | ~~0.89~~ | ~~0.02~~ | ~~0.12~~ | ~~0.00~~ |
| ~~R3\_Stream~~ | ~~1.749~~ | ~~0.02~~ | **~~1.25~~** | ~~0.03~~ | ~~0.17~~ | ~~0.01~~ |
| ~~R4\_Stream~~ | ~~1.25~~ | ~~0.02~~ | ~~0.89~~ | ~~0.02~~ | ~~0.13~~ | ~~0.00~~ |
| **~~Step 4 (10 m buffer zone)~~** | | | | | | |
| ~~D1\_Ditch~~ | ~~0.9102~~ | ~~0.01~~ | ~~0.65~~ | ~~0.01~~ | ~~0.09~~ | ~~0.00~~ |
| ~~D1\_Stream~~ | ~~0.3952~~ | ~~0.01~~ | ~~0.28~~ | ~~0.01~~ | ~~0.04~~ | ~~0.00~~ |
| ~~D2\_Ditch~~ | ~~1.027~~ | ~~0.01~~ | ~~0.73~~ | ~~0.02~~ | ~~0.10~~ | ~~0.00~~ |
| ~~D2\_Stream~~ | ~~0.5778~~ | ~~0.01~~ | ~~0.41~~ | ~~0.01~~ | ~~0.06~~ | ~~0.00~~ |
| ~~D3\_Ditch~~ | ~~0.777~~ | ~~0.01~~ | ~~0.56~~ | ~~0.01~~ | ~~0.08~~ | ~~0.00~~ |
| ~~D4\_Pond~~ | ~~0.1685~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~0.3456~~ | ~~0.00~~ | ~~0.25~~ | ~~0.01~~ | ~~0.03~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.1652~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~0.3713~~ | ~~0.01~~ | ~~0.27~~ | ~~0.01~~ | ~~0.04~~ | ~~0.00~~ |
| ~~D6\_Ditch~~ | ~~0.5588~~ | ~~0.01~~ | ~~0.40~~ | ~~0.01~~ | ~~0.06~~ | ~~0.00~~ |
| ~~R1\_Pond~~ | ~~0.1657~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~R1\_Stream~~ | ~~0.4823~~ | ~~0.01~~ | ~~0.34~~ | ~~0.01~~ | ~~0.05~~ | ~~0.00~~ |
| ~~R3\_Stream~~ | ~~0.7117~~ | ~~0.01~~ | ~~0.51~~ | ~~0.01~~ | ~~0.07~~ | ~~0.00~~ |
| ~~R4\_Stream~~ | ~~0.718~~ | ~~0.01~~ | ~~0.51~~ | ~~0.01~~ | ~~0.07~~ | ~~0.00~~ |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5‑6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Spiroxamine for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in winter cereals (early application)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | | **Invertebrate acute** | **Invertebrate prolonged** | **Algae** | | **Sed. dwell. prolonged** | **Aquatic macrophytes** | | |
| **Test species** |  | ***Danio rerio*** | ***Danio rerio*** | | ***Daphnia magna*** | ***Daphnia magna*** | ***Skeletonema costatum*** | | ***Chironomus riparius*** | ***Lemna gibba*** | | |
| **Endpoint (µg/L)** |  | LC50 = 2410 | EC10 = 2 | | EC50 = 3000 | NOEC = 34 | ErC50 = 6.3 | | EC15 = 5600 | ErC50 = 6780 | EyC50 = 3020 | |
| **AF** |  | 100 | 10 | | 100 | 10 | 10 | | 10 | 10 | 10 | |
| **RAC (µg/L)** |  | 24.1 | 0.2 | | 30 | 3.4 | 0.63 | | 560 | 678 | 302 | |
| **FOCUS Scenario** | **PECmax (µg/L)** |  | | **PEC/RAC ratio** | | | | | | | | |
| **Step 1** |  |  |  | |  |  |  |  |  |  |  |  |
|  | 26.4557 | **1.1** | **132.3** | | 0.88 | **7.7** | **42.0** | | 0.05 | 0.04 | 0.09 | |
| **Step 2** |  |  |  | |  |  |  |  |  |  |  |  |
| N-Europe  (Oct-Feb) | 9.4404 | 0.4 | **47.2** | | 0.06 | **2.8** | **15.0** | | <0.01 | <0.01 | <0.01 | |
| **Step 3** |  |  |  | |  |  |  |  |  |  |  |  |
| D1\_Ditch | 1.897 | 0.08 | **9.49** | | 0.06 | 0.56 | **3.01** | | <0.01 | <0.01 | 0.01 | |
| D1\_Stream | 1.475 | 0.06 | **7.38** | | 0.05 | 0.43 | **2.34** | | <0.01 | <0.01 | <0.01 | |
| D2\_Ditch | 1.908 | 0.08 | **9.54** | | 0.06 | 0.56 | **3.03** | | <0.01 | <0.01 | 0.01 | |
| D2\_Stream | 1.621 | 0.07 | **8.11** | | 0.05 | 0.48 | **2.57** | | <0.01 | <0.01 | 0.01 | |
| D3\_Ditch | 1.89 | 0.08 | **9.45** | | 0.06 | 0.56 | **3.00** | | <0.01 | <0.01 | 0.01 | |
| D4\_Pond | 0.0649 | <0.01 | 0.32 | | <0.01 | 0.02 | 0.10 | | <0.01 | <0.01 | <0.01 | |
| D4\_Stream | 1.397 | 0.06 | **6.99** | | 0.05 | 0.41 | **2.22** | | <0.01 | <0.01 | <0.01 | |
| D5\_Pond | 0.06491 | <0.01 | 0.32 | | <0.01 | 0.02 | 0.10 | | <0.01 | <0.01 | <0.01 | |
| D5\_Stream | 1.508 | 0.06 | **7.54** | | 0.05 | 0.44 | **2.39** | | <0.01 | <0.01 | <0.01 | |
| D6\_Ditch | 1.868 | 0.08 | **9.34** | | 0.06 | 0.55 | **2.97** | | <0.01 | <0.01 | 0.01 | |
| R1\_Pond | 0.06494 | <0.01 | 0.32 | | <0.01 | 0.02 | 0.10 | | <0.01 | <0.01 | <0.01 | |
| R1\_Stream | 1.245 | 0.05 | **6.23** | | 0.04 | 0.37 | **1.98** | | <0.01 | <0.01 | <0.01 | |
| R3\_Stream | 1.749 | 0.07 | **8.75** | | 0.06 | 0.51 | **2.78** | | <0.01 | <0.01 | 0.01 | |
| R4\_Stream | 1.25 | 0.05 | **6.25** | | 0.04 | 0.37 | **1.98** | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (10 m no spray buffer zone)** | | | | |
| D1\_Ditch | 0.272 | 0.01 | **1.36** | | <0.01 | 0.08 | 0.43 | | <0.01 | <0.01 | <0.01 | |
| D1\_Stream | 0.2851 | 0.01 | **1.43** | | <0.01 | 0.08 | 0.45 | | <0.01 | <0.01 | <0.01 | |
| D2\_Ditch | 0.2737 | 0.01 | **1.37** | | <0.01 | 0.08 | 0.43 | | <0.01 | <0.01 | <0.01 | |
| D2\_Stream | 0.3134 | 0.01 | **1.57** | | <0.01 | 0.09 | 0.50 | | <0.01 | <0.01 | <0.01 | |
| D3\_Ditch | 0.2711 | 0.01 | **1.36** | | <0.01 | 0.08 | 0.43 | | <0.01 | <0.01 | <0.01 | |
| D4\_Pond | 0.04032 | <0.01 | 0.20 | | <0.01 | 0.01 | 0.06 | | <0.01 | <0.01 | <0.01 | |
| D4\_Stream | 0.27 | 0.01 | **1.35** | | <0.01 | 0.08 | 0.43 | | <0.01 | <0.01 | <0.01 | |
| D5\_Pond | 0.04033 | <0.01 | 0.20 | | <0.01 | 0.01 | 0.06 | | <0.01 | <0.01 | <0.01 | |
| D5\_Stream | 0.2916 | 0.01 | **1.46** | | <0.01 | 0.09 | 0.46 | | <0.01 | <0.01 | <0.01 | |
| D6\_Ditch | 0.268 | 0.01 | **1.34** | | <0.01 | 0.08 | 0.43 | | <0.01 | <0.01 | <0.01 | |
| R1\_Pond | 0.04036 | <0.01 | 0.20 | | <0.01 | 0.01 | 0.06 | | <0.01 | <0.01 | <0.01 | |
| R1\_Stream | 0.3526 | 0.01 | **1.76** | | <0.01 | 0.10 | 0.56 | | <0.01 | <0.01 | <0.01 | |
| R3\_Stream | 0.4327 | 0.02 | **2.16** | | <0.01 | 0.13 | 0.69 | | <0.01 | <0.01 | <0.01 | |
| R4\_Stream | 0.718 | 0.03 | **3.59** | | <0.01 | 0.21 | **1.14** | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (10 m no spray buffer zone and 50 % nozzle reduction)** | | | | | | | | | | | | |
| D1\_Ditch | 0.1359 | 0.01 | 0.68 | | <0.01 | 0.04 | 0.22 | | <0.01 | <0.01 | <0.01 | |
| D1\_Stream | 0.1424 | 0.01 | 0.71 | | <0.01 | 0.04 | 0.23 | | <0.01 | <0.01 | <0.01 | |
| D2\_Ditch | 0.1367 | 0.01 | 0.68 | | <0.01 | 0.04 | 0.22 | | <0.01 | <0.01 | <0.01 | |
| D2\_Stream | 0.1565 | 0.01 | 0.78 | | <0.01 | 0.05 | 0.25 | | <0.01 | <0.01 | <0.01 | |
| D3\_Ditch | 0.1354 | 0.01 | 0.68 | | <0.01 | 0.04 | 0.21 | | <0.01 | <0.01 | <0.01 | |
| D4\_Stream | 0.1349 | 0.01 | 0.67 | | <0.01 | 0.04 | 0.21 | | <0.01 | <0.01 | <0.01 | |
| D5\_Stream | 0.1457 | 0.01 | 0.73 | | <0.01 | 0.04 | 0.23 | | <0.01 | <0.01 | <0.01 | |
| D6\_Ditch | 0.1338 | 0.01 | 0.67 | | <0.01 | 0.04 | 0.21 | | <0.01 | <0.01 | <0.01 | |
| R1\_Stream | 0.3526 | 0.01 | **1.76** | | <0.01 | 0.10 | 0.56 | | <0.01 | <0.01 | <0.01 | |
| R3\_Stream | 0.4327 | 0.02 | **2.16** | | <0.01 | 0.13 | 0.69 | | <0.01 | <0.01 | <0.01 | |
| R4\_Stream | 0.718 | 0.03 | **3.59** | | <0.01 | 0.21 | **1.14** | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (10 m unsprayed vegetated buffer zone)** | | | | | | | | | | | | |
| R1\_Stream | 0.2406 | 0.01 | **1.20** | | <0.01 | 0.07 | 0.38 | | <0.01 | <0.01 | <0.01 | |
| R3\_Stream | 0.3382 | 0.01 | **1.69** | | <0.01 | 0.10 | 0.54 | | <0.01 | <0.01 | <0.01 | |
| R4\_Stream | 0.3263 | 0.01 | **1.63** | | <0.01 | 0.10 | 0.52 | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (10 m vegetated buffer zone, 50 % nozzle reduction)** | | | | | | | | | | | | |
| R1\_Stream | 0.16 | 0.01 | 0.80 | | <0.01 | 0.05 | 0.25 | | <0.01 | <0.01 | <0.01 | |
| R3\_Stream | 0.1972 | 0.01 | 0.99 | | <0.01 | 0.06 | 0.31 | | <0.01 | <0.01 | <0.01 | |
| R4\_Stream | 0.3263 | 0.01 | **1.63** | | <0.01 | 0.10 | 0.52 | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (20 m unsprayed vegetated buffer zone)** | | | | | | | | | | | | |
| D1\_Ditch | 0.1412 | 0.01 | 0.71 | | <0.01 | 0.04 | 0.22 | | <0.01 | <0.01 | <0.01 | |
| D1\_Stream | 0.148 | 0.01 | 0.74 | | <0.01 | 0.04 | 0.23 | | <0.01 | <0.01 | <0.01 | |
| D2\_Ditch | 0.1421 | 0.01 | 0.71 | | <0.01 | 0.04 | 0.23 | | <0.01 | <0.01 | <0.01 | |
| D2\_Stream | 0.1627 | 0.01 | 0.81 | | <0.01 | 0.05 | 0.26 | | <0.01 | <0.01 | <0.01 | |
| D3\_Ditch | 0.1407 | 0.01 | 0.70 | | <0.01 | 0.04 | 0.22 | | <0.01 | <0.01 | <0.01 | |
| D4\_Pond | 0.0269 | <0.01 | 0.13 | | <0.01 | 0.01 | 0.04 | | <0.01 | <0.01 | <0.01 | |
| D4\_Stream | 0.1402 | 0.01 | 0.70 | | <0.01 | 0.04 | 0.22 | | <0.01 | <0.01 | <0.01 | |
| D5\_Pond | 0.02691 | <0.01 | 0.13 | | <0.01 | 0.01 | 0.04 | | <0.01 | <0.01 | <0.01 | |
| D5\_Stream | 0.1514 | 0.01 | 0.76 | | <0.01 | 0.04 | 0.24 | | <0.01 | <0.01 | <0.01 | |
| D6\_Ditch | 0.1391 | 0.01 | 0.70 | | <0.01 | 0.04 | 0.22 | | <0.01 | <0.01 | <0.01 | |
| R1\_Pond | 0.02692 | <0.01 | 0.13 | | <0.01 | 0.01 | 0.04 | | <0.01 | <0.01 | <0.01 | |
| R1\_Stream | 0.1249 | 0.01 | 0.62 | | <0.01 | 0.04 | 0.20 | | <0.01 | <0.01 | <0.01 | |
| R3\_Stream | 0.1755 | 0.01 | 0.88 | | <0.01 | 0.05 | 0.28 | | <0.01 | <0.01 | <0.01 | |
| R4\_Stream | 0.1708 | 0.01 | 0.85 | | <0.01 | 0.05 | 0.27 | | <0.01 | <0.01 | <0.01 | |

F: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Conclusion for Poland:** If the relevant scenarios (D3, D4, R1) are considered, the risk assessment is acceptable taking into account the following mitigations:

10 m vegetated buffer zone and 50 % nozzle reduction or:

20 m unsprayed vegetated buffer zone

Table 9.5‑7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Spiroxamine for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in winter cereals (late application)

| ~~Group~~ |  | ~~Fish acute~~ | ~~Fish prolonged~~ | ~~Inverteb. acute~~ | ~~Inverteb. prolonged~~ | ~~Sed. dwell. prolonged~~ |
| --- | --- | --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Lepomis macrochirus~~* | *~~O. mykiss~~* | *~~Daphnia magna~~* | *~~D. magna~~* | *~~Chironomus riparius~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~NOEC~~ | ~~EC~~~~15~~ |
| ~~(µg/L)~~ |  | ~~7130~~ | ~~14~~ | ~~6100~~ | ~~100~~ | ~~3200~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ | ~~100~~ | ~~10~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~71.3~~ | ~~1.4~~ | ~~61~~ | ~~10~~ | ~~320~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |  |  |
| ~~Step 1~~ |  | | | | | |
|  | ~~26.4557~~ | ~~0.37~~ | **~~18.90~~** | ~~0.43~~ | **~~2.65~~** | ~~0.08~~ |
| ~~Step 2~~ |  | | | | | |
| ~~N-Europe~~  ~~(Oct-Feb)~~ | ~~9.4404~~ | ~~0.13~~ | **~~6.74~~** | ~~0.15~~ | ~~0.94~~ | ~~0.03~~ |
| **~~Step 3~~** | | | | | | |
| ~~D1\_Ditch~~ | ~~1.913~~ | ~~0.03~~ | **~~1.37~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D1\_Stream~~ | ~~1.673~~ | ~~0.02~~ | **~~1.20~~** | ~~0.03~~ | ~~0.17~~ | ~~0.01~~ |
| ~~D2\_Ditch~~ | ~~1.915~~ | ~~0.03~~ | **~~1.37~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D2\_Stream~~ | ~~1.704~~ | ~~0.02~~ | **~~1.22~~** | ~~0.03~~ | ~~0.17~~ | ~~0.01~~ |
| ~~D3\_Ditch~~ | ~~1.894~~ | ~~0.03~~ | **~~1.35~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D4\_Pond~~ | ~~0.06494~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~1.577~~ | ~~0.02~~ | **~~1.13~~** | ~~0.03~~ | ~~0.16~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.06494~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~1.597~~ | ~~0.02~~ | **~~1.14~~** | ~~0.03~~ | ~~0.16~~ | ~~0.00~~ |
| ~~D6\_Ditch~~ | ~~1.868~~ | ~~0.03~~ | **~~1.33~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~R1\_Pond~~ | ~~0.06493~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~R1\_Stream~~ | ~~1.24~~ | ~~0.02~~ | ~~0.89~~ | ~~0.02~~ | ~~0.12~~ | ~~0.00~~ |
| ~~R3\_Stream~~ | ~~1.759~~ | ~~0.02~~ | **~~1.26~~** | ~~0.03~~ | ~~0.18~~ | ~~0.01~~ |
| ~~R4\_Stream~~ | ~~1.25~~ | ~~0.02~~ | ~~0.89~~ | ~~0.02~~ | ~~0.13~~ | ~~0.00~~ |
| **~~Step 4 (10 m buffer zone)~~** | | | | | | |
| ~~D1\_Ditch~~ | ~~1.022~~ | ~~0.01~~ | ~~0.73~~ | ~~0.02~~ | ~~0.10~~ | ~~0.00~~ |
| ~~D1\_Stream~~ | ~~0.8604~~ | ~~0.01~~ | ~~0.61~~ | ~~0.01~~ | ~~0.09~~ | ~~0.00~~ |
| ~~D2\_Ditch~~ | ~~0.9992~~ | ~~0.01~~ | ~~0.71~~ | ~~0.02~~ | ~~0.10~~ | ~~0.00~~ |
| ~~D2\_Stream~~ | ~~0.3423~~ | ~~0.00~~ | ~~0.24~~ | ~~0.01~~ | ~~0.03~~ | ~~0.00~~ |
| ~~D3\_Ditch~~ | ~~0.7859~~ | ~~0.01~~ | ~~0.56~~ | ~~0.01~~ | ~~0.08~~ | ~~0.00~~ |
| ~~D4\_Pond~~ | ~~0.1636~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~0.4988~~ | ~~0.01~~ | ~~0.36~~ | ~~0.01~~ | ~~0.05~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.1655~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~0.4325~~ | ~~0.01~~ | ~~0.31~~ | ~~0.01~~ | ~~0.04~~ | ~~0.00~~ |
| ~~D6\_Ditch~~ | ~~0.5588~~ | ~~0.01~~ | ~~0.40~~ | ~~0.01~~ | ~~0.06~~ | ~~0.00~~ |
| ~~R1\_Pond~~ | ~~0.1625~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~R1\_Stream~~ | ~~0.5217~~ | ~~0.01~~ | ~~0.37~~ | ~~0.01~~ | ~~0.05~~ | ~~0.00~~ |
| ~~R3\_Stream~~ | ~~0.7341~~ | ~~0.01~~ | ~~0.52~~ | ~~0.01~~ | ~~0.07~~ | ~~0.00~~ |
| ~~R4\_Stream~~ | ~~0.6687~~ | ~~0.01~~ | ~~0.48~~ | ~~0.01~~ | ~~0.07~~ | ~~0.00~~ |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5‑6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Spiroxamine for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in winter cereals (late application)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Invertebrate acute** | | **Invertebrate prolonged** | | **Algae** | | | **Sed. dwell. prolonged** | | | **Aquatic macrophytes** | | | | |
| **Test species** |  | ***Danio rerio*** | ***Danio rerio*** | ***Daphnia magna*** | | ***Daphnia magna*** | | ***Skeletonema costatum*** | | | ***Chironomus riparius*** | | | ***Lemna gibba*** | | | | |
| **Endpoint (µg/L)** |  | LC50 = 2410 | EC10 = 2 | EC50 = 3000 | | NOEC = 34 | | ErC50 = 6.3 | | | EC15 = 5600 | | | ErC50 = 6780 | EyC50 = 3020 | | | |
| **AF** |  | 100 | 10 | 100 | | 10 | | 10 | | | 10 | | | 10 | 10 | | | |
| **RAC (µg/L)** |  | 24.1 | 0.2 | 30 | | 3.4 | | 0.63 | | | 560 | | | 678 | 302 | | | |
| **FOCUS Scenario** | **PECmax (µg/L)** | **PEC/RAC ratio** | | | | | | | | | | | | | | | | |
| **Step 1** |  |  |  |  |  | |  | |  | |  | |  |  | |  | |  | |
|  | 26.4557 | **1.1** | **132.3** | 0.88 | | **7.7** | | **42.0** | | | 0.05 | | | 0.04 | 0.09 | | | |
| **Step 2** |  |  |  |  | |  | |  | |  | |  | |  |  | |  | |
| N-Europe  (Oct-Feb) | 9.4404 | 0.4 | **47.2** | - | | **2.8** | | **15.0** | | | - | | | - | **-** | | | |
| **Step 3** |  |  |  |  | |  | |  | |  | |  | |  |  | |  | |
| D1\_Ditch | 1.913 | 0.08 | **9.57** | 0.06 | | 0.56 | | **3.04** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D1\_Stream | 1.673 | 0.07 | **8.37** | 0.06 | | 0.49 | | **2.66** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D2\_Ditch | 1.915 | 0.08 | **9.58** | 0.06 | | 0.56 | | **3.04** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D2\_Stream | 1.704 | 0.07 | **8.52** | 0.06 | | 0.50 | | **2.70** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D3\_Ditch | 1.894 | 0.08 | **9.47** | 0.06 | | 0.56 | | **3.01** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D4\_Pond | 0.06494 | <0.01 | 0.32 | <0.01 | | 0.02 | | 0.10 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Stream | 1.577 | 0.07 | **7.89** | 0.05 | | 0.46 | | **2.50** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D5\_Pond | 0.06494 | <0.01 | **0.32** | <0.01 | | 0.02 | | 0.10 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Stream | 1.597 | 0.07 | **7.99** | 0.05 | | 0.47 | | **2.53** | | | <0.01 | | | <0.01 | 0.01 | | | |
| D6\_Ditch | 1.868 | 0.08 | **9.34** | 0.06 | | 0.55 | | **2.97** | | | <0.01 | | | <0.01 | 0.01 | | | |
| R1\_Pond | 0.06493 | <0.01 | **0.32** | <0.01 | | 0.02 | | 0.10 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Stream | 1.24 | 0.05 | **6.20** | 0.04 | | 0.36 | | **1.97** | | | <0.01 | | | <0.01 | <0.01 | | | |
| R3\_Stream | 1.759 | 0.07 | **8.80** | 0.06 | | 0.52 | | **2.79** | | | <0.01 | | | <0.01 | 0.01 | | | |
| R4\_Stream | 1.25 | 0.05 | **6.25** | 0.04 | | 0.37 | | **1.98** | | | <0.01 | | | <0.01 | <0.01 | | | |
| **Step 4 (10 m no spray buffer zone)** | | | | | | | | | | | | | | | | | | |
| D1\_Ditch | 0.2744 | 0.01 | **1.37** | 0.01 | | 0.08 | | 0.44 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D1\_Stream | 0.3235 | 0.01 | **1.62** | 0.01 | | 0.10 | | 0.51 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D2\_Ditch | 0.2747 | 0.01 | **1.37** | 0.01 | | 0.08 | | 0.44 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D2\_Stream | 0.3294 | 0.01 | **1.65** | 0.01 | | 0.10 | | 0.52 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D3\_Ditch | 0.2716 | 0.01 | **1.36** | 0.01 | | 0.08 | | 0.43 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Pond | 0.04035 | <0.01 | **0.20** | <0.01 | | 0.01 | | 0.06 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Stream | 0.3048 | 0.01 | **1.52** | 0.01 | | 0.09 | | 0.48 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Pond | 0.04035 | <0.01 | **0.20** | <0.01 | | 0.01 | | 0.06 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Stream | 0.3088 | 0.01 | **1.54** | 0.01 | | 0.09 | | 0.49 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D6\_Ditch | 0.268 | 0.01 | **1.34** | 0.01 | | 0.08 | | 0.43 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Pond | 0.04231 | <0.01 | **0.21** | <0.01 | | 0.01 | | 0.07 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Stream | 0.5217 | 0.02 | **2.61** | 0.02 | | 0.15 | | 0.83 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R3\_Stream | 0.4118 | 0.02 | **2.06** | 0.01 | | 0.12 | | 0.65 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R4\_Stream | 0.6687 | 0.03 | **3.34** | 0.02 | | 0.20 | | **1.06** | | | <0.01 | | | <0.01 | <0.01 | | | |
| **Step 4 (10 m no spray buffer zone and 50 % nozzle reduction)** | | | | | | | | | | | | | | | | | | |
| D1\_Ditch | 0.1371 | 0.01 | 0.69 | <0.01 | | 0.04 | | 0.22 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D1\_Stream | 0.1616 | 0.01 | 0.81 | <0.01 | | 0.05 | | 0.26 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D2\_Ditch | 0.1372 | 0.01 | 0.69 | <0.01 | | 0.04 | | 0.22 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D2\_Stream | 0.1645 | 0.01 | 0.82 | <0.01 | | 0.05 | | 0.26 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D3\_Ditch | 0.1357 | 0.01 | 0.68 | <0.01 | | 0.04 | | 0.22 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Pond | 0.02014 | <0.01 | 0.10 | <0.01 | | 0.01 | | 0.03 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Stream | 0.1522 | 0.01 | 0.76 | <0.01 | | 0.04 | | 0.24 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Pond | 0.02014 | <0.01 | 0.10 | <0.01 | | 0.01 | | 0.03 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Stream | 0.1542 | 0.01 | 0.77 | <0.01 | | 0.05 | | 0.24 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D6\_Ditch | 0.1338 | 0.01 | 0.67 | <0.01 | | 0.04 | | 0.21 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Pond | 0.0406 | <0.01 | 0.20 | <0.01 | | 0.01 | | 0.06 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Stream | 0.5217 | 0.02 | **2.61** | <0.01 | | 0.15 | | 0.83 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R3\_Stream | 0.4118 | 0.02 | **2.06** | <0.01 | | 0.12 | | 0.65 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R4\_Stream | 0.6687 | 0.03 | **3.34** | <0.01 | | 0.20 | | **1.06** | | | <0.01 | | | <0.01 | <0.01 | | | |
| **Step 4 (10 m unsprayed vegetated buffer zone)** | | | | | | | | | | | | | | | | | | |
| R1\_Stream | 0.2367 | 0.01 | **1.18** | <0.01 | | 0.07 | | 0.38 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R3\_Stream | 0.3402 | 0.01 | **1.70** | <0.01 | | 0.10 | | 0.54 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R4\_Stream | 0.3047 | 0.01 | **1.52** | <0.01 | | 0.09 | | 0.48 | | | <0.01 | | | <0.01 | <0.01 | | | |
| **Step 4 (10 m vegetated buffer zone, 50 % nozzle reduction)** | | | | | | | | | | | | | | | | | | |
| R1\_Stream | 0.2367 | 0.01 | **1.18** | <0.01 | | 0.07 | | 0.38 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R3\_Stream | 0.1877 | 0.01 | 0.94 | <0.01 | | 0.06 | | 0.30 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R4\_Stream | 0.3047 | 0.01 | **1.52** | <0.01 | | 0.09 | | 0.48 | | | <0.01 | | | <0.01 | <0.01 | | | |
| **Step 4 (20 m unsprayed vegetated buffer zone)** | | | | | | | | | | | | | | | | | | |
| D1\_Ditch | 0.1424 | 0.01 | 0.71 | <0.01 | | 0.04 | | 0.23 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D1\_Stream | 0.1679 | 0.01 | 0.84 | <0.01 | | 0.05 | | 0.27 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D2\_Ditch | 0.1426 | 0.01 | 0.71 | <0.01 | | 0.04 | | 0.23 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D2\_Stream | 0.171 | 0.01 | 0.86 | <0.01 | | 0.05 | | 0.27 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D3\_Ditch | 0.141 | 0.01 | 0.71 | <0.01 | | 0.04 | | 0.22 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Pond | 0.02692 | <0.01 | 0.13 | <0.01 | | 0.01 | | 0.04 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D4\_Stream | 0.1582 | 0.01 | 0.79 | <0.01 | | 0.05 | | 0.25 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Pond | 0.02692 | <0.01 | 0.13 | <0.01 | | 0.01 | | 0.04 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D5\_Stream | 0.1603 | 0.01 | 0.80 | <0.01 | | 0.05 | | 0.25 | | | <0.01 | | | <0.01 | <0.01 | | | |
| D6\_Ditch | 0.1391 | 0.01 | 0.70 | <0.01 | | 0.04 | | 0.22 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Pond | 0.02691 | <0.01 | 0.13 | <0.01 | | 0.01 | | 0.04 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R1\_Stream | 0.1244 | 0.01 | 0.62 | <0.01 | | 0.04 | | 0.20 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R3\_Stream | 0.1766 | 0.01 | 0.88 | <0.01 | | <0.01 | | <0.01 | | | <0.01 | | | <0.01 | <0.01 | | | |
| R4\_Stream | 0.1596 | 0.01 | 0.80 | <0.01 | | <0.01 | | <0.01 | | | <0.01 | | | <0.01 | <0.01 | | | |

F: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Conclusion for Poland:** If the relevant scenarios (D3, D4, R1) are considered, the risk assessment is acceptable taking into account the following mitigations:

20 m unsprayed vegetated buffer zone

Table 9.5‑8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Spiroxamine for each organism group based on FOCUS Steps 1- 2, Step 3 and FOCUS SWAN calculations for the use of ULTRACENT 460 EC in spring cereals (early application)

| ~~Group~~ |  | ~~Fish acute~~ | ~~Fish prolonged~~ | ~~Inverteb. acute~~ | ~~Inverteb. prolonged~~ | ~~Sed. dwell. prolonged~~ |
| --- | --- | --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Lepomis macrochirus~~* | *~~O. mykiss~~* | *~~Daphnia magna~~* | *~~D. magna~~* | *~~Chironomus riparius~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~NOEC~~ | ~~EC~~~~15~~ |
| ~~(µg/L)~~ |  | ~~7130~~ | ~~14~~ | ~~6100~~ | ~~100~~ | ~~3200~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ | ~~100~~ | ~~10~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~71.3~~ | ~~1.4~~ | ~~61~~ | ~~10~~ | ~~320~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |  |  |
| ~~Step 1~~ |  | | | | | |
|  | ~~26.4557~~ | ~~0.37~~ | **~~18.90~~** | ~~0.43~~ | **~~2.65~~** | ~~0.08~~ |
| **~~Step 2~~** | | | | | | |
| ~~N-Europe~~  ~~(Oct-Feb)~~ | ~~9.4404~~ | ~~0.13~~ | **~~6.74~~** | ~~0.15~~ | ~~0.94~~ | ~~0.03~~ |
| **~~Step 3~~** | | | | | | |
| ~~D1\_Ditch~~ | ~~1.913~~ | ~~0.03~~ | **~~1.37~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D1\_Stream~~ | ~~1.673~~ | ~~0.02~~ | **~~1.20~~** | ~~0.03~~ | ~~0.17~~ | ~~0.01~~ |
| ~~D3\_Ditch~~ | ~~1.892~~ | ~~0.03~~ | **~~1.35~~** | ~~0.03~~ | ~~0.19~~ | ~~0.01~~ |
| ~~D4\_Pond~~ | ~~0.06494~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~1.546~~ | ~~0.02~~ | **~~1.10~~** | ~~0.03~~ | ~~0.15~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.06493~~ | ~~0.00~~ | ~~0.05~~ | ~~0.00~~ | ~~0.01~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~1.588~~ | ~~0.02~~ | **~~1.13~~** | ~~0.03~~ | ~~0.16~~ | ~~0.00~~ |
| ~~R4\_Stream~~ | ~~1.25~~ | ~~0.02~~ | ~~0.89~~ | ~~0.02~~ | ~~0.13~~ | ~~0.00~~ |
| **~~Step 4 (10 m buffer zone)~~** | | | | | | |
| ~~D1\_Ditch~~ | ~~1.022~~ | ~~0.01~~ | ~~0.73~~ | ~~0.02~~ | ~~0.10~~ | ~~0.00~~ |
| ~~D1\_Stream~~ | ~~0.8604~~ | ~~0.01~~ | ~~0.61~~ | ~~0.01~~ | ~~0.09~~ | ~~0.00~~ |
| ~~D3\_Ditch~~ | ~~0.7721~~ | ~~0.01~~ | ~~0.55~~ | ~~0.01~~ | ~~0.08~~ | ~~0.00~~ |
| ~~D4\_Pond~~ | ~~0.1635~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~D4\_Stream~~ | ~~0.4686~~ | ~~0.01~~ | ~~0.33~~ | ~~0.01~~ | ~~0.05~~ | ~~0.00~~ |
| ~~D5\_Pond~~ | ~~0.1655~~ | ~~0.00~~ | ~~0.12~~ | ~~0.00~~ | ~~0.02~~ | ~~0.00~~ |
| ~~D5\_Stream~~ | ~~0.426~~ | ~~0.01~~ | ~~0.30~~ | ~~0.01~~ | ~~0.04~~ | ~~0.00~~ |
| ~~R4\_Stream~~ | ~~0.7174~~ | ~~0.01~~ | ~~0.51~~ | ~~0.01~~ | ~~0.07~~ | ~~0.00~~ |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5‑8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Spiroxamine for each organism group based on FOCUS Steps 1-4 calculations for the use of ULTRACENT 460 EC in spring cereals (early application)

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Invertebrate acute** | **Invertebrate prolonged** | **Algae** | | **Sed. dwell. prolonged** | **Aquatic macrophytes** | | |
| **Test species** |  | ***Danio rerio*** | ***Danio rerio*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Skeletonema costatum*** | | ***Chironomus riparius*** | ***Lemna gibba*** | | |
| **Endpoint (µg/L)** |  | LC50 = 2410 | EC10 = 2 | EC50 = 3000 | NOEC = 34 | ErC50 = 6.3 | | EC15 = 5600 | ErC50 = 6780 | EyC50 = 3020 | |
| **AF** |  | 100 | 10 | 100 | 10 | 10 | | 10 | 10 | 10 | |
| **RAC (µg/L)** |  | 24.1 | 0.2 | 30 | 3.4 | 0.63 | | 560 | 678 | 302 | |
| **FOCUS Scenario** | **PECmax (µg/L)** | **PEC/RAC ratio** | | | | | | | | | | |
| **Step 1** |  |  |  |  |  |  |  |  |  |  |  |
|  | 26.4557 | **1.1** | **132.3** | 0.88 | **7.7** | **42.0** | | 0.05 | 0.04 | 0.09 | |
| **Step 2** |  |  |  |  |  |  |  |  |  |  |  |
| N-Europe  (Oct-Feb) | 9.4404 | 0.4 | **47.2** | 0.06 | **2.8** | **15.0** | | <0.01 | <0.01 | <0.01 | |
| **Step 3** |  |  |  |  |  |  |  |  |  |  |  |
| D1\_Ditch | 1.913 | 0.08 | **9.57** | 0.06 | 0.56 | **3.04** | | <0.01 | <0.01 | 0.01 | |
| D1\_Stream | 1.673 | 0.07 | **8.37** | 0.06 | 0.49 | **2.66** | | <0.01 | <0.01 | 0.01 | |
| D3\_Ditch | 1.892 | 0.08 | **9.46** | 0.06 | 0.56 | **3.00** | | <0.01 | <0.01 | 0.01 | |
| D4\_Pond | 0.06494 | <0.01 | 0.32 | <0.01 | 0.02 | 0.10 | | <0.01 | <0.01 | <0.01 | |
| D4\_Stream | 1.546 | 0.06 | **7.73** | 0.05 | 0.45 | **2.45** | | <0.01 | <0.01 | 0.01 | |
| D5\_Pond | 0.06493 | <0.01 | 0.32 | <0.01 | 0.02 | 0.10 | | <0.01 | <0.01 | <0.01 | |
| D5\_Stream | 1.588 | 0.07 | **7.94** | 0.05 | 0.47 | **2.52** | | <0.01 | <0.01 | 0.01 | |
| R4\_Stream | 1.25 | 0.05 | **6.25** | 0.04 | 0.37 | **1.98** | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (10 m no spray buffer zone)** | | | | | | | | | | | |
| D1\_Ditch | 0.2744 | <0.01 | **1.37** | <0.01 | 0.08 | 0.44 | | <0.01 | <0.01 | <0.01 | |
| D1\_Stream | 0.3235 | <0.01 | **1.62** | <0.01 | 0.10 | 0.51 | | <0.01 | <0.01 | <0.01 | |
| D3\_Ditch | 0.2713 | <0.01 | **1.36** | <0.01 | 0.08 | 0.43 | | <0.01 | <0.01 | <0.01 | |
| D4\_Pond | 0.04035 | <0.01 | 0.20 | <0.01 | 0.01 | 0.06 | | <0.01 | <0.01 | <0.01 | |
| D4\_Stream | 0.299 | <0.01 | **1.50** | <0.01 | 0.09 | 0.47 | | <0.01 | <0.01 | <0.01 | |
| D5\_Pond | 0.04034 | <0.01 | 0.20 | <0.01 | 0.01 | 0.06 | | <0.01 | <0.01 | <0.01 | |
| D5\_Stream | 0.3071 | <0.01 | **1.54** | <0.01 | 0.09 | 0.49 | | <0.01 | <0.01 | <0.01 | |
| R4\_Stream | 0.7174 | <0.01 | **3.59** | <0.01 | 0.21 | **1.14** | | <0.01 | <0.01 | <0.01 | |
| **Step 4 (10 m spray buffer zone and 50 % nozzle reduction)** | | | | | | | | | | | |
| D1\_Ditch | 0.1371 | 0.01 | 0.69 | 0.09 | <0.01 | 0.04 | | 0.22 | <0.01 | <0.01 | |
| D1\_Stream | 0.1616 | 0.01 | 0.81 | 0.10 | <0.01 | 0.05 | | 0.26 | <0.01 | <0.01 | |
| D3\_Ditch | 0.1355 | 0.01 | 0.68 | 0.09 | <0.01 | 0.04 | | 0.22 | <0.01 | <0.01 | |
| D4\_Stream | 0.1493 | 0.01 | 0.75 | 0.09 | <0.01 | 0.04 | | 0.24 | <0.01 | <0.01 | |
| D5\_Stream | 0.1534 | 0.01 | 0.77 | 0.10 | <0.01 | 0.05 | | 0.24 | <0.01 | <0.01 | |
| R4\_Stream | 0.7174 | 0.03 | **3.59** | 0.45 | <0.01 | 0.21 | | **1.14** | <0.01 | <0.01 | |
| **Step 4 (10 m unsprayed vegetated buffer zone)** | | | | | | | | | | | |
| R4\_Stream | 0.326 | 0.01 | **1.63** | 0.21 | <0.01 | 0.10 | | 0.52 | <0.01 | <0.01 | |
| **Step 4 (20 m no spray buffer zone)** | | | | | | | | | | | |
| D1\_Ditch | 0.1424 | 0.01 | 0.71 | 0.09 | <0.01 | 0.04 | | 0.23 | <0.01 | <0.01 | |
| D1\_Stream | 0.1679 | 0.01 | 0.84 | 0.11 | <0.01 | 0.05 | | 0.27 | <0.01 | <0.01 | |
| D3\_Ditch | 0.1408 | 0.01 | 0.70 | 0.09 | <0.01 | 0.04 | | 0.22 | <0.01 | <0.01 | |
| D4\_Pond | 0.02692 | <0.01 | 0.13 | 0.02 | <0.01 | 0.01 | | 0.04 | <0.01 | <0.01 | |
| D4\_Stream | 0.1552 | 0.01 | 0.78 | 0.10 | <0.01 | 0.05 | | 0.25 | <0.01 | <0.01 | |
| D5\_Pond | 0.02692 | <0.01 | 0.13 | 0.02 | <0.01 | 0.01 | | 0.04 | <0.01 | <0.01 | |
| D5\_Stream | 0.1594 | 0.01 | 0.80 | 0.10 | <0.01 | 0.05 | | 0.25 | <0.01 | <0.01 | |
| R4\_Stream | 0.7174 | 0.03 | **3.59** | 0.45 | <0.01 | 0.21 | | **1.14** | <0.01 | <0.01 | |
| **Step 4 (20 m unsprayed vegetated buffer zone)** | | | | | | | | | | | |
| R4\_Stream | 0.1706 | 0.01 | 0.85 | 0.11 | <0.01 | 0.05 | | 0.27 | <0.01 | <0.01 | |

**Conclusion for Poland:** If the relevant scenarios (D3, D4) are considered, the risk assessment is acceptable taking into account the following mitigations:

10 m spray buffer zone and 50 % nozzle reduction or:

20 m spray buffer zone

#### Metabolites of sprioxamine

Table 9.5‑9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for spiroxamine metabolites for each organism group based on FOCUS Steps 1- 2 calculations for the use of ULTRACENT 460 EC in winter/spring cereals

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Metabolite**  **KWG 4168-desethyl (M01)** | | **Metabolite**  **KWG 4168-N-oxide (M03)** | | | **Metabolite**  **KWG 4168-acid (M06)** | |
| **Group** |  | **Algae** |  | **Inverteb. acute** | **Algae** |  | **Algae** |
| **Test**  **species** |  | *D.subspicatus* |  | *D.magna* | *D. subspicatus* |  | *D. subspicatus* |
| **Endpoint** |  | ErC50 |  | EC50 | ErC50 |  | ErC50 |
| **[µg/L]** | 737 |  | > 100000 | 31680 |  | > 3200 |
| **AF** | 10 |  | 10 | 10 |  | 10 |
| **RAC [µg/L]** | **73.7** |  | **> 10000** | **3168** |  | **> 320** |
| **FOCUS Scenario** | **PEC gl-max [µg/L]** |  | **PEC gl-max [µg/L]** |  |  | **PEC gl-max [µg/L]** |  |
| **Step 1** | 1.0738 | 0.01 | 9.8244 | 0.0 | 0.0 | 35.4071 | 0.11 |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

#### Mixture toxicity of the product

The combined risk assessment for the active substances prothioconazole and spiroxamine was determined as per the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11 (7): 3290) using the Aquatic mixtox assessment (v1.15).

The ETR is determined via a step-wise approach.

First the plausibility of the measured formulation toxicity (ECxPPP) against the calculated mixture toxicity ECxmix-CA (assuming concentration addition) for exactly the mixture composition of the a.i. in the formulation (ECxPPP) by means of the model deviation ratio (MDR = ECxmix-CA/ECxPPP) should be checked especially with regards to potential synergism of the mixture.

**Step 1**: the measured formulation toxicity (ECx PPP) must be checked against the calculated toxicity (ECx mix-CA). The Concentration Addition (CA) is determined via the following equation:

**ECx mix-CA = (∑ pi / ECxi)-1**

where:

p = the component as a relative fraction of the mixture composition

ECxi = concentration on the component provoking x% effect

**Step 2**: the ECx PPP and ECx mix-CA are compared to give a model deviation ratio (MDR).

If the MDR is 0.2 – 5.0 then it can be concluded that the predicted toxicity is comparable to the measured toxicity, allowing the use of measured toxicity values in the formulation risk assessment.

If the MDR is < 0.2 it can be conducted that the measured toxicity is less toxic than the ECx mix-CA, and the ECx mix-CA should be used in the risk assessment.

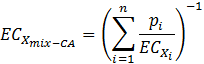
**MDR = ECx mix-CA / ECx PPP**

Table 9.5‑10: Calculation of EC50mix-CA and Model Deviation Ration (MDR) using the acute and chronic toxicity data for aquatic species

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Active**  **substance** | **EC50ai**  **[mg a.i./L]** | **Concentration in**  **formulation**  **[g a.i./L]** | **pi** | **EC50 mix-CA**  **[mg sum a.s./L]** | **EC50product measured**  **[mg/L]** | **ECxPPP (mg sum  a.s. /L)** | **MDR** |
| Fish | Prothio-conazole | 1.83 | 160 | 0.35 | 2.17 | 6.57 | 3.08 | 0.70 |
| Spiroxamine | 2.41 | 300 | 0.65 |
| Daphnia | Prothio-conazole | 1.3 | 160 | 0.35 | 2.06 | 6.3 | 2.96 | 0.70 |
| Spiroxamine | 3.0 | 300 | 0.65 |
| Algae | Prothio-conazole | 2.18 | 160 | 0.35 | 0.0096 | 0.16 | 0.08 | 0.13 |
| Spiroxamine | 0.0063 | 300 | 0.65 |

For the acute toxicity to fish and aquatic invertebrates, the MDR is between 0.2-5, therefore the measured EC50product can be used for the risk assessment. However, for algae the MDR is < 0.2, thus antagonism is indicated. However, measured mixture toxicity is plausible, as different test species were used for each active substance and the plant protection product.

**Step 3:** To determine if the mixture composition in the formulation study is similar to the mixture composition at the PECmix, a comparison is made based on the calculated mixture toxicity for both compositions. The EC50Mix-CA for the mixture composition of the active substances at the PECmix is calculated and compared with the estimate calculated for the formulation. This comparison helps assess the similarity or differences in toxicity between the two mixture compositions.

****

where:

n: number of mixture components

p = the component as a relative fraction of the mixture composition

ECx: concentration of component i provoking x % effect

**Table 9.5‑13: Calculation for ECxmix-CA (a.s. in PPP)/ ECxmix-CA (a.s. in PECmix)**

|  |  |  |  |
| --- | --- | --- | --- |
| **ECxmix-CA (a.s. in PPP)/ ECxmix-CA (a.s. in PECmix)** | | | |
| **Scenario** | **Fish** | **Invertebrates** | **Algae** |
| **Step 1** | 1.01 | 1.04 | 0.93 |
| **Step 2** |  |  |  |
| **N-Europe** | 0.96 | 0.87 | 1.21 |
| **S-Europe** |  |  |  |
| **Step 3** |  |  |  |
| **D1 Ditch** | 0.95 | 0.86 | 1.24 |
| **D1 Stream** | 0.95 | 0.83 | 1.29 |
| **D2 Ditch** | 0.98 | 0.93 | 1.12 |
| **D2 Stream** | 0.96 | 0.88 | 1.21 |
| **D3 Ditch** | 0.91 | 0.70 | 1.50 |
| **D4 Pond** | 0.97 | 0.91 | 1.15 |
| **D4 Stream** | 0.91 | 0.73 | 1.45 |
| **D5 Pond** | 0.93 | 0.79 | 1.36 |
| **D5 Stream** | 0.91 | 0.71 | 1.49 |
| **D6 Ditch** | 0.91 | 0.72 | 1.47 |
| **R1 Pond** | 1.02 | 1.05 | 0.91 |
| **R1 Stream** | 0.95 | 0.86 | 1.24 |
| **R2 Stream** |  |  |  |
| **R3 Stream** | 0.95 | 0.86 | 1.24 |
| **R4 Stream** | 1.00 | 1.00 | 1.01 |

For the acute toxicity to fish the mixture is similar in every scenario. Hence, all scenarios can be assessed via product tests (Step 4). For the acute toxicity to invertebrates and algae, the mixture is sometimes similar. Further assessment according to Step 4 or 5 is necessary.

**Step 4:** A mixture risk assessment is conducted by calculating the exposure-toxicity ratio (ETRmix) using the Predicted Environmental Concentration (PECMix) divided by the measured EC50Mix. The ETRmix values are then compared to the acceptability criteria, which are set at 0.01 for fish and invertebrates, and 0.1 for algae.

**Table 9.5‑13: Calculation for ECxmix-CA (a.s. in PPP)/ ECxmix-CA (a.s. in PECmix)**

|  |  |  |  |
| --- | --- | --- | --- |
| **ETRmix-PPP** | | | |
| **Scenario** | **Fish** | **Invertebrates** | **Algae** |
| **Step 1** | **0.01** | **0.01** | **0.58** |
| **Step 2** |  |  |  |
| **N-Europe** | 0.00 | 0.00 | **Go to 5/8** |
| **S-Europe** |  |  |  |
| **Step 3** |  |  |  |
| **D1 Ditch** | 0.00 | 0.00 | **Go to 5/8** |
| **D1 Stream** | 0.00 | 0.00 | **Go to 5/8** |
| **D2 Ditch** | 0.00 | 0.00 | 0.03 |
| **D2 Stream** | 0.00 | 0.00 | **Go to 5/8** |
| **D3 Ditch** | 0.00 | **Go to 5/8** | **Go to 5/8** |
| **D4 Pond** | 0.00 | 0.00 | 0.00 |
| **D4 Stream** | 0.00 | **Go to 5/8** | **Go to 5/8** |
| **D5 Pond** | 0.00 | **Go to 5/8** | **Go to 5/8** |
| **D5 Stream** | 0.00 | **Go to 5/8** | **Go to 5/8** |
| **D6 Ditch** | 0.00 | **Go to 5/8** | **Go to 5/8** |
| **R1 Pond** | 0.00 | 0.00 | 0.00 |
| **R1 Stream** | 0.00 | 0.00 | **Go to 5/8** |
| **R2 Stream** |  |  |  |
| **R3 Stream** | 0.00 | 0.00 | **Go to 5/8** |
| **R4 Stream** | 0.00 | 0.00 | 0.03 |

According to Step 4 the risk is acceptable in all FOCUS Step 1-3 scenarios for fish, invertebrates and algae. Nevertheless, for invertebrates and algae further assessment according to Step 5 were performed.

**Step 5:** Individual toxicity units (TUs) are used to determine if a single component of a mixture is primarily responsible for its toxicity. This is done by comparing the measured toxicity (EC50PPP) to the sum of TUs calculated for each component. If more than 90% of the total TUs come from a single substance, it indicates that this component is the main driver of toxicity in the mixture.

****

where:

n: number of mixture components

c = concentration in the mixture (PPP or PECmix), e.g. concentration of the individual a.s. (mg a.s./L) at the ECx-PPP (expressed as mg sum a.s./L)

ECx: concentration of component i provoking x % effect

For invertebrates spiroxamine was found to be the toxicity driver in some scenarios. However, for algae, spiroxamine was found to be the driver for each scenario. Hence further assessment according Step 6 and Step 8 were necessary.

**Table 9.5‑15: Calculation for toxicity driver**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Next Step for:** | **Invertrebrates** | | | **Algae** | | |
| **FOCUS** | **Prothioconazole** | **Spiroxamine** | **Conclusion** | **Prothioconazole** | **Spiroxamine** | **Conclusion** |
| **Step 1** |  |  | Go to 8 |  | Driver | Go to 6 |
| **Step 2** |  |  |  |  |  |  |
| **N-Europe** |  |  | Go to 8 |  | Driver | Go to 6 |
| **S-Europe** |  |  |  |  |  |  |
| **Step 3** |  |  |  |  |  |  |
| **D1 Ditch** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D1 Stream** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D2 Ditch** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D2 Stream** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D3 Ditch** |  | Driver | Go to 6 |  | Driver | Go to 6 |
| **D4 Pond** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D4 Stream** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D5 Pond** |  |  | Go to 8 |  | Driver | Go to 6 |
| **D5 Stream** |  | Driver | Go to 6 |  | Driver | Go to 6 |
| **D6 Ditch** |  | Driver | Go to 6 |  | Driver | Go to 6 |
| **R1 Pond** |  |  | Go to 8 |  | Driver | Go to 6 |
| **R1 Stream** |  |  | Go to 8 |  | Driver | Go to 6 |
| **R2 Stream** |  |  |  |  |  |  |
| **R3 Stream** |  |  | Go to 8 |  | Driver | Go to 6 |
| **R4 Stream** |  |  | Go to 8 |  | Driver | Go to 6 |

**Step 6:** A risk assessment based on single-substance toxicity data (EC50a.s.) for the identified driver of mixture toxicity is conducted, with the exposure-toxicity ratio (ETRa.s.) being defined as the PECa.s. divided by the measured EC50a.s. and the outcome is compared with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.

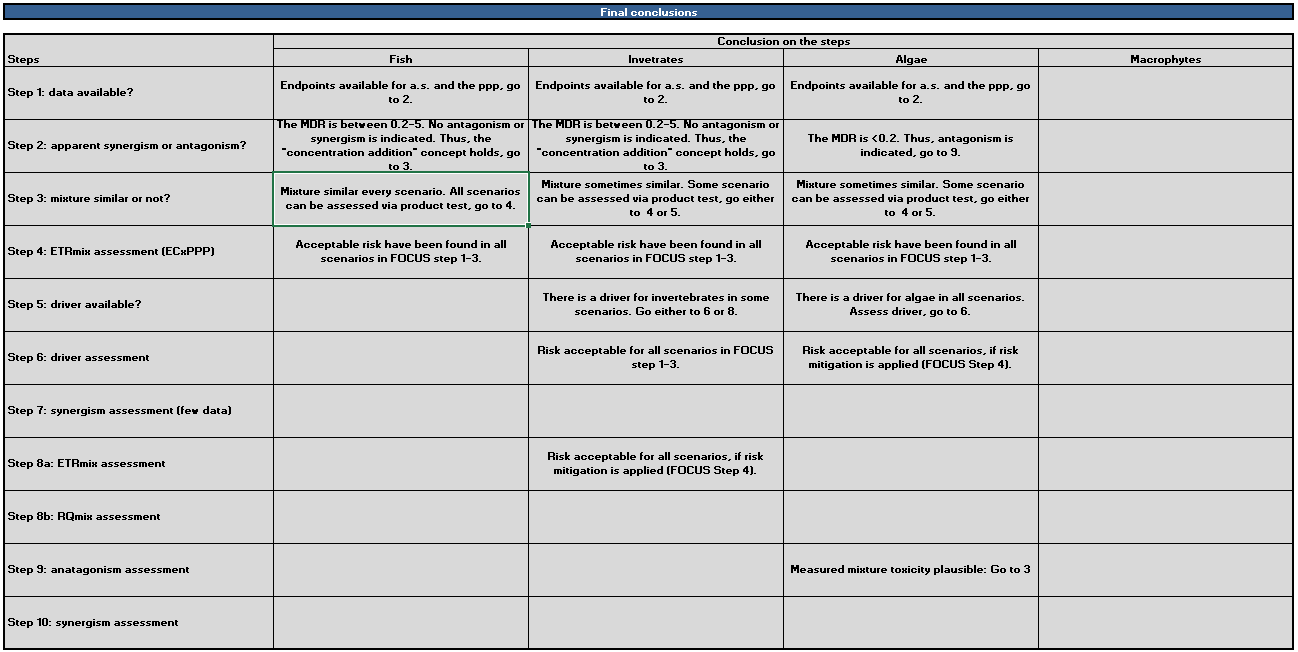
The risk assessment for the single substances has already been presented in section 9.5.2.1 – 9.5.2.4. For invertebrates the risk is acceptable for all scenarios in FOCUS Step 1-3 and for algae the risk is acceptable when mitigation are applied (FOCUS Step 4).

**Step 8:** Conduct Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 of EFSA Journal 2013; 11 (7): 3290. ECxmix-CA is the mixture toxicity at PECmix (i.e. ECxmix-CA (a.s. in PECmix))

****

The risk assessment for invertebrates was acceptable in all Scenarios when mitigations were applied (FOCUS Step 4).

In conclusion, the combined risk for aquatic organisms is considered acceptable.



|  |
| --- |
| **Review Comments:**  The risk assessment (mixture toxicity) submitted by the Applicant has been accepted. |

### Overall conclusions

|  |
| --- |
| **Review Comments**:  The relevant predicted environmental concentrations in water (PECsw) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The initial risk assessment was based on the worst case PECsw values and the results of laboratory toxicity testing.  According to Polish national requirements given on the website of the Ministry of Agriculture and Rural Development, for each crop the appropriate for Poland scenarios must be included (for surface water: D3, D4, R1). Due to the lack of R1 scenarios for spring cereals, the winter cereals for this scenario are use as surrogate crop.  The calculated PEC/RAC ratios indicate an acceptable risk for all groups of aquatic organisms with following mitigation measures:  To protect aquatic organisms respect 20 m unsprayed, vegetated buffer zone to surface water bodies. |

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

~~The risk assessment demonstrates that no significant risk to the aquatic organisms is present for the central zone relevant scenarios for the zRMS following the intended GAP use of ULTRACENT 460 EC in cereals (winter and spring) when following mitigation measures are taken into consideration.~~

|  |  |
| --- | --- |
| ~~Winter Cereals: 1.0 L/ha, BBCH 30-59~~ | ~~10 m vegetative buffer zone~~ |
| ~~Spring Cereals: 1.0 L/ha, BBCH 30-59~~ | ~~10 m no spray buffer zone~~ |

## Effects on bees (KCP 10.3.1)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

|  |
| --- |
| **Review Comments:**  One of the representative formulated product for the EU evaluation of spiroxamine was Input an EC formulation containing 160 g/L prothioconazole and 300 g/L spiroxamine. The representative uses evaluated were applications in wheat, triticale, rye, barley and oats with the Input formulation.  From ecotoxicological perspective ULTRACENT 460 EC is considered equivalent to Input. Thus data evaluated at EU level for Input can be used to evaluate this product. |

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Studies on the toxicity to bees have been carried out with prothioconazole and spiroxamine. Full details of these studies are provided in the respective EFSA conclusions and related documents.

Effects on bees of ULTRACENT 460 EC were not evaluated as part of the EU assessment of prothioconazole and spiroxamine. No new data has been submitted with this application.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Study type** | **Tested substance** | **Toxicity endpoint** | **Information on study** |
| **Acute oral toxicity** | Input 460 EC | 48h/LD5o > 346 µg a.s./bee | Barth, M. (2001)  Rep. No: 01 10 48 033  GLP  Study accepted |
| **Acute contact toxicity** | Input 460 EC | 48hLD5o > 420 µg a.s./bee |

|  |  |
| --- | --- |
| Studies on residues, in cages, in tunnels, in the field | The performance of semi-field or field studies was not necessary due to the clarification of the risk based on laboratory studies |

#### Justification for new endpoints

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The risk assessment of the effect of ULTRACENT 460 EC on bees was conducted using the EU agreed endpoints.

### Risk assessment

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The risk assessment for bees was based on acute oral and contact toxicity testing of Input 460 EC.~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~Acute toxicity~~** | **~~LD50 µg product/bee~~** | **~~dose g product/ha~~** | **~~HQ~~** | **~~Limit value~~** |
| **~~oral (48h)~~** | ~~368~~ | ~~980\*~~ | ~~2.7~~ | ~~< 50~~ |
| **~~contact (24h)~~** | ~~383~~ | ~~980\*~~ | ~~2.6~~ | ~~< 50~~ |

~~\*dose after accounting for density = 0.98 g/l~~

~~The risk assessment carried out showed that the use of Input 460 EC does not pose a risk to bees as the HQ risk factors are below the cut-off value of 50. The product can therefore be categorised as low risk to bees.~~

~~The risk assessment carried out indicates that the product will not cause unacceptable effects on bees and therefore meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839). No risk management measures are required in this respect.~~

#### Hazard quotients for bees

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

**Risk assessment according to SANCO 2002**

The acute risk to honey bees from use of ULTRACENT 460 EC was assessed in accordance to SANCO/10329/2002, using the maximum single application rate and the LD50 values to calculate hazard quotients (EPPO 2010)[[6]](#footnote-6) as follows:

Hazard quotients were calculated for oral exposure (QHO) and contact exposure (QHC) to ULTRACENT 460 EC.

Table 9.6‑1: First-tier assessment of the risk for bees due to the use of ULTRACENT 460 EC in cereals

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use | Cereals | | |
| Product | ULTRACENT 460 EC | | |
| Application rate (g/ha) | 1 × 0.98\* | | |
| Test design | LD50 (lab.)  (µg/bee) | Single application rate  (µg/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity  (*A. mellifera*) | >346 | 980 | 2.83 |
| Contact toxicity  (*A. mellifera*) | >420 | 2.33 |

QHO, QHC: Hazard quotients for oral and contact exposure. QH values shown in bold breach the relevant trigger.

\*application rate calculated taking the density of 0.98 g/mL into consideration

The hazard quotient for toxicity against ULTRACENT 460 EC is less than 50, indicating that the GAP use of product poses no unacceptable risk to the bees.

#### Higher-tier risk assessment for bees (tunnel test, field studies)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Effects on bumble bees

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Effects on solitary bees

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Overall conclusions

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The hazard quotient for toxicity against ULTRACENT 460 EC is less than 50, indicating that the GAP use of product poses no unacceptable risk to the bees.

|  |
| --- |
| **Review Comments:**  The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).  The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible risk associated with the exposure of beesto ULTRACENT 460 EC.  No studies on chronic effects of the formulation to adult bees or to larvae were provided in the risk assessment to bees, although this is a data requirement set by the Commission Regulation (EU) 284/2013. The deficiencies should be addressed before the new EFSA guidance becomes applicable. |

## Effects on arthropods other than bees (KCP 10.3.2)

### Toxicity data

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~Extended laboratory studies~~** | | | | |
| **~~Species~~** | **~~Study type~~** | **~~Tested substance~~** | **~~Toxicity endpoint~~** | **~~Information on study~~** |
| ~~Extended laboratory studies~~ | | | | |
| *~~Typhlodromus pyri~~* | ~~14 dni, on bean leaves~~ | ~~Input 460 EC~~ | ~~LR50 >2.5 l/ha~~  ~~(no effect on reproduction up to dose 1.25 l/ha)~~ | ~~Rolling,U.(2002) Rep.: 011048031 GLP~~  ~~Study accepted~~ |
| *~~Typhlodromus pyri~~* | ~~14 dni, older residues on maize~~ | ~~Input 460 EC~~ | ~~LR50 >2 x 1.25~~  ~~(no effect on reproduction~~  ~~(1,4%) for dose 2 x 1.25 l/ha))~~ | ~~Rolling,U.(2002) Rep.: 011048032 GLP~~  ~~Study accepted~~ |
| *~~Aphidius rhopalosiphi~~* | ~~14 dni, on maize~~ | ~~Input 460 EC~~ | ~~LR50 > 1.25 < 2.5 l/ha~~  ~~(no effect on reproduction up to dose 1,25 l/ha)~~ | ~~Rolling,U.(2002) Rep.: 011048029 GLP~~  ~~Study accepted~~ |
| *~~Aphidius rhopalosiphi~~* | ~~14 dni, older residues on maize~~ | ~~Input 460 EC~~ | ~~LR50 > 1.25 < 2.5 l/ha~~  ~~(no effect on reproduction~~  ~~(9% ) for dose 2 x 1,.25 l/ha)~~ | ~~Rolling,U.(2002) Rep.: 011048030 GLP~~  ~~Study accepted~~ |

|  |  |
| --- | --- |
| ~~Semi-field and field tests~~ | ~~The performance of field or semi-field trials was not necessary, as extended laboratory tests showed that Input 460 EC applied at the maximum proposed dose of 1.0 l/ha has no adverse effects on beneficial arthropods~~ |

|  |  |  |  |
| --- | --- | --- | --- |
| **Organism** | **Tested Formulation  study type, Duration,  exposure** | **Ecotoxicological endpoint** | **Reference** |
| *Aphidius* *rhopalosiphi* | EC 460 Ext. lab., maize plants,  2.5 L/ha 1.25 L/ha | LR50 >1.25 <2.5 L/ha corr. mortality [%] effect on reproduction [%]  100 -  0 -3 | Röhling (2002) 011048029 |
| *Aphidius* *rhopalosiphi* | EC 460  Ext. lab., maize plants,  aged residues,  2 × 1.25 L/ha (21 day interval) | LR50 >2x 1.25 L/ha  corr. mortality [%] effect on reproduction [%]  DAT 0 : 0 DAT 0 : 3  DAT 7 : 0 DAT 7 : 9 | Röhling (2002) 011048030 |
| *Aphidius* *rhopalosiphi* | EC 460  Ext. lab., barley plants,  aged residues,  3 × 1.25 L/ha (14 day interval) | LR50 >3x 1.25 L/ha  corr. mortality [%] effect on reproduction [%]  DAT 0 : 0 DAT 0 : 13.4  DAT 7 : 3.4 DAT 7 : -10.6 | Moll (2005) 26221003 |
| *Typhlodromus pyri* | EC 460 Ext. lab., bean leaves,  2.5 L/ha 1.25 L/ha | LR50 >2.5 L/ha corr. mortality [%] effect on reproduction [%]  6.3 6.5  2.1 0 | Röhling (2002) 011048031 |
| *Typhlodromus pyri* | EC 460 Ext. lab., on maize plants,  aged residues  2 x 1.25 L/ha (21 day interval) | LR50 >2x 1.25 L/ha  corr. mortality [%] effect on reproduction [%]  DAT 0 : 0 DAT 0 : 0  DAT 7 : 2 DAT 7 : 1.4 | Röhling (2002) 011048032 |
| *Coccinella septempunctata* | EC 460 Ext. lab., bean leaves   control  0.012 L/ha  0.058 L/ha  0.266 L/ha  1.250 L/ha  2.875 L/ha | LR50 >2.875 L/ha  Fertile eggs/ Larval  corr. Mortality [%] female/day hatching rate [%]  -- 16.6 78.1  21.4 11.1 70.9  25.0 9.1 71.7  21.4 44.4 71.6  10.7 19.4 66.3  25.0 13.9 74.4 | Moll (2005) 26222012 |
| *Aleochara bilineata* | EC 460 Ext. lab., sandy soil (LUFA 2.1) control  0.175 L/ha  0.340 L/ha  0.661 L/ha  1.286 L/ha  2.500 L/ha | LR50 >2.5 L/ha   Parasitation rate [%] Effect on reproduction [%] 37.9 --  36.6 3.4  34.0 10.2  36.2 4.4  33.6 11.3  34.4 9.2 | Röhling (2008) 071048029A |

#### Justification for new endpoints

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~Toxicity studies for indicator arthropod species were carried out for representative formulations of each active substance: spiroxamine - KWG 4168 EC 500 and prothioconazole - JAU 6476 EC 250 (information is included in the DAR for spiroxamine and prothioconazole). On the basis of these studies and extended laboratory tests, prothioconazole was found to have no adverse effects on arthropods both in and out of the field when applied at doses up to 380 g a.s./ha, This dose is higher than the dose proposed for use in Poland, therefore the risk assessment for 380 g a.s./ha covers the application in Poland. For spiroxamine, the risk to arthropods was found to be acceptable for two applications per growing season at 750 g a.s./ha, which is also the lower case and covers the risk for the proposed use in Poland.~~

~~Since the product contains two active substances, a formulation study of Input 460 EC was conducted for the most sensitive terrestrial arthropod species (Typhlodromus pyri and Aphidius rhopalosiphi). Extended laboratory tests were carried out omitting the laboratory tests, due to the fact that the results of these tests are available in the DAR for the individual active substances.~~

~~Risk assessment using the results of extended laboratory testing.~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **~~Species~~** | **~~Tested maximum dose of Input 460 EC (l/ha)~~** | **~~% mortality~~** | **~~% impact on reproduction~~** | **~~Limit value~~** |
| *~~Typhlodromus pyri~~* | ~~2.5~~ | ~~6.5~~ | ~~6.5~~ | ~~< 50%~~ |
| *~~Typhlodromus pyri~~* | ~~2x1.25~~ | ~~0~~ | ~~1.4~~ | ~~< 50%~~ |
| *~~Aphidius rhopalosiphi~~* | ~~1.25~~ | ~~0~~ | ~~0~~ | ~~< 50%~~ |
| *~~Aphidius rhopalosiphi~~* | ~~2x1.25~~ | ~~0~~ | ~~9~~ | ~~< 50%~~ |

~~The application of the product at a dose equivalent to 2.5 l/ha has no adverse effects ≥ 50% compared to the control.~~

~~The risk to terrestrial arthropods was also assessed based on French guidelines considering two applications of the product in cereals at single doses equal to 1.25 l/ha and this represented a worse case than that resulting from the proposed use in Poland.~~

~~Based on the above data, it can be concluded that Input 460 EC does not pose a risk to terrestrial arthropods other than bees.~~

~~No risk management actions are required for the proposed use of Input 460 EC in the label.~~

~~The risk assessment for terrestrial arthropods other than bees indicates that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

#### Risk assessment for in-field exposure

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for non-target arthropods from all other intended uses.

Table 9.7‑1: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of ULTRACENT 460 EC in winter/spring cereals

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use | Winter/spring cereals | | |
| Active substance/product | ULTRACENT 460 EC | | |
| Application rate (L/ha) | 1 × 1.0 | | |
| MAF | 1.0\* | | |
| Test species  Higher-tier | LR50 (lab.)  (L product/ha) | PERin‑field  (L product/ha) | HQin-field criterion: HQ ≤ ~~2~~ 1 |
| *Typhlodromus pyri* | L(E)R50 >2.5 | 1 | <0.4 |
| *Aphidius rhopalosiphi* | L(E)R50 > 1.25 | <0.80 |
| *Coccinella septempunctata* | L(E)R50 > 2.875 | < 0.35 |
| *Aleochara bilineata* | L(E)R50 > 2.5 | < 0.4 |

\*taken from ESCORT II, Appendix V

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient.

Criteria values shown in bold breach the relevant trigger

#### Risk assessment for off-field exposure

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Table 9.7‑2: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of ULTRACENT 460 EC in winter/spring cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter/spring cereals | | | | |
| Active substance/product | | ULTRACENT 460 EC | | | | |
| Application rate (L/ha) | | 1 × ~~1250~~ 1 | | | | |
| MAF | | 1.0 | | | | |
| vdf | | 10\* | | | | |
| Test species  Higher-tier | LR50 (lab.)  (L product/ha) | | Drift rate\*\* | PERoff‑field  (L product/ha) | CF | HQoff-field criterion: HQ ≤ 2 |
| *Typhlodromus pyri* | LR50 >2.5 | | 2.77 | ~~0.01~~ 0.00277 | 5 | ~~<0.01~~ 0.00554 |
| *Aphidius rhopalosiphi* | LR50 > 1.25 | | 2.77 | ~~0.01~~ 0.0277 | 5 | <~~0.01~~ 0.111 |

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* According to the Working document on risk assessment of plant protection products in the central zone (v2.0, August 2023) as long as the adjustment of vdf of 5 to the guidance document has not been made, a VDF of 10 should be applied in core assessment.

\*\* according to ESCORT II, field crops, 1 applications, 1 m distance

#### Additional higher-tier risk assessment

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

#### Risk mitigation measures

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Overall conclusions

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The risk of ULTRACENT 460 EC was demonstrated to be acceptable if the product is applied according to the intended GAP use.

|  |
| --- |
| **Review Comments:**  Based on the results of the conducted risk assessment it can be concluded that low risk for non-target arthropods is expected from the use of ULTRACENT 460 EC according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats. |

## Effects on non-target soil meso- and macrofauna (KCP 10.4)

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with prothioconazole and spiroxamine. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of ULTRACENT 460 EC were not evaluated as part of the EU assessment of prothioconazole and spiroxamine. No new data has been submitted with this application.

Table 9.8‑1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Folsomia candida* | Prothioconazole | Chronic, mixed into substrate | NOEC = 64 mg a.i./kg soil  **NOECcorr = 32 mg a.i./kg soil\*** | EFSA scientific report (2007) 106, 1-98 |
| *Hypoaspis aculeifer* | Chronic | NOEC = 100 mg a.i./kg dws |
| *E. fetida* | JAU 6476-desthio | Acute | LC50 >1000 mg p.m./kg dws |
| *E. fetida* | Chronic, 56 day, artificial soil | NOEC = 1\*\*\* mg p.m./kg soil  **NOECcorr =** **0.50 mg p.m./kg soil**\* |
| *F. candida* | Chronic | NOEC = 62.5 mg a.i./kg soil  **NOECcorr =** **31.25 mg p.m./kg soil**\* |
| *E. fetida* | JAU 6576-S-methyl | Chronic, 56 day, artificial soil | NOEC = 100 mg p.m./kg dws  NOECcorr = 50 mg p.m./kg soil\* |
| *F. candida* | Chronic, mixed into substrate | NOEC = 31.6 mg p.m./kg dws  **NOECcorr =** **15.8 mg p.m./kg soil**\* |
| *E. fetida* | Spiroxamine | Acute, 14 day | LC50corr >500 mg a.i./kg | EFSA Journal 2010;8(10)1719 |
| *F. candida* | Chronic, 28 day | **NOEC = 32 mg a.i./kg** |
| *E. fetida* | Metabolite KWG 4168-desethyl (M01) | Chronic, 56 day | **NOEC = 100 mg met./kg** |
| *F. candida* | Chronic, 28 day | **NOEC = 316 mg met./kg** |
| *F. candida* | Metabolite KWG 4168-despropyl (M02) | Chronic, 28 day | **NOEC = 316 mg met./kg** |
| *E. fetida* | Metabolite KWG 4168-N-oxide (M03) | Chronic, 56 day | **NOEC = 100 mg met./kg** |
| *Eisenia fetida* | Input 460 EC | Chronic, 56 day | NOEC [mg prep./kg soil] 32  (corresponding to ≥9.51 mg as/kg soil Spiroxamine content) |  |
| *Folsomia candida* | Input 460 EC | chronic, 28d  (5 % peat in test soil) | NOEC [mg prod./kg d.wt.s.] 10 |  |

\* Corrected value derived by dividing the endpoint by a factor of 2 for substances with a logPow > 2 in accordance with the EPPO earthworm scheme 2002

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

Effects on earthworms

|  |  |  |  |
| --- | --- | --- | --- |
| Laboratory studies | | | |
| **Study type** | **Tested substance** | **Toxicity endpoint** | **Information on study** |
| **Acute toxicity** | Input 460 EC | 14 d/LC50 > 1000 mg/kg | Lechelt-Kunze,C. (2002) No: LKC/Rg 398/02 GLP, study accepted |
| **Reproduction toxicity** | Input 460 EC | NOEC = 32 mg/kg | Luhrs,U. (2002) No: 13531022 GLP, study accepted |
| **~~Acute toxicity~~** | ~~Prothioconazoole metabolite JAU 6476-desthio~~ | ~~LC50 > 1000 mg/kg~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| **~~Reproduction toxicity~~** | ~~Prothioconazoole metabolite JAU 6476-desthio~~ | ~~NOEC = 1.0 mg/kg~~ |
| **~~Acute toxicity~~** | ~~Prothioconazoole metabolite JAU 6476- S- metyl~~ | ~~LC50 > 1000 mg/kg~~ |

|  |  |
| --- | --- |
| ~~Semi-field and field tests~~ | ~~The performance of semi-field or field studies was not necessary due to the clarification of the risk based on laboratory studies~~ |

~~Effects on other soil macro-organisms~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ~~Laboratory studies~~ | | | | |
| ~~Study type~~ | ~~Species~~ | ~~Tested substance~~ | ~~Toxicity endpoint~~ | ~~Information on study~~ |
| ~~Reproduction toxicity, 28d~~ | *~~Folsomia candida~~* | ~~Prothiokonazole~~ | ~~NOEC mortality, reproduction > 64 mg/kg~~ | ~~Prothioconazole EFSA SC -Final~~  ~~12 07.2007~~ |
| ~~Reproduction toxicity, 34d~~ | *~~Hypoaspis aculeifer~~* | ~~Prothioconazole~~ | ~~NOEC mortality, reproduction > 100 mg/kg~~ |
| ~~Reproduction toxicity, 28d~~ | *~~Folsomia candida~~* | ~~JAU 6476- desthio~~ | ~~NOEC = 62.5 mg/kg~~ |
| ~~Reproduction toxicity, 28d~~ | *~~candida~~* | ~~JAU 6476- S- methyl~~ | ~~NOEC > 31.6 mg/kg~~ |
| ~~JAU 6476‑ desthio~~ | ~~NOEC > 64 mg/kg~~ |
| ~~JAU 6476- desthio~~ | ~~NOEC~~ ~~mortality>~~ ~~1000 mg/kg NOEC reproduction = 62.5 mg/kg~~ |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ~~Field studies~~ | | | | |
| ~~Study type~~ | ~~Time of testing~~ | ~~Tested substance~~ | ~~Toxicity endpoint~~ | ~~Information on study~~ |
| ~~Studies on the decomposition of organic matter "Litter bag"~~ | ~~126 d~~ | ~~Prothioconazole (formulation FS 100 (23.2 g a.s./ha replaced by the formulation EC250 (200g a.s./ha)~~ | ~~92 % decomposition after 126 days~~  ~~91.2% decomposition after 126 days (control)~~ | ~~Prothioconazole EFSA SC -Final~~  ~~12 07.2007~~ |

#### Justification for new endpoints

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The risk assessment of the effects of ULTRACENT 460 EC on non-target soil meso- and macrofauna was conducted using the EU agreed endpoints.

### Risk assessment

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~A risk assessment was carried out for the formulation of Input 460 EC and the prothioconazole metabolites. Acute toxicity values were divided by 2, due to the fact that the log Pow value for the active substance is greater than 2.~~

~~Risk assessment for earthworms~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **~~Organism~~** | **~~Tested substance~~** | **~~Toxicity endpoint~~** | **~~PECini (mg/kg soil)\*~~** | **~~TER~~** | **~~Limit value~~** |
| *~~Eisenia foetida~~* | ~~Input 460 EC~~ | ~~LC50 > 1000 mg/kg~~ | ~~0.66~~ | ~~>769~~ | ~~10~~ |
| *~~Eisenia foetida~~* | ~~Input 460 EC~~ | ~~NOEC = 32 mg/kg~~ | ~~0.66~~ | ~~22.4~~ | ~~5~~ |
| *~~Eisenia foetida~~* | ~~JAU 6476-desthio~~ | ~~LC50 > 1000 mg/kg~~ | ~~0.055~~ | ~~>909~~ | ~~10~~ |
| *~~Eisenia foetida~~* | ~~JAU 6476-desthio~~ | ~~NOEC = 1.0 mg/kg~~ | ~~0.055~~ | ~~9.1~~ | ~~5~~ |
| *~~Eisenia foetida~~* | ~~JAU 6476- S- methyl~~ | ~~LC50 > 1000 mg/kg~~ | ~~0.016~~ | ~~>31 250~~ | ~~10~~ |

~~\*PEC values calculated at a product density of Input 460 EC = 0.985 mg/cm3~~

~~The toxic exposure factors TERa and TERlt exceed the limit value. This means that the risk from acute and long-term exposure of earthworms to Input 460 EC is acceptable.~~

~~A risk assessment for other soil macro-organisms was carried out for prothioconazole and its metabolites JAU 6476-desthio JAU 6476- S- methyl.~~

~~It was not necessary to test the other active substance spiroxamine in this regard, as its DT90f value in soil varies between 100 and 365 days. In addition, the results for arthropods, earthworms and soil microorganisms do not indicate a threat to soil macrofauna and microfauna.~~

~~Risk assessment for other soil macro-organisms~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **~~Organism~~** | **~~Tested substance~~** | **~~Toxicity endpoint\*\*~~** | **~~PECmax (mg/kg soil)\*~~** | **~~TER~~** | **~~Limit value~~** |
| *~~Folsomia~~* | ~~prothioconazole~~ | ~~NOEC = 64 mg/kg~~ | ~~0.107~~ | ~~598~~ | ~~5~~ |
| *~~Hypoaspis~~* | ~~prothioconazole~~ | ~~NOEC> 100 mg/kg~~ | ~~0.107~~ | ~~934~~ | ~~5~~ |
| *~~Folsomia~~* | ~~JAU 6476-desthio~~ | ~~NOEC = 62.5 mg/kg~~ | ~~0.055~~ | ~~1136~~ | ~~5~~ |
| *~~Folsomia~~* | ~~JAU 6476- S- methyl~~ | ~~NOEC = 31.6 mg/kg~~ | ~~0.016~~ | ~~1975~~ | ~~5~~ |

~~\*PEC values calculated at a product density of Input 460 EC = 0.985 mg/cm3~~

~~The long-term toxic exposure factors TERlt for prothioconazole and its metabolites JAU 6476-desthio JAU 6476- S- methyl exceed the limit value.~~

~~Based on the above assessment, it can be concluded that the risk from acute and long-term exposure of other soil macro-organisms to Input 460 EC is acceptable.~~

~~The risk assessment carried out for earthworms and other soil macro-organisms indicates that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

#### First-tier risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for prothioconazole.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses.

Table 9.8‑2: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of ULTRACENT 460 EC in cereals

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use | Winter / spring cereals | | |
| Chronic effects on earthworms | | | |
| Product/active substance | NOECcorr  (mg/kg dw) | PECsoil  (mg/kg dw) | TERlt  (criterion TER ≥ 5) |
| JAU6476-desthio | 0.50 | 0.022 | 22.7 |
| JAU6476-S-methyl | 50 | 0.006 | >1000 |
| Metabolite KWG 4168-desethyl (M01) | 100 | ~~0.032~~ 0.033 | >1000 |
| Metabolite KWG 4168-N-oxide (M03) | 100 | 0.007 | >1000 |
| ULTRACENT (Input) 460 EC | 32 | 0.261 | 122.6 |
| Chronic effects on *Folsomia candida* | | | |
| Product/active substance | NOEC  (mg/kg dw) | PECsoil  (mg/kg dw) | TERlt  (criterion TER ≥ 5) |
| Prothioconazole | 32 | 0.043 | 744.2 |
| JAU6476-desthio | 31.25 | 0.022 | >1000 |
| JAU6476-S-methyl | 15.8 | 0.006 | >1000 |
| Spiroxamine | 32 | 0.082 | 395.1 |
| Metabolite KWG 4168-desethyl (M01) | 316 | 0.033 | >1000 |
| Metabolite KWG 4168-despropyl (M02) | 316 | 0.033 | >1000 |
| Input 460 EC | 10 | 0.261 | 38.3 |
| **Chronic effects on *Hypoaspis aculeifer*** | | | |
| Prothioconazole | 100 | 0.043 | >1000 |

TER values shown in bold fall below the relevant trigger.

#### Higher-tier risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Not required.

### Overall conclusions

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The TER calculations demonstrates that no unacceptable exposure of soil macro-organisms is to be expected and no unacceptable effects from the GAP use of ULTRACENT 460 EC to earthworms and other non-target soil organisms is to be expected.

|  |
| --- |
| **Review Comments:**  The long-term risks of ULTRACENT 460 EC to soil meso- and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PECsoil. The relevant predicted environmental concentrations in soil (PECsoil) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).  Safe use of ULTRACENT 460 EC in cereals (worst case exposure scenario) were confirmed based on TERLT calculations for active substances, their metabolites and for formulation. Based on it, safe use of ULTRACENT 460 EC in cereals (worst case exposure scenario) was identified. |

## Effects on soil microbial activity (KCP 10.5)

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

|  |  |  |
| --- | --- | --- |
| ~~Laboratory studies~~ | | |
| **~~Type of study Effect Information~~** ~~on study~~ | | |
| **~~Spiroxamine~~** | | |
| ~~Nitrogen transformation in the soil~~  ~~(clay loam, loamy sand)~~ | ~~No effects > 25 % were found at a dose of 7.5 l/ha form (EC 500) which corresponds to 3.75 kg a.s./ha~~ | ~~Spiroxamine 7584/VI/Final 22.5.99~~ |
| ~~Carbon transformation in the soil~~ | ~~No effects > 25 % were found at a dose of 7.5 l/ha form (EC 500) which corresponds to 3.75 kg a.s./ha~~ | ~~Spiroxamine 7584/VI/Final 22.5.99~~ |
| **~~Prothioconazole~~** | | |
| ~~Nitrogen transformation in the soil~~ | ~~No effects > 25 % were found at a dose of up to 2 kg a.s./ha~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| ~~Carbon transformation in the soil~~ | ~~No effects > 25 % were found at a dose of up to 2 kg a.s./ha~~ |
| **~~JAU 6476 –S-methyl~~** | | |
| ~~Nitrogen transformation in the soil~~ | ~~No effects > 25 % were found at a dose of up to 2 kg p.m./ha~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |
| ~~Carbon transformation in the soil~~ | ~~No effects > 25 % were found at a dose of up to 2 kg p.m./ha~~ |
| ~~JAU 6476-desthio~~ | | |
| ~~Nitrogen transformation in the soil~~ | ~~No effects > 25 % were found at a dose of up to 1 kg p.m./ha~~ | ~~Prothioconazole EFSA SC -Final 12 07.2007~~ |

Studies on effects soil microorganisms have been carried out with prothioconazole and spiroxamine and their respective metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of ULTRACENT 460 EC were not evaluated as part of the EU assessment of prothioconazole or of spiroxamine.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9‑1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

| Endpoint | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| N-mineralisation | Prothioconazole | 28 d, aerobic sandy loam soil | No effect at day 28 at 2 kg a.i./ha | EFSA scientific report (2007) 106, 1-98 |
| Prothioconazole-desthio | 28 d, aerobic sandy loam soil | No effect at day 28 at 0.2 kg and 1 kg p.m./ha |
| Prothioconazole-S-methyl | 28 d, aerobic sandy loam soil | No effect at day 28 at 2 kg p.m./ha |
| Spiroxamine | 28 d | No unacceptable effects at 7.5 kg a.i./kg soil dw | EFSA Journal 2010;8(10)1719 |
| KWG 4168-desethyl (M01) | 28 d | No unacceptable effects at 3.75 kg a.i../kg soil dw |

#### Justification for new endpoints

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Risk assessment

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~Risk assessment for soil microorganisms~~

|  |  |
| --- | --- |
| **~~spiroxamine~~** | |
| ~~Maximum application rate per surface area~~ | ~~0.3 kg a.s./ha~~ |
| ~~Tested dose applied with an effect of less than 25% C- and N-mineralisation compared to control value~~ | ~~(C- mineralisation) - 0.75 kg a.s./ha (N- mineralisation) – 0.75 kg a.s./ha~~ |
| **~~prothioconazole~~** | |
| ~~Maximum application rate per surface area~~ | ~~0.16 kg a.s./ha~~ |
| ~~Tested dose applied with an effect of less than 25% C- and N-mineralisation compared to control value~~ | ~~2.0 kg a.s./ha~~ |
| **~~JAU 6476-S-methyl~~** | |
| ~~Maximum application rate per surface area~~ | ~~PEC max = 0.016 µg/kg soil~~ |
| ~~Tested dose applied with an effect of less than 25% C- and N-mineralisation compared to control value~~ | ~~2.0 kg a.s./ha (which corresponds to 2.67 mg/ kg soil)~~ |
| **~~Jau 6476-desthio~~** | |
| ~~Maximum application rate per surface area~~ | ~~PEC max = 0.055 µg/kg soil~~ |
| ~~Tested dose applied with an effect of less than 25% C- and N-mineralisation compared to control value~~ | ~~(C- mineralisation) – 2.0 kg a.s./ha (which corresponds to 2.67 mg/ kg soil) (N- mineralisation) – 1.0 kg a.s./ha (which corresponds to 1.33 mg/kg soil)~~ |

~~In laboratory tests, both nitrogen mineralisation and respiration in both soils treated with the active substances and prothioconazole metabolites at doses exceeding the maximum PECs expected after application of Input 460 EC, showed no significant differences from these transformations occurring in untreated soil.~~

~~The risk assessment for soil microorganisms indicates that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for the soil microorganisms from all other intended uses.

Table 9.9‑2: Assessment of the risk for effects on soil micro-organisms due to the use of ULTRACENT 460 EC in cereals

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use | 1× 160~~0~~ g prothioconazole/ha  1× 300 g spiroxamine/ha | | |
| N-mineralisation | | | |
| Product/active substance | Max. conc. with effects ≤ 25 % (mg/kg dw) | PECsoil  (mg/kg dw) | Risk acceptable? |
| Prothioconazole | 2.71 | 0.043 | Yes |
| Prothioconazole-desthio | 1.37 | 0.022 | Yes |
| Prothioconazole-S-methyl | 2.69 | 0.006 | Yes |
| Spiroxamine | 10 | 0.082 | Yes |
| KWG 4168-desehtyl (M01) | 5 | 0.033 | Yes |

### Overall conclusions

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The evaluation of the risk for soil microorganisms was performed according to the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the intended GAP use, risk for soil microorganisms after exposure to ULTRACENT 460 EC is acceptable.

|  |
| --- |
| **Review Comments:**  ULTRACENT 460 EC, active substances and their metabolites had no significant effect on soil micro-organisms. This supports the conclusion that under field conditions, use of ULTRACENT 460 EC at the proposed rates poses no unacceptable risk to non-target soil micro-organisms. |

## Effects on non-target terrestrial plants (KCP 10.6)

### Toxicity data

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

Studies on the toxicity to non-target terrestrial plants have been carried out with prothioconazole and spiroxamine. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of ULTRACENT 460 EC were not evaluated as part of the EU assessment of prothioconazole or spiroxamine. No new data has been submitted with this application.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Species | Tested sinstamce | Study type | Maximum phytotoxicity effects in % | Information on study |
| *Amaranthus retroflexus* | Prothioconazole | before germination | 5 % for an application rate of 200 g a.s./ha | EFSA scientific report (2007) 106, 1-98 Prothioconazole EFSA SC -Final 12 07.2007 |
| *Amaranthus retroflexus Beta vulgaris* | Prothioconazole | after germination | 10 % for an application rate of 200 g a.s./ha |

|  |
| --- |
| **Review Comments:**  Based on the results of studies for both active substance, no herbicidal effect is expected. |

#### Justification for new endpoints

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Risk assessment

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

Risk assessment for terrestrial plants

(Annex C does not include assessment criteria for terrestrial plants)

The results of the preliminary biological studies and the results of the studies conducted in accordance with OECD guidelines indicate that Input 460 EC will not cause unacceptable impacts on neighbouring terrestrial plants.

#### Tier-1 risk assessment (based screening data)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

#### Tier-2 risk assessment (based on dose-response data)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

#### Higher-tier risk assessment

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

#### Risk mitigation measures

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Overall conclusions

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

## Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

## Monitoring data (KCP 10.8)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

## Classification and Labelling

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The risk assessment has shown that the use of Input 460 EC under the conditions proposed in the label - instructions requires the following risk management measures:~~

~~- in order to protect aquatic organisms it is necessary to define a protection zone at a distance of 20 m from bodies of water and watercourses~~

~~According to the criteria set out in the chemical substances and preparations legislation, Input 460 EC is classified as:~~

~~hazardous for the environment with the symbol N and the phrase R50/53 (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment)~~

~~Reason for classification:~~

~~The acute toxicity of the product to aquatic organisms was:~~

~~- fish LC50 > 6.57 mg/l~~

~~- aquatic invertebrates EC50 = 6.3 mg/l~~

~~- algae EC50 > 0.16 mg/l~~

~~The product is not classified for toxicity to bees due to the low risk demonstrated by the risk assessment.~~

~~The classification was made according to the Regulation of the Minister of Health of 2 September 2003 on the criteria and classification of chemical substances and preparations (Journal of Laws No. 171, item 1666 and Journal of Laws of 2004 No. 243, item 2440).~~

~~Proposed labelling of packaging~~

~~S60 Dispose of product and its container as hazardous waste~~

~~SP1 Do not contaminate water with the product or its container.~~

~~Spe3 In order to protect aquatic organisms it is necessary to define the protective zone at a distance of 20 meters from water reservoirs and watercourses.~~

~~Labelling was performed according to the Regulation of the Minister of Health on the labelling of hazardous substances and preparations (Dz. U. No. 173, item 1679 and Dz. U. No. 260, item 2595) of 2 September 2003.~~

~~Other label - instruction for use of Mospilan 20 SP~~

~~In the case of aquatic organisms, no risk management tools are required, including the use of buffer zones, however, according to Polish law, the buffer zone for the use of spraying equipment is 20 m, which should be included in the label of Axial 100 EC (Journal of Laws 2003, No. 11, item 94, Art. 77, paragraph 1, as amended),~~

~~It should also be included in the label that, for environmental protection reasons, plant protection products must not be used only in national parks and reserves, not in the buffer zones of national parks and reserves. In addition, it should be included in the label that the plant protection product should be applied at a distance of 20 m from apiaries, nature reserves, national parks, sites of plants under species protection and from the border of the inner protection area of the intermediate zone of water intakes (Journal of Laws 2003, No. 11, item 94, Art. 77, paragraph 1, as amended).~~

|  |
| --- |
| Classification and labelling of the product ULTRACENT 460 EC has been carried out applying the criteria outlined in the Regulation 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 for environmental hazards.  Taking into account all of the ecotoxicological data classification and labelling is:  Acute Category 1, Chronic Category 1  Signal word: Warning  GHS pictogram 09: Aquatic-pollut-red.gif  H410: Very toxic to aquatic life with long lasting effects  EUH401: To avoid risks to human health and the environment, comply with the instructions for use.  P391: Collect spillage/liquid.  P501: Dispose of contents/container in accordance with national regulations.  SP1: Do not contaminate water with the product or its container (Do not clean application equipment near surface water/ Avoid contamination via drains from farmyards and roads) |

1. Lists of data considered in support of the evaluation

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP 10.2  IIA 8.2.5 Addendum | Anonymous | 2014 | Zebrafisch (*Danio rerio*), full life cycle test under static conditions in a water sediment system - Test item: spiroxamine  Doc ID: BAY-033/4-61/A  GLP  Not published | Y | BAY |
|  |  |  |  |  |  |

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

List of data relied on not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| I A, 10.1 /02 | Mooij, J. H. | 1998 | Goose damage to grassland and winter cereals by white-fronted and bean geese (Anser albifrons and A. fabalis) in the lower rhine area, Germany  Die Vogelwarte, Wesel, Germany  Publisher:Biologische Station im Kreis Wesel,  Year:1998,  Journal:Die Vogelwarte, Volume:39, Pages:264-280, Report No.: REG01-0044, Date: 1998-12-31  Non-GLP  Published | N |  |
| I A, 10.1 /04 | Cramp | 1998 | The complete birds of the western palearctic - selected chapters about the following specie: Wren – Troglodytes troglodytes Publisher:Oxofrd University Press, Location:Oxford,  Year: 1998,  Journal: The complete Birds of the Western Palearctic on CD-ROM, Volume:CD 1,  Raport No: MO-03-011989,  Date: 1998-12-31  Non-GLP  Published | N |  |
| I A, 10.1 /07 | Christensen, K. D.; Falk, K.; Petersen, B. S. | 1996 | Feeding biology of danish farmland birds  Publisher:Ministry of Environment and Energy, Location:Kopenhagen, Denmark,  Year: 1996,  Journal: Working Report, Volume:12, Pages:1-69, Report No: Lit. 2627,  Date: 1996-12-31  Non-GLP  Published | N |  |
| I A, 10.1 /09 | Middleton, A.D.;Chitty, H. | 1937 | The food of adult partridges, Perdix perdix and Alectoris rufa in Great Britain  Year: 1937,  Journal:Journal of Animal Ecobiology, Volume:6, Pages:322-336,  Report no.: MO-03-011985,  Date: 1937-12-31  Non-GLP  Published | N |  |
| I A, 10.1 /10 | Wilson, J.D.; Taylor, R.; Muirhead, L.B | 1996 | Field use by farmland birds in winter: an analysis of field type preferences using resampling methods  Publisher:British Trust for Ornithology,  Location:Great Britain, Year:1996,  Journal: Bird Study, Volume:43, Pages: 320-332,  Report no.: MO-03-011957, Date: 1996-05-03  Non-GLP  Published | N |  |
| I A, 10.1 /11 | Church, K.E. | 1994 | Summer habitat use of 23 radio-tagged grey partridge (Peridx perdix) in New York State, USA  Year: 1994,  Journal: Gibier Faune Sauvage Game Wildl., Volume: 11, Issue: 2, Pages:145-153,  Report no.: MO-03-011955,  Date: 1994-06-30  Non-GLP  Published |  |  |
| I A, 10.1 /12 | Buxton, J. M.; Crocker, D. R. | 1996 | Milestone report: Birds and farming: information for risk assessment Central Science Laboratory, Slough, Great Britain  Year: 1996,  Report no.: R-1031,  Date: 1996-01-01  Non-GLP  Published |  |  |
| I A, 10.1 /13 | Rands, M.R.W. | 1985 | The survival of gamebird (Galliformes) chicks in relation to pesticide use on cereals  Year:1985,  Journal: Ibis, Volume:128, Pages: 57-64,  Report no.: Lit. 07863,  Date: 1985-07-05  Non-GLP  Published |  |  |
| I A, 10.1 /14 | Heinemann, O. E. Elke | 2001 | Determination of residues of JAU 6476-Desthio & KWG4168 on spring barley following spray application of JAU 6476&KWG 4168 460 EC in Germany, France and Great Britain Bayer CropScience AG,  Report no.: RA-2096/00,  Date: 2001-12-07  GLP  Unpublished | N | BCS |
| I A, 10.1 /15 | Hall, A. T.; Duah, F. K. | 2002 | JAU 6476 480 SC - Magnitude of residue in/on wheat forage, a potential wildlife feed item  Bayer Corporation, Stilwell, KS, USA  Bayer CropScience AG,  Report no.: 111032,  Date: 2002-02-26  GLP  Unpublished | N | BCS |
| I A, 10.1 /16 | Heinemann, O. E. Elke | 2001 | Determination of residues of JAU 6476-Desthio & KWG4168 on spring barley following spray application of JAU 6476&KWG 4168 460 EC in Germany, France and Great Britain and Italy  Bayer CropScience AG,  Report no.: RA-2092/00,  Date: 2001-11-28  GLP  Unpublished | N | BCS |
| I A, 10.2.1 /01 |  | 2002a | Acute toxicity of JAU 6476 & Spiroxamine EC 460 to fish (Oncorhynchus mykiss)  Bayer AG, Leverkusen, Germany  Bayer CropScience AG,  Report No.: DOM 21059,  Date: 2002-02-05  GLP  Unpublished | Y | BCS |
| I A, 10.2.1  /02 | Dorgerloh, M.; Sommer, H. | 2002b | Acute toxicity of JAU 6476 EC 160 & spiroxamine 300 to water fleas (Daphnia magna)  Bayer AG, Leverkusen, Germany  Bayer CropScience AG,  Report no.: DOM 22017,  Date: 2002-06-03  GLP  Unpublished | N | BCS |
| I A, 10.2.1  /03 | Baetscher, R. | 2002a | Toxicity of JAU 6476 & KWG 4168 EC 460 to Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum) in a 72-hour algal growth inhibition test RCC Ltd., Itingen, Switzerland  Bayer CropScience AG,  Report no.: 841378,  Date: 2002-08-15  GLP  Unpublished | N | BCS |
| I A, 10.2.1  /04 | Baetscher, R. | 2002b | Toxicity of JAU 6476 & KWG 4168 EC 460 to the aquatic higher plant Lemna gibba (duckweed) in a 7-day semistatic growth inhibition test RCC Ltd., Itingen, Switzerland  Bayer CropScience AG,  Report no.: 841376,  Date: 2002-08-15  GLP  Unpublished | N | BCS |
| I A, 10.3 /01 | Kroetlinger, F. | 2001 | JAU 6476 160 EC & KWG 4168 300 (c.n.: --; Spiroxamine) - Study for acute oral toxicity in rats  Bayer AG, Wuppertal, Germany  Bayer CropScience AG,  Report no.: 31560,  Date: 2001-12-03,  GLP  Unpublished | Y | BCS |
| I A, 10.3 /02 | Niethammer, J.; Krapp, F. | 2001 | Microtus arvalis (Pallas, 1779) - Feldmaus  Publisher:Akademische Verlagsgesellschaft, Wiesbaden,  Year: 1982,  Journal:Handbuch der Säugetiere Europas, Issue:2/1, Pages:284-318,  Report no.: MO-01-015395, Date: 2001-08-17  Non-GLP  Published | N |  |
| I A, 10.3 /03 | Giraudoux, P.; Delattre, P.; Quéré, J.-P.; Damange, J.-P | 1994 | Structure and kinetics of rodent populations, in a region under agricultural land abandonment  Publisher:Gauthier-Villars,  Location: Frankreich,  Year: 1994,  Journal: Acta Ecologica, Volume:15, Issue:4, Pages:385-400,  Report no.: MO-03-012335,  Date: 1994-12-31  Non-GLP  Published | N |  |
| I A, 10.3 /04 | Delattre, P., Giraudoux, P., Baudry, J., Quere, J. P., Fichet, E. | 1996 | Effect of landscape structure on common vole (Microtus arvalis) distribution and abundance at several space scales  Publisher: SPB Academic Publishing,  Location: Amsterdam,  Year: 1996,  Journal: Landscape Ecology, Volume:11, Issue:5, Pages:279-288,  Report no.: MO-03-011736,  Date: 1996-12-31  Non-GLP  Published | N |  |
| I A, 10.3 /05 | Butet, A.; Leroux, A, | 1994 | Spatial and temporal density fluctuations in common vole populations in a marsh in Western France  Year:1994,  Journal: Polish ecological Studies, Volume:20, Issue:3-4, Pages:137-146,  Report no.: MO-03-011944,  Date: 1994-12-31  Non-GLP  Published | N |  |
| I A, 10.3 /06 | Ryszkowski, L.; Goszczynski,  J.;  Truszkowski, J. | 2001 | Trophic relationship of the common vole in cultivated fields  Year: 1973,  Journal: Acta Theriologica, Volume:18, Issue:7, Pages:125-165,  Report no.: MO-01-015497,  Date: 2001-08-20  Non-GLP  Published | N |  |
| I A, 10.3 /07 | Truszkowski, J. | 2001 | The impact of the common vole on the vegetation of agroecosystems  Year: 1982,  Journal: Acta Theriologica, Volume:27, Issue:23, Pages:305-345,  Report no.: MO-01-015227,  Date: 2001-08-15  Non-GLP  Published | N |  |
| I A, 10.3 /08 | Butet, A.; Leroux, B.A. | 2001 | Effects of agriculture development on vole dynamics and conservation of Montagu's harrier in western French wetlands  Publisher:Elsevier Science Ltd.,  Location:Great Britain,  Year: 2001,  Journal: Biological Conservation, Volume:100, Pages:289-295,  Report Nr.: MO-03-012069,  Date: 2001-12-31  Non-GLP  Published | N |  |
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1. Detailed evaluation of the new studies

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

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