|  |
| --- |
| FINAL REGISTRATION REPORT  Part B  Section 8  Environmental Fate  Detailed summary of the risk assessment |
| Product code: SAP250F  Product name(s): **Dyllis** (prev. INDOFIL Prothio 250 EC)  Chemical active substance:  Prothioconazole, 250 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT |
| Applicant: Indofil Industries (Netherlands) BV  Submission date: 30/04/2021  MS Finalisation date: 08/2022; 02/2023; 05/2024; 07/2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| April 2021 | V0 - Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009. |
| August 2022 | zRMS first assessment |
| February 2023 | zRMS assessment after commenting |
| April 2024 | Applicant updates addresing evaluator’s comment about buffer zone |
| May, July 2024 | zRMS assessment new PECsw calculations |

Table of Contents

[8 Fate and behaviour in the environment (KCP 9) 4](#_Toc75164753)

[8.2 Metabolites considered in the assessment 9](#_Toc75164754)

[8.3 Rate of degradation in soil (KCP 9.1.1) 9](#_Toc75164755)

[8.3.1 Aerobic degradation in soil (KCP 9.1.1.1) 10](#_Toc75164756)

[8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1) 11](#_Toc75164757)

[8.4 Field studies (KCP 9.1.1.2) 11](#_Toc75164758)

[8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) 12](#_Toc75164759)

[8.4.2 Soil accumulation testing (KCP 9.1.1.2.2) 13](#_Toc75164760)

[8.5 Mobility in soil (KCP 9.1.2) 13](#_Toc75164761)

[8.5.1 Column leaching (KCP 9.1.2.1) 14](#_Toc75164762)

[8.5.2 Lysimeter studies (KCP 9.1.2.2) 15](#_Toc75164763)

[8.5.3 Field leaching studies (KCP 9.1.2.3) 15](#_Toc75164764)

[8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) 15](#_Toc75164765)

[8.7 Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3) 17](#_Toc75164766)

[8.7.1 Justification for new endpoints 17](#_Toc75164767)

[8.7.2 Active substance(s) and relevant metabolite(s) 17](#_Toc75164768)

[8.7.2.1 PECsoil of SAP250F 19](#_Toc75164769)

[8.8 Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4) 21](#_Toc75164770)

[8.8.1 Justification for new endpoints 21](#_Toc75164771)

[8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1) 21](#_Toc75164772)

[8.9 Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5) 26](#_Toc75164773)

[8.9.1 Justification for new endpoints 26](#_Toc75164774)

[8.9.2 Active substance(s), relevant metabolite(s) (KCP 9.2.5) 26](#_Toc75164775)

[8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1) 41](#_Toc75164776)

[Appendix 1 Lists of data considered in support of the evaluation 42](#_Toc75164777)

[Appendix 2 Additional PECsw and PECsed values using alternative substance inputs 43](#_Toc75164778)

# Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product SAP250F an emulsifiable concentrate formulation containing 250 g/L Prothioconazole for use on wheat, barley, oat, rye, triticale and oilseed rape. Prothioconazole was first included in Annex I to Directive 91/414/EEC by Commission Directive 2008/44/EC of 4 April 2008.

A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of Prothioconazole. This will be where:

• the active substance data are relied upon in the risk assessment of the formulation; or when

• the EU review concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

This product was not the representative formulation and has not been previously evaluated according to the Uniform Principles.

The EFSA Scientific report for prothioconazole (EFSA Scientific Report, 2007) is considered to provide the relevant review information or a reference to where such information can be found.

The Commission Implementing Regulation for prothioconazole (540/2011) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the operator safety in spray applications. Conditions of use shall include adequate protective measures,

— the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,

— the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

Conditions of use shall include risk mitigation measures, where appropriate.

Information on the detailed composition of SAP250F can be found in the confidential dossier of this submission (Registration Report – Part C).

* 1. **Critical GAP and overall conclusions**

**Table 8.2‑1:** **Table of critical GAPs**

|  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No. \*** | **Member state(s)** | **Crop and/ or situation**  (crop destination / purpose of crop) | **F, Fn, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max) | 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 | Groundwater |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | |
| 1 | DE, AT, UK, IE, NL, BE, CZ, SI,  PL  SK, HU, RO | Wheat (winter and spring) | F | Septoria leaf spot (Septoria tritici/Mycosphaerella gramincola) Brown Rust (Puccinia triticina) Yellow Rust (Puccinia striiformis) Ear blight (Fusarium spp.)  Powdery mildew (Erysiphe graminis) Eyespot (Oculimacula spp.)  Tan Spot (Drechslera tritici-repentis) Septoria nodorum | foliar spray | BBCH 25-69 | 3 | 14 | a) 0,8 b) 2.4 | a) 200 b) 600 | 150-400 | NA |  | A |
| 2 | DE, AT, UK, IE, NL, BE, CZ, SI,  PL  SK, HU, RO | Barley (spring and winter) | F | Ramularia (Ramularia collo-cygni) Leaf blotch (Rhynchosporium secalis)  Net blotch (Pyrenophora teres) Dwarf Rust (Puccinia hordei) Spot blotch (Helminthosporium) Powdery mildew (Erysiphe graminis) Fusarium spp. | foliar spray | BBCH 25-69 | 2 | 14 | a) 0,8 b) 1,6 | a) 200 b) 400 | 150-400 | NA |  | A |
| 3 | DE, AT, UK, IE, NL, BE, CZ, SI,  PL  SK, HU, RO | Triticale | F | Leaf Spot (Mycosphaerella graminicola) Brown Rust (Puccinia recondita) Septoria (Septoria tritici) Powdery mildew (Erysiphe graminis) Groundbreak Disease (Pseudocercosporella herpotrichoides) | foliar spray | 25 - 69 (From beginning of spring at infestation or when the first symptoms become visible) | 3 | 14 | a) 0,8 b) 2.4 | a) 200 b) 600 | 150-400 | NA |  | A |
| 4 | DE, AT, UK, IE, NL, BE, CZ, SI,  PL  SK, HU, RO | Rye | F | Leaf Blotch (Rhynchosporium secalis) Brown Rust (Puccinia recondita) Powdery mildew (Erysiphe graminis) Eyespot (Oculimacula spp.) Glume Blotch (Leptosphaeria (syn. Septoria) nodorum) Leaf Spot (Mycosphaerella graminicola) | foliar spray | BBCH 25-69 | 3 | 14 | a) 0,8 b) 2.4 | a) 200 b) 600 | 150-400 | NA |  | A |
| 5 | DE, AT, UK, IE, NL, BE, CZ, SI,  PL  SK, HU, RO | Oats | F | Leaf Spot (Mycosphaerella graminicola) Brown Rust (Puccinia recondita) Septoria spp. Powdery mildew (Erysiphe graminis) Groundbreak Disease (Pseudocercosporella herpotrichoides), | foliar spray | BBCH 25-69 | 2 | 14 | a) 0,8 b) 1,6 | a) 200 b) 400 | 150-400 | NA |  | A |
| 6 | DE, AT, UK, IE, NL, BE, CZ, SI,  PL  SK, HU, RO | Oilseed Rape | F | Sclerotinia stem rot (Sclerotinia sclerotiorum) Phoma leaf spot / Stem canker (Leptosphaeria maculans / L. biglobosa) Alternaria brassicae Powdery mildew (Erysiphe cruciferarum) Mycosphaerella Cylindrosporiose Light leaf spot (Pyrenopeziza brassicae) | foliar spray | BBCH 20-80 | 2 | 14-21 | a) 0,7 b) 1,4 | a) 175 b) 350 | 150-400 | 56 |  | 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 “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 heading:** | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| **Remarks**  **columns:** | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when 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 |

## zRMS comments:

## All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency. Updateds are presented in yellow.

## Metabolites considered in the assessment

Table 8.2‑1: Metabolites of Prothioconazole found in soil, water and sediment

| Metabolite | Molar mass | Chemical structure | Maximum observed occurrence in compartments | Exposure assessment required due to |
| --- | --- | --- | --- | --- |
| M01:  JAU 6476-S methyl  Prothioconazole-S-Methyl  CAS 178928-71-7 | 358.3 |  | Soil:  13,7% AR (phenyl )  14,6% AR ( triazole)  Sediment: 77.0% AR, day 240 | PECsoil  PECgw  PECsw |
| M04:  JAU 6476-desthio  Prothioconazole-desthio  CAS 120983-64-4 | 312.2 |  | Soil: 49.4% AR, day 7  Water: 55.7% AR, day 11(aq photolysis); 32.3% day 7 (water/sediment)  Sediment: 26.9% AR, day 14 | PECsoil  PECgw  PECsw |
| M12:  Prothioconazole-thiazocine | - |  | Water: 14.1% AR, day 5 under photolysis conditions | PECsw |
| M13:  1,2,4-triazole | 69.1 |  | Water: 11.9% AR, day 18 (aq photolysis)  Water/Sedminent: 32.7%  (triazole) maks.  0,8 – 37,2 % AR, 59 – 121 dn | PECsw |

## Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Rate of degradation studies of the active substance in soil are discussed in detail in the corresponding documents of the EU review dossiers (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

### Aerobic degradation in soil (KCP 9.1.1.1)

The aerobic route of degradation of phenyl-UL-14C and 3,5-triazole-14C labelled prothioconazole was investigated in four different soils at 20 ºC and 48-49% maximum water holding capacity (MWHC) under dark conditions. The soils covered a range of pH values (5.9-7.2), clay contents (5.0-39.6%) and organic carbon contents (0.79-2.14%).

Two additional laboratory studies were performed to investigate the aerobic degradation of the major metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04), under dark conditions at 20 ºC with four soils. By the end of the study (125 and 120 days) the maximum levels of M01 and M04 detected were in the range 2.5%-18.6% AR and 2.3%-20.4% AR, respectively.

Table 8.3‑1: Summary of aerobic degradation rates for Prothioconazole - laboratory studies

| Prothioconazole, Laboratory studies, aerobic conditions | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) 20°C | DT90 (d) | r2 | Kinetic model | Evaluated on EU level y/n/  Reference |
| Laacher Hof | Sandy loam | 7.2 | 20 | 48 | 0.07 | 5.3 | 1.000 | FOMC | Yes  Gilges, M. (2000, rev. 2001) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Stanley | Silty clay loam | 5.9 | 20 | 48 | 0.70 | 78.2 | 0.989 | FOMC |
| Höfchen | Silt | 7.1 | 20 | 49 | 0.30 | 0.99 | 0.99 | SFO | Yes  Hellpointner, E. (2001b) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Byromville | Loamy sand | 6.8 | 20 | 65 | 1.27 | 4.22 | 0.981 | SFO |
| Geometric mean/Median (n=4) | | | | | **0.37** / 0.50 | | | | |
| pH-dependency: y/n | | | | | No | | | | |

Bold values were used in modelling

Table 8.3‑1: Summary of aerobic degradation rates for Prothioconazole-S-methyl (M01) - laboratory studies

| Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) 20°C | **DT90 (d)** | r2 | Kinetic model | Evaluated on EU level y/n/ Reference |
| Höfchen | Loamy silt | 7.3 | 20 | 40 | 5.9 | 19.6 | 0.97 | SFO | Yes  Gilges, M. (2001a) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Laacher Hof AIII | Loamy Silt | 7.9 | 20 | 40 | 27.2 | 90.2 | 0.955 | SFO |
| Laacher Hof AXXa | Sandy loam | 7.2 | 20 | 40 | 8.2 | 27.2 | 0.959 | SFO |
| Stanley | Silty clay | 6.3 | 20 | 40 | **46.0** | 153 | 0.965 | SFO |
| Geometric mean/Median (n=4) | | | | | **15.7** / 17.7 | | | | |
| pH-dependency: y/n | | | | | No | | | | |

Bold values were used in modelling

Table 8.3‑3: Summary of aerobic degradation rates for Prothioconazole-desthio (M04) - laboratory studies

| Prothioconazole-desthio (M04), Laboratory studies, aerobic conditions | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) 20°C | **DT90 (d)** | r2 | Kinetic model | Evaluated on EU level y/n/ Reference |
| Höfchen | Loamy silt | 7.3 | 20 | 40 | 34 | 113 | 0.820 | SFO | Yes  Gilges, M. (2001b) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Laacher Hof AIII | Loamy silt | 7.9 | 20 | 40 | 29.6 | 98.3 | 0.987 | SFO |
| Laacher Hof AXXa | Sandy loam | 7.2 | 20 | 40 | 7.0 | 23.2 | 0.985 | SFO |
| Stanley | Silty clay | 6.3 | 20 | 40 | 18.6 | 61.9 | 0.979 | SFO |
| Geometric mean/Median (n=4) | | | | | **19.03** / 24.1 | | | | |
| pH-dependency: y/n | | | | | No | | | | |

Bold values were used in modelling

### Anaerobic degradation in soil (KCP 9.1.1.1)

Anaerobic degradation in soil of the active substance prothioconazole was not investigated (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

## Field studies (KCP 9.1.1.2)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

### Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Field dissipation of prothioconazole has been investigated in eight studies at different sites in northern Europe (Germany, Great Britain and France) and southern Europe (France, Italy). Four of the sites were not cropped and the remaining four were sown with spring barley just prior to the application of the test substance directly to the soil surface.

Analyses from each site were conducted on samples from depths up to 50cm. Soil residues were restricted to the top 10cm soil horizon. Neither prothioconazole nor the two metabolites M01 and M04 were detected below this soil layer at any sampling interval in any study.

The maximum levels of prothioconazole detected in the 0-10 cm soil layer were in the range 35.5-70.3 μg/kg and the maximum levels of the metabolite prothioconazole-desthio in the top 10cm horizon were in the range 30.4 – 67.8 μg/kg. The first order half-lives obtained from the field studies were 1.3-2.8 days for prothioconazole, and 16.3-72.3 days for M04.

The metabolite M01 was not detected above the LOQ in any study and was not consider, primally, to be a major metabolite under field conditions. The need for predicted environmental concentration (PEC) in soil for this metabolite was discussed in a meeting of experts (PRAPeR 02). It was agreed that even if the detection limit in the field studies did pick up the metabolite at levels below the LOQ (6 μg/kg), the LOQ (2 μg/kg) was only about 10% relative to the initial concentration of prothioconazole in the field studies. Therefore, it was concluded that the analytical method was not appropriate to measure M01 concentrations in the field studies, and consequently, an exposure assessment for M01 was required.

Table 8.4‑1: Summary of aerobic degradation rates for prothioconazole - field studies

| Prothioconazole, Field studies | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DT50  20ºC | r2 | Evaluated on EU level y/n/  Reference |
| Silt loam | Höfchen (bare soil) | 6.25 | 50 | 1.2 | 1.000 | Yes  Schramel (2001a) and Schad (2001c) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Sandy clay loam | Elm Farm (bare soil) | 7.56 | 50 | 0.8 | 0.999 |
| Silt | l’Archeveque (bare soil) | 6.42 | 50 | **1.6** | 0.995 |
| Sandy clay loam | Elm Farm (cropped) | 7.56 | 50 | 1.4 | 0.997 |
| Silt | l’Archeveque (cropped) | 6.42 | 50 | **1.6** | 0.998 |
| Silt loam | St. Etienne du Gres (cropped) | 7.61 | 50 | 1.1 | 1.000 |
| Sandy loam | Di Nogarole Rocca (cropped) | 7.56 | 50 | 1.5 | 0.999 |
| Sandy loam | Laacherhof (bare soil) | 6.32 | 50 | 0.6 | 1.000 |
| Geometric mean (n=8) | | | | **1.2** | | |
| pH-dependency y/n | | | | No | | |

Bold values were used in modelling

Table 8.4‑2: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - field studies

| Prothioconazole-desthio (M04), Field studies | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DT50  20ºC | r2 | Evaluated on EU level y/n/  Reference |
| Silt loam | Höfchen (bare soil) | 6.25 | 50 | 10.3 | 0.994 | Yes  Schramel (2001a) and Schad (2001c) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Sandy clay loam | Elm Farm (bare soil) | 7.56 | 50 | 27.0 | 0.978 |
| Silt | l’Archeveque (bare soil) | 6.42 | 50 | 27.5 | 0.859 |
| Sandy clay loam | Elm Farm (cropped) | 7.56 | 50 | 23.4 | 0.939 |
| Silt | l’Archeveque (cropped) | 6.42 | 50 | 20.1 | 0.859 |
| Silt loam | St. Etienne du Gres (cropped) | 7.61 | 50 | **61.9** | 0.969 |
| Sandy loam | Di Nogarole Rocca (cropped) | 7.56 | 50 | 20.7 | 0.951 |
| Sandy loam | Laacherhof (bare soil) | 6.32 | 50 | 15.2 | 0.996 |
| Geometric mean (n=8) | | | | **22.7** | | |
| pH-dependency y/n | | | | No | | |

Bold values were used in modelling

### Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation of the active substance prothioconazole was not investigated (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

## Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Mobility in soil are discussed in detail in the corresponding documents of the EU review dossiers (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

Adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, the distribution of prothioconazole in an aged column leaching study was used to estimate Kd and Koc values.

Adsorption/desorption of prothioconazole-S-methyl (M01) and prothioconazole–desthio (M04) were investigated by batch equilibrium experiments in four soils. The calculated adsorption Koc for M01 was in the range 1973.6 – 2995.0 mL/g, and for M04, the calculated adsorption Koc was in the range 523.0 – 625.3 mL/g (slightly mobile). Based on the agreed (PRAPeR experts’’ meeting 12) list of end points for 1,2,4-triazole, the Kfoc values for this minor soil metabolite of prothioconazole are in the range of 43-202 mL/g (n=4).

Table 8.5‑1: Summary of soil adsorption/desorption for prothioconazole-S-methyl (M01)

| Prothioconazole-S-methyl (M01) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level y/n/ Reference |
| Laacher Hof AXXa | Sandy loam | 2.02 | 7.2 | 56.0 | 2772.4 | 0.87 | Yes  Hein (1999) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Höfchen | Silt | 2.14 | 7.1 | 64.1 | 2995.0 | 0.88 |
| Stanley | Silty clay loam | 1.66 | 5.9 | 41.2 | 2484.0 | 0.91 |
| Byromville | Loamy sand | 0.79 | 6.8 | 15.6 | 1973.6 | 0.85 |
| Geometric mean (n=4) | | | | | **2525.9** | - |  |
| Arithmetic mean (n=4) | | | | | 2556.3 | **0.88** |  |
| pH-dependency y/n | | | | | No | | |

Bold values were used in modelling

Table 8.5‑2: Summary of soil adsorption/desorption for prothioconazole-desthio (M04)

| Prothioconazole-desthio (M04) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH | Kd  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level y/n/ Reference |
| Laacher Hof AXXa | Sandy loam | 2.02 | 7.2 | 56.0 | 616.8 | 0.79 | Yes  Fent (1998) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Höfchen | Silt | 2.14 | 7.1 | 64.1 | 625.3 | 0.83 |
| Stanley | Silty clay loam | 1.66 | 5.9 | 41.2 | 536.4 | 0.83 |
| Byromville | Loamy sand | 0.79 | 6.8 | 15.6 | 523.0 | 0.80 |
| Geometric mean (n=4) | | | | | **573.5** | - |  |
| Arithmetic mean (n=4) | | | | | 575.4 | **0.81** |  |
| pH-dependency y/n | | | | | No | | |

Bold values were used in modelling

### Column leaching (KCP 9.1.2.1)

The distribution of prothioconazole in an aged column leaching study (Reigner, 1999; DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)) was used to estimate Kd and Koc values. Phenyl-UL-14C radiolabelled prothioconazole was applied on a loamy sand soil and incubated at 20ºC under aerobic conditions for 30 hours. The resulting values for prothioconazole were Kd = 15.2 and **Koc =** **1765 mL/g** (slightly mobile compound). At the end of the study, the extracted radioactivity was composed of 22.7% unchanged parent compound, the known metabolites from the soil metabolism study M04 (31.8% AR), M01 (8.1% AR) and prothioconazole-sulfonic acid (M02) (1.5%). The total radioactivity in the leachate accounted for only 1.1% AR of the applied radioactivity, and in the leachate fraction a radioactivity content of < 0.2% of the applied radioactivity was measured.

The leaching behaviour of phenyl-UL-14C radiolabelled prothioconazole was further investigated in a non-aged soil column leaching study (Babczinski, 2001; DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)) on four soils. The level of radioactivity detected in the leachates was < 1% AR in all samples. Therefore, the leachate fractions were not analysed. The majority of the residue of the active substance was detected in the top 6 cm layer (14.6-40.7% AR in 0-6 cm layer, not detected in the 6-12 cm layer), this also being the case for the metabolites prothioconazole-Smethyl (5.5-11.2% AR in the 0-6 cm layer, not detected in the 6-12 cm layer) and prothioconazoledesthio (15.4-28.0% AR in the 0-6 cm layer, not detected in the 6-12 cm layer).

No column leaching studies with metabolites were performed.

### Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies are not required for Prothioconazole since no leaching is expected.

### Field leaching studies (KCP 9.1.2.3)

Field leaching studies are not required for Prothioconazole since no leaching is expected.

## Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Degradation in the water/sediment systems are discussed in detail in the corresponding documents of the EU review dossiers (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

The behaviour of prothioconazole in two different water/sediment systems was investigated under aerobic conditions in the dark at 20ºC. Two radiolabelled compounds, [phenyl-UL-14C] and [3,5- triazole-14C] prothioconazole were used as test substances. A proportion of the active substance partitioned quite rapidly into the sediment, with maximum levels of prothioconazole reaching 22.6% to 23.4% AR in the sediment on day 1 and decreased at the study end (3.3-6.8% AR and 3.4-9.5% AR after 121 days). The amount of the unextracted residues increased significantly during the course of the study. More than 12 metabolites were formed and five of them were identified. Major metabolites in water were prothioconazole-desthio M04 (maximum = 32.3% AR by day 7) and 1,2,4-triazole M13 (maximum = 37.2% AR by day 121). The high levels of metabolite M13 were observed in only one of the systems. In the sediment extracts, M04 was the only major metabolite (maximum = 26.9% AR by day 14).

Table 8.6‑1: Summary of degradation in water/sediment of Prothioconazole (laboratory studies)

| Water/sediment system | pH  water/sed. | DT50 water  (d) | DT50  whole system  (d) | DT90 water  (d) | DT90  whole system  (d) | r2 | Method of calculation | Evaluated on EU level y/n/ Reference |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hönniger Weiher (Pond system) | 7.84/6.6 | 0.8 | - | 2.7 | - | 0.947 | SFO | Yes  Brumhard and Oi (2001, amended 2002) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| - | 2.8 | - | 76.4 | 0.953 | Bi-phasic (‘Hockey Stick’) |
| Angler Weiher (Lake System) | 7.45/8.5 | 1.0 | - | 3.4 | - | 0.999 | SFO |
| - | 1.6 | - | 23.6 | 0.998 | Bi-phasic (‘Hockey Stick’) |
| Geometric mean (n=4) | | - | **2.1** | - | - | - | - | - |

Bold values were used in modelling

An aqueous photolysis study was conducted. Continuous exposure was used. The degradation of prothioconazole in the dark control samples demonstrated that photolysis was the main process of degradation.

Prothioconazole-desthio (M04) was identified as the main photolytic degradation product (max. 56% AR). Other two major degradation products were identified as prothioconazole-thiazocine (M12) at 14% AR and 1,2,4-triazole (M13) at 12% AR.

The anaerobic degradation of prothioconazole was investigated in an anaerobic water/sediment system was conducted. The amounts of 14CO2 and organic volatile radioactive substances were very low (< 0.1% AR throughout the study). Prothioconazole-S-methyl (M01) was identified as major metabolite in the sediment (maximum 77.0% AR by day 240).

Table 8.6‑2: Summary of observed metabolites

|  |  |  |
| --- | --- | --- |
| **Substance** | **Maximum observed** | **Evaluated on EU level y/n/ Reference** |
| Prothioconazole -desthio (M04) | Max. in water, 55.7 % after 11 d  Max. in sediment 26.9 % after 14 d | Yes  Gilges and Bornatsch (2001) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |
| Prothioconazole-thiazocine (M12) | Max. in water, 14.1 % after 5 d |
| 1,2,4-triazole (M13) | Max. in water, 11.9 % after 18 d |
| Prothioconazole-S-methyl (M01) | Max. in sediment 77.0 % after 240 d | Yes  Scholz (2001) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005) |

## Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3)

### Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registration.

### Active substance(s) and relevant metabolite(s)

The predicted environmental concentrations in soil were calculated for the active substance prothioconazole and its metabolites, according to recommendations by the “FOCUS” group (FOCUS report, 29.02.1997). Calculations were based on a simple first tier approach (Excel sheet). Crop interception data, which correspond to the intended growth stages, were taken from the EFSA Journal 2014; 12(5):3662. The maximum PECsoil values will be used in the ecotoxicological risk assessment.

The input parameters used for PECsoil calculation are described in Table 8.7-1.

Table 8.7‑1: Input parameters related to application for PECsoil calculations

|  |  |  |
| --- | --- | --- |
| Use No. | 1, 2, 3, 4 and 5 | 6 |
| Crop | Cereals (Winter and Spring) | Oilseed Rape (Winter and Spring) |
| Application rate (g as/ha) | 200 | 175 |
| Number of applications/interval | 3 / 14 days | 2 / 14 days |
| Crop interception (%) | 20 (BBCH 25-69) | ~~20~~  80 (BBCH 20-80) |
| Depth of soil layer (cm) | 5 | |

Since cereals use have the lower interception, (due to BBCH) and the application rate is the higher, the calculations were performed only for cereals assuming that it covers the result for oilseed rape. The application rate for each metabolite was calculated using the respective maximum occurrence and multiplying by a molecular weight conversion factor (metabolite mol. wt. ÷ parent mol. wt.).

Table 8.7‑2: Input parameter for active substance(s) and relevant metabolite(s) for PECsoil calculation

| Compound | Molecular weight (g/mol) | Max. occurrence (%) | DT50 (days) | Application rate (g/ha) | Value in accordance to EU endpoint y/n/  Reference |
| --- | --- | --- | --- | --- | --- |
| Prothioconazole | 344.3 | - | 2.8 d (Maximum value from field studies) | 200 | Y  EFSA Scientific Report (2007) 106 |
| Prothioconazole-S-methyl (M01) | 358.3 | 14.6 | 46.0 d (Maximum value from lab studies) | 30.4 |
| Prothioconazole-desthio (M04) | 312.2 | 57.1 | 72.3 (Maximum value from field studies) | 103.5 |

The PECsoil values for prothioconazole and its metabolites are presented in the following tables.

Table 8.7‑3: PECsoil for Prothioconazole after application of SAP250F

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PECsoil  (mg/kg) | | **Single application** | | **Multiple applications** | |
| **Actual** | **TWA** | **Actual** | **TWA** |
| Initial | | 0.213 | - | **0.220** | - |
| Short term | 24h | 0.167 | 0.189 | 0.172 | 0.195 |
| 2d | 0.130 | 0.168 | 0.134 | 0.174 |
| 4d | 0.079 | 0.135 | 0.082 | 0.140 |
| Long term | 7d | 0.038 | 0.101 | 0.039 | 0.105 |
| 14d | 0.007 | 0.060 | 0.007 | 0.061 |
| 21d | 0.001 | 0.041 | 0.001 | 0.042 |
| 28d | 0.000 | 0.031 | 0.000 | 0.032 |
| 50d | 0.000 | 0.017 | 0.000 | 0.018 |
| 100d | 0.000 | 0.009 | 0.000 | 0.009 |

Bold values will be used in risk assessment (see section 9)

Table 8.7‑4: PECsoil for Prothioconazole-S-methyl (M01) after application of SAP250F

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PECsoil  (mg/kg) | | **Single application** | | **Multiple applications** | |
| **Actual** | **TWA** | **Actual** | **TWA** |
| Initial | | 0.032 | - | **0.261** | - |
| Short term | 24h | 0.032 | 0.032 | 0.257 | 0.259 |
| 2d | 0.031 | 0.032 | 0.253 | 0.257 |
| 4d | 0.031 | 0.031 | 0.246 | 0.253 |
| Long term | 7d | 0.029 | 0.031 | 0.235 | 0.248 |
| 14d | 0.026 | 0.029 | 0.211 | 0.235 |
| 21d | 0.024 | 0.028 | 0.190 | 0.224 |
| 28d | 0.021 | 0.026 | 0.171 | 0.213 |
| 50d | 0.015 | 0.023 | 0.123 | 0.183 |
| 100d | 0.007 | 0.017 | 0.058 | 0.135 |
| Plateau concentration (5 cm) after year 3 | | - | - | 0.001 | - |
| PECsoil accumulation (5 cm) | | - | - | **0.080** | - |

Bold values will be used in risk assessment (see section 9)

Table 8.7‑5: PECsoil for Prothioconazole-desthio (M04) after application of SAP250F

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PECsoil  (mg/kg) | | **Single application** | | **Multiple applications** | |
| **Actual** | **TWA** | **Actual** | **TWA** |
| Initial | | 0.110 | - | **0.394** |  |
| Short term | 24h | 0.109 | 0.110 | 0.391 | 0.392 |
| 2d | 0.108 | 0.109 | 0.387 | 0.391 |
| 4d | 0.106 | 0.108 | 0.379 | 0.387 |
| Long term | 7d | 0.103 | 0.107 | 0.369 | 0.381 |
| 14d | 0.097 | 0.103 | 0.345 | 0.369 |
| 21d | 0.090 | 0.100 | 0.322 | 0.357 |
| 28d | 0.084 | 0.097 | 0.301 | 0.346 |
| 50d | 0.068 | 0.088 | 0.244 | 0.313 |
| 100d | 0.042 | 0.071 | 0.151 | 0.254 |
| Plateau concentration (5 cm) after year 2 | | - | - | 0.012 | - |
| PECsoil accumulation (5 cm) | | - | - | **0.300** | - |

Bold values will be used in risk assessment (see section 9)

#### PECsoil of SAP250F

The application rate in g formulation/ha is based on a specific density of 0.98 and the maximum application rate of 0.8 L/ha. Therefore, the initial PECsoil is based on a single application of 784 g formulation/ha. A soil depth of 5 cm and a bulk density of 1.5 g/cm3 are assumed.

Time-dependent PECsoil values are not required to be calculated for the formulation since it is considered to be separated in to its individual components by transport and dissipation processes.

Table 8.7‑6: PECsoil for SAP250F

| Preparation | Crop | Application rate (L/ha) | Application rate (g/ha) | Interception (%) | PECact (mg/kg) |
| --- | --- | --- | --- | --- | --- |
| SAP250F | Cereals | 0.8 | 784 | 20 (BBCH 25-69) | 0.836 |
| SAP250F | Cereals | 2.4 | 2352 | 20 (BBCH 25-69) | 2.509 |

**ZRMS comments:**

The calculations PECsoil has been accepted for the active substance prothioconazole and its metabolites M01 and M04.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion onScientific Report (2007) 106, 1-98. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

The acceptable predicted environmental concentrations of prothioconazole and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

PECs for cereals as worst case used in risk assessment:

Prothioconazole: **0.220 (mg/kg)**

JAU 6476-S-methyl (M01): **~~0.261~~ 0.080 (mg/kg)**

JAU 6476-desthio (M04): **~~0.394~~ 0.0303** **(mg/kg)**

Formulations SAP250F: **0.836 (mg/kg); for multiple applications: 2.509 (mg/kg)**

**Below new calculation for metabolites after commenting:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| JAU 6476-S-methyl (M01) | |  |  |  | | --- | --- | --- | |  | **Actual** | **TWA** | | PECINI mg/kg (3rd) | **0.080** | - | | 1 | 0.079 | 0.079 | | 2 | 0.078 | 0.079 | | 4 | 0.075 | 0.078 | | 7 | 0.072 | 0.076 | | 14 | 0.065 | 0.072 | | 21 | 0.058 | 0.069 | | 28 | 0.052 | 0.065 | | 48 | 0.039 | 0.057 | | 100 | 0.018 | 0.041 | |
| Plateau concentration (5 cm) after year 3 | 0.001 |
| PECsoil accumulation (5 cm) | **0.080** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Prothioconazole-desthio (M04) | |  |  |  | | --- | --- | --- | |  | **Actual** | **TWA** | | PECINI mg/kg (3rd) | **0,291** | - | | 1 | 0,289 | 0,290 | | 2 | 0,286 | 0,289 | | 4 | 0,280 | 0,286 | | 7 | 0,272 | 0,282 | | 14 | 0,255 | 0,273 | | 21 | 0,238 | 0,264 | | 28 | 0,223 | 0,256 | | 48 | 0,184 | 0,234 | | 100 | 0,112 | 0,187 | |
| Plateau concentration (5 cm) after year 3 | 0.012 |
| PECsoil accumulation (5 cm) | **0.303** |

The acceptable predicted environmental concentrations of prothioconazole and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

## Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4)

### Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registration.

### Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

The PECGW values for Prothioconazole and its metabolites were calculated using FOCUS modelling. A separate report was not produced and all inputs and procedures are described below. For each crop. the following scenarios were included. which are the relevant scenarios for Central Europe: Châteaudun. Hamburg. Kremsmünster. Okehampton. Piacenza. Porto

The application data for Prothioconazole are shown in the following table.

Table 8.8‑1: Input parameters related to application for PECGW calculations

|  |  |  |
| --- | --- | --- |
| Plant protection product | SAP250F | |
| Use No. | 1. 2. 3. 4 and 5 | 6 |
| Crop | Winter and Spring Cereals | Winter and Spring Oilseed Rape |
| Application rate (g as/ha) | 200 | 175 |
| Number of applications/interval (d) | 3 / 14 | 2 / 14 |
| Growth stage of crop | BBCH 25-69 | BBCH 20-80 |
| Crop interception (%) | 20 | 80 |
| Total rate reaching soil (g as/ha) | 160 | 35 |
| Frequency of application | Annual | |
| Models used for calculation | FOCUS PELMO v5.5.3. FOCUS PEARL v4.4.4 | |

To define the application dates. the AppDate software (M. Klein. 2006. Fraunhofer IME. Germany) was used. AppDate is a software tool that calculates application dates based growth development stages (BBCH) of each crop in the different groundwater and surface water scenarios.

For winter OSR. in order to cover the wide application window. two sets of application dates were used. one in autumn and one in early spring. The earliest autumn application date for winter OSR at BBCH 20 in each scenario was selected using the AppDate calculator. The earliest spring applications to winter OSR are estimated to occur at BBCH 21 and this date was selected by AppDate for each scenario.

For spring OSR. there are only two central European scenarios that include this crop (Okehampton and Porto). Therefore. it is considered that the early spring applications to winter OSR will cover applicationd to spring OSR. and no groundwater simulations for spring OSR have been performed.

The selected dates for applications at the earliest crop growth stage are shown in the following table.

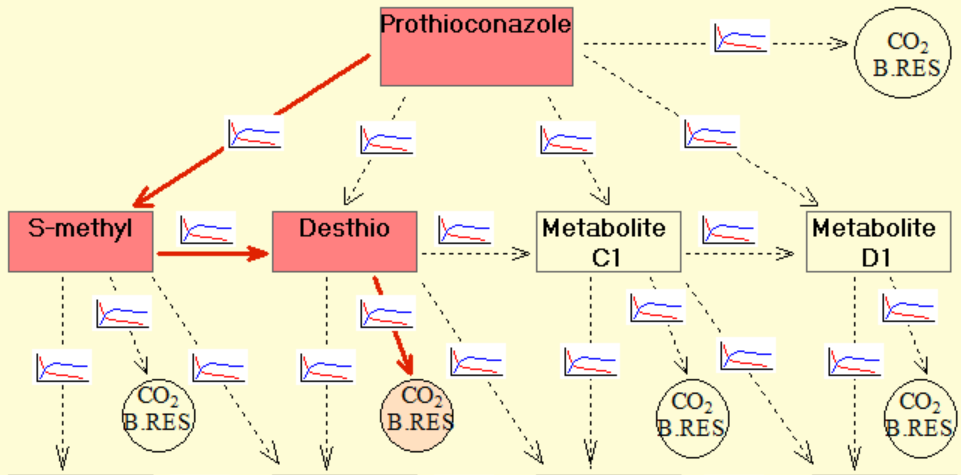
Table 8.8‑2: Application dates used for groundwater risk assessment

| Scenario | Crop | | | |
| --- | --- | --- | --- | --- |
| Winter cereals (BBCH 25) | Spring cereals (BBCH 25) | Winter OSR. early (BBCH 20) | Winter OSR. late (BBCH 21) |
| Châteaudun | 10. 24 Apr. 8 May | 7. 21 Apr. 5 May | 22 Sep. 6 Oct | 2. 16 Mar |
| Hamburg | 29 Apr. 13. 27 May | 21 Apr. 5. 19 May | 17 Sep. 1 Oct | 9. 23 Apr |
| Kremsmünster | 19 Apr. 3. 17 May | 21 Apr. 5. 19 May | 17 Sep. 1 Oct | 6. 20 Apr |
| Okehampton | 16. 30 Apr. 13 May | 17 Apr. 1. 15 May | 29 Aug. 12 Sep | 31 Mar. 14 Apr |
| Piacenza | 14. 28 Mar. 11 Apr | NR | 20 Oct. 3 Nov | 26 Feb. 12 Mar |
| Porto | 15. 29 Jan. 12 Feb | 7. 21 Apr. 5 May | 3. 17 Nov | 17 Feb. 3 Mar\* |

\* Due to earlier growth season. BBCH 39 was selected for Porto

The assessment was performed using the leaching models FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4. All runs were performed with annual applications over a total period of 26 years. The first 6 years were run as a warming-up period and the results were excluded from the assessment to give 20 years. The modelled pathway used in PELMO is shown in Figure 8.8-1.

**Figure 8.8-1:** **Prothioconazole degradation scheme used in PELMO**



The substance input parameters for the parent active substance and its metabolites are shown in the following table. Inputs were selected according to current guidance if possible (*e.g.* geomean DT50 and Koc values).

Table 8.8‑3: Summary of input parameters of Prothioconazole for the leaching simulation models FOCUS PELMO and FOCUS PEARL

| **Parameter** | | | **Value** | **Remarks** |
| --- | --- | --- | --- | --- |
| **Physico-Chemical parameters** | | | | |
| Molecular weight [g mol-1]  Prothioconazole  S-methyl (M01)  Desthio (M04) | | | 344.3  358.3  312.2 | EFSA. 2007;  DAR (July. 2005) and Final Addendum (May. 2007) |
| Water solubility [mg L-1]  Prothioconazole  S-methyl (M01)  Desthio (M04) | | | pH 4: 0.005 g/L at 20°C  pH 8: 0.3 g/L at 20°C  pH 9: 2.0 g/L at 20°C  22.5 at pH 7 (20ºC)  4.6 at pH 7 (20ºC)  50.6 at pH 7 (20ºC) |
| Vapour pressure [Pa]  Prothioconazole  S-methyl (M01)  Desthio (M04) | | | 4 x 10-7 Pa (20°C)  8.2 x 10-6 Pa (20°C)  1 x 10-10 (20ºC) |
| **Degradation in soil** | | | | |
| S-methyl. formation fraction (from parent) | | | 1/0.146 | Conservative value (worst case) /  EFSA. 2007 |
| Desthio formation fraction (from S-methyl) | | | 1 /0.571 |
| DT50 soil [d] | Prothioconazole | | 1.2 | EFSA. 2007; Geomean field. n=8 |
| S-methyl (M01) | | 15.7 | EFSA. 2007; Geomean lab. n=4 |
| Desthio (M04) | | 22.7 | EFSA. 2007; Geomean field. n=8 |
| **Sorption to soil** | | | | |
| Kf.oc [mL g-1] | | Prothioconazole | 1765 | EFSA. 2007; Aged soil column leaching study |
| S-methyl (M01) | 2556 | EFSA. 2007; Arith. mean ~~Geomean. n=4~~ |
| Desthio (M04) | 573.5 | EFSA. 2007; Arith. mean ~~Geomean. n=4~~ |
| Kf.om [mL g-1] | | Prothioconazole | 1023.8 | EFSA. 2007  Kf.oc / 1.724 |
| S-methyl (M01) | 1465.1 |
| Desthio (M04) | 332.7 |
| Freundlich exponent 1/n [-] | | Prothioconazole | 1 | EFSA default if no data |
| S-methyl (M01) | 0.88 | EFSA. 2007; Arith. mean. n=4 |
| Desthio (M04) | 0.81 | EFSA. 2007; Arith. mean. n=4 |
| Method of sorption subroutine description | | | pH independent |  |
| **Crop/management related parameters** | | | | |
| Crop uptake factor [-] | | | 0.0 | Default worst case |

The 80th percentile PECgw values for prothioconazole and its metabolites calculated by FOCUS PELMO and FOCUS PEARL following use of SAP250F in cereals and oilseed rape are presented in the following tables.

Table 8.8‑4: PECgw for Prothioconazole and its metabolites on Winter and Spring Cereals (with FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (g/L)** | | | | | |
| **FOCUS PELMO** | | | **FOCUS PEARL** | | |
| **Parent** | **S-methyl** | **Desthio** | **Parent** | **S-methyl** | **Desthio** |
| Winter Cereals | Châteaudun | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Piacenza | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Porto | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Spring Cereals | Châteaudun | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Porto | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |

Table 8.8‑5: PECgw for Prothioconazole and its metabolites on Winter Oilseed Rape   
(with FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (g/L)** | | | | | |
| **FOCUS PELMO** | | | **FOCUS PEARL** | | |
| **Parent** | **S-methyl** | **Desthio** | **Parent** | **S-methyl** | **Desthio** |
| Winter OSR (early) | Châteaudun | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Piacenza | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Porto | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Winter OSR (late) | Châteaudun | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Hamburg | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Kremsmünster | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Okehampton | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Piacenza | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |
| Porto | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |

The 80th percentile PECgw values for parent prothioconazole and its metabolites were < 0.001 µg/L for all scenarios and crops. significantly lower than the regulatory threshold of 0.1 µg/L. and demonstrating a negligible risk of contamination of groundwater after SAP250F application in cereals and oilseed rape.

**ZRMS comments:**

The calculations PECgw has been accepted for the active substance prothioconazole and its metabolites M01 and M04.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion onScientific Report (2007) 106. 1-98. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

In simulations PUF value of 0 was assumed for all compounds. in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

Nevertheless. additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

The PECgw values for active substance prothioconazole and its metabolites are below the trigger value 0.1 g/L in all existing scenarios.

## Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5)

### Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registration.

### Active substance(s). relevant metabolite(s) (KCP 9.2.5)

The PECSW and PECSED values for Prothioconazole and its metabolites were calculated using FOCUS modelling. A separate report was not produced and all inputs and procedures are described below.

FOCUS Step 1-2 in calculations were conducted for Prothioconazole and its three major metabolites. Further assessment was required for the desthio metabolite and. therefore. Step 3 and 4 modelling was conducted with desthio as a metabolite of parent Prothioconazole. Only the FOCUS scenarios that are relevant for the Central Zone were included in the modelling (D3. D4. D5. R1. R3. R4). The application data for Prothioconazole are shown in the following table.

Table 8.9‑1: Input parameters related to application for PECSW/SED calculations

|  |  |  |  |
| --- | --- | --- | --- |
| Plant protection product | SAP250F | | |
| Use No. | 1. 3. 4 | 2. 5 | 6 |
| Crop | Winter and Spring Cereals | Winter and Spring Cereals | Winter and Spring Oilseed Rape (OSR) |
| Application rate (g as/ha) | 200 | 200 | 175 |
| No. of applications/interval (d) | 3 / 14 | 2 / 14 | 2 / 14 |
| Application window: Step 1-2: | Oct-Feb and Mar – May for Winter Cereals  Mar – May for Spring Cereals  Average crop cover (BBCH 25) | | Jun-Sept and Oct-Feb for Winter OSR  Mar – May for Spring OSR  Average crop cover (BBCH 20) |
| Application window: Step 3-4: | BBCH 25-69  (see Table 8.9-2) | BBCH 25-69  (see Table 8.9-2) | BBCH 20-80  (see Table 8.9-3) |
| CAM (Chemical application method) | 2 | | |
| Soil depth (cm) | 4 | | |
| Models used for calculation | STEP 1-2 v3.2. FOCUS SWASH v5.3. FOCUS PRZM v4.3.1. FOCUS MACRO v5.5.4. FOCUS TOXWA v5.5.3. SWAN v5.0.0 | | |

To define the application windows for Step 3 modelling. the AppDate software (M. Klein. 2006. Fraunhofer IME. Germany) was used. AppDate is a software tool that calculates application dates based growth development stages (BBCH) of each crop in the different groundwater and surface water scenarios.

For cereals. all FOCUS scenarios were run using the maximum seasonal application rate of 3 x 200 g as/ha. Additional Step 3 calculations were conducted using a single application of 200 g as/ha in order to evaluate the most conservative drift inputs. Since the aquatic risk for parent prothioconazole and the desthio metabolite was acceptable at Step 3 for all drainage scenarios using the maximum seasonal use rate. the lower seasonal rate of 2 x 200 g as/ha was only assessed for the run-off scenarios in order to refine the risk assessment for the desthio metabolite. which exceeded the RAC as a result of run-off. The application windows for cereals are shown in the following table.

Table 8.9‑2: FOCUS Step 3 application windows for cereals

| **Scenario** | **Winter cereals (BBCH 25)** | | **Spring cereals (BBCH 25)** | |
| --- | --- | --- | --- | --- |
| **DD/MM** | **Julian day** | **DD/MM** | **Julian day** |
| D3 | 11/04 – 08/06 | 101 - 159 | 21/04 – 18/06 | 111 - 169 |
| D4 | 13/03 – 10/05 | 72 - 130 | 13/05 – 10/07 | 133 - 191 |
| D5 | 10/03 – 07/05 | 69 - 127 | 03/04 – 31/05 | 93 - 151 |
| R1 | 19/04 – 16/06 | 109 - 167 | NR | NR |
| R3 | 14/03 – 11/05 | 73 - 131 | NR | NR |
| R4 | 06/01 – 05/03 | 6 - 64 | 03/04 – 31/05 | 93 - 151 |

NR = scenario not relevant

For winter OSR. in order to cover the wide application window. two sets of application dates were used. one in autumn and one in early spring. The earliest autumn application date for winter oilseed rape at BBCH 20 in each scenario was selected using the AppDate calculator. The earliest spring applications to winter OSR are estimated to occur at BBCH 21 and this date was selected by AppDate for each scenario. The application windows for OSR are shown in the following table.

Table 8.9‑3: FOCUS Step 3 application windows for oilseed rape

| **Scenario** | **Winter Oilseed Rape** | | | | **Spring Oilseed Rape  (BBCH 20)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **(Autumn. BBCH 20)** | | **(Spring. BBCH 21)** | |
| **DD/MM** | **Julian day** | **DD/MM** | **Julian day** | **DD/MM** | **Julian day** |
| D3 | 17/09 – 31/10 | 260 - 304 | 12/02 – 28/03 | 43 - 87 | 27/04 – 10/06 | 117 - 161 |
| D4 | 18/09 – 01/11 | 261 - 305 | 20/02 – 05/04 | 51 - 95 | 14/05 – 27/06 | 134 - 178 |
| D5 | 05/10 – 18/11 | 278 - 322 | 20/02 – 05/04 | 51 - 95 | 03/04 – 17/05 | 93 - 137 |
| R1 | 19/09 – 02/11 | 262 - 306 | 06/04 – 20/05 | 96 - 140 | 25/04 – 08/06 | 115 - 159 |
| R3 | 20/10 – 03/12 | 293 - 337 | 26/02 – 11/04 | 57 - 101 | NR | NR |
| R4 | NR | NR | NR | NR | NR | NR |

NR = scenario not relevant for crop

The substance input parameters for the parent active substance and its metabolites are shown in the following table. Note that for many inputs. there are no agreed EFSA end points since FOCUS surface water models were not available for the active substance approval process. Therefore. inputs were selected according to current guidance if possible (*e.g.* geomean DT50 and Koc values).

Because the KOC values for both Prothioconazole and the desthio metabolite are between 100 and 2000 mL/g. two sets of simulations should be conducted according to EFSA guidance. The first uses the whole system DT50 of 2.1 days in the water compartment and a default of 1000 days in sediment. The second uses the opposite combination (*i.e.* 1000 days in water and 2.1 days in sediment). Note that this approach was only required for parent Prothioconazole since a worst-case DT50 value of 1000 days was already used for the desthio metabolite in both compartments. Therefore. two sets of simulations were required for the parent + metabolite combination.

Table 8.9‑4: Input parameters for Prothioconazole and its metabolites for PECsw/sed calculations STEP 1/2 and 3(/4) (if necessary)

| **Input Parameter** | **Prothio- conazole** | **Prothioconazole-S-methyl (M01)** | **Prothioconazole-desthio (M04)** | **1.2.4-triazole (M13)** | **Value in accordance to EU endpoint y/n Reference** |
| --- | --- | --- | --- | --- | --- |
| Mol. weight (g/mol) | 344.26 | 358.3 | 312.2 | 69.065 | Yes EFSA Scientific Report (2007) 106 |
| Water solubility (mg/L) | 22.5 (20ºC. pH 7) | 4.6 (20ºC. pH 7) | 50.6 (20ºC. pH 7) | 700000 (20ºC. pH 7) |
| Vapour Press (Pa) | 4x10-7 (20ºC) | Not necessary for Step 1-2 | 1x10-10 | Not necessary for Step 1-2 |
| Diffusion coeff. in water (m²/d) | 4.3 x 10-5 | 4.3 x 10-5 | Default |
| Diffusion coeff. in air (m²/d) | 0.43 | 0.43 |
| Plant Uptake | 0 | 0 | FOCUS default |
| Wash-Off factor from Crop (1/mm) | 0.05 (MACRO)  0.50 (PRZM) | 0.05 (MACRO)  0.50 (PRZM) | Default |
| Freundlich Exponent 1/n | 1 (default value) | 0.81 (arith. mean. n=4) | Yes EFSA Scientific Report (2007) 106 |
| Kfoc (mL/g) | 1765 (Aged soil column leaching study) | 2526 (geomean. n=4) | 573.5  (geomean. n=4) | 83  (geomean. n=4) |
| DT50.soil (d) | 1.2 (field. geomean. n=8) | 15.7 (lab.. geomean. n=4) | 22.7 (field. geomean. n=) | 1000 (default value) |
| DT50.water (d) | 2.1 (geomean whole system value. n = 2)\* | 1000 (default value) | 1000 (default value) | 1000 (default value) |
| DT50.sed (d) | 1000 (default value)\* | 1000 (default value) | 1000 (default value) | 1000 (default value) |
| DT50.whole system (d) | 2.1 (geomean whole system value. n = 2) | 1000 (default value) | 1000 (default value) | 1000 (default value) |
| Maximum observed  (Step 1-2) | - | Soil: 14.6%  Sediment: 77% | Soil: 49.4%  Water: 55.7%  Sediment: 26.9% | Soil: 0.1% (minor)  Total wat/sed: 15.1% |
| Formation fraction (Step 3 and 4) | - | - | Soil: 0.571 (max. from field)  Water: 1 (default)  Sed: 1 (default) | - | - |

\* additional simulations were performed using the whole system DT50 in sediment and default 1000 days in water

For Step 4 calculations, the FOCUS recommended reductions in water volume, sediment mass and pesticide flux were implemented as follows.

|  |  |  |
| --- | --- | --- |
| Buffer distance: | 10 m | 20 m |
| Reduction in volume of run-off water (%) | 60 | 80 |
| Reduction in mass of pesticide in water (%) | 60 | 80 |
| Reduction in mass of eroded soil (%) | 85 | 95 |
| Reduction in mass of pesticide in eroded soil (%) | 85 | 95 |

**FOCUS Steps 1 and 2 results**

The results of the FOCUS Step 1-2 modelling are presented in the following tables. Note that winter and spring cereals gave identical results as did winter and spring oilseed rape. so only one set of results are shown for both of these crops

Table 8.9‑5: FOCUS Step 1-2 PECsw and PECsed for Prothioconazole following application of SAP250F to cereals and oilseed rape

| FOCUS Step | Multiple application | | Single application | |
| --- | --- | --- | --- | --- |
| PECsw (µg/L) | PECsed (µg/kg) | PECsw (µg/L) | PECsed (µg/kg) |
| **Cereals (winter and spring). 3 x 200 g as/ha** | | | | |
| Step 1 | 21.72 | 350.9 | 21.72 | 350.9 |
| Step 2: N. Europe. Oct-Feb\* | 1.447 / 1.410 | 19.36 / 16.76 | 1.839 / 1.839 | 19.79 / 17.47 |
| Step 2: N. Europe. Mar – May\* | 1.447 / 1.410 | 11.01 / 8.40 | 1.839 / 1.839 | 11.43 / 9.117 |
| **Cereals (winter and spring). 2 x 200 g as/ha** | | | | |
| Step 1 | 21.72 | 350.9 | 21.72 | 350.9 |
| Step 2: N. Europe. Oct-Feb\* | 1.72 / 1.69 | 20.23 / 17.32 | 1.839 / 1.839 | 19.79 / 17.47 |
| Step 2: N. Europe. Mar – May\* | 1.72 / 1.69 | 11.87 / 8..96 | 1.839 / 1.839 | 11.43 / 9.117 |
| **Cereals (winter and spring). 1 x 200 g as/ha** | | | | |
| Step 1 | - | - | 21.72 | 350.9 |
| Step 2: N. Europe. Oct-Feb\* | - | - | 1.839 / 1.839 | 19.79 / 17.47 |
| Step 2: N. Europe. Mar – May\* | - | - | 1.839 / 1.839 | 11.43 / 9.117 |
| **Oilseed rape (winter and spring). 2 x 175 g/as/ha** | | | | |
| Step 1 | 19.01 | 307.0 | 19.01 | 307.0 |
| Step 2: N. Europe. Jun-Sep\* | 1.507 / 1.482 | 7.343 / 4.791 | 1.609 / 1.609 | 6.957 / 4.931 |
| Step 2: N. Europe. Oct-Feb\* | 1.507 / 1.482 | 10.09 / 7.534 | 1.609 / 1.609 | 9.699 / 7.673 |
| Step 2: N. Europe. Mar – May\* | 1.507 / 1.482 | 7.343 / 4.791 | 1.609 / 1.609 | 6.957 / 4.931 |

\* two values were calculated with the whole system DT50 of 2.1 days applied to the water and sediment compartments. respectively (1000 days applied to the other compartment)

Table 8.9‑6: FOCUS Step 1-2 PECsw and PECsed for Prothioconazole-S-methyl (M01) following application of SAP250F to cereals and oilseed rape

| FOCUS Step | Multiple application | | Single application | |
| --- | --- | --- | --- | --- |
| PECsw (µg/L) | PECsed (µg/kg) | PECsw (µg/L) | PECsed (µg/kg) |
| **Cereals (winter and spring). 3 x 200 g as/ha** | | | | |
| Step 1 | 48.07 | 1300 | - | - |
| Step 2: N. Europe. Oct-Feb | 2.898 | 66.67 | 1.720 | 40.37 |
| Step 2: N. Europe. Mar – May | 1.754 | 37.78 | 1.474 | 21.24 |
| **Oilseed rape (winter and spring). 2 x 175 g as/ha** | | | | |
| Step 1 | 28.04 | 657.6 | - | - |
| Step 2: N. Europe. Jun-Sep | 1.487 | 18.64 | 1.290 | 11.62 |
| Step 2: N. Europe. Oct-Feb | 1.487 | 27.00 | 1.290 | 17.89 |
| Step 2: N. Europe. Mar – May | 1.487 | 18.64 | 1.290 | 11.62 |

Table 8.9‑7: FOCUS Step 1-2 PECsw and PECsed for Prothioconazole-desthio (M04) following application of SAP250F to cereals and oilseed rape

| FOCUS Step | Multiple application | | Single application | |
| --- | --- | --- | --- | --- |
| PECsw (µg/L) | PECsed (µg/kg) | PECsw (µg/L) | PECsed (µg/kg) |
| **Cereals (winter and spring). 3 x 200 g as/ha** | | | | |
| Step 1 | 110.8 | 619.4 | - | - |
| Step 2: N. Europe. Oct-Feb | 14.54 | 82.22 | 7.362 | 41.68 |
| Step 2: N. Europe. Mar – May | 6.619 | 36.82 | 3.313 | 18.48 |
| **Cereals (winter and spring). 2 x 200 g as/ha** | | | | |
| Step 1 | 73.87 | 418.76 | - | - |
| Step 2: N. Europe. Oct-Feb | 11.74 | 66.36 | 7.362 | 41.68 |
| Step 2: N. Europe. Mar – May | 5.34 | 29.72 | 3.313 | 18.48 |
| **Cereals (winter and spring). 1 x 200 g as/ha** | | | | |
| Step 1 | - | - | 73.87 | 418.76 |
| Step 2: N. Europe. Oct-Feb | - | - | 7.362 | 41.68 |
| Step 2: N. Europe. Mar – May | - | - | 3.313 | 18.48 |
| **Oilseed rape (winter and spring). 2 x 175 g as/ha** | | | | |
| Step 1 | 64.63 | 366.4 | - | - |
| Step 2: N. Europe. Jun-Sep | 2.343 | 12.64 | 1.423 | 7.708 |
| Step 2: N. Europe. Oct-Feb | 4.441 | 24.67 | 2.751 | 15.32 |
| Step 2: N. Europe. Mar – May | 2.343 | 12.64 | 1.423 | 7.708 |

Table 8.9‑8: FOCUS Step 1-2 PECsw and PECsed for 1.2.4-triazole (M13) following application of SAP250F to cereals and oilseed rape

| FOCUS Step | Multiple application | | Single application | |
| --- | --- | --- | --- | --- |
| PECsw (µg/L) | PECsed (µg/kg) | PECsw (µg/L) | PECsed (µg/kg) |
| **Cereals (winter and spring). 3 x 200 g as/ha** | | | | |
| Step 1 | 5.66 | 4.68 | - | - |
| Step 2: N. Europe. Oct-Feb | 0.199 | 0.162 | 0.129 | 0.105 |
| Step 2: N. Europe. Mar – May | 0.147 | 0.119 | 0.083 | 0.067 |
| **Oilseed rape (winter and spring). 2 x 175 g as/ha** | | | | |
| Step 1 | 3.30 | 2.73 | - | - |
| Step 2: N. Europe. Jun-Sep | 0.090 | 0.073 | 0.055 | 0.045 |
| Step 2: N. Europe. Oct-Feb | 0.107 | 0.086 | 0.071 | 0.057 |
| Step 2: N. Europe. Mar – May | 0.090 | 0.073 | 0.055 | 0.045 |

PECsw values for the aqueous photolysis product Prothioconazole thiazocine (M12) were calculated by multiplying the peak parent PECsw by the maximum observed metabolite level in the photolysis study (14.1%) and correcting for molecular weight difference (307.8/344.3). The PECsw values were only calculated from the highest FOCUS Step 1-2 parent value for cereals and oilseed rape.

Table 8.9‑9: FOCUS Step 1-2 PECsw and PECsed for Prothioconazole thiazocine (M12) following application of SAP250F to cereals and oilseed rape

| Crop | FOCUS Step | Max. PECsw (µg/L) | |
| --- | --- | --- | --- |
| Multiple | Single |
| Cereals.  3 x 200 g as/ha | Step 1 | 2.738 | - |
| Step 2 | 0.182 | 0.232 |
| Oilseed rape.  2 x 175 g as/ha | Step 1 | 2.396 | - |
| Step 2 | 0.190 | 0.203 |

**FOCUS Steps 3 and 4 results**

The results of the FOCUS Step 3 and 4 modelling are presented in the following tables. Only the results of the simulations with the whole system DT50 in water (and default 1000 days in sediment) are presented below since. in almost all cases. this combination resulted in the highest PECsw values. For reference. the results from the reverse combination of water/sediment DT50 values are shown in Appendix 2.

In addition to multiple applications. Step 3 simulations were conducted with single applications to each crop. since this results in higher drift deposition due to the use of a higher percentile drift input. This resulted in increased PECsw values for parent prothioconazole but generally gave lower values for the desthio metabolite. Since prothioconazole gave an acceptable risk at Step 3 for both single and multiple applications. Step 4 simulations were not required for the single applications.

Table 8.9‑10: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following applications of SAP250F to winter cereals   
(3 x 200 g as/ha)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **Single PECsw (µg/L)** | **Multiple PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | | |
| D3 Ditch | 10-Apr-92 | 1.264 | 0.924 | Drift | 0.128 | Drift | 0.066 | Drift |
| D4 Pond | 19-Mar-85 | 0.044 | 0.037 | Drift | 0.023 | Drift | 0.015 | Drift |
| D4 Stream | 19-Mar-85 | 0.935 | 0.733 | Drift | 0.138 | Drift | 0.071 | Drift |
| D5 Pond | 08-Apr-78 | 0.044 | 0.036 | Drift | 0.022 | Drift | 0.015 | Drift |
| D5 Stream | 08-Apr-78 | 1.010 | 0.857 | Drift | 0.161 | Drift | 0.083 | Drift |
| R1 Pond | 26-Apr-84 | 0.044 | 0.036 | Drift | 0.021 | Drift | 0.014 | Drift |
| R1 Stream | 26-Apr-84 | 0.834 | 0.605 | Drift | 0.129 | Runoff | 0.066 | Runoff |
| R3 Stream | 28-Mar-80 | 1.171 | 0.856 | Drift | 0.222 | Runoff | 0.116 | Runoff |
| R4 Stream | 21-Jan-80 | 0.826 | 0.608 | Drift | 0.148 | Runoff | 0.078 | Runoff |
| **Desthio metabolite (M04)** | | | | | | | | |
| D3 Ditch | 10-Apr-92 | 0.058 | 0.090 | Drift | 0.012 | Drift | 0.006 | Drift |
| D4 Pond | 19-Mar-85 | 0.021 | 0.048 | Drift | 0.029 | Drift | 0.019 | Drift |
| D4 Stream | 19-Mar-85 | 0.074 | 0.058 | Drift | 0.014 | Drainflow | 0.014 | Drainflow |
| D5 Pond | 08-Apr-78 | 0.026 | 0.057 | Drift | 0.035 | Drift | 0.023 | Drift |
| D5 Stream | 08-Apr-78 | 0.114 | 0.115 | Drift | 0.022 | Drift | 0.011 | Drift |
| R1 Pond | 26-Apr-84 | 0.056 | 0.207 | Runoff | 0.094 | Runoff | 0.051 | Runoff |
| R1 Stream | 26-Apr-84 | **0.363** | **1.073** | Runoff | **0.487** | Runoff | 0.255 | Runoff |
| R3 Stream | 28-Mar-80 | **0.472** | **1.161** | Runoff | **0.530** | Runoff | 0.278 | Runoff |
| R4 Stream | 21-Jan-80 | **0.565** | **2.412** | Runoff | **1.097** | Runoff | **0.575** | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑11: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following applications of SAP250F to winter cereals   
(2 x 200 g as/ha) ~~- run-off scenarios only~~

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | |
| D3 Ditch | 10-Apr-92 | 1.107 | Drift | 0.149 | Drift | 0.076 | Drift |
| D4 Pond | 19-Mar-85 | 0.039 | Drift | 0.0237 | Drift | 0.016 | Drift |
| D4 Stream | 19-Mar-85 | 0.837 | Drift | 0.154 | Drift | 0.078 | Drift |
| D5 Pond | 08-Apr-78 | 0.042 | Drift | 0.0258 | Drift | 0.017 | Drift |
| D5 Stream | 08-Apr-78 | 0.965 | Drift | 0.177 | Drift | 0.090 | Drift |
| R1 Pond | 26-Apr-84 | 0.041 | Drift | 0.025 | Drift | 0.016 | Drift |
| R1 Stream | 26-Apr-84 | 0.721 | Drift | 0.132 | Drift | 0.067 | Drift |
| R3 Stream | 28-Mar-80 | 1.019 | Drift | 0.222 | Drift | 0.095 | Drift |
| R4 Stream | 21-Jan-80 | 0.724 | Drift | 0.133 | Drift | 0.068 | Drift |
| **Desthio metabolite (M04)** | | | | | | | |
| D3 Ditch | 10-Apr-92 | 0.056 | Drift | 0.0075 | Drift | 0.0038 | Drift |
| D4 Pond | 19-Mar-85 | 0.036 | Drainage | 0.021 | Drainage | 0.014 | Drainage |
| D4 Stream | 19-Mar-85 | 0.067 | Drift | 0.012 | Drift | 0.0086 | Drift |
| D5 Pond | 08-Apr-78 | 0.044 | Drainage | 0.027 | Drainage | 0.017 | Drainage |
| D5 Stream | 08-Apr-78 | 0.110 | Drift | 0.020 | Drift | 0.010 | Drift |
| R1 Pond | 26-Apr-84 | 0.144 | Runoff | 0.066 | Runoff | 0.037 | Runoff |
| R1 Stream | 26-Apr-84 | **1.072** | Runoff | **0.487** | Runoff | 0.255 | Runoff |
| R3 Stream | 28-Mar-80 | **1.161** | Runoff | **0.530** | Runoff | 0.278 | Runoff |
| R4 Stream | 21-Jan-80 | **1.343** | Runoff | **0.611** | Runoff | 0.320 | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑12: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following applications of SAP250F to BBCH 25 winter cereals   
(1 x 200 g as/ha)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | |
| D3 Ditch | 10-Apr-92 | 1.265 | Drift | 0.182 | Drift | 0.0084 | Drift |
| D4 Pond | 19-Mar-85 | 0.044 | Drift | 0.027 | Drift | 0.013 | Drift |
| D4 Stream | 19-Mar-85 | 0.935 | Drift | 0.181 | Drift | 0.014 | Drift |
| D5 Pond | 08-Apr-78 | 0.044 | Drift | 0.027 | Drift | 0.016 | Drift |
| D5 Stream | 08-Apr-78 | 1.010 | Drift | 0.196 | Drift | 0.022 | Drift |
| R1 Pond | 26-Apr-84 | 0.044 | Drift | 0.027 | Drift | 0.028 | Drift |
| R1 Stream | 26-Apr-84 | 0.834 | Drift | 0.162 | Drift | 0.165 | Drift |
| R3 Stream | 28-Mar-80 | 1.171 | Drift | 0.227 | Drift | 0.215 | Drift |
| R4 Stream | 21-Jan-80 | 0.826 | Drift | 0.160 | Drift | 0.204 | Drift |
| **Desthio metabolite (M04)** | | | | | | | |
| D3 Ditch | 10-Apr-92 | 0.058 | Drift | 0.0084 | Drift | 0.0043 | Drift |
| D4 Pond | 19-Mar-85 | 0.021 | Drainage | 0.013 | Drainage | 0.0084 | Drainage |
| D4 Stream | 19-Mar-85 | 0.074 | Drift | 0.014 | Drift | 0.0075 | Drift |
| D5 Pond | 08-Apr-78 | 0.026 | Drainage | 0.016 | Drainage | 0.011 | Drainage |
| D5 Stream | 08-Apr-78 | 0.114 | Drift | 0.022 | Drift | 0.011 | Drift |
| R1 Pond | 26-Apr-84 | 0.056 | Runoff | 0.028 | Runoff | 0.014 | Runoff |
| R1 Stream | 26-Apr-84 | **0.363** | Runoff | 0.165 | Runoff | 0.065 | Runoff |
| R3 Stream | 28-Mar-80 | **0.472** | Runoff | 0.215 | Runoff | 0.086 | Runoff |
| R4 Stream | 06-Jan-80 | **0.448** | Runoff | 0.204 | Runoff | 0.081 | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑13: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following application of SAP250F to spring cereals   
(3 x 200 g as/ha)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **Single PECsw (µg/L)** | **Multiple PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | | |
| D3 Ditch | 20-Apr-92 | 1.265 | 0.924 | Drift | 0.128 | Drift | 0.066 | Drift |
| D4 Pond | 30-May-85 | 0.044 | 0.032 | Drift | 0.020 | Drift | 0.013 | Drift |
| D4 Stream | 30-May-85 | 1.036 | 0.794 | Drift | 0.149 | Drift | 0.077 | Drift |
| D5 Pond | 08-Apr-78 | 0.044 | 0.036 | Drift | 0.022 | Drift | 0.015 | Drift |
| D5 Stream | 08-Apr-78 | 1.006 | 0.802 | Drift | 0.151 | Drift | 0.077 | Drift |
| R4 Stream | 29-Apr-84 | 0.836 | 1.550 | Runoff | 0.699 | Runoff | 0.365 | Runoff |
| **Desthio metabolite (M04)** | | | | | | | | |
| D3 Ditch | 20-Apr-92 | 0.060 | 0.091 | Drift | 0.013 | Drift | 0.006 | Drift |
| D4 Pond | 30-May-85 | 0.028 | 0.057 | Drift | 0.035 | Drift | 0.023 | Drift |
| D4 Stream | 30-May-85 | 0.085 | 0.082 | Drift | 0.032 | Drainflow | 0.032 | Drainflow |
| D5 Pond | 08-Apr-78 | 0.026 | 0.055 | Drift | 0.033 | Drift | 0.022 | Drift |
| D5 Stream | 08-Apr-78 | 0.113 | 0.091 | Drift | 0.017 | Drift | 0.009 | Drift |
| R4 Stream | 29-Apr-84 | **0.713** | **1.941** | Runoff | **0.883** | Runoff | **0.463** | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑14: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following applications of SAP250F to spring cereals   
(2 x 200 g as/ha) - run-off scenarios only

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | |
| R4 Stream | 29-Apr-84 | 1.550 | Drift | 0.699 | Runoff | 0.365 | Runoff |
| **Desthio metabolite (M04)** | | | | | | | |
| R4 Stream | 29-Apr-84 | **1.940** | Runoff | **0.883** | Runoff | **0.463** | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Note that the maximum PECsw values shown above for the R4 scenario following two applications are the same as those calculated for three applications. This is because the maximum run-off peak occurs five days after the second application. Any run-off peaks arising from the third application are lower than this maximum value.

Table 8.9‑15: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following application of SAP250F to winter oilseed rape - early season application (2 x 175 g as/ha)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **Single PECsw (µg/L)** | **Multiple PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | | |
| D3 Ditch | 26-Sep-92 | 1.112 | 0.973 | Drift | 0.131 | Drift | 0.067 | Drift |
| D4 Pond | 28-Sep-85 | 0.038 | 0.032 | Drift | 0.020 | Drift | 0.013 | Drift |
| D4 Stream | 28-Sep-85 | 0.958 | 0.829 | Drift | 0.152 | Drift | 0.077 | Drift |
| D5 Pond | 31-Oct-78 | 0.038 | 0.037 | Drift | 0.023 | Drift | 0.015 | Drift |
| D5 Stream | 31-Oct-78 | 1.034 | 0.894 | Drift | 0.164 | Drift | 0.083 | Drift |
| R1 Pond | 19-Sep-78 | 0.038 | 0.033 | Drift | 0.020 | Drift | 0.013 | Drift |
| R1 Stream | 19-Sep-78 | 0.733 | 0.634 | Drift | 0.116 | Drift | 0.059 | Drift |
| R3 Stream | 27-Oct-80 | 1.024 | 0.886 | Drift | 0.163 | Drift | 0.083 | Drift |
| **Desthio metabolite (M04)** | | | | | | | | |
| D3 Ditch | 26-Sep-92 | 0.148 | 0.129 | Drift | 0.017 | Drift | 0.009 | Drift |
| D4 Pond | 28-Sep-85 | 0.027 | 0.058 | Drainflow | 0.048 | Drainflow | 0.042 | Drainflow |
| D4 Stream | 28-Sep-85 | 0.091 | 0.210 | Drainflow | 0.210 | Drainflow | 0.210 | Drainflow |
| D5 Pond | 31-Oct-78 | 0.025 | 0.038 | Drainflow | 0.023 | Drainflow | 0.020 | Drainflow |
| D5 Stream | 31-Oct-78 | 0.136 | 0.118 | Drift | 0.099 | Drainflow | 0.099 | Drainflow |
| R1 Pond | 19-Sep-78 | 0.038 | 0.090 | Runoff | 0.040 | Runoff | 0.022 | Runoff |
| R1 Stream | 19-Sep-78 | 0.305 | **0.861** | Runoff | **0.378** | Runoff | 0.195 | Runoff |
| R3 Stream | 27-Oct-80 | **0.749** | **1.269** | Runoff | **0.576** | Runoff | 0.302 | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑16: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following application of SAP250F to winter oilseed rape - late season application (2 x 175 g as/ha)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | | **10 m** | |
| **No-spray buffer:** | | **Step 3** | | | **10 m** | |
| **Scenario/ Water body** | **1st App date** | **Single PECsw (µg/L)** | **Multiple PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | |
| D3 Ditch | 29-Feb-92 | 1.104 | 0.967 | Drift | 0.130 | Drift |
| D4 Pond | 24-Feb-85 | 0.038 | 0.036 | Drift | 0.022 | Drift |
| D4 Stream | 24-Feb-85 | 0.861 | 0.744 | Drift | 0.137 | Drift |
| D5 Pond | 21-Feb-78 | 0.038 | 0.038 | Drift | 0.023 | Drift |
| D5 Stream | 21-Feb-78 | 0.718 | 0.762 | Drift | 0.140 | Drift |
| R1 Pond | 07-Apr-84 | 0.038 | 0.035 | Drift | 0.021 | Drift |
| R1 Stream | 07-Apr-84 | 0.728 | 0.630 | Drift | 0.116 | Drift |
| R3 Stream | 26-Feb-81 | 1.032 | 0.893 | Drift | 0.223 | Drift |
| **Desthio metabolite (M04)** | | | | | | |
| D3 Ditch | 29-Feb-92 | 0.033 | 0.036 | Drift | 0.005 | Drift |
| D4 Pond | 24-Feb-85 | 0.019 | 0.029 | Drift | 0.017 | Drainflow |
| D4 Stream | 24-Feb-85 | 0.068 | 0.059 | Drift | 0.011 | Drift |
| D5 Pond | 21-Feb-78 | 0.020 | 0.034 | Drift | 0.021 | Drainflow |
| D5 Stream | 21-Feb-78 | 0.081 | 0.086 | Drift | 0.016 | Drift |
| R1 Pond | 07-Apr-84 | 0.047 | 0.087 | Runoff | 0.041 | Runoff |
| R1 Stream | 07-Apr-84 | 0.287 | **0.610** | Runoff | 0.277 | Runoff |
| R3 Stream | 26-Feb-81 | **0.494** | **0.494** | Runoff | 0.218 | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑17: FOCUS Step 3 and 4 maximum PECsw values for prothioconazole and the desthio metabolite (M04) following application of SAP250F to spring oilseed rape   
(2 x 175 g as/ha)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Vegetative buffer strip:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **No-spray buffer:** | | **Step 3** | | | **10 m** | | **20 m** | |
| **Scenario/ Water body** | **1st App date** | **Single PECsw (µg/L)** | **Multiple PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** | **PECsw (µg/L)** | **Entry route** |
| **Prothioconazole** | | | | | | | | |
| D3 Ditch | 04-May-92 | 1.108 | 0.969 | Drift | 0.131 | Drift | 0.066 | Drift |
| D4 Pond | 30-May-85 | 0.038 | 0.033 | Drift | 0.020 | Drift | 0.013 | Drift |
| D4 Stream | 30-May-85 | 0.907 | 0.811 | Drift | 0.149 | Drift | 0.076 | Drift |
| D5 Pond | 08-Apr-78 | 0.038 | 0.037 | Drift | 0.023 | Drift | 0.015 | Drift |
| D5 Stream | 08-Apr-78 | 0.879 | 0.834 | Drift | 0.153 | Drift | 0.078 | Drift |
| R1 Pond | 26-Apr-84 | 0.038 | 0.035 | Drift | 0.022 | Drift | 0.014 | Drift |
| R1 Stream | 26-Apr-84 | 0.730 | 0.631 | Drift | 0.116 | Drift | 0.059 | Drift |
| **Desthio metabolite (M04)** | | | | | | | | |
| D3 Ditch | 04-May-92 | 0.109 | 0.100 | Drift | 0.013 | Drift | 0.007 | Drift |
| D4 Pond | 30-May-85 | 0.025 | 0.039 | Drift | 0.024 | Drift | 0.015 | Drainflow |
| D4 Stream | 30-May-85 | 0.075 | 0.071 | Drift | 0.013 | Drift | 0.008 | Drainflow |
| D5 Pond | 08-Apr-78 | 0.022 | 0.038 | Drift | 0.023 | Drift | 0.015 | Drainflow |
| D5 Stream | 08-Apr-78 | 0.099 | 0.094 | Drift | 0.017 | Drift | 0.009 | Drift |
| R1 Pond | 26-Apr-84 | 0.054 | 0.126 | Runoff | 0.058 | Runoff | 0.032 | Runoff |
| R1 Stream | 26-Apr-84 | **0.424** | **1.093** | Runoff | **0.496** | Runoff | 0.260 | Runoff |

Values in bold exceed the RAC (3.278 µg/L for prothioconazole. 0.334 µg/L for desthio metabolite)

Table 8.9‑18: FOCUS Step 3 maximum PECsed for prothioconazole and the desthio metabolite (M04) following application of SAP250F to winter cereals (3 x 200 g as/ha)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario/ Water body** | **1st App date** | **Max. PECsed (µg/kg)** | | | |
| **Multiple application** | | **Single application** | |
| **Prothioconazole** | **Desthio** | **Prothioconazole** | **Desthio** |
| D3 Ditch | 10-Apr-92 | 0.613 | 0.122 | 0.575 | 0.045 |
| D4 Pond | 19-Mar-85 | 0.109 | 0.606 | 0.075 | 0.278 |
| D4 Stream | 19-Mar-85 | 0.042 | 0.013 | 0.027 | 0.003 |
| D5 Pond | 08-Apr-78 | 0.090 | 0.730 | 0.062 | 0.352 |
| D5 Stream | 08-Apr-78 | 0.214 | 0.039 | 0.029 | 0.003 |
| R1 Pond | 26-Apr-84 | 0.095 | 1.868 | 0.061 | 0.594 |
| R1 Stream | 26-Apr-84 | 0.330 | 1.532 | 0.107 | 0.366 |
| R3 Stream | 28-Mar-80 | 0.865 | 1.231 | 0.215 | 0.573 |
| R4 Stream | 21-Jan-80 | 0.270 | 1.346 | 0.085 | 0.354 |

NR = scenario not relevant for crop

Table 8.9‑19: FOCUS Step 3 maximum PECsed for prothioconazole and the desthio metabolite (M04) following application of SAP250F to spring cereals (3 x 200 g as/ha)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario/ Water body** | **1st App date** | **Max. PECsed (µg/kg)** | | | |
| **Multiple application** | | **Single application** | |
| **Prothioconazole** | **Desthio** | **Prothioconazole** | **Desthio** |
| D3 Ditch | 20-Apr-92 | 0.630 | 0.125 | 0.596 | 0.050 |
| D4 Pond | 30-May-85 | 0.063 | 0.647 | 0.052 | 0.316 |
| D4 Stream | 30-May-85 | 0.172 | 0.036 | 0.069 | 0.006 |
| D5 Pond | 08-Apr-78 | 0.084 | 0.716 | 0.062 | 0.345 |
| D5 Stream | 08-Apr-78 | 0.058 | 0.009 | 0.028 | 0.003 |
| R1 Pond | NR | NR | NR | 0.355 | 0.977 |
| R1 Stream | NR | NR | NR | 0.596 | 0.050 |
| R3 Stream | NR | NR | NR | 0.052 | 0.316 |
| R4 Stream | 29-Apr-84 | 1.913 | 2.474 | 0.069 | 0.006 |

NR = scenario not relevant for crop

Table 8.9‑20: FOCUS Step 3 maximum PECsed for prothioconazole and the desthio metabolite (M04) following multiple applications (2 x 175 g as/ha) of SAP250F to winter oilseed rape

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario/ Water body** | **1st App date** | **Max. PECsed (µg/kg)** | | | |
| **Multiple application** | | **Single application** | |
| **Prothioconazole** | **Desthio** | **Prothioconazole** | **Desthio** |
| D3 Ditch | 26-Sep-92 | 0.806 | 0.156 | 0.664 | 0.177 |
| D4 Pond | 28-Sep-85 | 0.063 | 0.531 | 0.047 | 0.307 |
| D4 Stream | 28-Sep-85 | 0.156 | 0.121 | 0.180 | 0.049 |
| D5 Pond | 31-Oct-78 | 0.081 | 0.462 | 0.046 | 0.292 |
| D5 Stream | 31-Oct-78 | 0.257 | 0.048 | 0.245 | 0.041 |
| R1 Pond | 19-Sep-78 | 0.063 | 0.976 | 0.043 | 0.485 |
| R1 Stream | 19-Sep-78 | 0.090 | 0.458 | 0.104 | 0.183 |
| R3 Stream | 27-Oct-80 | 1.205 | 2.183 | 0.408 | 0.867 |
| R4 Stream | NR | NR | NR | 0.664 | 0.177 |

NR = scenario not relevant for crop

Table 8.9‑21: FOCUS Step 3 maximum PECsed for prothioconazole and the desthio metabolite (M04) following multiple applications (2 x 175 g as/ha) of SAP250F to spring oilseed rape

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario/ Water body** | **1st App date** | **Max. PECsed (µg/kg)** | | | |
| **Multiple application** | | **Single application** | |
| **Prothioconazole** | **Desthio** | **Prothioconazole** | **Desthio** |
| D3 Ditch | 04-May-92 | 0.586 | 0.126 | 0.534 | 0.098 |
| D4 Pond | 30-May-85 | 0.055 | 0.458 | 0.045 | 0.288 |
| D4 Stream | 30-May-85 | 0.099 | 0.012 | 0.061 | 0.006 |
| D5 Pond | 08-Apr-78 | 0.079 | 0.491 | 0.054 | 0.304 |
| D5 Stream | 08-Apr-78 | 0.053 | 0.007 | 0.024 | 0.003 |
| R1 Pond | 26-Apr-84 | 0.070 | 1.230 | 0.054 | 0.572 |
| R1 Stream | 26-Apr-84 | 0.173 | 0.895 | 0.094 | 0.355 |
| R3 Stream | NR | NR | NR | 0.534 | 0.098 |
| R4 Stream | NR | NR | NR | 0.045 | 0.288 |

NR = scenario not relevant for crop

**ZRM comments:**

The calculations PECsw/sed has been accepted for the active substance prothioconazole and its metabolites M01 and M04.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion onScientific Report (2007) 106. 1-98. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

PECsw/sed calculations performed at Step 1-2 and Step 3 and Step 4 for the active substance PECsw/sed have been accepted. Input parameters and PECsw/sed calculations can be considered acceptable.

The PECsw calculations have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS guidance recommendations.

Nevertheless. additional simulations may be required by the cMS that do not accept calculations performed using FOCUS models.

Additionally, the applicant presented new calculations of PECsw/sed for a dose of 1x200 g a.s./ha and 2x200g a.s./ha in winter cereals for Prothioconazole and Desthio metabolite (M04). The calculations were made in step 1, 2, 3 and 4 of the FOCUS models. The calculations were fully accepted by zRMS.

The mitigations measure will be recommended in ecotoxicological assessment.

The acceptable predicted environmental concentrations of prothiocozole and its metabolites are appropriate to be used for the subsequent risk assessment.

## Fate and behaviour in air (KCP 9.3. KCP 9.3.1)

Table 8.10‑1 Summary of atmospheric degradation and behaviour

|  |  |
| --- | --- |
| Compound | Prothioconazole |
| Direct photolysis in air | Not available |
| Photochemical oxidative degradation in air | Prothioconazole:  DT50: 1.1 hours  Chemical lifetime: 1.6 hours (calculated according Atkinson (AOPWIN ver. 1.87. 12 hour day. 1x5106 OH radicals/cm3))  Prothioconazole-desthio (M04):  DT50: 14.2 hours  Chemical lifetime: 20.5 hours (calculated according Atkinson (AOPWIN ver. 1.87. 12 hour day. 1x5106 OH radicals/cm3)) |
| Volatilisation | Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (M04) is unlikely to take place because no volatiles were detected at levels above 0.1% AR. |

The vapour pressure at 20°C of the active substance Prothioconazole is < 4x10‑7 Pa. Hence the active substance prothioconazole is regarded as non-volatile. Therefore. exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition is not required.

**ZRMS comments:**

Accepted.

1. Lists of data considered in support of the evaluation

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 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Additional PECsw and PECsed values using alternative substance inputs

The following PECsw and PECsed values were calculated with the whole system water/sediment DT50 assigned to the sediment phase and a default worst case DT50 of 1000 days assigned to the water phase.

**Table A2-1: FOCUS Step 3 maximum PECsw/sed for prothioconazole and the desthio metabolite following application of SAP250F to Winter Cereals (3 x 200 g as/ha)**

| **FOCUS Scenario** | **Waterbody** | **Max PECsw (μg/L)** | | **Max PECsed  (μg/kg)** | |
| --- | --- | --- | --- | --- | --- |
| **Prothioconazole** | **Desthio (M04)** | **Prothioconazole** | **Desthio (M04)** |
| D3 | ditch | 0.923 | 0.002 | 0.434 | 0.426 |
| D4 | pond | 0.067 | 0.020 | 0.125 | 0.636 |
| D4 | stream | 0.733 | 0.014 | 0.037 | 0.019 |
| D5 | pond | 0.074 | 0.026 | 0.117 | 0.759 |
| D5 | stream | 0.857 | 0.002 | 0.199 | 0.076 |
| R1 | pond | 0.077 | 0.164 | 0.118 | 1.896 |
| R1 | stream | 0.605 | 0.983 | 0.258 | 1.722 |
| R3 | stream | 0.855 | 1.067 | 0.753 | 1.613 |
| R4 | stream | 0.608 | 2.243 | 0.231 | 1.425 |

**Table A2-1: FOCUS Step 3 maximum PECsw/sed for prothioconazole and the desthio metabolite following application of SAP250F to Winter OSR (2 x 175 g as/ha)**

| **FOCUS Scenario** | **Waterbody** | **Max PECsw (μg/L)** | | **Max PECsed  (μg/kg)** | |
| --- | --- | --- | --- | --- | --- |
| **Prothioconazole** | **Desthio (M04)** | **Prothioconazole** | **Desthio (M04)** |
| D3 | ditch | 0.972 | 0.004 | 0.658 | 0.416 |
| D4 | pond | 0.051 | 0.038 | 0.111 | 0.539 |
| D4 | stream | 0.829 | 0.209 | 0.153 | 0.152 |
| D5 | pond | 0.056 | 0.021 | 0.112 | 0.469 |
| D5 | stream | 0.894 | 0.099 | 0.221 | 0.092 |
| R1 | pond | 0.053 | 0.079 | 0.097 | 0.986 |
| R1 | stream | 0.634 | 0.845 | 0.088 | 0.474 |
| R3 | stream | 0.886 | 1.040 | 0.935 | 2.267 |