Bayer CropScience

Document Title

# Summary of the ecotoxicological studies
# Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L)

Data Requirements

## EU Regulation 1107/2009 & EU Regulation 284/2013
## Document MCP
## Section 10: Ecotoxicological studies

**According to the guidance document, SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance**

Date

**2016-01-12**

Author(s)

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[redacted] (tier3 solutions)

**Bayer CropScience**

M-544116-01-5

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# Version history

| Date | Data points containing amendments or additions[1] and brief description | Document identifier and version number |
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[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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# CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

## Introduction

The representative formulation submitted in the first Annex I listing process is no longer considered as a representative formulation for the renewal of fluoxastrobin. One of the two representative formulations used for the submission of the renewal of the approval of fluoxastrobin is the spray formulation Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L; 'BIX + FXA + PTZ EC190'). The summaries of formulation studies and the risk assessment will be presented in this Dossier.

Ecotoxicological endpoints used in the following risk assessment were derived from studies with the formulated product, the active substance fluoxastrobin and the metabolites listed in the residue definition for risk assessment.

In this dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for fluoxastrobin and its metabolites please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the Annex I inclusion process, the previously evaluated information is written in grey font.

## Use pattern considered in the risk assessment

There are two key use patterns for the formulation, BIX+FXA+PTZ EC 190. The first consists of two applications in wheat, rye, triticale and spelt at a maximum rate of 2 x 1.75 L per hectare at growth stage 30-69. The second consists of two applications in barley and oats at a maximum rate of 1.75 L per hectare at growth stage 30-61.

**Table CP 10- 1: Intended application pattern**

| Crop | Timing of application (range) | Number of applications | Application interval | Maximum label rate per treatment (range) | Application rate per treatment [g/ha] | | |
|---|---|---|---|---|---|---|---|
| | | | [days] | [L/ha] | Bixafen | Fluoxastrobin | Prothioconazole |
| Wheat, rye, triticale | BBCH 30-69 | 1-2 | 14-21 | 1.75 | 70 | 87.5 | 175 |
| Barley | BBCH 30-61 | 1-2 | 14-21 | 1.50 | 60 | 75 | 150 |
| Oats | BBCH 30-61 | 1-2 | 14-21 | 1.75 | 70 | 87.5 | 175 |

## Risk envelope

For envelope type risk assessment, the critical application pattern is defined as multiple application of 2 × 1.75 L product/ha at BBCH 30–69 with an application interval of 14 days. All other are considered as less critical. To enable a possible differentiation in mitigation measures adapted to the use rate, TER calculations for the less critical application patterns will also be provided in domains where exposure mitigation via use restriction is needed to pass risk assessment for the critical GAP (envelope rate).

## Definition of the residue for risk assessment

Due to changes in the requirements under EU Regulation 1107/2009, additional degradation products were proposed to be included in the residue definition. All studies necessary to describe the ecotoxicological profile of these metabolites in the relevant environmental compartments are summarized in this document. The residue definition is presented in Table CP 10- 2.

**Table CP 10- 2: Definition of the residue for risk assessment**

| Compartment | Residue Definition for Risk Assessment |
|---|---|
| Soil | fluoxastrobin (*E*- isomer),<br>HEC 5725 -*Z*-isomer,<br>HEC 5725-carboxylic acid (*M40*),<br>HEC 5725-*E*-des-chlorophenyl (*M48-E*),<br>2-chlorophenol (*M82*) |
| Groundwater | fluoxastrobin (*E*-isomer),<br>HEC 5725-*Z*-isomer,<br>HEC 5725-carboxylic acid (*M40*),<br>HEC 5725-*E*-des-chlorophenyl (M48-*E*),<br>2-chlorophenol (M82) |
| Surface water | fluoxastrobin (*E*- isomer),<br>HEC 5725-*Z*-isomer,<br>HEC 5725-carboxylic acid (*M40*),<br>HEC 5725-*E*-des-chlorophenyl (*M48-E*) |
| Sediment | fluoxastrobin (*E*- isomer),<br>HEC 5725-*Z*-isomer |
| Air | none |

A list of metabolites, which contains the structures, the synonyms and code numbers attributed to the compound fluoxastrobin, is presented in Document N3 of this dossier.

**Compounds addressed in this document**

In addition to the active substance fluoxastrobin, the degradation products summarised in the Table CP 10- 2 were addressed in this document.
In this paragraph the approach to the risk assessment of the Z-isomer of fluoxastrobin is specifically considered. The chemical structure of fluoxastrobin contains an oxime ether moiety. Due to the substitution pattern of that double bond E- and Z-isomers exist. The common name fluoxastrobin denotes the *E*-isomer. The Z-isomer is known to be an impurity in technical fluoxastrobin (specification limit 2 mg/kg). The Z-isomer can be formed from the E-isomer by photolytic processes exclusively. The transformation will lead to an equilibrium state in which the E-isomer is the more stable and energetically preferred isomer (ratio in aqueous solution about 10:1 = E / Z). In the environment the Z-isomer shows very similar degradation behaviour and a better soil sorption than the E-isomer. Further, the Z-isomer shows a very similar toxicological profile. A study with *Daphnia magna* performed with an increased amount of Z-Isomer (isomer ratio (E/Z) = 65/35 demonstrated an at least comparable, potentially lower ecotoxicological profile than the parent E-isomer, demonstrating that there is no further risk for the aquatic compartment (please refer to CA 8.2.4.1 M-030533-01-1). Taking this information into account, both isomers can be evaluated as sum of E+Z-isomers, providing a conservative environmental risk assessment.

## CP 10.1 Effects on birds and other terrestrial vertebrates

The risk assessment has been performed according to "European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA GD 2009".

### CP 10.1.1 Effects on birds

**Table CP 10.1.1- 1: Endpoints used in Tier 1 risk assessment**

| Test substance | Exposure | species/origin | Endpoint | | Reference |
|---|---|---|---|---|---|
| Fluoxastrobin | Acute risk assessment | *Colinus virginianus* (Bobwhite quail) | $LD_{50}$<br>$LD_{50\ extrapol.}$ | > 2000 mg a.s./kg bw<br>**≡ 3776 mg/kg bw**[1] | [redacted]; 2003; M-024735-02-1 |
| | Reproductive risk assessment | Lowest NOEL from *Anas platyrhynchos* (Mallard duck) | NOEC<br>**NOEL** | 461 mg/kg diet<br>**51 mg as/kg bw/d** | [redacted] 2003; M-087968-01-1 |

**Bold values** used for the risk assessment
[1] $LD_{50}$ extrapolated with EFSA GD factor 1.888 (10 birds, no mortality; EFSA GD Birds & Mammals (2009), Section 2.1.2, Tab. 1)

**Table CP 10.1.1- 2: Relevant generic avian focal species for risk assessment on Tier 1 level according to EFSA GD 2009**

| Crop scenario | Scenario | Generic focal species | Representative species | Short cut values based on | |
|---|---|---|---|---|---|
| | | | | $RUD_{90}$ | $RUD_m$ |
| Cereals<br>2 × 0.0875 kg/ha<br>BBCH 30-69<br>14 d interval | BBCH 30-39 | Small omnivorous bird "lark" | Woodlark (*Lullula arborea*) | **12.0** | **5.4** |
| | BBCH ≥ 40 | Small omnivorous bird "lark" | Woodlark (*Lullula arborea*) | 7.2 | 3.3 |

**Bold:** Species considered in risk assessment (only worst case for each species)

#### ACUTE DIETARY RISK ASSESSMENT

**Table CP 10.1.1- 3: Tier 1 acute risk assessment for birds**

| Crop scenario | Generic focal species | DDD | | | DDD | $LD_{50}$ [mg a.s./kg bw] | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|---|---|
| | | Appl. rate [kg a.s./ha] | $SV_{90}$ | $MAF_{90}$ | | | | |
| **Fluoxastrobin** | | | | | | | | |
| Cereals BBCH 30-39 | Small omnivorous bird "lark" | 0.0875 | 12.0 | 1.2 | 1.3 | 3776 | 2997 | 10 |

The $TER_A$ value calculated in the acute risk assessment on Tier 1 level exceeds the a-priori-acceptability trigger of 10 for the evaluated scenario. Thus, the acute risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

#### Acute risk assessment for birds drinking contaminated water from pools in leaf whorls

In the EFSA GD 2009, section 5.5, step 1 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mammals:

Leaf scenario: Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.
Puddle scenario: Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.
For the crops under assessment in this evaluation (cereals) the leaf scenario is not considered relevant. The risk for birds from drinking water in puddles is addressed in Table CP 10.1.1- 5.

## LONG-TERM REPRODUCTIVE ASSESSMENT

**Table CP 10.1.1- 4: Tier 1 reproductive risk assessment for birds**

| Crop | Generic focal species | DDD | | | | DDD | NOEL [mg a.s./ kg bw/d] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|---|---|---|
| | | Appl. rate [kg a.s./ha] | $SV_m$ | $MAF_m$ | $f_{TWA}$ | | | | |
| **Fluoxastrobin** | | | | | | | | | |
| Cereals BBCH 30-39 | Small omnivorous bird "lark" | 0.0875 | 5.4 | 1.4 | 0.53 | 0.4 | 51 | 146 | 5 |

The $TER_{LT}$ value calculated in the reproductive risk assessment on Tier 1 level exceeds the a-priori-acceptability trigger of 5 for the evaluated scenario. Thus, the risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

### Long-term risk assessment for birds drinking contaminated water in puddles

**Table CP 10.1.1- 5: Evaluation of potential concern for exposure of birds drinking water (escape clause)**

| Crop | Koc [L/kg] | Application rate * 2 [a)] [g as/ha] | NO(A)EL [mg as/ kg bw/d] | Ratio (Application rate * MAF) / NO(A)EL | "Escape clause" No concern if ratio | Conclusion |
|---|---|---|---|---|---|---|
| **Fluoxastrobin** | | | | | | |
| Cereals | 848.2 | 87.5 * 2 | 51 | 3.4 | ≤ 3000 | No concern |

[a)] annual application rate (without interception) used as theoretical worst case

## RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds feeding on contaminated prey like fish or earthworms. For organic chemicals, a log $P_{OW} \geq 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As the log $P_{OW}$ of the active substance fluoxastrobin and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see Document MCA 2.7).

## CP 10.1.1.1 Acute oral toxicity

No additional studies are available or required as the toxicity can be derived from the studies on the active substance.

## CP 10.1.1.2 Higher tier data on birds

Since fluoxastrobin is of low toxicity to birds, no higher tier data are needed.

## CP 10.1.2 Effects on terrestrial vertebrates other than birds

**Table CP 10.1.2- 1: Endpoints used in risk assessment**

| Test substance | Exposure | species/origin | Endpoint | | Reference |
|---|---|---|---|---|---|
| Fluoxastrobin | Acute risk assessment | Rat | **$LD_{50}$** | **> 2000 mg a.s./kg bw** | [redacted] 1996; M-012717-01-1 |
| | Long-term risk assessment | Rat | NOAEC<br>NOAEL | 2000 mg a.s./kg diet (F)<br>**163 mg a.s./kg bw/d** | [redacted] 1998; M-012710-01-1 |

**Bold values** used for the risk assessment

**Table CP 10.1.2- 2: Relevant generic focal species for Tier 1 risk assessment**

| Crop | Scenario | Generic focal species | Representative species | Shortcut value | |
|---|---|---|---|---|---|
| | | | | Long-term RA based on $RUD_m$ | acute RA based on $RUD_{90}$ |
| Cereals<br>2 × 0.0875 kg/ha<br>BBCH 30-69<br>14 d interval | BBCH ≥ 20 | Small insectivorous mammal "shrew" | Common shrew (*Sorex araneus*) | **1.9** | **5.4** |
| | BBCH ≥ 40 | Small herbivorous mammal "vole" | Common vole (*Microtus arvalis*) | **21.7** | **40.9** |
| | BBCH 30 - 39 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | **3.9** | **8.6** |
| | BBCH ≥ 40 | Small omnivorous mammal "mouse" | Wood mouse (*Apodemus sylvaticus*) | 2.3 | 5.2 |

**Bold:** Species considered in Tier 1 risk assessment (only worst case for each species)

### ACUTE DIETARY RISK ASSESSMENT

**Table CP 10.1.2- 3: Tier 1 acute DDD and TER calculation for mammals**

| Crop | Generic focal species | DDD | | | DDD | $LD_{50}$ [mg/kg bw] | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|---|---|
| | | Appl. rate [kg/ha] | $SV_{90}$ | $MAF_{90}$ | | | | |
| **Fluoxastrobin** | | | | | | | | |
| Cereals BBCH ≥ 20 | Small insectivorous mammal "shrew" | | 5.4 | | 0.6 | | > 3527 | 10 |
| Cereals BBCH ≥ 40 | Small herbivorous mammal "vole" | 0.0875 | 40.9 | 1.2 | 4.3 | > 2000 | > 466 | 10 |
| Cereals BBCH 30 - 39 | Small omnivorous mammal "mouse" | | 8.6 | | 0.9 | | > 2215 | 10 |

The $TER_A$ values calculated in the acute risk assessment on Tier 1 level exceed the a-priori acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

## LONG-TERM REPRODUCTIVE ASSESSMENT

**Table CP 10.1.2- 4: Tier 1 long-term DDD and TER calculation for mammals**

| Crop | Generic focal species | DDD | | | | DDD | NO(A)EL [mg kg/bw/d] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|---|---|---|
| | | Appl. rate [kg/ha | $SV_m$ | $MAF_m$ | $f_{twa}$ | | | | |
| **Fluoxastrobin** | | | | | | | | | |
| Cereals BBCH ≥ 20 | Small insectivorous mammal "shrew" | 0.0875 | 1.9 | 1.4 | 0.53 | 0.1 | 163 | 1321 | 5 |
| Cereals BBCH ≥ 40 | Small herbivorous mammal "vole" | | 21.7 | | | 1.4 | | 116 | 5 |
| Cereals BBCH 30 - 39 | Small omnivorous mammal "mouse" | | 3.9 | | | 0.3 | | 644 | 5 |

The $TER_{LT}$ values calculated in the reproductive risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 5 for all evaluated scenarios. Thus, the risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

### Long-term risk assessment for mammals drinking contaminated water

The puddle scenario is relevant for the long-term risk assessment.

**Table CP 10.1.2- 5: Evaluation of potential concern for exposure of mammals drinking water**

| Crop | Koc [L/kg] | Application rate * 2 [a] [g as/ha] | NO(A)EL [mg as/ kg bw/d] | Ratio (Application rate * MAF) / NO(A)EL | "Escape clause" No concern if ratio | Conclusion |
|---|---|---|---|---|---|---|
| **Fluoxastrobin** | | | | | | |
| Cereals | 848.2 | 87.5 * 2 | 163 | 1.07 | **≤ 3000** | No concern |

[a]: annual application rate (without interception) used as theoretical worst case

## RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a $\log P_{OW} > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As the $\log P_{OW}$ of the active substance fluoxastrobin and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see Document MCA 2.7).

## CP 10.1.2.1 Acute oral toxicity to mammals

The acute oral toxicity of the product Bixafen + Fluoxastrobin + Prothioconazole EC 190 in rat was studied by [redacted], 2010; M-388101-01-1, the study is summarised in the MCP 7 document (toxicology). According to OECD guideline 423 the results of this study correspond to $LD_{50}$ ≥ 5000 mg/kg body weight.

## CP 10.1.2.2 Higher tier data on mammals

No additional studies are required; the risk assessment indicates acceptable risk at Tier 1.

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

No additional studies are available or required under the data requirements of EC 1107/2009.

## CP 10.2 Effects on aquatic organisms

The risk assessment was performed according to the Regulation (EC) No 1107/2009 and following the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013).

## Ecotoxicological endpoints used in risk assessment

**Table CP 10.2- 1: Endpoints relevant for risk assessment**

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| Fluoxastrobin | Fish, acute *Oncorhynchus mykiss* (rainbow trout) | **$LC_{50}$** | **0.435 mg a.s./L** | [redacted]; 1999; M-016770-01-1 |
| | Fish, chronic *Oncorhynchus mykiss* (rainbow trout) | **NOEC** | **0.0286 mg a.s./L** | [redacted]; 2001; M-084463-01-1 |
| | Invertebrate, acute *Daphnia magna* (cladoceran) | **$EC_{50}$** | **0.48 mg a.s./L** | [redacted]; 1999; M-011257-01-1 |
| | Invertebrate, acute *Gammarus pulex* (amphipod) | **$EC_{50}$** | **0.15 mg a.s./L** | [redacted]; 2003; M-109491-01-1 |
| | *Acanthocyclops venustus* (copepod) | $EC_{50}$ | 0.9 mg a.s./L | |
| | *Cloeon dipterum* (mayfly) | $EC_{50}$ | 1.0 mg a.s./L | |
| | *Daphnia gr. galeata* (cladoceran) | $EC_{50}$ | 1.3 mg a.s./L | |
| | *Asellus aquaticus* (isopod) | $EC_{50}$ | 2.3 mg a.s./L | |
| | *Chaoborus obscuripes* (diptera) | $EC_{50}$ | > 3.2 mg a.s./L | |
| | *Simocephalus vetulus* (cladoceran) | $EC_{50}$ | 3.2 mg a.s./L | |
| | Marine invertebrate, acute *Americamysis bahia* (*Mysidopsis bahia*, mysid shrimp) | **$LC_{50}$** | **0.0604 mg a.s./L** | [redacted]; 2002; M-082793-01-1 |
| | Invertebrate, acute geometric mean using 7 species | **$EC_{50}$** | **0.488 mg a.s./L[1]** | See. MCA 8.2.4.2 |
| | Invertebrate, chronic *Daphnia magna* (cladoceran) | **NOEC** | **0.18 mg a.s./L** | [redacted]; 2000; M-042059-01-1 |
| | Invertebrate, chronic *Gammarus pulex* (amphipod) (conducted with EC 100 formulation) | NOEC | 0.0316 mg a.s./L | [redacted] 2003; M-110286-01-1 |
| | Invertebrate, chronic *Habrophlebia lauta* (Mayfly) | NOEC | 0.0422 mg a.s./L | [redacted]; 2012; M-444119-01-1 KCA 8.2.5.2 |
| | Invertebrate, chronic *Neocaridina heteropoda* (Freshwater shrimp) | NOEC | 0.060 mg a.s./L | [redacted]; 2012; M-442121-01-1 KCA 8.2.5.2 |
| | Marine invertebrate, chronic *Americamysis bahia* (*Mysidopsis bahia*, mysid shrimp) | $NOEC_{survival}$ $NOEC_{repro}$ | **0.00061 mg a.s./L** 0.0047 mg a.s./L | [redacted]; 2002; M-082820-01-1 |

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| | Sediment dweller, chronic<br>*Chironomus riparius*<br>(chironomid) | $EC_{15}$ | **2.13 mg a.s./L** | [redacted] 2000; M-042042-01-1 |
| | *Pseudokirchneriella subcapitata*<br>(green algae) | $E_bC_{50}$<br>$E_rC_{50}$ | 0.35 mg a.s./L<br>**2.10 mg a.s./L** | [redacted]; 2000; M-033313-01-1 |
| | *Lemna gibba*<br>(Duck weed) | $E_bC_{50}$<br>$E_rC_{50}$ | > 6.0 mg a.s./L<br>> 6.0 mg a.s./L | [redacted]; 2001; M-037727-01-1 |
| | *Lemna gibba*<br>(Duck weed) | $E_bC_{50}$<br>$E_rC_{50}$ | 1.45 mg a.s./L<br>**3.88 mg a.s./L** | [redacted]; 2002; M-083021-01-1<br>KCA 8.2.7 |
| HEC 5725-E-des-chlorophenyl | Fish, acute<br>*Oncorhynchus mykiss*<br>(rainbow trout) | **$LC_{50}$** | **> 102 mg p.m./L** | [redacted]; 2000; M-033495-01-1 |
| | Invertebrate, acute<br>*Daphnia magna*<br>(cladoceran) | **$EC_{50}$** | **> 100 mg p.m.//L** | [redacted]; 2000; M-038222-01-1 |
| | *Pseudokirchneriella subcapitata*<br>(green algae) | $E_bC_{50}$<br>**$E_rC_{50}$** | > 100 mg p.m./L<br>**> 100 mg p.m.//L** | [redacted]; 2000; M-025012-01-1 |
| HEC 5725-carboxylic acid | Fish, acute<br>*Oncorhynchus mykiss*<br>(rainbow trout) | **$LC_{50}$** | **>95.7 mg p.m./L** | [redacted] 2001; M-052093-01-1 |
| | Invertebrate, acute<br>*Daphnia magna*<br>(cladoceran) | **$EC_{50}$** | **> 100 mg p.m./L** | [redacted] 2001; M-030332-01-1 |
| | Sediment dweller, chronic<br>*Chironomus riparius*<br>(chironomid) | **$EC_{15}$** | **98.5 mg p.m./L** | [redacted].; 2001; M-078605-01-1 |
| | *Pseudokirchneriella subcapitata*<br>(*Selenastrum capricornutum*, green algae) | $E_bC_{50}$<br>**$E_rC_{50}$** | 115 mg p.m./L<br>**> 160 mg p.m./L** | [redacted].; 2001; M-073836-01-1 |
| 2-chlorophenol | Fish, acute<br>*Oncorhynchus mykiss*<br>(rainbow trout) | **$LC_{50}$** | **2.6 mg p.m./L** | [redacted]; 2006; M-277036-01-1<br>KCA 8.2.1 |
| | Fish, chronic<br>*Pimephales promelas*<br>(fathead minnow) | **NOEC** | **4 mg p.m./L** | EFSA Scientific Report 102 (2007)<br>[redacted]; 2006; M-277036-01-1 |
| | Invertebrate, acute<br>*Daphnia magna*<br>(cladoceran) | **$EC_{50}$** | **7.4 mg p.m./L** | [redacted]; 2006; M-277036-01-1<br>KCA 8.2.1 |
| | Invertebrate, chronic<br>*Daphnia magna*<br>(cladoceran) | **NOEC** | **0.3 mg p.m./L[2)]** | EFSA Scientific Report 102 (2007)<br>[redacted]; 2006; M-277036-01-1 |
| | *Pseudokirchneriella subcapitata*<br>(*Selenastrum capricornutum*, green algae) | **$E_rC_{50}$** | **70 mg p.m./L** | EFSA Scientific Report 102 (2007)<br>[redacted]; 2006; M-277036-01-1<br>KCA 8.2.1 |

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| BIX+FXA+PTZ EC 190 (40+50+100) G | Fish, acute *Oncorhynchus mykiss* (Rainbow trout) | $LC_{50}$ | 3.02 mg prod./L | [redacted],; 2010; M-385971-01-1 KCP 10.2.1 |
| | Invertebrate, acute *Daphnia magna* (Cladoceran) | $EC_{50}$ | 2.08 mg prod./L | [redacted]; 2010; M-385961-01-1 KCP 10.2.1 |
| | *Pseudokirchneriella subcapitata* (Green alga) | $E_rC_{50}$ NOE$_r$C | 5.86 mg prod./L 0.98 mg prod./L | [redacted],; 2010; M-387053-01-1 KCP 10.2.2 |

a.s.: active substance; p.m.: pure metabolite; prod.: formulated product.

1) When using the above acute invertebrate toxicity data (including Mysid, excluding the two "greater than" values), with the geomean approach according to the most recent aquatic guidance document (SANTE-2015-00080, 15 January 2015) a geometric mean value of 0.488 mg a.s./L can be calculated

2) In the statement on the exposure of aquatic organisms to 2-chlorophenol ([redacted]; 2006; M-277036-01-1) a NOEC of 0.5 mg/L is presented as most sensitive chronic endpoint for Daphnia based on nominal concentrations applied during testing. According to the EFSA Scientific Report (2007) the minimum measured concentration of 0.3 mg/l must be considered as relevant endpoint for the renewal of approval of fluoxastrobin.

**Bold values** used for the risk assessment

### Selection of endpoints for risk assessment

The relevant endpoint from each aquatic study was defined according to the current data requirements from the EU Regulation 283/2013 and the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013), and based on recommendations from the relevant standard test guideline e.g. Growth rate (r) is the most suitable endpoint from algae inhibition tests for use in risk assessment, as stated by OECD Guideline 201 and the EFSA guidance document. TER and RAC calculations presented in this dossier are thus based on the $E_rC_{50}$ values. Indeed, processes in ecosystems are dominantly rate driven and therefore, the unit development per time (growth rate) appears more suitable to measure effects in algae. Also, growth rates and their inhibition can easily be compared between species, test durations and test conditions, which is not the case for biomass. After numerous discussions, the current test guidelines OECD TG 201, the EU-Method C3, the EC regulation for Classification and Labeling (EC regulation 1272/2008) and the PPR Opinion (EFSA Journal 461, 1-44, 2007) list growth rate as the most suitable endpoint of the algae inhibition test.

In accordance with Regulation (EC) No 1107/2009 and with the EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (2013), studies resulting in lower endpoints were used for the risk assessment, including endpoints from estuarine or marine species.

### Predicted environmental concentrations used in risk assessment

Full details of the predicted environmental concentrations are given in MCP 9.2.5([redacted]; [redacted]; 2015; M-537907-01-1).

**Table CP 10.2- 2: Initial max $PEC_{sw}$ values – FOCUS Step 1, 2**

| Use pattern | Scenario | Fluoxastrobin (E+Z) | HEC 5725 -E-des-chlorophenyl | HEC 5725 -carboxylic acid | 2-chlorophenol |
|---|---|---|---|---|---|
| | | $PEC_{sw}$ [µg/L] | $PEC_{sw}$ [µg/L] | $PEC_{sw}$ [µg/L] | $PEC_{sw}$ [µg/L] |
| Cereals, 2 x 87.5 g/ha | Step 1 | 30.74 | 20.96 | 11.35 | 13.74 |
| | Step 2 | | | | |
| | N-EU Multi | 4.69 | 3.03 | 1.34 | 1.70 |
| | S-EU Multi | **8.55** | **5.89** | **2.61** | **3.28** |
| | N-EU Single | 2.65 | 1.67 | 0.82 | 1.03 |
| | S-EU Single | 4.82 | 3.24 | 1.61 | 1.99 |
| Cereals, 2 x 75 g/ha | Step 1 | 26.35 | 17.97 | 9.73 | 11.78 |
| | Step 2 | | | | |
| | N-EU Multi | 4.02 | 2.60 | 1.15 | 1.46 |
| | S-EU Multi | 7.33 | 5.05 | 2.24 | 2.81 |
| | N-EU Single | 2.27 | 1.43 | 0.71 | 0.88 |
| | S-EU Single | 4.13 | 2.77 | 1.38 | 1.70 |

**Bold** values considered in risk assessment

**Table CP 10.2- 3: Winter cereals: Maximum $PEC_{sw}$ and $TWAC_{sw}$-7 values for fluoxastrobin at Step 3**

| Use pattern | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Cereals (winter), 2 × 87.5 g a.s./ha | | | | Cereals (winter), 2 × 75.0 g a.s./ha | | | |
| | Single application | | Multiple applications | | Single application | | Multiple applications | |
| FOCUS scenario | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] |
| D1 (ditch) | **0.600** | **0.467** | **0.598** | **0.498** | **0.510** | **0.396** | **0.509** | **0.423** |
| D1 (stream) | **0.498** | **0.049** | **0.457** | **0.113** | **0.425** | **0.039** | **0.389** | **0.090** |
| D2 (ditch) | **0.592** | **0.394** | **0.636** | **0.453** | **0.501** | **0.332** | **0.538** | **0.380** |
| D2 (stream) | **0.481** | **0.039** | **0.465** | **0.206** | **0.410** | **0.030** | **0.394** | **0.172** |
| D3 (ditch) | **0.555** | **0.116** | **0.486** | **0.116** | **0.476** | **0.099** | **0.417** | **0.100** |
| D4 (pond) | **0.019** | 0.017 | **0.025** | 0.023 | **0.016** | 0.015 | **0.021** | 0.020 |
| D4 (stream) | **0.426** | **0.005** | **0.399** | **0.010** | **0.365** | **0.004** | **0.342** | **0.008** |
| D5 (pond) | **0.019** | 0.018 | **0.028** | 0.026 | **0.016** | 0.015 | **0.024** | 0.022 |
| D5 (stream) | **0.442** | **0.002** | **0.422** | **0.006** | **0.379** | **0.002** | **0.362** | **0.005** |
| D6 (ditch) | **0.553** | **0.086** | **0.486** | **0.205** | **0.474** | **0.073** | **0.417** | **0.176** |
| R1 (pond) | **0.043** | 0.040 | **0.113** | **0.107** | **0.036** | 0.034 | **0.096** | **0.091** |
| R1 (stream) | **0.365** | **0.039** | **0.908** | **0.113** | **0.313** | **0.033** | **0.763** | **0.095** |
| R3 (stream) | **0.515** | **0.061** | **0.731** | **0.100** | **0.442** | **0.051** | **0.615** | **0.084** |
| R4 (stream) | **0.449** | **0.124** | **0.950** | **0.271** | **0.379** | **0.105** | **0.801** | **0.230** |

**Bold** values considered in risk assessment
*Italic* values considered in refined risk assessment

**Table CP 10.2- 4: Spring cereals: Maximum $PEC_{sw}$ and $TWAC_{SW}$-7 values for fluoxastrobine at Step 3**

| Use pattern | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Cereals (spring), 2 × 87.5 g a.s./ha | | | | Cereals (spring), 2 × 75.0 g a.s./ha | | | |
| | Single application | | Multiple applications | | Single application | | Multiple applications | |
| FOCUS scenario | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] | $PEC_{sw}$ [µg/L] | $TWAC_{sw}$-7 [µg/L] |
| D1 (ditch) | **0.583** | **0.473** | **0.810** | **0.692** | **0.497** | **0.403** | **0.692** | **0.590** |
| D1 (stream) | **0.490** | **0.063** | **0.424** | **0.146** | **0.420** | **0.054** | **0.364** | **0.113** |
| D3 (ditch) | **0.554** | **0.090** | **0.485** | **0.082** | **0.475** | **0.077** | **0.416** | **0.070** |
| D4 (pond) | **0.019** | 0.017 | **0.027** | 0.025 | **0.016** | 0.015 | **0.023** | 0.022 |
| D4 (stream) | **0.453** | **0.006** | **0.404** | **0.012** | **0.388** | **0.005** | **0.347** | **0.010** |
| D5 (pond) | **0.019** | 0.018 | **0.027** | 0.025 | **0.017** | 0.015 | **0.023** | 0.021 |
| D5 (stream) | **0.465** | **0.004** | **0.418** | **0.005** | **0.399** | **0.003** | **0.358** | **0.004** |
| R4 (stream) | **0.607** | **0.187** | **1.211** | **0.273** | **0.511** | **0.158** | **1.023** | **0.231** |

**Bold** values considered in risk assessment
*Italic* values considered in refined risk assessment

**Table CP 10.2- 5: $TWAC_{sw}$ values at day 7 for fluoxastrobin – use in winter cereals FOCUS Step 4**

| | | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cereals (winter), 2 × 87.5 g a.s./ha | | | | | | | |
| | | Single application | | | | Multiple applications | | | |
| Buffer Width & Type[#] | Scenario | $TWAC_{sw}$-7 [µg/L] Drift Reduction | | | | $TWAC_{sw}$-7 [µg/L] Drift Reduction | | | |
| | | 0% | 50% | 75% | 90% | 0% | 50% | 75% | 90% |
| 20m SD & RO | D1 (ditch) | 0.079 | 0.079 | 0.079 | **0.079** | 0.181 | 0.181 | 0.181 | **0.181** |
| | D1 (stream) | 0.049 | 0.049 | 0.049 | 0.049 | 0.113 | 0.113 | 0.113 | **0.113** |
| | D2 (ditch) | 0.077 | 0.077 | 0.077 | **0.077** | 0.194 | 0.194 | 0.194 | **0.194** |
| | D2 (stream) | 0.035 | 0.035 | 0.035 | **0.035** | 0.101 | 0.101 | 0.101 | **0.101** |
| | D3 (ditch) | 0.009 | 0.004 | 0.002 | **0.001** | 0.008 | 0.004 | 0.002 | **0.001** |
| | D4 (pond) | 0.007 | 0.005 | 0.004 | 0.004 | 0.011 | 0.010 | 0.010 | 0.009 |
| | D4 (stream) | 0.005 | 0.005 | 0.005 | 0.005 | 0.010 | 0.010 | 0.010 | 0.010 |
| | D5 (pond) | 0.007 | 0.004 | 0.002 | 0.001 | 0.011 | 0.006 | 0.003 | 0.001 |
| | D5 (stream) | 0.000 | 0.000 | 0.000 | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 |
| | D6 (ditch) | 0.006 | 0.003 | 0.002 | **0.001** | 0.014 | 0.007 | 0.003 | **0.002** |
| | R1 (pond) | 0.010 | 0.008 | 0.007 | 0.007 | 0.025 | 0.022 | 0.020 | **0.019** |
| | R1 (stream) | 0.009 | 0.009 | 0.009 | 0.009 | 0.027 | 0.027 | 0.027 | **0.027** |
| | R3 (stream) | 0.015 | 0.015 | 0.015 | 0.015 | 0.023 | 0.023 | 0.023 | **0.023** |
| | R4 (stream) | 0.029 | 0.029 | 0.029 | **0.029** | 0.065 | 0.065 | 0.065 | **0.065** |

[#] SD and RO denote spray drift and runoff buffer
**Bold** values considered in refined risk assessment

**Table CP 10.2- 6: TWAC$_{sw}$ values at day 7 for fluoxastrobin – use in spring cereals FOCUS Step 4**

| | | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cereals (spring), 2 × 87.5 g a.s./ha | | | | | | | |
| | | Single application | | | | Multiple applications | | | |
| Buffer Width & Type# | Scenario | TWAC$_{sw}$-7 [µg/L] Drift Reduction | | | | TWAC$_{sw}$-7 [µg/L] Drift Reduction | | | |
| | | 0% | 50% | 75% | 90% | 0% | 50% | 75% | 90% |
| 20m SD & RO | D1 (ditch) | 0.097 | 0.097 | 0.097 | **0.097** | 0.234 | 0.234 | 0.234 | **0.234** |
| | D1 (stream) | 0.061 | 0.061 | 0.061 | **0.061** | 0.146 | 0.146 | 0.146 | **0.146** |
| | D3 (ditch) | 0.007 | 0.003 | 0.002 | **0.001** | 0.006 | 0.003 | 0.001 | **0.001** |
| | D4 (pond) | 0.007 | 0.005 | 0.005 | 0.005 | 0.013 | 0.012 | 0.011 | 0.011 |
| | D4 (stream) | 0.005 | 0.005 | 0.005 | 0.005 | 0.012 | 0.012 | 0.012 | 0.012 |
| | D5 (pond) | 0.007 | 0.004 | 0.002 | 0.001 | 0.010 | 0.005 | 0.003 | 0.001 |
| | D5 (stream) | 0.000 | 0.000 | 0.000 | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 |
| | R4 (stream) | 0.045 | 0.045 | 0.045 | **0.045** | 0.063 | 0.063 | 0.234 | **0.062** |

# SD and RO denote spray drift and runoff buffer
**Bold** values considered in refined risk assessment

**Table CP 10.2- 7: TWAC$_{sw}$ values at day 7 for fluoxastrobin – use in winter cereals FOCUS Step 4**

| | | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cereals (winter), 2 × 75.0 g a.s./ha | | | | | | | |
| | | Single application | | | | Multiple applications | | | |
| Buffer Width & Type# | Scenario | TWAC$_{sw}$-7 [µg/L] Drift Reduction | | | | TWAC$_{sw}$-7 [µg/L] Drift Reduction | | | |
| | | 0% | 50% | 75% | 90% | 0% | 50% | 75% | 90% |
| 20m SD & RO | D1 (ditch) | 0.062 | 0.062 | 0.062 | **0.062** | 0.144 | 0.144 | 0.144 | **0.144** |
| | D1 (stream) | 0.039 | 0.039 | 0.039 | 0.039 | 0.090 | 0.090 | 0.090 | **0.090** |
| | D2 (ditch) | 0.059 | 0.059 | 0.059 | **0.059** | 0.149 | 0.149 | 0.149 | **0.149** |
| | D2 (stream) | 0.026 | 0.026 | 0.026 | 0.026 | 0.076 | 0.076 | 0.076 | **0.076** |
| | D3 (ditch) | 0.007 | 0.004 | 0.002 | **0.001** | 0.007 | 0.003 | 0.002 | **0.001** |
| | D4 (pond) | 0.006 | 0.004 | 0.004 | 0.003 | 0.009 | 0.008 | 0.008 | 0.008 |
| | D4 (stream) | 0.004 | 0.004 | 0.004 | 0.004 | 0.008 | 0.008 | 0.008 | 0.008 |
| | D5 (pond) | 0.006 | 0.003 | 0.002 | 0.001 | 0.009 | 0.005 | 0.002 | 0.001 |
| | D5 (stream) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | D6 (ditch) | 0.005 | 0.003 | 0.001 | **0.001** | 0.012 | 0.006 | 0.003 | **0.001** |
| | R1 (pond) | 0.008 | 0.007 | 0.006 | 0.006 | 0.021 | 0.018 | 0.017 | **0.016** |
| | R1 (stream) | 0.008 | 0.008 | 0.008 | 0.008 | 0.023 | 0.023 | 0.023 | **0.023** |
| | R3 (stream) | 0.012 | 0.012 | 0.012 | 0.012 | 0.020 | 0.020 | 0.020 | **0.020** |
| | R4 (stream) | 0.025 | 0.025 | 0.025 | **0.025** | 0.055 | 0.055 | 0.055 | **0.055** |

# SD and RO denote spray drift and runoff buffer
**Bold** values considered in refined risk assessment

**Table CP 10.2- 8: TWAC$_{sw}$ values at day 7 for fluoxastrobin – use in spring cereals FOCUS Step 4**

| | | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cereals (spring), 2 × 75.0 g a.s./ha | | | | | | | |
| | | Single application | | | | Multiple applications | | | |
| Buffer Width & Type[#] | Scenario | TWAC$_{sw}$-7 [µg/L] Drift Reduction | | | | TWAC$_{sw}$-7 [µg/L] Drift Reduction | | | |
| | | 0% | 50% | 75% | 90% | 0% | 50% | 75% | 90% |
| 20m SD & RO | D1 (ditch) | 0.078 | 0.078 | 0.078 | **0.078** | 0.182 | 0.182 | 0.182 | **0.182** |
| | D1 (stream) | 0.049 | 0.049 | 0.049 | 0.049 | 0.113 | 0.113 | 0.113 | **0.113** |
| | D3 (ditch) | 0.006 | 0.003 | 0.001 | **0.001** | 0.005 | 0.002 | 0.001 | **0.000** |
| | D4 (pond) | 0.006 | 0.004 | 0.004 | 0.004 | 0.010 | 0.010 | 0.009 | 0.009 |
| | D4 (stream) | 0.004 | 0.004 | 0.004 | 0.004 | 0.010 | 0.010 | 0.010 | 0.010 |
| | D5 (pond) | 0.006 | 0.003 | 0.002 | 0.001 | 0.009 | 0.004 | 0.002 | 0.001 |
| | D5 (stream) | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | R4 (stream) | 0.038 | 0.038 | 0.038 | **0.038** | 0.053 | 0.053 | 0.053 | **0.053** |

[#] SD and RO denote spray drift and runoff buffer
**Bold** values considered in refined risk assessment

## ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

**Table CP 10.2- 9: TER$_A$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 87.5 g a.s./ha)**

| Compound | Species | Endpoint [µg/L] | | PEC$_{sw,max}$ [µg/L] | TER$_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Cereals (spring/winter)** | | | | | | |
| Fluoxastrobin (E+Z) | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 8.55 | **50.9** | 100 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 8.55 | **56.1** | 100 |
| | Invertebrate, acute *Gammarus pulex* | $EC_{50}$ | 150 | 8.55 | **17.5** | 100 |
| | Invertebrate, acute *Americamysis bahia* | $EC_{50}$ | 60.4 | 8.55 | **7.1** | 100 |
| HEC 5725-E-des-chlorophenyl | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | > 102 000 | 5.89 | > 17 317 | 100 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ | > 100 000 | 5.89 | > 16 978 | > 100 |
| HEC 5725-carboxylic acid | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | > 95 700 | 2.61 | > 36 667 | >100 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ | > 100 000 | 2.61 | > 38 314 | 100 |
| 2-chlorophenol | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 2600 | 3.28 | 793 | 100 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 7400 | 3.28 | 2256 | 100 |

**Bold** values do not meet the trigger

**Table CP 10.2- 10: $RAC_{sw;\,ac}$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 87.5 g a.s./ha (acceptability of risk: PEC/RAC < 1)**

| Compound | Species | Endpoint [µg/L] | $RAC_{sw;\,ac}$ ($LC_{50}$/100) | $PEC_{sw,max}$ [µg/L] | PEC/RAC |
|---|---|---|---|---|---|
| **Cereals (Winter/spring)** | | | | | |
| Fluoxastrobin (E+Z) | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ 435 | 4.35 | 8.55 | **1.97** |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ 480 | 4.8 | 8.55 | **1.78** |
| | Invertebrate, acute *Gammarus pulex* | $EC_{50}$ 150 | 1.5 | 8.55 | **5.70** |
| | Invertebrate, acute *Americamysis bahia* | $EC_{50}$ 60.4 | 0.604 | 8.55 | **14.16** |
| HEC 5725-E-des-chlorophenyl | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ > 102 000 | > 1020 | 5.89 | < 0.01 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ > 100 000 | > 1000 | 5.89 | < 0.01 |
| HEC 5725-carboxylic acid | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ > 95 700 | > 957 | 2.61 | < 0.003 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ > 100 000 | > 1000 | 2.61 | < 0.003 |
| 2-chlorophenol | Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ 2600 | 26 | 3.28 | 0.13 |
| | Invertebrate, acute *Daphnia magna* | $EC_{50}$ 7400 | 74 | 3.28 | 0.04 |

All TER values for the metabolites of fluoxastrobin meet the trigger for acute exposure. For fluoxastrobin the acute triggers were not met for fish and the invertebrates *D. magna*, *G. pulex* and *A. bahia*. Therefore, a refined risk assessment is required. The consideration of the more realistic FOCUS Step 3 surface water concentrations is presented below.

In accordance with the EFSA PPR Panel opinion on lowering the uncertainty factor when data on additional species are available (EFSA Journal (2005) 301, 1-45), as well as the recommendations provided in the new EFSA Guidance Document on Aquatic Ecotoxicology (EFSA Journal 2013;11(7):3290), the geomean of the available acute toxicity data on aquatic invertebrates (EU agreed endpoints) could be calculated and used in the refined risk assessment in combination with the trigger value of 100:

| Species | $EC_{50}$/$LC_{50}$ (mg a.s./L) |
|---|---|
| *Americamysis bahia* | 0.0604 |
| *Gammarus pulex* | 0.15 |
| *Daphnia magna* | 0.48 |
| *Acanthocyclops venustus* | 0.9 |
| *Cloeon dipterum* | 1.0 |
| *Daphnia* gr. *galeata* | 1.3 |
| *Asellus aquaticus* | 1.3 |
| *Chaoborus obscuripes* | >3.2 |
| *Simocephalus vetulus* | >3.2 |
| Geometric mean | 0.488 |

It has to be noted that the "greater than" endpoints for *Chaoborus obscuripes* and *Simocephalus vetulus* were not considered suitable for use in the calculation of the geometric mean, since they do not represent true effect values.

The geomean value of 0.488 mg a.s./L can be used for further refinement of the acute risk of Fluoxastrobin to aquatic organisms.

**Table CP 10.2- 11: $TER_A$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)**

| Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.598 | D1 (ditch) | 727.4 | 100 |
| | | | 0.457 | D1 (stream) | 951.9 | 100 |
| | | | 0.636 | D2 (ditch) | 684.0 | 100 |
| | | | 0.465 | D2 (stream) | 935.5 | 100 |
| | | | 0.486 | D3 (ditch) | 895.1 | 100 |
| | | | 0.025 | D4 (pond) | 17 400 | 100 |
| | | | 0.399 | D4 (stream) | 1090 | 100 |
| | | | 0.028 | D5 (pond) | 15 536 | 100 |
| | | | 0.422 | D5 (stream) | 1031 | 100 |
| | | | 0.486 | D6 (ditch) | 895.1 | 100 |
| | | | 0.113 | R1 (pond) | 3850 | 100 |
| | | | 0.908 | R1 (stream) | 479.1 | 100 |
| | | | 0.731 | R3 (stream) | 595.1 | 100 |
| | | | 0.950 | R4 (stream) | 457.9 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.598 | D1 (ditch) | 802.7 | 100 |
| | | | 0.457 | D1 (stream) | 1050 | 100 |
| | | | 0.636 | D2 (ditch) | 754.7 | 100 |
| | | | 0.465 | D2 (stream) | 1032 | 100 |
| | | | 0.486 | D3 (ditch) | 987.7 | 100 |
| | | | 0.025 | D4 (pond) | 19 200 | 100 |
| | | | 0.399 | D4 (stream) | 1203 | 100 |
| | | | 0.028 | D5 (pond) | 17 143 | 100 |
| | | | 0.422 | D5 (stream) | 1137 | 100 |
| | | | 0.486 | D6 (ditch) | 987.7 | 100 |
| | | | 0.113 | R1 (pond) | 4248 | 100 |
| | | | 0.908 | R1 (stream) | 528.6 | 100 |
| | | | 0.731 | R3 (stream) | 656.6 | 100 |
| | | | 0.950 | R4 (stream) | 505.3 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}/EC_{50}$ | 488 | 0.598 | D1 (ditch) | 816.1 | 100 |
| | | | 0.457 | D1 (stream) | 1068 | 100 |
| | | | 0.636 | D2 (ditch) | 767.3 | 100 |
| | | | 0.465 | D2 (stream) | 1050 | 100 |
| | | | 0.486 | D3 (ditch) | 1004 | 100 |

| Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| | | | 0.025 | D4 (pond) | 19 520 | 100 |
| | | | 0.399 | D4 (stream) | 1223 | 100 |
| | | | 0.028 | D5 (pond) | 17 429 | 100 |
| | | | 0.422 | D5 (stream) | 1156 | 100 |
| | | | 0.486 | D6 (ditch) | 1004 | 100 |
| | | | 0.113 | R1 (pond) | 4319 | 100 |
| | | | 0.908 | R1 (stream) | 537.4 | 100 |
| | | | 0.731 | R3 (stream) | 667.6 | 100 |
| | | | 0.950 | R4 (stream) | 513.7 | 100 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.810 | D1 (ditch) | 537.0 | 100 |
| | | | 0.424 | D1 (stream) | 1026 | 100 |
| | | | 0.485 | D3 (ditch) | 896.9 | 100 |
| | | | 0.027 | D4 (pond) | 16 111 | 100 |
| | | | 0.404 | D4 (stream) | 1077 | 100 |
| | | | 0.027 | D5 (pond) | 16 111 | 100 |
| | | | 0.418 | D5 (stream) | 1041 | 100 |
| | | | 1.211 | R4 (stream) | 359.2 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.810 | D1 (ditch) | 592.6 | 100 |
| | | | 0.424 | D1 (stream) | 1132 | 100 |
| | | | 0.485 | D3 (ditch) | 989.7 | 100 |
| | | | 0.027 | D4 (pond) | 17 778 | 100 |
| | | | 0.404 | D4 (stream) | 1188 | 100 |
| | | | 0.027 | D5 (pond) | 17 778 | 100 |
| | | | 0.418 | D5 (stream) | 1148 | 100 |
| | | | 1.211 | R4 (stream) | 396.4 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}/EC_{50}$ | 488 | 0.810 | D1 (ditch) | 602.5 | 100 |
| | | | 0.424 | D1 (stream) | 1151 | 100 |
| | | | 0.485 | D3 (ditch) | 1006 | 100 |
| | | | 0.027 | D4 (pond) | 18 074 | 100 |
| | | | 0.404 | D4 (stream) | 1208 | 100 |
| | | | 0.027 | D5 (pond) | 18 074 | 100 |
| | | | 0.418 | D5 (stream) | 1168 | 100 |
| | | | 1.211 | R4 (stream) | 403.0 | 100 |

**Table CP 10.2- 12: $TER_A$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)**

| Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.600 | D1 (ditch) | 725.0 | 100 |
| | | | 0.498 | D1 (stream) | 873.5 | 100 |
| | | | 0.592 | D2 (ditch) | 734.8 | 100 |
| | | | 0.481 | D2 (stream) | 904.4 | 100 |
| | | | 0.555 | D3 (ditch) | 783.8 | 100 |
| | | | 0.019 | D4 (pond) | 22 895 | 100 |
| | | | 0.426 | D4 (stream) | 1021 | 100 |
| | | | 0.019 | D5 (pond) | 22 895 | 100 |
| | | | 0.442 | D5 (stream) | 984.2 | 100 |
| | | | 0.553 | D6 (ditch) | 786.6 | 100 |
| | | | 0.043 | R1 (pond) | 10116 | 100 |
| | | | 0.365 | R1 (stream) | 1192 | 100 |
| | | | 0.515 | R3 (stream) | 844.7 | 100 |
| | | | 0.449 | R4 (stream) | 968.8 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.600 | D1 (ditch) | 800.0 | 100 |
| | | | 0.498 | D1 (stream) | 963.9 | 100 |
| | | | 0.592 | D2 (ditch) | 810.8 | 100 |
| | | | 0.481 | D2 (stream) | 997.9 | 100 |
| | | | 0.555 | D3 (ditch) | 864.9 | 100 |
| | | | 0.019 | D4 (pond) | 25 263 | 100 |
| | | | 0.426 | D4 (stream) | 1127 | 100 |
| | | | 0.019 | D5 (pond) | 25 263 | 100 |
| | | | 0.442 | D5 (stream) | 1086 | 100 |
| | | | 0.553 | D6 (ditch) | 868.0 | 100 |
| | | | 0.043 | R1 (pond) | 11 163 | 100 |
| | | | 0.365 | R1 (stream) | 1315 | 100 |
| | | | 0.515 | R3 (stream) | 932.0 | 100 |
| | | | 0.449 | R4 (stream) | 1069 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}/EC_{50}$ | 488 | 0.600 | D1 (ditch) | 813.3 | 100 |
| | | | 0.498 | D1 (stream) | 979.9 | 100 |
| | | | 0.592 | D2 (ditch) | 824.3 | 100 |
| | | | 0.481 | D2 (stream) | 1015 | 100 |
| | | | 0.555 | D3 (ditch) | 879.3 | 100 |
| | | | 0.019 | D4 (pond) | 25 684 | 100 |
| | | | 0.426 | D4 (stream) | 1146 | 100 |
| | | | 0.019 | D5 (pond) | 25 684 | 100 |
| | | | 0.442 | D5 (stream) | 1104 | 100 |
| | | | 0.553 | D6 (ditch) | 882.5 | 100 |
| | | | 0.043 | R1 (pond) | 11349 | 100 |

| Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| | | | 0.365 | R1 (stream) | 1337 | 100 |
| | | | 0.515 | R3 (stream) | 947.6 | 100 |
| | | | 0.449 | R4 (stream) | 1087 | 100 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.583 | D1 (ditch) | 746.1 | 100 |
| | | | 0.490 | D1 (stream) | 887.8 | 100 |
| | | | 0.554 | D3 (ditch) | 785.2 | 100 |
| | | | 0.019 | D4 (pond) | 22 895 | 100 |
| | | | 0.453 | D4 (stream) | 960.3 | 100 |
| | | | 0.019 | D5 (pond) | 22 895 | 100 |
| | | | 0.465 | D5 (stream) | 935.5 | 100 |
| | | | 0.607 | R4 (stream) | 716.6 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.583 | D1 (ditch) | 823.3 | 100 |
| | | | 0.490 | D1 (stream) | 979.6 | 100 |
| | | | 0.554 | D3 (ditch) | 866.4 | 100 |
| | | | 0.019 | D4 (pond) | 25 263 | 100 |
| | | | 0.453 | D4 (stream) | 1060 | 100 |
| | | | 0.019 | D5 (pond) | 25 263 | 100 |
| | | | 0.465 | D5 (stream) | 1032 | 100 |
| | | | 0.607 | R4 (stream) | 790.8 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}/EC_{50}$ | 488 | 0.583 | D1 (ditch) | 837.0 | 100 |
| | | | 0.490 | D1 (stream) | 995.9 | 100 |
| | | | 0.554 | D3 (ditch) | 880.9 | 100 |
| | | | 0.019 | D4 (pond) | 25 684 | 100 |
| | | | 0.453 | D4 (stream) | 1077 | 100 |
| | | | 0.019 | D5 (pond) | 25 684 | 100 |
| | | | 0.465 | D5 (stream) | 1050 | 100 |
| | | | 0.607 | R4 (stream) | 804.0 | 100 |

**Table CP 10.2- 13: TER$_A$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)**

| Species | Endpoint [µg/L] | | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | TER$_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.509 | D1 (ditch) | 854.6 | 100 |
| | | | 0.389 | D1 (stream) | 1118 | 100 |
| | | | 0.538 | D2 (ditch) | 808.6 | 100 |
| | | | 0.394 | D2 (stream) | 1104 | 100 |
| | | | 0.417 | D3 (ditch) | 1043 | 100 |
| | | | 0.021 | D4 (pond) | 20 714 | 100 |
| | | | 0.342 | D4 (stream) | 1272 | 100 |
| | | | 0.024 | D5 (pond) | 18 125 | 100 |
| | | | 0.362 | D5 (stream) | 1202 | 100 |
| | | | 0.417 | D6 (ditch) | 1043 | 100 |
| | | | 0.096 | R1 (pond) | 4531 | 100 |
| | | | 0.763 | R1 (stream) | 570.1 | 100 |
| | | | 0.615 | R3 (stream) | 707.3 | 100 |
| | | | 0.801 | R4 (stream) | 543.1 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.509 | D1 (ditch) | 943.0 | 100 |
| | | | 0.389 | D1 (stream) | 1234 | 100 |
| | | | 0.538 | D2 (ditch) | 892.2 | 100 |
| | | | 0.394 | D2 (stream) | 1218 | 100 |
| | | | 0.417 | D3 (ditch) | 1151 | 100 |
| | | | 0.021 | D4 (pond) | 22 857 | 100 |
| | | | 0.342 | D4 (stream) | 1404 | 100 |
| | | | 0.024 | D5 (pond) | 20 000 | 100 |
| | | | 0.362 | D5 (stream) | 1326 | 100 |
| | | | 0.417 | D6 (ditch) | 1151 | 100 |
| | | | 0.096 | R1 (pond) | 5000 | 100 |
| | | | 0.763 | R1 (stream) | 629.1 | 100 |
| | | | 0.615 | R3 (stream) | 780.5 | 100 |
| | | | 0.801 | R4 (stream) | 599.3 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ | 488 | 0.509 | D1 (ditch) | 958.7 | 100 |
| | | | 0.389 | D1 (stream) | 1254 | 100 |
| | | | 0.538 | D2 (ditch) | 907.1 | 100 |
| | | | 0.394 | D2 (stream) | 1239 | 100 |
| | | | 0.417 | D3 (ditch) | 1170 | 100 |
| | | | 0.021 | D4 (pond) | 23 238 | 100 |
| | | | 0.342 | D4 (stream) | 1427 | 100 |
| | | | 0.024 | D5 (pond) | 20 333 | 100 |
| | | | 0.362 | D5 (stream) | 1348 | 100 |
| | | | 0.417 | D6 (ditch) | 1170 | 100 |
| | | | 0.096 | R1 (pond) | 5083 | 100 |

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|
| | | 0.763 | R1 (stream) | 639.6 | 100 |
| | | 0.615 | R3 (stream) | 793.5 | 100 |
| | | 0.801 | R4 (stream) | 609.2 | 100 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0g a.s./ha** | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ 435 | 0.692 | D1 (ditch) | 628.6 | 100 |
| | | 0.364 | D1 (stream) | 1195 | 100 |
| | | 0.416 | D3 (ditch) | 1046 | 100 |
| | | 0.023 | D4 (pond) | 18 913 | 100 |
| | | 0.347 | D4 (stream) | 1254 | 100 |
| | | 0.023 | D5 (pond) | 18 913 | 100 |
| | | 0.358 | D5 (stream) | 1215 | 100 |
| | | 1.023 | R4 (stream) | 425.2 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ 480 | 0.692 | D1 (ditch) | 693.6 | 100 |
| | | 0.364 | D1 (stream) | 1319 | 100 |
| | | 0.416 | D3 (ditch) | 1154 | 100 |
| | | 0.023 | D4 (pond) | 20 870 | 100 |
| | | 0.347 | D4 (stream) | 1383 | 100 |
| | | 0.023 | D5 (pond) | 20 870 | 100 |
| | | 0.358 | D5 (stream) | 1341 | 100 |
| | | 1.023 | R4 (stream) | 469.2 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ 488 | 0.692 | D1 (ditch) | 705.2 | 100 |
| | | 0.364 | D1 (stream) | 1341 | 100 |
| | | 0.416 | D3 (ditch) | 1173 | 100 |
| | | 0.023 | D4 (pond) | 21 217 | 100 |
| | | 0.347 | D4 (stream) | 1406 | 100 |
| | | 0.023 | D5 (pond) | 21 217 | 100 |
| | | 0.358 | D5 (stream) | 1363 | 100 |
| | | 1.023 | R4 (stream) | 477.0 | 100 |

**Table CP 10.2- 14: $TER_A$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 and the refined aquatic invertebrates endpoint (geometric mean)**

| Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.510 | D1 (ditch) | 852.9 | 100 |
| | | | 0.425 | D1 (stream) | 1024 | 100 |
| | | | 0.501 | D2 (ditch) | 868.3 | 100 |
| | | | 0.410 | D2 (stream) | 1061 | 100 |
| | | | 0.476 | D3 (ditch) | 913.9 | 100 |
| | | | 0.016 | D4 (pond) | 27 188 | 100 |
| | | | 0.365 | D4 (stream) | 1192 | 100 |
| | | | 0.016 | D5 (pond) | 27 188 | 100 |
| | | | 0.379 | D5 (stream) | 1148 | 100 |
| | | | 0.474 | D6 (ditch) | 917.7 | 100 |
| | | | 0.036 | R1 (pond) | 12 083 | 100 |
| | | | 0.313 | R1 (stream) | 1390 | 100 |
| | | | 0.442 | R3 (stream) | 984.2 | 100 |
| | | | 0.379 | R4 (stream) | 1148 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.510 | D1 (ditch) | 941.2 | 100 |
| | | | 0.425 | D1 (stream) | 1129 | 100 |
| | | | 0.501 | D2 (ditch) | 958.1 | 100 |
| | | | 0.410 | D2 (stream) | 1171 | 100 |
| | | | 0.476 | D3 (ditch) | 1008 | 100 |
| | | | 0.016 | D4 (pond) | 30 000 | 100 |
| | | | 0.365 | D4 (stream) | 1315 | 100 |
| | | | 0.016 | D5 (pond) | 30 000 | 100 |
| | | | 0.379 | D5 (stream) | 1266 | 100 |
| | | | 0.474 | D6 (ditch) | 1013 | 100 |
| | | | 0.036 | R1 (pond) | 13 333 | 100 |
| | | | 0.313 | R1 (stream) | 1534 | 100 |
| | | | 0.442 | R3 (stream) | 1086 | 100 |
| | | | 0.379 | R4 (stream) | 1266 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}/EC_{50}$ | 488 | 0.510 | D1 (ditch) | 956.9 | 100 |
| | | | 0.425 | D1 (stream) | 1148 | 100 |
| | | | 0.501 | D2 (ditch) | 974.1 | 100 |
| | | | 0.410 | D2 (stream) | 1190 | 100 |
| | | | 0.476 | D3 (ditch) | 1025 | 100 |
| | | | 0.016 | D4 (pond) | 30 500 | 100 |
| | | | 0.365 | D4 (stream) | 1337 | 100 |
| | | | 0.016 | D5 (pond) | 30 500 | 100 |
| | | | 0.379 | D5 (stream) | 1288 | 100 |
| | | | 0.474 | D6 (ditch) | 1030 | 100 |
| | | | 0.036 | R1 (pond) | 13 556 | 100 |

| Species | Endpoint [µg/L] | | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_A$ | Trigger |
|---|---|---|---|---|---|---|
| | | | 0.313 | R1 (stream) | 1559 | 100 |
| | | | 0.442 | R3 (stream) | 1104 | 100 |
| | | | 0.379 | R4 (stream) | 1288 | 100 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 0.497 | D1 (ditch) | 875.3 | 100 |
| | | | 0.420 | D1 (stream) | 1036 | 100 |
| | | | 0.475 | D3 (ditch) | 915.8 | 100 |
| | | | 0.016 | D4 (pond) | 27 188 | 100 |
| | | | 0.388 | D4 (stream) | 1121 | 100 |
| | | | 0.017 | D5 (pond) | 25 588 | 100 |
| | | | 0.399 | D5 (stream) | 1090 | 100 |
| | | | 0.511 | R4 (stream) | 851.3 | 100 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 0.497 | D1 (ditch) | 965.8 | 100 |
| | | | 0.420 | D1 (stream) | 1143 | 100 |
| | | | 0.475 | D3 (ditch) | 1011 | 100 |
| | | | 0.016 | D4 (pond) | 30 000 | 100 |
| | | | 0.388 | D4 (stream) | 1237 | 100 |
| | | | 0.017 | D5 (pond) | 28 235 | 100 |
| | | | 0.399 | D5 (stream) | 1203 | 100 |
| | | | 0.511 | R4 (stream) | 939.3 | 100 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}/EC_{50}$ | 488 | 0.497 | D1 (ditch) | 981.9 | 100 |
| | | | 0.420 | D1 (stream) | 1162 | 100 |
| | | | 0.475 | D3 (ditch) | 1027 | 100 |
| | | | 0.016 | D4 (pond) | 30 500 | 100 |
| | | | 0.388 | D4 (stream) | 1258 | 100 |
| | | | 0.017 | D5 (pond) | 28 706 | 100 |
| | | | 0.399 | D5 (stream) | 1223 | 100 |
| | | | 0.511 | R4 (stream) | 955.0 | 100 |

**Table CP 10.2- 15: $RAC_{sw; ac}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | $RAC_{sw; ac}$ ($LC_{50}$/100) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 4.35 | 0.598 | D1 (ditch) | 0.14 |
| | | | | 0.457 | D1 (stream) | 0.11 |
| | | | | 0.636 | D2 (ditch) | 0.15 |
| | | | | 0.465 | D2 (stream) | 0.11 |
| | | | | 0.486 | D3 (ditch) | 0.11 |
| | | | | 0.025 | D4 (pond) | 0.01 |
| | | | | 0.399 | D4 (stream) | 0.09 |
| | | | | 0.028 | D5 (pond) | 0.01 |
| | | | | 0.422 | D5 (stream) | 0.10 |
| | | | | 0.486 | D6 (ditch) | 0.11 |
| | | | | 0.113 | R1 (pond) | 0.03 |
| | | | | 0.908 | R1 (stream) | 0.21 |
| | | | | 0.731 | R3 (stream) | 0.17 |
| | | | | 0.950 | R4 (stream) | 0.22 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 4.80 | 0.598 | D1 (ditch) | 0.12 |
| | | | | 0.457 | D1 (stream) | 0.10 |
| | | | | 0.636 | D2 (ditch) | 0.13 |
| | | | | 0.465 | D2 (stream) | 0.10 |
| | | | | 0.486 | D3 (ditch) | 0.10 |
| | | | | 0.025 | D4 (pond) | 0.01 |
| | | | | 0.399 | D4 (stream) | 0.08 |
| | | | | 0.028 | D5 (pond) | 0.01 |
| | | | | 0.422 | D5 (stream) | 0.09 |
| | | | | 0.486 | D6 (ditch) | 0.10 |
| | | | | 0.113 | R1 (pond) | 0.02 |
| | | | | 0.908 | R1 (stream) | 0.19 |
| | | | | 0.731 | R3 (stream) | 0.15 |
| | | | | 0.950 | R4 (stream) | 0.20 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ | 488 | 4.88 | 0.598 | D1 (ditch) | 0.12 |
| | | | | 0.457 | D1 (stream) | 0.09 |
| | | | | 0.636 | D2 (ditch) | 0.13 |
| | | | | 0.465 | D2 (stream) | 0.10 |
| | | | | 0.486 | D3 (ditch) | 0.10 |
| | | | | 0.025 | D4 (pond) | 0.01 |
| | | | | 0.399 | D4 (stream) | 0.08 |
| | | | | 0.028 | D5 (pond) | 0.01 |
| | | | | 0.422 | D5 (stream) | 0.09 |
| | | | | 0.486 | D6 (ditch) | 0.10 |
| | | | | 0.113 | R1 (pond) | 0.02 |

| Species | Endpoint [µg/L] | RAC$_{sw; ac}$ ($LC_{50}$/100) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.908 | R1 (stream) | 0.19 |
| | | | 0.731 | R3 (stream) | 0.15 |
| | | | 0.950 | R4 (stream) | 0.19 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ 435 | 4.35 | 0.810 | D1 (ditch) | 0.19 |
| | | | 0.424 | D1 (stream) | 0.10 |
| | | | 0.485 | D3 (ditch) | 0.11 |
| | | | 0.027 | D4 (pond) | 0.01 |
| | | | 0.404 | D4 (stream) | 0.09 |
| | | | 0.027 | D5 (pond) | 0.01 |
| | | | 0.418 | D5 (stream) | 0.10 |
| | | | 1.211 | R4 (stream) | 0.28 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ 480 | 4.80 | 0.810 | D1 (ditch) | 0.17 |
| | | | 0.424 | D1 (stream) | 0.09 |
| | | | 0.485 | D3 (ditch) | 0.10 |
| | | | 0.027 | D4 (pond) | 0.01 |
| | | | 0.404 | D4 (stream) | 0.08 |
| | | | 0.027 | D5 (pond) | 0.01 |
| | | | 0.418 | D5 (stream) | 0.09 |
| | | | 1.211 | R4 (stream) | 0.25 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ 488 | 4.88 | 0.810 | D1 (ditch) | 0.17 |
| | | | 0.424 | D1 (stream) | 0.09 |
| | | | 0.485 | D3 (ditch) | 0.10 |
| | | | 0.027 | D4 (pond) | 0.01 |
| | | | 0.404 | D4 (stream) | 0.08 |
| | | | 0.027 | D5 (pond) | 0.01 |
| | | | 0.418 | D5 (stream) | 0.09 |
| | | | 1.211 | R4 (stream) | 0.25 |

**Table CP 10.2- 16: $RAC_{sw; ac}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | $RAC_{sw; ac}$ ($LC_{50}$/100) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ | 435 | 4.35 | 0.600 | D1 (ditch) | 0.14 |
| | | | | 0.498 | D1 (stream) | 0.11 |
| | | | | 0.592 | D2 (ditch) | 0.14 |
| | | | | 0.481 | D2 (stream) | 0.11 |
| | | | | 0.555 | D3 (ditch) | 0.13 |
| | | | | 0.019 | D4 (pond) | 0.00 |
| | | | | 0.426 | D4 (stream) | 0.10 |
| | | | | 0.019 | D5 (pond) | 0.004 |
| | | | | 0.442 | D5 (stream) | 0.10 |
| | | | | 0.553 | D6 (ditch) | 0.13 |
| | | | | 0.043 | R1 (pond) | 0.01 |
| | | | | 0.365 | R1 (stream) | 0.08 |
| | | | | 0.515 | R3 (stream) | 0.12 |
| | | | | 0.449 | R4 (stream) | 0.10 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ | 480 | 4.80 | 0.600 | D1 (ditch) | 0.13 |
| | | | | 0.498 | D1 (stream) | 0.10 |
| | | | | 0.592 | D2 (ditch) | 0.12 |
| | | | | 0.481 | D2 (stream) | 0.10 |
| | | | | 0.555 | D3 (ditch) | 0.12 |
| | | | | 0.019 | D4 (pond) | 0.00 |
| | | | | 0.426 | D4 (stream) | 0.09 |
| | | | | 0.019 | D5 (pond) | 0.004 |
| | | | | 0.442 | D5 (stream) | 0.09 |
| | | | | 0.553 | D6 (ditch) | 0.12 |
| | | | | 0.043 | R1 (pond) | 0.01 |
| | | | | 0.365 | R1 (stream) | 0.08 |
| | | | | 0.515 | R3 (stream) | 0.11 |
| | | | | 0.449 | R4 (stream) | 0.09 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ | 488 | 4.88 | 0.600 | D1 (ditch) | 0.12 |
| | | | | 0.498 | D1 (stream) | 0.10 |
| | | | | 0.592 | D2 (ditch) | 0.12 |
| | | | | 0.481 | D2 (stream) | 0.10 |
| | | | | 0.555 | D3 (ditch) | 0.11 |
| | | | | 0.019 | D4 (pond) | 0.00 |
| | | | | 0.426 | D4 (stream) | 0.09 |
| | | | | 0.019 | D5 (pond) | 0.004 |
| | | | | 0.442 | D5 (stream) | 0.09 |
| | | | | 0.553 | D6 (ditch) | 0.11 |
| | | | | 0.043 | R1 (pond) | 0.01 |

| Species | Endpoint [µg/L] | $RAC_{sw; ac}$ ($LC_{50}$/100) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.365 | R1 (stream) | 0.07 |
| | | | 0.515 | R3 (stream) | 0.11 |
| | | | 0.449 | R4 (stream) | 0.09 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ 435 | 4.35 | 0.583 | D1 (ditch) | 0.13 |
| | | | 0.490 | D1 (stream) | 0.11 |
| | | | 0.554 | D3 (ditch) | 0.13 |
| | | | 0.019 | D4 (pond) | 0.004 |
| | | | 0.453 | D4 (stream) | 0.10 |
| | | | 0.019 | D5 (pond) | 0.00 |
| | | | 0.465 | D5 (stream) | 0.11 |
| | | | 0.607 | R4 (stream) | 0.14 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ 480 | 4.80 | 0.583 | D1 (ditch) | 0.12 |
| | | | 0.490 | D1 (stream) | 0.10 |
| | | | 0.554 | D3 (ditch) | 0.12 |
| | | | 0.019 | D4 (pond) | 0.004 |
| | | | 0.453 | D4 (stream) | 0.09 |
| | | | 0.019 | D5 (pond) | 0.00 |
| | | | 0.465 | D5 (stream) | 0.10 |
| | | | 0.607 | R4 (stream) | 0.13 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ 488 | 4.88 | 0.583 | D1 (ditch) | 0.12 |
| | | | 0.490 | D1 (stream) | 0.10 |
| | | | 0.554 | D3 (ditch) | 0.11 |
| | | | 0.019 | D4 (pond) | 0.004 |
| | | | 0.453 | D4 (stream) | 0.09 |
| | | | 0.019 | D5 (pond) | 0.00 |
| | | | 0.465 | D5 (stream) | 0.10 |
| | | | 0.607 | R4 (stream) | 0.12 |

**Table CP 10.2- 17: RAC$_{sw; ac}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | RAC$_{sw; ac}$ (LC$_{50}$/100) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | LC$_{50}$ | 435 | 4.35 | 0.509 | D1 (ditch) | 0.12 |
| | | | | 0.389 | D1 (stream) | 0.09 |
| | | | | 0.538 | D2 (ditch) | 0.12 |
| | | | | 0.394 | D2 (stream) | 0.09 |
| | | | | 0.417 | D3 (ditch) | 0.10 |
| | | | | 0.021 | D4 (pond) | 0.005 |
| | | | | 0.342 | D4 (stream) | 0.08 |
| | | | | 0.024 | D5 (pond) | 0.01 |
| | | | | 0.362 | D5 (stream) | 0.08 |
| | | | | 0.417 | D6 (ditch) | 0.10 |
| | | | | 0.096 | R1 (pond) | 0.02 |
| | | | | 0.763 | R1 (stream) | 0.18 |
| | | | | 0.615 | R3 (stream) | 0.14 |
| | | | | 0.801 | R4 (stream) | 0.18 |
| Invertebrate, acute *Daphnia magna* | EC$_{50}$ | 480 | 4.80 | 0.509 | D1 (ditch) | 0.11 |
| | | | | 0.389 | D1 (stream) | 0.08 |
| | | | | 0.538 | D2 (ditch) | 0.11 |
| | | | | 0.394 | D2 (stream) | 0.08 |
| | | | | 0.417 | D3 (ditch) | 0.09 |
| | | | | 0.021 | D4 (pond) | 0.004 |
| | | | | 0.342 | D4 (stream) | 0.07 |
| | | | | 0.024 | D5 (pond) | 0.01 |
| | | | | 0.362 | D5 (stream) | 0.08 |
| | | | | 0.417 | D6 (ditch) | 0.09 |
| | | | | 0.096 | R1 (pond) | 0.02 |
| | | | | 0.763 | R1 (stream) | 0.16 |
| | | | | 0.615 | R3 (stream) | 0.13 |
| | | | | 0.801 | R4 (stream) | 0.17 |
| Invertebrate, acute Geomean, 7 species | LC$_{50}$/EC$_{50}$ | 488 | 4.88 | 0.509 | D1 (ditch) | 0.10 |
| | | | | 0.389 | D1 (stream) | 0.08 |
| | | | | 0.538 | D2 (ditch) | 0.11 |
| | | | | 0.394 | D2 (stream) | 0.08 |
| | | | | 0.417 | D3 (ditch) | 0.09 |
| | | | | 0.021 | D4 (pond) | 0.004 |
| | | | | 0.342 | D4 (stream) | 0.07 |
| | | | | 0.024 | D5 (pond) | 0.00 |
| | | | | 0.362 | D5 (stream) | 0.07 |
| | | | | 0.417 | D6 (ditch) | 0.09 |
| | | | | 0.096 | R1 (pond) | 0.02 |

| Species | Endpoint [µg/L] | RAC$_{sw; ac}$ (LC$_{50}$/100) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.763 | R1 (stream) | 0.16 |
| | | | 0.615 | R3 (stream) | 0.13 |
| | | | 0.801 | R4 (stream) | 0.16 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | |
| Fish, acute *Oncorhynchus mykiss* | LC$_{50}$ 435 | 4.35 | 0.692 | D1 (ditch) | 0.16 |
| | | | 0.364 | D1 (stream) | 0.08 |
| | | | 0.416 | D3 (ditch) | 0.10 |
| | | | 0.023 | D4 (pond) | 0.01 |
| | | | 0.347 | D4 (stream) | 0.08 |
| | | | 0.023 | D5 (pond) | 0.01 |
| | | | 0.358 | D5 (stream) | 0.08 |
| | | | 1.023 | R4 (stream) | 0.24 |
| Invertebrate, acute *Daphnia magna* | EC$_{50}$ 480 | 4.80 | 0.692 | D1 (ditch) | 0.14 |
| | | | 0.364 | D1 (stream) | 0.08 |
| | | | 0.416 | D3 (ditch) | 0.09 |
| | | | 0.023 | D4 (pond) | 0.005 |
| | | | 0.347 | D4 (stream) | 0.07 |
| | | | 0.023 | D5 (pond) | 0.005 |
| | | | 0.358 | D5 (stream) | 0.07 |
| | | | 1.023 | R4 (stream) | 0.21 |
| Invertebrate, acute Geomean, 7 species | LC$_{50}$/EC$_{50}$ 488 | 4.88 | 0.692 | D1 (ditch) | 0.14 |
| | | | 0.364 | D1 (stream) | 0.07 |
| | | | 0.416 | D3 (ditch) | 0.09 |
| | | | 0.023 | D4 (pond) | 0.005 |
| | | | 0.347 | D4 (stream) | 0.07 |
| | | | 0.023 | D5 (pond) | 0.005 |
| | | | 0.358 | D5 (stream) | 0.07 |
| | | | 1.023 | R4 (stream) | 0.21 |

**Table CP 10.2- 18: RAC$_{sw; ac}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | RAC$_{sw; ac}$ (LC$_{50}$/100) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| Fish, acute *Oncorhynchus mykiss* | LC$_{50}$ | 435 | 4.35 | 0.510 | D1 (ditch) | 0.12 |
| | | | | 0.425 | D1 (stream) | 0.10 |
| | | | | 0.501 | D2 (ditch) | 0.12 |
| | | | | 0.410 | D2 (stream) | 0.09 |
| | | | | 0.476 | D3 (ditch) | 0.11 |
| | | | | 0.016 | D4 (pond) | 0.004 |
| | | | | 0.365 | D4 (stream) | 0.08 |
| | | | | 0.016 | D5 (pond) | 0.004 |
| | | | | 0.379 | D5 (stream) | 0.09 |
| | | | | 0.474 | D6 (ditch) | 0.11 |
| | | | | 0.036 | R1 (pond) | 0.01 |
| | | | | 0.313 | R1 (stream) | 0.07 |
| | | | | 0.442 | R3 (stream) | 0.10 |
| | | | | 0.379 | R4 (stream) | 0.09 |
| Invertebrate, acute *Daphnia magna* | EC$_{50}$ | 480 | 4.80 | 0.510 | D1 (ditch) | 0.11 |
| | | | | 0.425 | D1 (stream) | 0.09 |
| | | | | 0.501 | D2 (ditch) | 0.10 |
| | | | | 0.410 | D2 (stream) | 0.09 |
| | | | | 0.476 | D3 (ditch) | 0.10 |
| | | | | 0.016 | D4 (pond) | 0.003 |
| | | | | 0.365 | D4 (stream) | 0.08 |
| | | | | 0.016 | D5 (pond) | 0.003 |
| | | | | 0.379 | D5 (stream) | 0.08 |
| | | | | 0.474 | D6 (ditch) | 0.10 |
| | | | | 0.036 | R1 (pond) | 0.01 |
| | | | | 0.313 | R1 (stream) | 0.07 |
| | | | | 0.442 | R3 (stream) | 0.09 |
| | | | | 0.379 | R4 (stream) | 0.08 |
| Invertebrate, acute Geomean, 7 species | LC$_{50}$/EC$_{50}$ | 488 | 4.88 | 0.510 | D1 (ditch) | 0.10 |
| | | | | 0.425 | D1 (stream) | 0.09 |
| | | | | 0.501 | D2 (ditch) | 0.10 |
| | | | | 0.410 | D2 (stream) | 0.08 |
| | | | | 0.476 | D3 (ditch) | 0.10 |
| | | | | 0.016 | D4 (pond) | 0.003 |
| | | | | 0.365 | D4 (stream) | 0.07 |
| | | | | 0.016 | D5 (pond) | 0.003 |
| | | | | 0.379 | D5 (stream) | 0.08 |
| | | | | 0.474 | D6 (ditch) | 0.10 |
| | | | | 0.036 | R1 (pond) | 0.01 |

| Species | Endpoint [µg/L] | $RAC_{sw; ac}$ ($LC_{50}$/100) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.313 | R1 (stream) | 0.06 |
| | | | 0.442 | R3 (stream) | 0.09 |
| | | | 0.379 | R4 (stream) | 0.08 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | |
| Fish, acute *Oncorhynchus mykiss* | $LC_{50}$ 435 | 4.35 | 0.497 | D1 (ditch) | 0.11 |
| | | | 0.420 | D1 (stream) | 0.10 |
| | | | 0.475 | D3 (ditch) | 0.11 |
| | | | 0.016 | D4 (pond) | 0.004 |
| | | | 0.388 | D4 (stream) | 0.09 |
| | | | 0.017 | D5 (pond) | 0.004 |
| | | | 0.399 | D5 (stream) | 0.09 |
| | | | 0.511 | R4 (stream) | 0.12 |
| Invertebrate, acute *Daphnia magna* | $EC_{50}$ 480 | 4.80 | 0.497 | D1 (ditch) | 0.10 |
| | | | 0.420 | D1 (stream) | 0.09 |
| | | | 0.475 | D3 (ditch) | 0.10 |
| | | | 0.016 | D4 (pond) | 0.003 |
| | | | 0.388 | D4 (stream) | 0.08 |
| | | | 0.017 | D5 (pond) | 0.004 |
| | | | 0.399 | D5 (stream) | 0.08 |
| | | | 0.511 | R4 (stream) | 0.11 |
| Invertebrate, acute Geomean, 7 species | $LC_{50}$/$EC_{50}$ 488 | 4.88 | 0.497 | D1 (ditch) | 0.10 |
| | | | 0.420 | D1 (stream) | 0.09 |
| | | | 0.475 | D3 (ditch) | 0.10 |
| | | | 0.016 | D4 (pond) | 0.003 |
| | | | 0.388 | D4 (stream) | 0.08 |
| | | | 0.017 | D5 (pond) | 0.003 |
| | | | 0.399 | D5 (stream) | 0.08 |
| | | | 0.511 | R4 (stream) | 0.10 |

The trigger is met for all evaluated scenarios. Consequently, a safe use can be assumed according to the proposed GAP.

## CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

**Table CP 10.2- 19: $TER_{LT}$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 x 87.5 g a.s./ha)**

| Compound | Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Cereals (Winter/spring)** | | | | | |
| Fluoxastrobin (E+Z) | Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 8.55 | **3.3** | 10 |
| | Invertebrate, chronic *Daphnia magna* | NOEC 180 | 8.55 | 21 | 10 |
| | Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 8.55 | **3.7** | 10 |
| | Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 8.55 | **0.07** | 10 |
| | Sediment dweller, chronic *Chironomus riparius* | $EC_{15}$ 2130 | 8.55 | 249 | 10 |
| | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ 2100 | 8.55 | 246 | 10 |
| | Aquatic plant, chronic *Lemna gibba* | $E_rC_{50}$ 3880 | 8.55 | 454 | 10 |
| HEC 5725-E-des-chlorophenyl | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ > 100 000 | 5.89 | > 16 978 | 10 |
| HEC 5725-carboxylic acid | Sediment dweller, chronic *Chironomus riparius* | $EC_{15}$ 98 500 | 2.61 | 37 739 | 10 |
| | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ > 160 000 | 2.61 | > 31 303 | 10 |
| 2-chlorophenol | Fish, chronic *Pimephales promelas* | NOEC 4000 | 3.28 | 1220 | 10 |
| | Invertebrate, chronic *Daphnia magna* | NOEC 300 | 3.28 | 91 | 10 |
| | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ 70 000 | 3.28 | 21 341 | 10 |

* Endpoint from study conducted with EC 100 formulation
**Bold** values do not meet the trigger

**Table CP 10.2- 20: $RAC_{sw, ch}$ calculations based on FOCUS Step 2 (PEC values based for cereals on worst-case GAP 2 × 87.5 g a.s./ha) (acceptability of risk: PEC/RAC < 1)**

| Compound | Species | Endpoint [µg/L] | $RAC_{sw, ch}$ (NOEC/10) ($E_rC_{50}$/10) | $PEC_{sw,max}$ [µg/L] | PEC/RAC |
|---|---|---|---|---|---|
| **Cereals (Winter/spring)** | | | | | |
| Fluoxastrobin (E+Z) | Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 2.86 | 8.55 | **2.99** |
| | Invertebrate, chronic *Daphnia magna* | NOEC 180 | 18.0 | 8.55 | 0.48 |
| | Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 3.16 | 8.55 | **2.71** |
| | Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 8.55 | **140** |
| | Sediment dweller, chronic *Chironomus riparius* | $EC_{15}$ 2130 | 213.0 | 8.55 | 0.04 |
| | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ 2100 | 210.0 | 8.55 | 0.04 |
| | Aquatic plant, chronic *Lemna gibba* | $E_rC_{50}$ 3880 | 388 | 8.55 | 0.02 |
| HEC 5725-E-des-chlorophenyl | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ > 100 000 | > 10 000 | 5.89 | < 0.0006 |
| HEC 5725-carboxylic acid | Sediment dweller, chronic *Chironomus riparius* | $EC_{15}$ 98 500 | 9850 | 2.61 | < 0.0003 |
| | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ > 160 000 | > 16 000 | 2.61 | < 0.0002 |
| 2-chlorophenol | Fish, chronic *Pimephales promelas* | NOEC 4000 | 400.0 | 3.28 | 0.01 |
| | Invertebrate, chronic *Daphnia magna* | NOEC 300 | 30.0 | 3.28 | 0.11 |
| | Green alga, chronic *Pseudokirchneriella subcapitata* | $E_rC_{50}$ 70 000 | 7000 | 3.28 | 0.0005 |

* Endpoint from study conducted with EC 100 formulation

Results indicated in bold letter need further refinement. The consideration of the more realistic FOCUS Step 3 surface water concentrations is presented below.

**Table CP 10.2- 21: $TER_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3**

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.598 | D1 (ditch) | 48 | 10 |
| | | 0.457 | D1 (stream) | 63 | 10 |
| | | 0.636 | D2 (ditch) | 45 | 10 |
| | | 0.465 | D2 (stream) | 62 | 10 |
| | | 0.486 | D3 (ditch) | 59 | 10 |
| | | 0.025 | D4 (pond) | 1144 | 10 |
| | | 0.399 | D4 (stream) | 72 | 10 |
| | | 0.028 | D5 (pond) | 1021 | 10 |
| | | 0.422 | D5 (stream) | 68 | 10 |
| | | 0.486 | D6 (ditch) | 59 | 10 |
| | | 0.113 | R1 (pond) | 253 | 10 |
| | | 0.908 | R1 (stream) | 31 | 10 |
| | | 0.731 | R3 (stream) | 39 | 10 |
| | | 0.950 | R4 (stream) | 30 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.598 | D1 (ditch) | 53 | 10 |
| | | 0.457 | D1 (stream) | 69 | 10 |
| | | 0.636 | D2 (ditch) | 50 | 10 |
| | | 0.465 | D2 (stream) | 68 | 10 |
| | | 0.486 | D3 (ditch) | 65 | 10 |
| | | 0.025 | D4 (pond) | 1264 | 10 |
| | | 0.399 | D4 (stream) | 79 | 10 |
| | | 0.028 | D5 (pond) | 1129 | 10 |
| | | 0.422 | D5 (stream) | 75 | 10 |
| | | 0.486 | D6 (ditch) | 65 | 10 |
| | | 0.113 | R1 (pond) | 280 | 10 |
| | | 0.908 | R1 (stream) | 35 | 10 |
| | | 0.731 | R3 (stream) | 43 | 10 |
| | | 0.950 | R4 (stream) | 33 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.598 | D1 (ditch) | **1.0** | 10 |
| | | 0.457 | D1 (stream) | **1.3** | 10 |
| | | 0.636 | D2 (ditch) | **1.0** | 10 |
| | | 0.465 | D2 (stream) | **1.3** | 10 |
| | | 0.486 | D3 (ditch) | **1.3** | 10 |
| | | 0.025 | D4 (pond) | 24.4 | 10 |
| | | 0.399 | D4 (stream) | **1.5** | 10 |
| | | 0.028 | D5 (pond) | 21.8 | 10 |
| | | 0.422 | D5 (stream) | **1.4** | 10 |
| | | 0.486 | D6 (ditch) | **1.3** | 10 |
| | | 0.113 | R1 (pond) | **5.4** | 10 |
| | | 0.908 | R1 (stream) | **0.7** | 10 |
| | | 0.731 | R3 (stream) | **0.8** | 10 |

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| | | 0.950 | R4 (stream) | **0.6** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.810 | D1 (ditch) | 35 | 10 |
| | | 0.424 | D1 (stream) | 67 | 10 |
| | | 0.485 | D3 (ditch) | 59 | 10 |
| | | 0.027 | D4 (pond) | 1059 | 10 |
| | | 0.404 | D4 (stream) | 71 | 10 |
| | | 0.027 | D5 (pond) | 1059 | 10 |
| | | 0.418 | D5 (stream) | 68 | 10 |
| | | 1.211 | R4 (stream) | 24 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.810 | D1 (ditch) | 39 | 10 |
| | | 0.424 | D1 (stream) | 75 | 10 |
| | | 0.485 | D3 (ditch) | 65 | 10 |
| | | 0.027 | D4 (pond) | 1170 | 10 |
| | | 0.404 | D4 (stream) | 78 | 10 |
| | | 0.027 | D5 (pond) | 1170 | 10 |
| | | 0.418 | D5 (stream) | 76 | 10 |
| | | 1.211 | R4 (stream) | 26 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.810 | D1 (ditch) | **0.8** | 10 |
| | | 0.424 | D1 (stream) | **1.4** | 10 |
| | | 0.485 | D3 (ditch) | **1.3** | 10 |
| | | 0.027 | D4 (pond) | 22.6 | 10 |
| | | 0.404 | D4 (stream) | **1.5** | 10 |
| | | 0.027 | D5 (pond) | 22.6 | 10 |
| | | 0.418 | D5 (stream) | **1.5** | 10 |
| | | 1.211 | R4 (stream) | **0.5** | 10 |

* Endpoint from study conducted with EC 100 formulation
**Bold** values do not meet the trigger

**Table CP 10.2- 22: TER$_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3**

| Species | Endpoint [µg/L] | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | TER$_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.600 | D1 (ditch) | 48 | 10 |
| | | 0.498 | D1 (stream) | 57 | 10 |
| | | 0.592 | D2 (ditch) | 48 | 10 |
| | | 0.481 | D2 (stream) | 59 | 10 |
| | | 0.555 | D3 (ditch) | 52 | 10 |
| | | 0.019 | D4 (pond) | 1505 | 10 |
| | | 0.426 | D4 (stream) | 67 | 10 |
| | | 0.019 | D5 (pond) | 1505 | 10 |
| | | 0.442 | D5 (stream) | 65 | 10 |
| | | 0.553 | D6 (ditch) | 52 | 10 |
| | | 0.043 | R1 (pond) | 665 | 10 |
| | | 0.365 | R1 (stream) | 78 | 10 |
| | | 0.515 | R3 (stream) | 56 | 10 |
| | | 0.449 | R4 (stream) | 64 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.600 | D1 (ditch) | 53 | 10 |
| | | 0.498 | D1 (stream) | 63 | 10 |
| | | 0.592 | D2 (ditch) | 53 | 10 |
| | | 0.481 | D2 (stream) | 66 | 10 |
| | | 0.555 | D3 (ditch) | 57 | 10 |
| | | 0.019 | D4 (pond) | 1663 | 10 |
| | | 0.426 | D4 (stream) | 74 | 10 |
| | | 0.019 | D5 (pond) | 1663 | 10 |
| | | 0.442 | D5 (stream) | 71 | 10 |
| | | 0.553 | D6 (ditch) | 57 | 10 |
| | | 0.043 | R1 (pond) | 735 | 10 |
| | | 0.365 | R1 (stream) | 87 | 10 |
| | | 0.515 | R3 (stream) | 61 | 10 |
| | | 0.449 | R4 (stream) | 70 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.600 | D1 (ditch) | **1.0** | 10 |
| | | 0.498 | D1 (stream) | **1.2** | 10 |
| | | 0.592 | D2 (ditch) | **1.0** | 10 |
| | | 0.481 | D2 (stream) | **1.3** | 10 |
| | | 0.555 | D3 (ditch) | **1.1** | 10 |
| | | 0.019 | D4 (pond) | 32.1 | 10 |
| | | 0.426 | D4 (stream) | **1.4** | 10 |
| | | 0.019 | D5 (pond) | 32.1 | 10 |
| | | 0.442 | D5 (stream) | **1.4** | 10 |
| | | 0.553 | D6 (ditch) | **1.1** | 10 |
| | | 0.043 | R1 (pond) | 14.2 | 10 |
| | | 0.365 | R1 (stream) | **1.7** | 10 |
| | | 0.515 | R3 (stream) | **1.2** | 10 |

| Species | Endpoint [µg/L] | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | TER$_{LT}$ | Trigger |
|---|---|---|---|---|---|
| | | 0.449 | R4 (stream) | **1.4** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.583 | D1 (ditch) | 49 | 10 |
| | | 0.490 | D1 (stream) | 58 | 10 |
| | | 0.554 | D3 (ditch) | 52 | 10 |
| | | 0.019 | D4 (pond) | 1505 | 10 |
| | | 0.453 | D4 (stream) | 63 | 10 |
| | | 0.019 | D5 (pond) | 1505 | 10 |
| | | 0.465 | D5 (stream) | 62 | 10 |
| | | 0.607 | R4 (stream) | 47 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.583 | D1 (ditch) | 54 | 10 |
| | | 0.490 | D1 (stream) | 64 | 10 |
| | | 0.554 | D3 (ditch) | 57 | 10 |
| | | 0.019 | D4 (pond) | 1663 | 10 |
| | | 0.453 | D4 (stream) | 70 | 10 |
| | | 0.019 | D5 (pond) | 1663 | 10 |
| | | 0.465 | D5 (stream) | 68 | 10 |
| | | 0.607 | R4 (stream) | 52 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.583 | D1 (ditch) | **1.0** | 10 |
| | | 0.490 | D1 (stream) | **1.2** | 10 |
| | | 0.554 | D3 (ditch) | **1.1** | 10 |
| | | 0.019 | D4 (pond) | 32.1 | 10 |
| | | 0.453 | D4 (stream) | **1.3** | 10 |
| | | 0.019 | D5 (pond) | 32.1 | 10 |
| | | 0.465 | D5 (stream) | **1.3** | 10 |
| | | 0.607 | R4 (stream) | **1.0** | 10 |

* Endpoint from study conducted with EC 100 formulation
**Bold** values do not meet the trigger

**Table CP 10.2- 23: $TER_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3**

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.509 | D1 (ditch) | 56 | 10 |
| | | 0.389 | D1 (stream) | 74 | 10 |
| | | 0.538 | D2 (ditch) | 53 | 10 |
| | | 0.394 | D2 (stream) | 73 | 10 |
| | | 0.417 | D3 (ditch) | 69 | 10 |
| | | 0.021 | D4 (pond) | 1362 | 10 |
| | | 0.342 | D4 (stream) | 84 | 10 |
| | | 0.024 | D5 (pond) | 1192 | 10 |
| | | 0.362 | D5 (stream) | 79 | 10 |
| | | 0.417 | D6 (ditch) | 69 | 10 |
| | | 0.096 | R1 (pond) | 298 | 10 |
| | | 0.763 | R1 (stream) | 37 | 10 |
| | | 0.615 | R3 (stream) | 47 | 10 |
| | | 0.801 | R4 (stream) | 36 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.509 | D1 (ditch) | 62 | 10 |
| | | 0.389 | D1 (stream) | 81 | 10 |
| | | 0.538 | D2 (ditch) | 59 | 10 |
| | | 0.394 | D2 (stream) | 80 | 10 |
| | | 0.417 | D3 (ditch) | 76 | 10 |
| | | 0.021 | D4 (pond) | 1505 | 10 |
| | | 0.342 | D4 (stream) | 92 | 10 |
| | | 0.024 | D5 (pond) | 1317 | 10 |
| | | 0.362 | D5 (stream) | 87 | 10 |
| | | 0.417 | D6 (ditch) | 76 | 10 |
| | | 0.096 | R1 (pond) | 329 | 10 |
| | | 0.763 | R1 (stream) | 41 | 10 |
| | | 0.615 | R3 (stream) | 51 | 10 |
| | | 0.801 | R4 (stream) | 39 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.509 | D1 (ditch) | **1.2** | 10 |
| | | 0.389 | D1 (stream) | **1.6** | 10 |
| | | 0.538 | D2 (ditch) | **1.1** | 10 |
| | | 0.394 | D2 (stream) | **1.5** | 10 |
| | | 0.417 | D3 (ditch) | **1.5** | 10 |
| | | 0.021 | D4 (pond) | 29.0 | 10 |
| | | 0.342 | D4 (stream) | **1.8** | 10 |
| | | 0.024 | D5 (pond) | 25.4 | 10 |
| | | 0.362 | D5 (stream) | **1.7** | 10 |
| | | 0.417 | D6 (ditch) | **1.5** | 10 |
| | | 0.096 | R1 (pond) | **6.4** | 10 |
| | | 0.763 | R1 (stream) | **0.8** | 10 |
| | | 0.615 | R3 (stream) | **1.0** | 10 |

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| | | 0.801 | R4 (stream) | **0.8** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.692 | D1 (ditch) | 41 | 10 |
| | | 0.364 | D1 (stream) | 79 | 10 |
| | | 0.416 | D3 (ditch) | 69 | 10 |
| | | 0.023 | D4 (pond) | 1243 | 10 |
| | | 0.347 | D4 (stream) | 82 | 10 |
| | | 0.023 | D5 (pond) | 1243 | 10 |
| | | 0.358 | D5 (stream) | 80 | 10 |
| | | 1.023 | R4 (stream) | 28 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.692 | D1 (ditch) | 46 | 10 |
| | | 0.364 | D1 (stream) | 87 | 10 |
| | | 0.416 | D3 (ditch) | 76 | 10 |
| | | 0.023 | D4 (pond) | 1374 | 10 |
| | | 0.347 | D4 (stream) | 91 | 10 |
| | | 0.023 | D5 (pond) | 1374 | 10 |
| | | 0.358 | D5 (stream) | 88 | 10 |
| | | 1.023 | R4 (stream) | 31 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.692 | D1 (ditch) | **0.9** | 10 |
| | | 0.364 | D1 (stream) | **1.7** | 10 |
| | | 0.416 | D3 (ditch) | **1.5** | 10 |
| | | 0.023 | D4 (pond) | 26.5 | 10 |
| | | 0.347 | D4 (stream) | **1.8** | 10 |
| | | 0.023 | D5 (pond) | 26.5 | 10 |
| | | 0.358 | D5 (stream) | **1.7** | 10 |
| | | 1.023 | R4 (stream) | **0.6** | 10 |

* Endpoint from study conducted with EC 100 formulation
**Bold** values do not meet the trigger

**Table CP 10.2- 24: $TER_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3**

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.510 | D1 (ditch) | 56 | 10 |
| | | 0.425 | D1 (stream) | 67 | 10 |
| | | 0.501 | D2 (ditch) | 57 | 10 |
| | | 0.410 | D2 (stream) | 70 | 10 |
| | | 0.476 | D3 (ditch) | 60 | 10 |
| | | 0.016 | D4 (pond) | 1788 | 10 |
| | | 0.365 | D4 (stream) | 78 | 10 |
| | | 0.016 | D5 (pond) | 1788 | 10 |
| | | 0.379 | D5 (stream) | 75 | 10 |
| | | 0.474 | D6 (ditch) | 60 | 10 |
| | | 0.036 | R1 (pond) | 794 | 10 |
| | | 0.313 | R1 (stream) | 91 | 10 |
| | | 0.442 | R3 (stream) | 65 | 10 |
| | | 0.379 | R4 (stream) | 75 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.510 | D1 (ditch) | 62 | 10 |
| | | 0.425 | D1 (stream) | 74 | 10 |
| | | 0.501 | D2 (ditch) | 63 | 10 |
| | | 0.410 | D2 (stream) | 77 | 10 |
| | | 0.476 | D3 (ditch) | 66 | 10 |
| | | 0.016 | D4 (pond) | 1975 | 10 |
| | | 0.365 | D4 (stream) | 87 | 10 |
| | | 0.016 | D5 (pond) | 1975 | 10 |
| | | 0.379 | D5 (stream) | 83 | 10 |
| | | 0.474 | D6 (ditch) | 67 | 10 |
| | | 0.036 | R1 (pond) | 878 | 10 |
| | | 0.313 | R1 (stream) | 101 | 10 |
| | | 0.442 | R3 (stream) | 71 | 10 |
| | | 0.379 | R4 (stream) | 83 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.510 | D1 (ditch) | **1.2** | 10 |
| | | 0.425 | D1 (stream) | **1.4** | 10 |
| | | 0.501 | D2 (ditch) | **1.2** | 10 |
| | | 0.410 | D2 (stream) | **1.5** | 10 |
| | | 0.476 | D3 (ditch) | **1.3** | 10 |
| | | 0.016 | D4 (pond) | 38.1 | 10 |
| | | 0.365 | D4 (stream) | **1.7** | 10 |
| | | 0.016 | D5 (pond) | 38.1 | 10 |
| | | 0.379 | D5 (stream) | **1.6** | 10 |
| | | 0.474 | D6 (ditch) | **1.3** | 10 |
| | | 0.036 | R1 (pond) | 16.9 | 10 |
| | | 0.313 | R1 (stream) | **1.9** | 10 |
| | | 0.442 | R3 (stream) | **1.4** | 10 |

| Species | Endpoint [µg/L] | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| | | 0.379 | R4 (stream) | **1.6** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 0.497 | D1 (ditch) | 58 | 10 |
| | | 0.420 | D1 (stream) | 68 | 10 |
| | | 0.475 | D3 (ditch) | 60 | 10 |
| | | 0.016 | D4 (pond) | 1788 | 10 |
| | | 0.388 | D4 (stream) | 74 | 10 |
| | | 0.017 | D5 (pond) | 1682 | 10 |
| | | 0.399 | D5 (stream) | 72 | 10 |
| | | 0.511 | R4 (stream) | 56 | 10 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 0.497 | D1 (ditch) | 64 | 10 |
| | | 0.420 | D1 (stream) | 75 | 10 |
| | | 0.475 | D3 (ditch) | 67 | 10 |
| | | 0.016 | D4 (pond) | 1975 | 10 |
| | | 0.388 | D4 (stream) | 81 | 10 |
| | | 0.017 | D5 (pond) | 1859 | 10 |
| | | 0.399 | D5 (stream) | 79 | 10 |
| | | 0.511 | R4 (stream) | 62 | 10 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.497 | D1 (ditch) | **1.2** | 10 |
| | | 0.420 | D1 (stream) | **1.5** | 10 |
| | | 0.475 | D3 (ditch) | **1.3** | 10 |
| | | 0.016 | D4 (pond) | **38.1** | 10 |
| | | 0.388 | D4 (stream) | **1.6** | 10 |
| | | 0.017 | D5 (pond) | **35.9** | 10 |
| | | 0.399 | D5 (stream) | **1.5** | 10 |
| | | 0.511 | R4 (stream) | **1.2** | 10 |

* Endpoint from study conducted with EC 100 formulation
**Bold** values do not meet the trigger

**Table CP 10.2- 25: RAC $_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | RAC$_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 2.86 | 0.598 | D1 (ditch) | 0.21 |
| | | | 0.457 | D1 (stream) | 0.16 |
| | | | 0.636 | D2 (ditch) | 0.22 |
| | | | 0.465 | D2 (stream) | 0.16 |
| | | | 0.486 | D3 (ditch) | 0.17 |
| | | | 0.025 | D4 (pond) | 0.01 |
| | | | 0.399 | D4 (stream) | 0.14 |
| | | | 0.028 | D5 (pond) | 0.01 |
| | | | 0.422 | D5 (stream) | 0.15 |
| | | | 0.486 | D6 (ditch) | 0.17 |
| | | | 0.113 | R1 (pond) | 0.04 |
| | | | 0.908 | R1 (stream) | 0.32 |
| | | | 0.731 | R3 (stream) | 0.26 |
| | | | 0.950 | R4 (stream) | 0.33 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 3.16 | 0.598 | D1 (ditch) | 0.19 |
| | | | 0.457 | D1 (stream) | 0.14 |
| | | | 0.636 | D2 (ditch) | 0.20 |
| | | | 0.465 | D2 (stream) | 0.15 |
| | | | 0.486 | D3 (ditch) | 0.15 |
| | | | 0.025 | D4 (pond) | 0.01 |
| | | | 0.399 | D4 (stream) | 0.13 |
| | | | 0.028 | D5 (pond) | 0.01 |
| | | | 0.422 | D5 (stream) | 0.13 |
| | | | 0.486 | D6 (ditch) | 0.15 |
| | | | 0.113 | R1 (pond) | 0.04 |
| | | | 0.908 | R1 (stream) | 0.29 |
| | | | 0.731 | R3 (stream) | 0.23 |
| | | | 0.950 | R4 (stream) | 0.30 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.598 | D1 (ditch) | **9.80** |
| | | | 0.457 | D1 (stream) | **7.49** |
| | | | 0.636 | D2 (ditch) | **10.43** |
| | | | 0.465 | D2 (stream) | **7.62** |
| | | | 0.486 | D3 (ditch) | **7.97** |
| | | | 0.025 | D4 (pond) | 0.41 |
| | | | 0.399 | D4 (stream) | **6.54** |
| | | | 0.028 | D5 (pond) | 0.46 |
| | | | 0.422 | D5 (stream) | **6.92** |
| | | | 0.486 | D6 (ditch) | **7.97** |
| | | | 0.113 | R1 (pond) | **1.85** |

| Species | Endpoint [µg/L] | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.908 | R1 (stream) | **14.89** |
| | | | 0.731 | R3 (stream) | **11.98** |
| | | | 0.950 | R4 (stream) | **15.57** |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 2.86 | 0.810 | D1 (ditch) | 0.28 |
| | | | 0.424 | D1 (stream) | 0.15 |
| | | | 0.485 | D3 (ditch) | 0.17 |
| | | | 0.027 | D4 (pond) | 0.01 |
| | | | 0.404 | D4 (stream) | 0.14 |
| | | | 0.027 | D5 (pond) | 0.01 |
| | | | 0.418 | D5 (stream) | 0.15 |
| | | | 1.211 | R4 (stream) | 0.42 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 3.16 | 0.810 | D1 (ditch) | 0.26 |
| | | | 0.424 | D1 (stream) | 0.13 |
| | | | 0.485 | D3 (ditch) | 0.15 |
| | | | 0.027 | D4 (pond) | 0.01 |
| | | | 0.404 | D4 (stream) | 0.13 |
| | | | 0.027 | D5 (pond) | 0.01 |
| | | | 0.418 | D5 (stream) | 0.13 |
| | | | 1.211 | R4 (stream) | 0.38 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.810 | D1 (ditch) | **13.28** |
| | | | 0.424 | D1 (stream) | **6.95** |
| | | | 0.485 | D3 (ditch) | **7.95** |
| | | | 0.027 | D4 (pond) | 0.44 |
| | | | 0.404 | D4 (stream) | **6.62** |
| | | | 0.027 | D5 (pond) | 0.44 |
| | | | 0.418 | D5 (stream) | **6.85** |
| | | | 1.211 | R4 (stream) | **19.85** |

* Endpoint from study conducted with EC 100 formulation

**Table CP 10.2- 26: RAC $_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | RAC$_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 2.86 | 0.600 | D1 (ditch) | 0.21 |
| | | | 0.498 | D1 (stream) | 0.17 |
| | | | 0.592 | D2 (ditch) | 0.21 |
| | | | 0.481 | D2 (stream) | 0.17 |
| | | | 0.555 | D3 (ditch) | 0.19 |
| | | | 0.019 | D4 (pond) | 0.01 |
| | | | 0.426 | D4 (stream) | 0.15 |
| | | | 0.019 | D5 (pond) | 0.01 |
| | | | 0.442 | D5 (stream) | 0.15 |
| | | | 0.553 | D6 (ditch) | 0.19 |
| | | | 0.043 | R1 (pond) | 0.02 |
| | | | 0.365 | R1 (stream) | 0.13 |
| | | | 0.515 | R3 (stream) | 0.18 |
| | | | 0.449 | R4 (stream) | 0.16 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 3.16 | 0.600 | D1 (ditch) | 0.19 |
| | | | 0.498 | D1 (stream) | 0.16 |
| | | | 0.592 | D2 (ditch) | 0.19 |
| | | | 0.481 | D2 (stream) | 0.15 |
| | | | 0.555 | D3 (ditch) | 0.18 |
| | | | 0.019 | D4 (pond) | 0.01 |
| | | | 0.426 | D4 (stream) | 0.13 |
| | | | 0.019 | D5 (pond) | 0.01 |
| | | | 0.442 | D5 (stream) | 0.14 |
| | | | 0.553 | D6 (ditch) | 0.18 |
| | | | 0.043 | R1 (pond) | 0.01 |
| | | | 0.365 | R1 (stream) | 0.12 |
| | | | 0.515 | R3 (stream) | 0.16 |
| | | | 0.449 | R4 (stream) | 0.14 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.600 | D1 (ditch) | **9.84** |
| | | | 0.498 | D1 (stream) | **8.16** |
| | | | 0.592 | D2 (ditch) | **9.70** |
| | | | 0.481 | D2 (stream) | **7.89** |
| | | | 0.555 | D3 (ditch) | **9.10** |
| | | | 0.019 | D4 (pond) | 0.31 |
| | | | 0.426 | D4 (stream) | **6.98** |
| | | | 0.019 | D5 (pond) | 0.31 |
| | | | 0.442 | D5 (stream) | **7.25** |
| | | | 0.553 | D6 (ditch) | **9.07** |
| | | | 0.043 | R1 (pond) | 0.70 |

| Species | Endpoint [µg/L] | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.365 | R1 (stream) | **5.98** |
| | | | 0.515 | R3 (stream) | **8.44** |
| | | | 0.449 | R4 (stream) | **7.36** |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 2.86 | 0.583 | D1 (ditch) | 0.20 |
| | | | 0.490 | D1 (stream) | 0.17 |
| | | | 0.554 | D3 (ditch) | 0.19 |
| | | | 0.019 | D4 (pond) | 0.01 |
| | | | 0.453 | D4 (stream) | 0.16 |
| | | | 0.019 | D5 (pond) | 0.01 |
| | | | 0.465 | D5 (stream) | 0.16 |
| | | | 0.607 | R4 (stream) | 0.21 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 3.16 | 0.583 | D1 (ditch) | 0.18 |
| | | | 0.490 | D1 (stream) | 0.16 |
| | | | 0.554 | D3 (ditch) | 0.18 |
| | | | 0.019 | D4 (pond) | 0.01 |
| | | | 0.453 | D4 (stream) | 0.14 |
| | | | 0.019 | D5 (pond) | 0.01 |
| | | | 0.465 | D5 (stream) | 0.15 |
| | | | 0.607 | R4 (stream) | 0.19 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.583 | D1 (ditch) | **9.56** |
| | | | 0.490 | D1 (stream) | **8.03** |
| | | | 0.554 | D3 (ditch) | **9.08** |
| | | | 0.019 | D4 (pond) | 0.31 |
| | | | 0.453 | D4 (stream) | **7.43** |
| | | | 0.019 | D5 (pond) | 0.31 |
| | | | 0.465 | D5 (stream) | **7.62** |
| | | | 0.607 | R4 (stream) | **9.95** |

* Endpoint from study conducted with EC 100 formulation

**Table CP 10.2- 27: RAC $_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | RAC$_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC | 28.6 | 2.86 | 0.509 | D1 (ditch) | 0.18 |
| | | | | 0.389 | D1 (stream) | 0.14 |
| | | | | 0.538 | D2 (ditch) | 0.19 |
| | | | | 0.394 | D2 (stream) | 0.14 |
| | | | | 0.417 | D3 (ditch) | 0.15 |
| | | | | 0.021 | D4 (pond) | 0.01 |
| | | | | 0.342 | D4 (stream) | 0.12 |
| | | | | 0.024 | D5 (pond) | 0.01 |
| | | | | 0.362 | D5 (stream) | 0.13 |
| | | | | 0.417 | D6 (ditch) | 0.15 |
| | | | | 0.096 | R1 (pond) | 0.03 |
| | | | | 0.763 | R1 (stream) | 0.27 |
| | | | | 0.615 | R3 (stream) | 0.22 |
| | | | | 0.801 | R4 (stream) | 0.28 |
| Invertebrate, chronic *Gammarus pulex* | NOEC | 31.6* | 3.16 | 0.509 | D1 (ditch) | 0.16 |
| | | | | 0.389 | D1 (stream) | 0.12 |
| | | | | 0.538 | D2 (ditch) | 0.17 |
| | | | | 0.394 | D2 (stream) | 0.12 |
| | | | | 0.417 | D3 (ditch) | 0.13 |
| | | | | 0.021 | D4 (pond) | 0.01 |
| | | | | 0.342 | D4 (stream) | 0.11 |
| | | | | 0.024 | D5 (pond) | 0.01 |
| | | | | 0.362 | D5 (stream) | 0.11 |
| | | | | 0.417 | D6 (ditch) | 0.13 |
| | | | | 0.096 | R1 (pond) | 0.03 |
| | | | | 0.763 | R1 (stream) | 0.24 |
| | | | | 0.615 | R3 (stream) | 0.19 |
| | | | | 0.801 | R4 (stream) | 0.25 |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.509 | D1 (ditch) | **8.34** |
| | | | | 0.389 | D1 (stream) | **6.38** |
| | | | | 0.538 | D2 (ditch) | **8.82** |
| | | | | 0.394 | D2 (stream) | **6.46** |
| | | | | 0.417 | D3 (ditch) | **6.84** |
| | | | | 0.021 | D4 (pond) | 0.34 |
| | | | | 0.342 | D4 (stream) | **5.61** |
| | | | | 0.024 | D5 (pond) | 0.39 |
| | | | | 0.362 | D5 (stream) | **5.93** |
| | | | | 0.417 | D6 (ditch) | **6.84** |
| | | | | 0.096 | R1 (pond) | **1.57** |

| Species | Endpoint [µg/L] | | RAC$_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| | | | | 0.763 | R1 (stream) | **12.51** |
| | | | | 0.615 | R3 (stream) | **10.08** |
| | | | | 0.801 | R4 (stream) | **13.13** |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC | 28.6 | 2.86 | 0.692 | D1 (ditch) | 0.24 |
| | | | | 0.364 | D1 (stream) | 0.13 |
| | | | | 0.416 | D3 (ditch) | 0.15 |
| | | | | 0.023 | D4 (pond) | 0.01 |
| | | | | 0.347 | D4 (stream) | 0.12 |
| | | | | 0.023 | D5 (pond) | 0.01 |
| | | | | 0.358 | D5 (stream) | 0.13 |
| | | | | 1.023 | R4 (stream) | 0.36 |
| Invertebrate, chronic *Gammarus pulex* | NOEC | 31.6* | 3.16 | 0.692 | D1 (ditch) | 0.22 |
| | | | | 0.364 | D1 (stream) | 0.12 |
| | | | | 0.416 | D3 (ditch) | 0.13 |
| | | | | 0.023 | D4 (pond) | 0.01 |
| | | | | 0.347 | D4 (stream) | 0.11 |
| | | | | 0.023 | D5 (pond) | 0.01 |
| | | | | 0.358 | D5 (stream) | 0.11 |
| | | | | 1.023 | R4 (stream) | 0.32 |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.692 | D1 (ditch) | **11.34** |
| | | | | 0.364 | D1 (stream) | **5.97** |
| | | | | 0.416 | D3 (ditch) | **6.82** |
| | | | | 0.023 | D4 (pond) | 0.38 |
| | | | | 0.347 | D4 (stream) | **5.69** |
| | | | | 0.023 | D5 (pond) | 0.38 |
| | | | | 0.358 | D5 (stream) | **5.87** |
| | | | | 1.023 | R4 (stream) | **16.77** |

* Endpoint from study conducted with EC 100 formulation

**Table CP 10.2- 28: RAC $_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | RAC$_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | PEC$_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC | 28.6 | 2.86 | 0.510 | D1 (ditch) | 0.18 |
| | | | | 0.425 | D1 (stream) | 0.15 |
| | | | | 0.501 | D2 (ditch) | 0.18 |
| | | | | 0.410 | D2 (stream) | 0.14 |
| | | | | 0.476 | D3 (ditch) | 0.17 |
| | | | | 0.016 | D4 (pond) | 0.01 |
| | | | | 0.365 | D4 (stream) | 0.13 |
| | | | | 0.016 | D5 (pond) | 0.01 |
| | | | | 0.379 | D5 (stream) | 0.13 |
| | | | | 0.474 | D6 (ditch) | 0.17 |
| | | | | 0.036 | R1 (pond) | 0.01 |
| | | | | 0.313 | R1 (stream) | 0.11 |
| | | | | 0.442 | R3 (stream) | 0.15 |
| | | | | 0.379 | R4 (stream) | 0.13 |
| Invertebrate, chronic *Gammarus pulex* | NOEC | 31.6* | 3.16 | 0.510 | D1 (ditch) | 0.16 |
| | | | | 0.425 | D1 (stream) | 0.13 |
| | | | | 0.501 | D2 (ditch) | 0.16 |
| | | | | 0.410 | D2 (stream) | 0.13 |
| | | | | 0.476 | D3 (ditch) | 0.15 |
| | | | | 0.016 | D4 (pond) | 0.01 |
| | | | | 0.365 | D4 (stream) | 0.12 |
| | | | | 0.016 | D5 (pond) | 0.01 |
| | | | | 0.379 | D5 (stream) | 0.12 |
| | | | | 0.474 | D6 (ditch) | 0.15 |
| | | | | 0.036 | R1 (pond) | 0.01 |
| | | | | 0.313 | R1 (stream) | 0.10 |
| | | | | 0.442 | R3 (stream) | 0.14 |
| | | | | 0.379 | R4 (stream) | 0.12 |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.510 | D1 (ditch) | **8.36** |
| | | | | 0.425 | D1 (stream) | **6.97** |
| | | | | 0.501 | D2 (ditch) | **8.21** |
| | | | | 0.410 | D2 (stream) | **6.72** |
| | | | | 0.476 | D3 (ditch) | **7.80** |
| | | | | 0.016 | D4 (pond) | 0.26 |
| | | | | 0.365 | D4 (stream) | **5.98** |
| | | | | 0.016 | D5 (pond) | 0.26 |
| | | | | 0.379 | D5 (stream) | **6.21** |
| | | | | 0.474 | D6 (ditch) | **7.77** |
| | | | | 0.036 | R1 (pond) | 0.59 |

| Species | Endpoint [µg/L] | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | $PEC_{sw,max}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| | | | 0.313 | R1 (stream) | **5.13** |
| | | | 0.442 | R3 (stream) | **7.25** |
| | | | 0.379 | R4 (stream) | **6.21** |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | |
| Fish, chronic *Oncorhynchus mykiss* | NOEC 28.6 | 2.86 | 0.497 | D1 (ditch) | 0.17 |
| | | | 0.420 | D1 (stream) | 0.15 |
| | | | 0.475 | D3 (ditch) | 0.17 |
| | | | 0.016 | D4 (pond) | 0.01 |
| | | | 0.388 | D4 (stream) | 0.14 |
| | | | 0.017 | D5 (pond) | 0.01 |
| | | | 0.399 | D5 (stream) | 0.14 |
| | | | 0.511 | R4 (stream) | 0.18 |
| Invertebrate, chronic *Gammarus pulex* | NOEC 31.6* | 3.16 | 0.497 | D1 (ditch) | 0.16 |
| | | | 0.420 | D1 (stream) | 0.13 |
| | | | 0.475 | D3 (ditch) | 0.15 |
| | | | 0.016 | D4 (pond) | 0.01 |
| | | | 0.388 | D4 (stream) | 0.12 |
| | | | 0.017 | D5 (pond) | 0.01 |
| | | | 0.399 | D5 (stream) | 0.13 |
| | | | 0.511 | R4 (stream) | 0.16 |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.497 | D1 (ditch) | **8.15** |
| | | | 0.420 | D1 (stream) | **6.89** |
| | | | 0.475 | D3 (ditch) | **7.79** |
| | | | 0.016 | D4 (pond) | 0.26 |
| | | | 0.388 | D4 (stream) | **6.36** |
| | | | 0.017 | D5 (pond) | 0.28 |
| | | | 0.399 | D5 (stream) | **6.54** |
| | | | 0.511 | R4 (stream) | **8.38** |

* Endpoint from study conducted with EC 100 formulation

Most of the TERs meet the required trigger of 10, indicating a safe use of the product. However, the risk assessment for *Gammarus pulex* and *Americamysis bahia* need further refinement for some scenarios. Table CP 10.2- 29 summarizes the assessments which need further consideration

**Table CP 10.2- 29: Summary of the scenarios that did not pass the $TER_{LT}$/$RAC_{LT}$ calculations of fluoxastrobin based on FOCUS Step 3 following application to cereals***

| | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Invertebrate, chronic: *Americamysis bahia* | | | | | | | |
| **Scenario** | **2 x 87.5 g a.s. /ha** | | **1 x 87.5 g a.s. /ha** | | **2 x 75.0 g a.s. /ha** | | **1 x 75.0 g a.s. /ha** | |
| | **Winter cereals** | **Spring cereals** | **Winter cereals** | **Spring cereals** | **Winter cereals** | **Spring cereals** | **Winter cereals** | **Spring cereals** |
| D1 (ditch) | × | × | × | × | × | × | × | × |
| D1 (stream) | × | × | × | × | × | × | × | × |
| D2 (ditch) | × | - | × | - | × | - | × | - |
| D2 (stream) | × | - | × | - | × | - | × | - |
| D3 (ditch) | × | × | × | × | × | × | × | × |
| D4 (pond) | | | | | | | | |
| D4 (stream) | × | × | × | × | × | × | × | × |
| D5 (pond) | | | | | | | | |
| D5 (stream) | × | × | × | × | × | × | × | × |
| D6 (ditch) | × | - | × | - | × | - | × | - |
| R1 (pond) | × | - | | - | × | - | | - |
| R1 (stream) | × | - | × | - | × | - | × | - |
| R3 (stream) | × | - | × | - | × | - | × | - |
| R4 (stream) | × | × | × | × | × | × | × | × |

* Refinement for fish chronic (*Oncorhynchus mykiss*), and Invertebrate chronic (*Gammarus pulex*) passes the risk assessment based on FOCUS Step 3 with all scenarios and all intended applications.
× Scenario not passed
- Scenario not relevant for the crop

Results indicated with **x** need further refinement

For fluoxastrobin and aquatic invertebrates, a refinement option based on the FOCUS Step 3 -$TWA_{sw}$ (7 days) values is presented below. Justification for the use of the 7d $PEC_{sw;twa}$ is provided in Document MCA8, Point 8.2.5.1 (M-535147-01-1).

**Table CP 10.2- 30: TER$_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)**

| Species | Endpoint [µg/L] | 7-day TWA$_{sw}$ [µg/L] | FOCUS scenario | TER$_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.498 | D1 (ditch) | **1.2** | 10 |
| | | 0.113 | D1 (stream) | **5.4** | 10 |
| | | 0.453 | D2 (ditch) | **1.3** | 10 |
| | | 0.206 | D2 (stream) | **3.0** | 10 |
| | | 0.116 | D3 (ditch) | **5.3** | 10 |
| | | 0.010 | D4 (stream) | 61 | 10 |
| | | 0.006 | D5 (stream) | 102 | 10 |
| | | 0.205 | D6 (ditch) | **3.0** | 10 |
| | | 0.107 | R1 (pond) | **5.7** | 10 |
| | | 0.113 | R1 (stream) | **5.4** | 10 |
| | | 0.100 | R3 (stream) | **6.1** | 10 |
| | | 0.271 | R4 (stream) | **2.3** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.692 | D1 (ditch) | **0.9** | 10 |
| | | 0.146 | D1 (stream) | **4.2** | 10 |
| | | 0.090 | D3 (ditch) | **6.8** | 10 |
| | | 0.012 | D4 (stream) | 50.8 | 10 |
| | | 0.005 | D5 (stream) | 122 | 10 |
| | | 0.273 | R4 (stream) | **2.2** | 10 |

**Bold** values do not meet the trigger

**Table CP 10.2- 31: $TER_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)**

| Species | Endpoint [µg/L] | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.467 | D1 (ditch) | **1.3** | 10 |
| | | 0.049 | D1 (stream) | 12.4 | 10 |
| | | 0.394 | D2 (ditch) | **1.5** | 10 |
| | | 0.039 | D2 (stream) | 15.6 | 10 |
| | | 0.116 | D3 (ditch) | **5.3** | 10 |
| | | 0.005 | D4 (stream) | 122 | 10 |
| | | 0.002 | D5 (stream) | 305 | 10 |
| | | 0.086 | D6 (ditch) | **7.1** | 10 |
| | | 0.039 | R1 (stream) | 15.6 | 10 |
| | | 0.061 | R3 (stream) | 10.0 | 10 |
| | | 0.124 | R4 (stream) | **4.9** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.473 | D1 (ditch) | **1.3** | 10 |
| | | 0.063 | D1 (stream) | **9.7** | 10 |
| | | 0.554 | D3 (ditch) | **1.1** | 10 |
| | | 0.006 | D4 (stream) | 102 | 10 |
| | | 0.004 | D5 (stream) | 153 | 10 |
| | | 0.187 | R4 (stream) | **3.3** | 10 |

**Bold** values do not meet the trigger

**Table CP 10.2- 32: $TER_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)**

| Species | Endpoint [µg/L] | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.423 | D1 (ditch) | **1.4** | 10 |
| | | 0.090 | D1 (stream) | **6.8** | 10 |
| | | 0.380 | D2 (ditch) | **1.6** | 10 |
| | | 0.172 | D2 (stream) | **3.5** | 10 |
| | | 0.100 | D3 (ditch) | **6.1** | 10 |
| | | 0.008 | D4 (stream) | 76 | 10 |
| | | 0.005 | D5 (stream) | 122 | 10 |
| | | 0.176 | D6 (ditch) | **3.5** | 10 |
| | | 0.091 | R1 (pond) | **6.7** | 10 |
| | | 0.095 | R1 (stream) | **6.4** | 10 |
| | | 0.084 | R3 (stream) | **7.3** | 10 |
| | | 0.230 | R4 (stream) | **2.7** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.590 | D1 (ditch) | **1.0** | 10 |
| | | 0.113 | D1 (stream) | **5.4** | 10 |
| | | 0.077 | D3 (ditch) | **7.9** | 10 |
| | | 0.010 | D4 (stream) | 61 | 10 |
| | | 0.004 | D5 (stream) | 153 | 10 |
| | | 0.231 | R4 (stream) | **2.6** | 10 |

**Bold** values do not meet the trigger

Table CP 10.2- 33: $TER_{LT}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days)

| Species | Endpoint [µg/L] | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.396 | D1 (ditch) | **1.5** | 10 |
| | | 0.039 | D1 (stream) | 15.6 | 10 |
| | | 0.332 | D2 (ditch) | **1.8** | 10 |
| | | 0.030 | D2 (stream) | 20.3 | 10 |
| | | 0.099 | D3 (ditch) | **6.2** | 10 |
| | | 0.004 | D4 (stream) | 153 | 10 |
| | | 0.002 | D5 (stream) | 305 | 10 |
| | | 0.073 | D6 (ditch) | **8.4** | 10 |
| | | 0.033 | R1 (stream) | 18.5 | 10 |
| | | 0.051 | R3 (stream) | 12.0 | 10 |
| | | 0.105 | R4 (stream) | **5.8** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.403 | D1 (ditch) | **1.5** | 10 |
| | | 0.054 | D1 (stream) | 11.3 | 10 |
| | | 0.077 | D3 (ditch) | **7.9** | 10 |
| | | 0.005 | D4 (stream) | 122 | 10 |
| | | 0.003 | D5 (stream) | 203 | 10 |
| | | 0.158 | R4 (stream) | **3.9** | 10 |

**Bold** values do not meet the trigger

**Table CP 10.2- 34: $RAC_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.498 | D1 (ditch) | **8.16** |
| | | | 0.113 | D1 (stream) | **1.85** |
| | | | 0.453 | D2 (ditch) | **7.43** |
| | | | 0.206 | D2 (stream) | **3.38** |
| | | | 0.116 | D3 (ditch) | **1.90** |
| | | | 0.010 | D4 (stream) | 0.16 |
| | | | 0.006 | D5 (stream) | 0.10 |
| | | | 0.205 | D6 (ditch) | **3.36** |
| | | | 0.107 | R1 (pond) | **1.75** |
| | | | 0.113 | R1 (stream) | **1.85** |
| | | | 0.100 | R3 (stream) | **1.64** |
| | | | 0.271 | R4 (stream) | **4.44** |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.692 | D1 (ditch) | **11.34** |
| | | | 0.146 | D1 (stream) | **2.39** |
| | | | 0.090 | D3 (ditch) | **1.48** |
| | | | 0.012 | D4 (stream) | 0.20 |
| | | | 0.005 | D5 (stream) | 0.08 |
| | | | 0.273 | R4 (stream) | **4.48** |

**Table CP 10.2- 35: $RAC_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.467 | D1 (ditch) | **7.66** |
| | | | | 0.049 | D1 (stream) | 0.80 |
| | | | | 0.394 | D2 (ditch) | **6.46** |
| | | | | 0.039 | D2 (stream) | 0.64 |
| | | | | 0.116 | D3 (ditch) | **1.90** |
| | | | | 0.005 | D4 (stream) | 0.08 |
| | | | | 0.002 | D5 (stream) | 0.03 |
| | | | | 0.086 | D6 (ditch) | **1.41** |
| | | | | 0.039 | R1 (stream) | 0.64 |
| | | | | 0.061 | R3 (stream) | 1.00 |
| | | | | 0.124 | R4 (stream) | **2.03** |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.473 | D1 (ditch) | **7.75** |
| | | | | 0.063 | D1 (stream) | **1.03** |
| | | | | 0.554 | D3 (ditch) | **9.08** |
| | | | | 0.006 | D4 (stream) | 0.10 |
| | | | | 0.004 | D5 (stream) | 0.07 |
| | | | | 0.187 | R4 (stream) | **3.07** |

**Table CP 10.2- 36: $RAC_{sw;\,ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | $RAC_{sw;\,ch}$ (NOEC/10) ($E_rC_{50}$/10) | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.423 | D1 (ditch) | **6.93** |
| | | | 0.090 | D1 (stream) | **1.48** |
| | | | 0.380 | D2 (ditch) | **6.23** |
| | | | 0.172 | D2 (stream) | **2.82** |
| | | | 0.100 | D3 (ditch) | **1.64** |
| | | | 0.008 | D4 (stream) | 0.13 |
| | | | 0.005 | D5 (stream) | 0.08 |
| | | | 0.176 | D6 (ditch) | **2.89** |
| | | | 0.091 | R1 (pond) | **1.49** |
| | | | 0.095 | R1 (stream) | **1.56** |
| | | | 0.084 | R3 (stream) | **1.38** |
| | | | 0.230 | R4 (stream) | **3.77** |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC 0.61 | 0.061 | 0.590 | D1 (ditch) | **9.67** |
| | | | 0.113 | D1 (stream) | **1.85** |
| | | | 0.077 | D3 (ditch) | **1.26** |
| | | | 0.010 | D4 (stream) | 0.16 |
| | | | 0.004 | D5 (stream) | 0.07 |
| | | | 0.231 | R4 (stream) | **3.79** |

**Table CP 10.2- 37: $RAC_{sw; ch}$ calculations for cereals (winter and spring) calculation based on FOCUS Step 3 -TWAsw (7 days) (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.396 | D1 (ditch) | **6.49** |
| | | | | 0.039 | D1 (stream) | 0.64 |
| | | | | 0.332 | D2 (ditch) | **5.44** |
| | | | | 0.030 | D2 (stream) | 0.49 |
| | | | | 0.099 | D3 (ditch) | **1.62** |
| | | | | 0.004 | D4 (stream) | 0.07 |
| | | | | 0.002 | D5 (stream) | 0.03 |
| | | | | 0.073 | D6 (ditch) | **1.20** |
| | | | | 0.033 | R1 (stream) | 0.54 |
| | | | | 0.051 | R3 (stream) | 0.84 |
| | | | | 0.105 | R4 (stream) | **1.72** |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| Invertebrate, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.403 | D1 (ditch) | **6.61** |
| | | | | 0.054 | D1 (stream) | 0.89 |
| | | | | 0.077 | D3 (ditch) | **1.26** |
| | | | | 0.005 | D4 (stream) | 0.08 |
| | | | | 0.003 | D5 (stream) | 0.05 |
| | | | | 0.158 | R4 (stream) | **2.59** |

Table CP 10.2- 38 summarizes the scenarios which did not meet the required trigger of 10 when based on FOCUS Step 3 -TWAsw (7 days) risk assessment. Consequently, further refinement is needed.

**Table CP 10.2- 38: Scenarios that did not pass the TER$_{LT}$/RAC$_{LT}$ calculations of fluoxastrobin based on FOCUS Step 3 -TWAsw (7 days) following application to cereals**

| | Fluoxastrobin (E+Z) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Invertebrate, chronic: *Americamysis bahia* | | | | | | | |
| Scenario | 2 x 87.5 g a.s. /ha | | 1 x 87.5 g a.s. /ha | | 2 x 75.0 g a.s. /ha | | 1 x 75.0 g a.s. /ha | |
| | Winter cereals | Spring cereals | Winter cereals | Spring cereals | Winter cereals | Spring cereals | Winter cereals | Spring cereals |
| D1 (ditch) | × | × | × | × | × | × | × | × |
| D1 (stream) | × | × | | × | × | × | | |
| D2 (ditch) | × | - | × | - | × | - | × | - |
| D2 (stream) | × | - | | - | × | - | | - |
| D3 (ditch) | × | × | × | × | × | × | × | × |
| D4 (pond) | | | | | | | | |
| D4 (stream) | | | | | | | | |
| D5 (pond) | | | | | | | | |
| D5 (stream) | | | | | | | | |
| D6 (ditch) | × | - | × | - | × | - | × | - |
| R1 (pond) | × | - | | - | × | - | | - |
| R1 (stream) | × | - | | - | × | - | | - |
| R3 (stream) | × | - | | - | × | - | | - |
| R4 (stream) | × | × | × | × | × | × | × | × |

× Scenario not passed
- Scenario not relevant for the crop

Results indicated with x need further refinement. A refined risk assessment based on FOCUS Step 4-TWAsw (7 days) calculations is presented below.

Table CP 10.2- 39: $TER_{LT}$ calculations for invertebrates (long-term) based on FOCUS Step 4 -$TWA_{sw}$ (7 days) including mitigation measures

| Species | Endpoint [µg/L] | | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.181 | D1 (ditch) | **3.4** | 10 |
| | | | 0.113 | D1 (stream) | **5.4** | 10 |
| | | | 0.194 | D2 (ditch) | **3.1** | 10 |
| | | | 0.101 | D2 (stream) | **6.0** | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.002 | D6 (ditch) | 305 | 10 |
| | | | 0.019 | R1 (pond) | 32.1 | 10 |
| | | | 0.027 | R1 (stream) | 22.6 | 10 |
| | | | 0.023 | R3 (stream) | 26.5 | 10 |
| | | | 0.065 | R4 (stream) | **9.4** | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.234 | D1 (ditch) | **2.6** | 10 |
| | | | 0.146 | D1 (stream) | **4.2** | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.062 | R4 (stream) | **9.8** | 10 |
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.079 | D1 (ditch) | **7.7** | 10 |
| | | | 0.077 | D2 (ditch) | **7.9** | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.001 | D6 (ditch) | 610 | 10 |
| | | | 0.029 | R4 (stream) | 21.0 | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.097 | D1 (ditch) | **6.3** | 10 |
| | | | 0.061 | D1 (stream) | 10.0 | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.045 | R4 (stream) | 13.6 | 10 |
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.144 | D1 (ditch) | **4.2** | 10 |
| | | | 0.090 | D1 (stream) | **6.8** | 10 |
| | | | 0.149 | D2 (ditch) | **4.1** | 10 |
| | | | 0.076 | D2 (stream) | **8.0** | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.001 | D6 (ditch) | 610 | 10 |
| | | | 0.016 | R1 (pond) | 38.1 | 10 |

| Species | Endpoint [µg/L] | | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| | | | 0.023 | R1 (stream) | 26.5 | 10 |
| | | | 0.020 | R3 (stream) | 30.5 | 10 |
| | | | 0.055 | R4 (stream) | 11.1 | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.182 | D1 (ditch) | **3.4** | 10 |
| | | | 0.113 | D1 (stream) | **5.4** | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.053 | R4 (stream) | 11.5 | 10 |
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.062 | D1 (ditch) | **9.8** | 10 |
| | | | 0.059 | D2 (ditch) | 10.3 | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.001 | D6 (ditch) | 610 | 10 |
| | | | 0.025 | R4 (stream) | 24.4 | 10 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.078 | D1 (ditch) | **7.8** | 10 |
| | | | 0.001 | D3 (ditch) | 610 | 10 |
| | | | 0.038 | R4 (stream) | 16.1 | 10 |

**Bold** values do not meet the trigger

**Table CP 10.2- 40: $RAC_{sw; ch}$ calculations for invertebrates (long-term) based on FOCUS Step 4 - TWAsw (7 days) including mitigation measures (acceptability of risk: PEC/RAC < 1)**

| Species | Endpoint [µg/L] | | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| **Fluoxastrobin (E+Z), winter cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.181 | D1 (ditch) | **2.97** |
| | | | | 0.113 | D1 (stream) | **1.85** |
| | | | | 0.194 | D2 (ditch) | **3.18** |
| | | | | 0.101 | D2 (stream) | **1.66** |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.002 | D6 (ditch) | 0.03 |
| | | | | 0.019 | R1 (pond) | 0.31 |
| | | | | 0.027 | R1 (stream) | 0.44 |
| | | | | 0.023 | R3 (stream) | 0.38 |
| | | | | 0.065 | R4 (stream) | **1.07** |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.234 | D1 (ditch) | **3.84** |
| | | | | 0.146 | D1 (stream) | **2.39** |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.062 | R4 (stream) | **1.02** |
| **Fluoxastrobin (E+Z), winter cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.079 | D1 (ditch) | **1.30** |
| | | | | 0.077 | D2 (ditch) | **1.26** |
| | | | | 0.035 | D2 (stream) | 0.57 |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.001 | D6 (ditch) | 0.02 |
| | | | | 0.029 | R4 (stream) | 0.48 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 87.5 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.097 | D1 (ditch) | **1.59** |
| | | | | 0.061 | D1 (stream) | 1.00 |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.045 | R4 (stream) | 0.74 |
| **Fluoxastrobin (E+Z), winter cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.144 | D1 (ditch) | **2.36** |
| | | | | 0.090 | D1 (stream) | **1.48** |
| | | | | 0.149 | D2 (ditch) | **2.44** |
| | | | | 0.076 | D2 (stream) | **1.25** |
| | | | | 0.001 | D3 (ditch) | 0.02 |

| Species | Endpoint [µg/L] | | $RAC_{sw; ch}$ (NOEC/10) ($E_rC_{50}$/10) | 7-day $TWA_{sw}$ [µg/L] | FOCUS scenario | PEC/RAC |
|---|---|---|---|---|---|---|
| | | | | 0.001 | D6 (ditch) | 0.02 |
| | | | | 0.016 | R1 (pond) | 0.26 |
| | | | | 0.023 | R1 (stream) | 0.38 |
| | | | | 0.020 | R3 (stream) | 0.33 |
| | | | | 0.055 | R4 (stream) | 0.90 |
| **Fluoxastrobin (E+Z), spring cereals, 2 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.182 | D1 (ditch) | **2.98** |
| | | | | 0.113 | D1 (stream) | **1.85** |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.053 | R4 (stream) | 0.87 |
| **Fluoxastrobin (E+Z), winter cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.062 | D1 (ditch) | **1.02** |
| | | | | 0.059 | D2 (ditch) | 0.97 |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.001 | D6 (ditch) | 0.02 |
| | | | | 0.025 | R4 (stream) | 0.41 |
| **Fluoxastrobin (E+Z), spring cereals, 1 × 75.0 g a.s./ha** | | | | | | |
| ***20 m buffer zone, 90% drift reduction*** | | | | | | |
| Invertebrates, chronic *Americamysis bahia* | NOEC | 0.61 | 0.061 | 0.078 | D1 (ditch) | **1.28** |
| | | | | 0.001 | D3 (ditch) | 0.02 |
| | | | | 0.038 | R4 (stream) | 0.62 |

**Bold** values do not meet the trigger

Concerning two applications in winter and spring cereals at rates of 2 × 87.5 g a.s./ha and 2 × 75 g a.s./ha, safe use without any refinement was identified for the scenarios D4 (pond), D4 (stream), D5 (pond) and D5 (stream). Concerning one application in winter cereals at rates of 1 × 87.5 g a.s./ha and 1 × 75 g a.s./ha, safe use without any refinement was identified for the scenarios D1 (stream), D2 (stream), D4 (pond), D4 (stream), D5 (pond), D5 (stream), R1 (pond), R1 (stream) and R3 (stream). Concerning one application in spring cereals at a rate of 1 × 87.5 g a.s./ha, safe use without any refinement was identified for the scenarios D4 (pond), D4 (stream), D5 (pond) and D5 (stream).
Concerning one application in spring cereals at a rate of 1 × 75 g a.s./ha, safe use without any refinement was identified for the scenarios D1 (stream), D4 (pond), D4 (stream), D5 (pond) and D5 (stream).
Concerning two applications in winter cereals at a rate of 2 × 87.5 g a.s./ha, safe use was identified for the scenarios D3 (ditch), D6 (ditch), R1 (pond), R1 (stream) and R3 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used. Concerning two applications in winter cereals at a rate of 2 × 75 g a.s./ha, safe use was identified for the scenarios D3 (ditch), D6 (ditch), R1 (pond), R1 (stream), R3 (stream) and R4 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used. Concerning two applications in spring cereals at a rate of 2 × 87.5 g a.s./ha, safe use was identified for the scenario D3 (ditch) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used. Concerning one application in winter cereals at a rate of 1 × 87.5 g a.s./ha, safe use was identified for the scenarios D3 (ditch), D6 (ditch) and R4 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used.

Concerning one application in spring cereals at a rate of 1 × 87.5 g a.s./ha, safe use was identified for the scenarios D1 (stream), D3 (ditch) and R4 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used. Concerning two applications in spring cereals at a rate of 2 × 75 g a.s./ha, safe use was identified for the scenarios D3 (ditch) and R4 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used. Concerning one application in winter cereals at a rate of 1 × 75 g a.s./ha, safe use was identified for the scenarios D2 (ditch), D3 (ditch), D6 (ditch), and R4 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used. Concerning one application in spring cereals at a rate of 1 × 75 g a.s./ha, safe use was identified for the scenarios D3 (ditch) and R4 (stream) when mitigation measures of 20 meters buffer zone + 90% drift reduction are used.

**Conclusion**

For the representative uses considered for renewal of approval of Fluoxastrobin, acceptable risk can be considered for most scenarios, taking varying mitigation measures into account.

## CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

| | |
|---|---|
| **Report:** | KCP 10.2.1/01 [redacted].; 2010; M-385971-01-1 |
| Title: | Acute toxicity of bixafen+fluoxastrobin+prothioconazole EC 190 (40+50+100) G to fish (Oncorhynchus mykiss) under static conditions |
| Report No.: | EBDRP185 |
| Document No.: | M-385971-01-1 |
| Guideline(s): | OECD Guideline 203, Fish, Acute Toxicity Test (July, 1992); USEPA Pesticide Assessment Guidelines Subdivision E, FIFRA 72-1, Acute toxicity test for freshwater fish, October, 1982; USEPA OCSPP 850.1075 Fish Acute Toxicity Test, Freshwater and Marine, A |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The aim of this study was to determine the acute toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 to Rainbow trout (*Oncorhynchus mykiss*), expressed as 96 h-$LC_{50}$.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch No.: 2010-000848, Tox No.: 08908-00; Specification No.: 102000023924-NN; Master recipe ID: 0106974-001; Analysed content of active ingredients: 3.90 % w/w (41.5 g/L) bixafen (BYF 00587), 4.86 % w/w (51.7 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL(20 °C).

Rainbow trout (*Oncorhynchus mykiss*) were exposed for 96 hours under static conditions to nominal concentrations of 0.750, 1.50, 3.00, 6.00 and 12.0 mg test item./L against a control. At the beginning of the test the mean body length and the mean body weight of the tested rainbow trout were 4.4 cm and 1.3 g respectively. The biomass loading for this test was 0.33 g fish / L test medium.

Ten fish were used in each test concentration. The aquaria used were made of glass with a capacity of 40-litres and a dimension of 36 cm length, 32 cm width and 38 cm height. The water temperature during the 96-hour exposure ranged from 11.3 to 12.4°C in all aquaria over the whole test period. Dissolved oxygen concentrations ranged from 90 to 101% oxygen saturation. The pH values ranged from 6.9 to 7.5. Bixafen was analyzed in all test levels after 0 h, on day 2 and on day 4 of the exposure period to confirm nominal concentrations. During the test, fish were observed for mortalities and signs of intoxication four hours after application and then once daily (day 1 – 4).

**Dates of experimental work:** March 29, 2010 to May 18, 2010

**Findings:**

Validity criteria:
The test conditions met all validity criteria, given by the mentioned guidelines:
≤ 5% mortality within the 48-hour settling-in period;
≤ 10% mortality in the control (or one fish if less than ten are used);
dissolved oxygen saturation ≥ 60% throughout the test;
pH variation ≤ 1.0 units.

Analytical findings:
The analytical determination of bixafen (in water by HPLC-MS/MS and HPLC - UV) revealed mean measured values of 80% to 105 % of nominal over the whole testing period of 96 hours. Therefore all results are given as nominal values.
As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

Biological results:
In the controls no mortalities or sub-lethal findings were observed.
The lowest concentration causing 100% mortality (96h) was 6.00 mg test item/L. The highest concentration which did not result in any mortality within the exposure period (NOLEC) was 1.50 mg test item /L. The no-observed-effect-concentration (NOEC) after 96 hours was 1.50 mg test item /L.
After 96 h of exposure towards the nominal concentration of 3.00 mg form./L the fish showed the following behavioural symptoms:

- showed labored respiration
- displayed enhanced mucous excretions
- remained for unusually long periods at the water surface
- were dead

Cumulative mortality was observed as follows:

**Table CP 10.2.1- 1: Cumulative mortality of the rainbow trout exposed to Bixafen + Fluoxastrobin + Prothioconazole EC 190**

| Exposure time | 4 h | | 24 h | | 48 h | | 72 h | | 96 h | |
|---|---|---|---|---|---|---|---|---|---|---|
| Test item [mg / L] | no. of dead | % dead | no. of dead | % dead | no. of dead | % dead | no. of dead | % dead | no. of dead | % dead |
| control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.750 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.50 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.00 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 30 | 5 | 50 |
| 6.00 | 0 | 0 | 10 | 100 | 10 | 100 | 10 | 100 | 10 | 100 |
| 12.0 | 10 | 100 | 10 | 100 | 10 | 100 | 10 | 100 | 10 | 100 |

**Conclusion:**

Based on nominal concentrations the following endpoints were determined:

| | |
|---|---|
| $LC_{50}$ (96 h): | 3.02 mg test item/L (95% C.I.: 2.70 – 3-37 mg/L) |
| 100 % mortality: | 6.00 mg test item/L |
| NOEC (96 h): | 1.50 mg test item /L |
| NOLEC: | 1.50 mg test item /L |

| | |
|---|---|
| **Report:** | KCP 10.2.1/02 [redacted].; 2010; M-385961-01-1 |
| Title: | Acute toxicity of bixafen + fluoxastrobin + prothioconazole EC 190 (40+50+100) G to the waterflea Daphnia magna in a static laboratory test system |
| Report No.: | EBDRP184 |
| Document No.: | M-385961-01-1 |
| Guideline(s): | OECD Guideline 202, Daphnia sp. Acute Immobilisation Test (April, 2004); EEC Directive 92/69/EEC, part C.2 (1992) |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The study was performed, to detect possible effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on mobility of *Daphnia magna* caused by 48 hours of exposure in a static laboratory test system, expressed as $EC_{50}$ for immobilisation.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848; Analysis ref. code: TOX08908-00; BCS-Specification No.: 102000023924-NN; Analysed content of active ingredients: 3.90 % w/w (41.5 g/L) bixafen (BYF 00587), 4.86 % w/w (51.7 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

Seven groups of daphnids (1st instars, < 24h old), each group comprising 30 daphnids (6 replicates per test concentration, 5 daphnids per replicate), were exposed in a static test system for 48 hours to nominal concentrations of 0 (untreated control), 0.625, 1.25, 2.50, 5.00, 10.0 and 20.0 mg form./L without feeding. Each vessel (glass beakers; 100 mL) served as one replicate was filled with 50 mL of the test solution (10 mL test solution per daphnid). After 24 and 48 hours, behaviour of the water fleas was visually evaluated by counting mobile daphnids. Additionally all visible features of the test item in water as well as possible signs on sublethal affected daphnids had to be recorded. The content of bixafen in exposure media was measured for verification of the test item concentrations.
The water temperature ranged from 20.1°C to 20.6°C. The pH varied between 7.8 and 7.9. Oxygen concentration varied between 8.79 and 9.11 mg/L. The photoperiod was 16 hours of light and 8 hours dark with a maximum intensity of 1200 lux.

**Dates of experimental work:** April 19, 2010 to May 18, 2010

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| Control mortality | 10.0% | 0.0% |

The study meets the proposed validity criteria, thus the test is valid.

Analytical findings:
The accompanying chemical analysis of bixafen in the freshly prepared test solutions at test initiation ranged between 97% and 105% (mean: 101%) of the corresponding nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 98% and 106% (mean: 102%) of nominal, demonstrating stability in the test system.
No contaminations of bixafen were detected in samples from untreated water control.

As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

Biological findings:
The toxicity of the test item to *Daphnia magna* (based on nominal concentrations) is presented in the table below.

**Table CP 10.2.1- 2: Immobility data of *Daphnia magna* at 24 and 48 h exposure period**

| nominal test concentration (mg form. / L) | exposed daphnids (=100%) | immobilised daphnids | | | |
|---|---|---|---|---|---|
| | | 24 h | | 48 h | |
| | | n | % | n | % |
| control | 30 | 0 | 0.0 | 0 | 0.0 |
| 0.625 | 30 | 0 | 0.0 | 0 | 0.0 |
| 1.25 | 30 | 0 | 0.0 | 0 | 0.0 |
| 2.50 | 30 | 15 | 50.0 | 20 | 66.7 |
| 5.00 | 30 | 19 | 63.3 | 29 | 96.7 |
| 10.0 | 30 | 30 | 100.0 | 30 | 100.0 |
| 20.0 | 30 | 30 | 100.0 | 30 | 100.0 |

Observations:
No immobility or other effects on behaviour occurred in untreated control within 48 hours of exposure.

**Conclusion:**

Based on nominal concentrations of Bixafen + Fluoxastrobin + Prothioconazole EC 190, the acute toxicity endpoints to *Daphnia magna* are as follows:

24-h $EC_{50}$ = 3.04 mg form./L (95% confidence limits 2.25 – 4.10 mg form./L)
48-h $EC_{50}$ = 2.08 mg form./L (95% confidence limits 1.62 – 2.68 mg form./L)

## CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

| | |
|---|---|
| **Report:** | KCP 10.2.2/01 [redacted].; 2010; M-387053-01-1 |
| Title: | Pseudokirchneriella subcapitata growth inhibition test with bixafen + fluoxastrobin + prothioconazole EC 190 (40+50+100) G |
| Report No.: | EBDRP183 |
| Document No.: | M-387053-01-1 |
| Guideline(s): | OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006) |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The aim of the study was to determine the influence of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and $EC_x$ for growth rate of algal biomass (cells per volume).

**Material and methods:**

Test tem: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Tox No.: 08908-00; Specification No.: 102000023924-NN; Analysed content of active ingredients: 3.90 % w/w (41.5 g/L) bixafen (BYF 00587), 4.86 % w/w (51.7 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

*Pseudokirchneriella subcapitata* (freshwater microalgae, formerly known as *Selenastrum capricornutum*) with an initial cell density of 10 000 cells/mL in the test medium were exposed in a chronic multigeneration test for 3 days under static exposure conditions to nominal concentrations of 0.0960, 0.307, 0.980, 3.13 and 10.0 mg formulation/L in comparison to a control. Three replicate vessels per test level and 6 replicate vessels per control with 150 mL test medium per replicate were used.
The pH values ranged from 7.9 to 8.5 in the controls and the incubation temperature ranged from 21.3°C to 22.1°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8131 lux.
Morphological examinations of cells using a microscope were made over the exposure period on each study day. Quantitative amounts of bixafen were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

**Dates of experimental work:** May 14, 2010 to July 05, 2010

**Findings:**

Validity criteria:
Biomass increased in the control by more than 16-fold within the evaluation period. Mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35%. Percent coefficient of variation of the average growth rate in each control replicate did not exceed 7%. Test conditions met all validity criteria, given by the mentioned guideline(s).

Analytical findings:
The analytical findings of bixafen in the treatment levels found on day 0 were 98 % to 103 % of nominal (average 100 %). On day 3 analytical findings of 97 % to 104 % of nominal (average 99 %) were found. Given that the toxicity cannot be attributed to any of the a.s. compounds but to the formulation as a whole, all results are based on nominal test concentrations of the formulation.

Biological findings:
The static 72 hour algae growth inhibition test provided the following effects:

**Table CP 10.2.2- 1: Effects of the static 72 hour algae growth inhibition test**

| nominal concentration [mg form./L] | cell number after 72 h (means) per mL | (0-72h)-average specific growth rates [days$^{-1}$] | inhibition of average specific growth rate [%] |
|---|---|---|---|
| control | 872 000 | 1.489 | - |
| 0.0960 | 871 000 | 1.489 | 0.0 |
| 0.307 | 858 000 | 1.484 | 0.4 |
| 0.980 | 830 000 | 1.473 | 1.1 |
| 3.13 | 269 000 | 1.097 | 26.4 |
| 10.0 | 37 000 | 0.434 | 70.9 |

test initiation with 10,000 cells/mL

Observations:
No morphological change in algae was observed in any test concentration.

**Conclusion:**

The (0 - 72h)-$E_rC_{50}$ for Bixafen + Fluoxastrobin + Prothioconazole EC 190 is 5.86 mg form./L (95 % CI: 5.41 – 6.36 mg form./L) and the (0 - 72h) - $NOE_rC$ is 0.980 mg form./L.

## CP 10.2.3 Further testing on aquatic organisms

No further testing of the formulation is available or required.

## CP 10.3 Effects on arthropods

### CP 10.3.1 Effects on bees

The risk assessment has been performed according to the existing guidance in force at the time of the preparation and submission of this dossier namely the EU Guidance Document on Terrestrial Ecotoxicology (SANCO/ 10329/2002 rev 2) and EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees.

Commission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, to be conducted. Consequently in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided:

- Acute oral and contact toxicity of the active substance fluoxastrobin and the representative formulation Bixafen + Fluoxastrobin + Prothioconazole EC 190,
- Acute contact toxicity of fluoxastrobin to adult bumble bees under laboratory conditions,
- Chronic 10 day toxicity test with of Fluoxastrobin FS 480 on adult bees under laboratory conditions,
- Colony feeding study with Fluoxastrobin FS 480 according to [redacted] *et al.* 1992 (using a realistic worse case spray solution concentration and covering exposure for effects on brood (eggs, young and old larvae) and their development, nurse bee on-going behaviour in brood care and colony strength),
- Semi-field brood feeding study with Fluoxastrobin EC 100 following OECD guidance document 75 (using a more realistic spray scenario onto flowering *Phacelia tanacetifolia* at the maximum application rate for the approval renewal of fluoxastrobin and covering exposure for effects on brood (eggs) and their development and colony parameters).

Details of the honey bee testing with fluoxastrobin and ecotoxicological are presented together with the ecotoxicological endpoints in MCA, Section 8, Point 8.3.1, as well as within the EFSA Scientific Report (2007) 102. Furthermore, contact laboratory toxicity data for bumble bees indicated that non-*Apis* bees are not more sensitive than honey bees and consequently the risk assessment for honey bees is considered to protective to other bees.

The tests conducted with the formulation Bixafen + Fluoxastrobin + Prothioconazole EC 190 are presented in this MCP document.

A summary of the critical endpoints for fluoxastrobin, the formulated products Fluoxastrobin EC 100, Fluoxastrobin FS 480 and Bixafen + Fluoxastrobin + Prothioconazole EC 190 are provided in the following tables. Endpoints shown in bold are considered relevant for risk assessment.

**Table CP 10.3.1- 1: Critical endpoints for fluoxastrobin – acute toxicity to adult bees**

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| Fluoxastrobin | Honey Bee (oral 48 h) | **$LD_{50}$** | **> 129.1 µg a.s./bee** | [redacted] 2014; M-503275-01-1 KCA 8.3.1.1 KCA 8.3.1.2 |
| | Honey Bee (contact 48 h) | **$LD_{50}$** | **> 100 µg a.s./bee** | |
| | Bumble bee (contact 48 h) (*Bombus terrestris*) | $LD_{50}$ | > 100 µg a.s./bumble bee | [redacted]; 2014; M-512437-01-1 KCA 8.3.1.2 |
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Honey Bee (oral 48 h) | $LD_{50}$ | **> 210.4 µg prod./bee** | [redacted]; 2010; M-369681-01-1 |
| | Honey Bee (contact 48 h) | $LD_{50}$ | **> 200 µg prod./bee** | |

a.s. = active substance; prod. = product **Bold: values used in risk assessment**

**Table CP 10.3.1- 2: Critical endpoints for fluoxastrobin – chronic toxicity to adult bees**

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| Fluoxastrobin FS 480 | Honey bee Laboratory chronic oral (10 d) (adults) | $LC_{50}$<br>$LDD_{50}$<br>NOEC<br>NOEDD | > 3333 mg a.s./kg<br>> 73.3 µg a.s./bee/day<br>1667 mg a.s./kg<br>39.2 µg a.s./bee/day | [redacted].; 2015; M-534974-01-1 KCA 8.3.1.2 |

a.s. = active substance

**Table CP 10.3.1- 3: Critical endpoints for fluoxastrobin – toxicity to bee brood**

| Test substance | Test species | Endpoint | Reference |
|---|---|---|---|
| Fluoxastrobin FS 480 | Bee brood feeding test ([redacted] et al.) | No adverse effects on brood development and mortality after feeding honey bee colonies sugar syrup at 0.375 g a.s./L. | [redacted] 2013; M-476181-01-1 KCA 8.3.1.3 |
| Fluoxastrobin EC 100 | Semi-field brood study (OECD 75) | No adverse effects on brood development, mortality, foraging activity, behaviour, colony condition and strength after application of 150 g a.s./ha onto flowering *Phacelia tanacetifolia*. | [redacted] 2015; M-515147-01-1 KCA 8.3.1.3 |

a.s. = active substance

## Risk assessment for bees

The risk assessment for bees is based on the maximum application rate of 2 × 87.5 g fluoxastrobin/ha in cereals.

Hazard Quotients

The risk assessment is based on Hazard Quotient approach ($Q_H$) by calculating the ratio between the application rate (expressed in g a.s./ha or in g total substance/ha) and the laboratory contact and oral $LD_{50}$ (expressed in µg a.s./bee or in µg total substance/bee).

$Q_H$ values can be calculated using data from the studies performed with the active substance and with the formulation. $Q_H$ values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral: $$Q_{HO} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{oral}} = \frac{[\text{g a.s./ha or g total substance/ ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/ bee}]}$$

Hazard Quotient, contact: $$Q_{HC} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{contact}} = \frac{[\text{g a.s./ha or g total substance/ ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/ bee}]}$$

The maximum label rate of Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100) is 1.75 L (1750 mL) product/ha in cereals (BBCH 30 - 69). With the content of bixafen, fluoxastrobin and prothioconazole within the formulation being 40 g bixafen/L, 50 g fluoxastrobin/L and 100 g prothioconazole/L, respectively, this accounts to a maximum application rate of 87.5 g fluoxastrobin/ha in cereals. Considering a density of 1.064 g/mL of Bixafen + Fluoxastrobin + Prothioconazole EC 190, 1750 mL product/ha corresponds to 1862 g product/ha.

**Table CP 10.3.1- 4: Hazard quotients for bees – oral exposure**

| | Crop | $LD_{50}$ [µg/bee] | Application rate [g/ha] | Hazard quotient $Q_{HO}$ | Trigger |
|---|---|---|---|---|---|
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Cereals | > 210.4 | 1862* | < 8.8 | 50 |
| Fluoxastrobin | Cereals | > 129.1 | 87.5 | < 0.7 | 50 |

* based on a product density of 1.064 g/mL

The hazard quotients for oral exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HO} < 50$).

**Table CP 10.3.1- 5: Hazard quotients for bees – contact exposure**

| | Crop | $LD_{50}$ [µg/bee] | Application rate [g/ha] | Hazard quotient $Q_{HO}$ | Trigger |
|---|---|---|---|---|---|
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Cereals | > 200 | 1862* | < 9.3 | 50 |
| Fluoxastrobin | Cereals | > 100 | 87.5 | < 0.9 | 50 |

* based on a product density of 1.064 g/mL

The hazard quotients for contact exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HC} < 50$).

***Further considerations for the risk assessment***

In addition to acute laboratory studies with adult honey bees, fluoxastrobin was further subjected to topical acute bumble bee testing ([redacted]; 2014; M-512437-01-1; in CA 8.3.1.1.2). The study resulted in an $LD_{50}$ of > 100 µg a.s./bumble bee and did not reveal sensitivity differences between honey bee and bumble bee foragers.

Moreover, fluoxastrobin was further subjected to chronic laboratory testing with adult honey bees ([redacted]; 2015; M-534974-01-1; in CA 8.3.1.2).
This chronic study was designed as a dose-response test by exposing adult honey bees for 10 consecutive days to nominal concentration of 208, 417, 833, 1667 and 3333 mg fluoxastrobin/kg feeding solution, respectively. The actual test was conducted by using the formulated product Fluoxastrobin FS 480. After exposing honey bees for ten consecutive days exclusively to sugar solution containing fluoxastrobin, the 10 day $LC_{50}$ (Lethal Concentration) was determined to be > 3333 mg fluoxastrobin/kg, which corresponds to a $LDD_{50}$ (Lethal Dietary Dose) of > 73.3 µg a.s./bee/day. The respective NOEC (No Observed Effect Concentration) for mortality was determined to be 1667 mg fluoxastrobin/kg, which corresponds to the NOEDD (No Observed Effect Dietary Dose) of 39.2 µg a.s./bee/day.

In order to reveal whether fluoxastrobin poses a risk to immature honey bee life stages, a bee brood feeding study ([redacted]; 2013; M-476181-01-1, in CA 8.3.1.3) has been conducted by following the provisions/method of [redacted] (OEPP/EPPO Bulletin 22:613-616 (1992)), which require, amongst other parameters to *"...use formulated products only... products are fed at a concentration recommended for high-volume use..."*. The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the hive with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, young and old larvae by employing digital photo imaging technology.
This particular study was conducted with Fluoxastrobin FS 480. The administration of fluoxastrobin at a concentration of 0.375 g a.s to honeybee colonies via feeding of 1 litre spiked sucrose solution has neither resulted in adverse effects on brood development, worker or pupal mortality compared to the control. Regarding brood development, the brood termination rates of the test item treatment were overall on a low level with 7.1, 9.1 and 11.3% for eggs, young larvae and old larvae, respectively, which were not statistically significant different to the control with brood termination rates of 9.6, 24.4 and 3.3% for eggs, young larvae and old larvae, respectively at the end of the brood observation period.

In order to clarify whether fluoxastrobin poses a risk to honey bee brood and colony development in particular as well as on honey bees in general under realistic worst-case conditions, a higher tier semi-field honey bee brood study (according to the provisions of the OECD Guidance Document 75) was conducted under forced/confined exposure conditions using the formulation Fluoxastrobin EC 100, by application of 150 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* ([redacted]; 2015; M-515147-01-1; in CA 8.3.1.3).
The study included three treatment groups: Control (tap water), Test item (150 g a.s./ha and Reference item (300 g fenoxycarb/ha) with all applications being carried out with a spray volume of 400 L water/ha. For all treatment groups, four replicates (tunnels) were set up. The application of all treatments was conducted during daily bee flight activity at the time of full flowering of the crop. Thereafter, the bees were kept for 7 days within the tunnels (confined exposure phase) and were then relocated out of the tunnels and transferred to a monitoring site without flowering crops and intensive agricultural area for further monitoring (day 8 to day 28 after treatment). Daily, throughout the confined exposure phase, mortality of worker bees, larvae and pupae was assessed along with assessments of foraging activity and behaviour. Daily mortality assessments were continued along

with behaviour around the hive during the post-exposure observation period (day 8 to day 28 after treatment). Colony assessments (food stores, brood areas, colony strength) were made before confinement, after confinement and at the end of the study. Detailed brood assessments (brood termination rate, brood index and brood compensation index) by employing digital photo imaging technology, investigating the fate of more than 200 individually marked cells was performed on 5 occasions throughout the study, covering an entire brood cycle of honey bees.
The application of fluoxastrobin at the rate of 150 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* did not cause any adverse effects on mortality, flight intensity (except for a short term reduction in flight activity on the day of application), brood development (brood termination rate: 35.5%, brood index: 3.2, compensation index: 3.9 in test item compared to the control with brood termination rate: 30.0%, brood index: 3.5, compensation index: 4.0), as well as on colony strength and condition. Neither brood termination rate nor brood or compensation index were significantly different in the test item as compared to the control, indicating that these indices performed comparable to the control, including compensations of previous brood losses.

All in all, it can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study ([redacted] *et al.* and OECD Guidance Document 75) investigating side-effects on immature honey bee life stages, that fluoxastrobin is of low general intrinsic toxicity to honey bees.

<u>*Synopsis*</u>
Fluoxastrobin is of low acute toxicity to honey bees, with $LD_{50}$ (oral and contact) above the highest tested dose levels.
The calculated Hazard Quotients for fluoxastrobin are below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be expected at the maximum envisaged application rate. This conclusion is confirmed by the results of the bee brood feeding study as well as by the results of the bee brood semi-field study, which covered the maximum application rate of 150 g a.s./ha.
The acute laboratory study conducted with bumble bees revealed no sensitivity differences between honey bee and bumble bee foragers.
It can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study ([redacted] *et al.*) and bee brood semi-field study (OECD 75), investigating side-effects on immature honey bee life stages that fluoxastrobin is of low general intrinsic toxicity to honey bees.
Regarding potential side effects of fluoxastrobin on immature honey bee life stages, the conducted bee brood feeding study ([redacted] *et al.*, 1992) found no statistically significant differences between test item and control in brood termination rates of eggs, young and old larvae at 0.375 g a.s./L. Overall the study revealed no adverse effects on the survival of adult bees and pupae. Thus, when considering the severity of the exposure situation in this worst-case screening test in combination with the absence of effects on the overall development of bee brood, it can be concluded even on the basis of this worst-case screening study that the use of fluoxastrobin does not pose an unacceptable risk for adult honey bees, immature honey bee life stages and honey bee colonies.
In order to clarify whether the conclusions on the basis of lower tiered honey bee studies are correct, fluoxastrobin was subjected to confined semi-field testing (according to the provisions of OECD Guidance Document No. 75), by applying the two rates of 150 g a.s./ha to full-flowering *Phacelia* during honey bees actively foraging on the crop. This study design is from an apidological and apicultural point of view more realistic than an in-hive feeding of the test compound via a treated sugar solution, which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration). The results of this higher tier semi-field study confirmed the conclusions made above on the basis of the outcome of the lower-tiered studies, as no adverse direct or delayed effects on mortality of worker bees or pupae, foraging activity, behaviour, colony strength and colony development as well as the development of bee brood were observed, even under

aggravated, forced exposure conditions and by digitally following-up in a very detailed manner the fate of individually marked brood cells (digital photographic assessment) from egg stage until emergence.

**Conclusions**

Overall, it can be concluded that fluoxastrobin, when applied in cereals at the maximum application rate of 87.5 g a.s./ha, as foreseen for the use of Bixafen + Fluoxastrobin + Prothioconazole EC 190, does not pose an unacceptable risk to honey bees and honey bee colonies.

## CP 10.3.1.1 Acute toxicity to bees

### CP 10.3.1.1.1 Acute oral toxicity to bees

| | |
|---|---|
| **Report:** | KCP 10.3.1.1.1/01 [redacted],; 2010; M-369681-01-1 |
| Title: | Effects of bixafen + fluoxastrobin + prothioconazole EC 190 (40+50+100) G (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory |
| Report No.: | 55601035 |
| Document No.: | M-369681-01-1 |
| Guideline(s): | OECD Guideline 213/214 for the Testing of Chemicals on Honeybee, Acute Oral/Contact Toxicity Test, adopted on 21st September 1998; |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The aim of this study was to determine possible effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the honey bee, *Apis mellifera* L., in an acute contact test under laboratory conditions. Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000002392 -NN; Material No.: 79969775; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

Test units were stainless steel cages of 10 cm x 8.5 cm x 5.5 cm (length x width x height). Under laboratory conditions, *Apis mellifera* (50 worker bees per dose: 10 bees per replicate, 5 replicates per test item dose level, controls and reference item doses) were exposed for 48 hours to a single dose of 200.0 µg product per bee for topical application (contact) and with a single dose of 210.4 µg product per bee for feeding (oral value based on the actual intake of the test item).
For the contact test a single 5 µL droplet Bixafen + Fluoxastrobin + Prothioconazole EC 190, dissolved in tap water with 0.5 % Adhäsit, was placed on the dorsal bee thorax, likewise for the toxic reference (dimethoate) and the control (tap water). For the oral test aqueous stock solutions of the test item and reference item were prepared and mixed with ready-to-use sugar syrup (30 % saccharose, 31 % glucose, 39 % fructose) at a concentration of 50 % (w/w). For the control, tap water and sugar syrup was used at the same ratio (1 + 1). The treated food was offered in syringes, which were weighed before and after introduction into the cages. After a maximum of 3 hours 50 minutes, the uptake was complete (duration of uptake was 3 hours 50 minutes for the test item treatments) and the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.

The number of dead bees was determined after 4 hours (first day); 24 and 48 hours. Behavioural abnormalities (vomiting, apathy, intensive cleaning) were assessed after 4 hours (first day), 24 and 48 hours. Temperature during the test was 23 -25 °C; relative humidity was 30 – 63 %. Bees were kept in darkness (except during observation).

**Dates of work:** April 19, 2012 to April 22, 2010

**Findings:**

Validity Criteria:

| Validity Criteria | | Recommended | Obtained |
|---|---|---|---|
| Control Mortality | Contact Test | | |
| | $CO_2$/water control | ≤ 10% | 0.0 % |
| | Oral Test | | |
| | Water/ sugar control | ≤ 10% | 0.0 % |
| $LD_{50}$ of Reference Item (24 h) | Contact Test | | |
| | | 0.10 - 0.30 µg a.s./bee | 0.26 µg a.s./bee |
| | Oral Test | | |
| | | 0.10 - 0.35 µg a.s./bee | 0.16 µg a.s./bee |

The contact and oral test is considered valid as the control mortality in each case was ≤ 10% and the $LD_{50}$ values obtained with the reference item (dimethoate) were within the required ranges.

Biological results:

*Contact test:*

At the end of the contact toxicity test (48 hours after application), there was 14.0 % mortality at 200.0 µg product/bee. No mortality occurred in the control (water + 0.5 % Adhäsit). A few bees were behaving abnormal during the first 4 hours following the treatment (uncoordinated movements and apathy) and one bee had moving coordination problems during the 48-hours assessment.

*Oral test:*

In the oral toxicity test the maximum nominal test level of Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100) G (200 µg product/bee) corresponded to an actual intake of 210.4 µg product/bee. This dose level led to 40 % mortality after 48 hours. No mortality occurred in the control (50 % sugar solution). During the 4-hours assessment 20 out of the 50 bees showed uncoordinated movements or were apathetic. No further behavioural impairments occurred 24 and 48 hours following the application.

**Table CP 10.3.1.1.1- 1: Toxicity to honey bees; laboratory tests**

| Test item | Bixafen + Fluoxastrobin + Prothioconazole EC 190 | |
|---|---|---|
| Test object | *Apis mellifera* | |
| Application rate µg product/bee | 200.0 | 210.4 |
| Exposure | contact<br>(solution in Adhäsit (0.5 %)/water) | Oral<br>(sugar solution) |
| $LD_{50}$ µg product/bee | > 200.0 | > 210.4 |

The contact and oral $LD_{50}$ (24 h) values of the reference item (dimethoate) were calculated to be 0.26 and 0.16 µg a.s./bee, respectively.

**Conclusion:**

The toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 was tested in both, an acute contact and an oral toxicity test on honey bees. The $LD_{50}$ (48 h) was > 200.0 µg product/bee in the contact toxicity test. The $LD_{50}$ (48 h) was > 210.4 µg product/bee in the oral toxicity test.

## CP 10.3.1.1.2 Acute contact toxicity to bees

| | |
|---|---|
| **Report:** | KCP 10.3.1.1.2/01 [redacted]; 2010; M-369681-01-1 |
| Title: | Effects of bixafen + fluoxastrobin + prothioconazole EC 190 (40+50+100) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory |
| Report No.: | 55601035 |
| Document No.: | M-369681-01-1 |
| Guideline(s): | OECD Guideline 213/214 for the Testing of Chemicals on Honeybee, Acute Oral/Contact Toxicity Test, adopted on 21st September 1998. |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

Additionally, an acute contact toxicity study was conducted on bumble bees with fluoxastrobin; the corresponding summary is provided in Document MCA, Section 8.3.1.1.2 ([redacted]; 2014; M-512437-01-1).

## CP 10.3.1.2 Chronic toxicity to bees

A 10 day chronic oral toxicity study was conducted with fluoxastrobin; the corresponding summary is provided in Document MCA, Section 8.3.1.2 ([redacted]; 2015; M-534974-01-1).

## CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A honey bee brood feeding study according to the method of [redacted] *et al.* 1998 ([redacted] 2013; M-476181-01-1) has been conducted with Fluoxastrobin FS 480 and is included in Document MCA, Section 8.3.1.3.
A semi-field honey bee brood study (according to OECD 75) ([redacted]; 2015; M-515147-01-1) has been conducted with the Fluoxastrobin EC 100 and is included in Document MCA, Section 8.3.1.3.

## CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideline to assess "sub-lethal effects" in honey bees. However, in each laboratory study as well as in any higher-tier study, sub-lethal effects, if occurring, are described and reported.

## CP 10.3.1.5 Cage and tunnel tests

Based on the findings presented above, a study with the formulated product is not required.

## CP 10.3.1.6 Field tests with honeybees

Based on the findings presented above, a study with the formulated product is not required.

## CP 10.3.2 Effects on non-target arthropods other than bees

Toxicity tests on non-target arthropods were conducted with Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the sensitive standard species *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata* and *Chrysoperla carnea*. A summary of the results is provided in the table below.

**Table CP 10.3.2- 1: BIX + FXA + PTZ EC 190: Ecotoxicological endpoints for arthropods other than bees**

| **Test species, Dossier-File-No., Reference** | **Tested Formulation, Study Type, Exposure** | **Ecotoxicological Endpoint** | | |
|---|---|---|---|---|
| *Aphidius rhopalosiphi* | BIX+FXA+PTZ EC 190 | $LR_{50}$ >2500 mL product/ha; | | |
| M-370506-01-1 | Extended lab., exposure on | $ER_{50}$ >2500 mL product/ha | | |
| Rep. no: CW10/013 | potted barley plants | Corr. Mortality [%] | Effect on Reproduction [%] | Repellency rel. to control [%] |
| [redacted], 2010a | | | | |
| KCP 10.3.2.2 | 250 mL product/ha | 0 | -19.7[A] | -8.2 [B] n.sign. |
| | 445 mL product/ha | 6.7 | 10.9 | -27.9 [B] n.sign. |
| | 790 mL product/ha | 0 | -37.3[A] | -31.4 [B] n.sign. |
| | 1400 mL product/ha | 10.0 | -11.7[A] | -15.2 [B] n.sign. |
| | 2500 mL product/ha | 0 | -17.0[A] | 29.6 n.sign. |
| *Typhlodromus pyri* | BIX+FXA+PTZ EC 190 | $LR_{50}$ 2668 mL product/ha | | |
| M-389537-01-1 | Extended lab., exposure on | $ER_{50}$ >2000 mL prod./ha | | |
| Rep. no: CW10/014 | detached maize leaves | Corr. Mortality [%] | Effect on Reproduction [%] | |
| [redacted], 2010b | 375 mL product/ha | 3.4 | 28.5 | |
| KCP 10.3.2.2 | 655 mL product/ha | 14.9 | 0.3 | |
| | 1150 mL product/ha | 21.8 | 21.3 | |
| | 2000 mL product/ha | 26.4 | 43.7 | |
| | 3500 mL product/ha | 70.1 | n.a. | |
| *Coccinella septempunctata* | BIX+FXA+PTZ EC 190 | $LR_{50}$ 2867 mL product/ha, no effect on reproduction | | |
| M-370455-01-1 | Extended lab., exposure on | | | |
| Rep. no: CW10/015 | detached maize leaves | Corr. Mortality [%] | Fertile Eggs/Female/Day | Hatching [%] |
| [redacted], 2010c | Control | - | 10.1 | 85.8 |
| KCP 10.3.2.2 | 350 mL product/ha | 3.4 | 6.8 | 83.4 |
| | 600 mL product/ha | 3.4 | 9.6 | 88.3 |
| | 1025 mL product/ha | 0 | 9.8 | 86.7 |
| | 1750 mL product/ha | 27.6 | 14.7 | 81.7 |
| | 3000 mL product/ha | 51.7 | 21.7 | 87.6 |
| *Chrysoperla carnea* | BIX+FXA+PTZ EC 190 | $LR_{50}$ 1107 mL product/ha, | | |
| M-384778-01-1 | Extended lab., exposure on | no effect on reproduction at 1150 mL product/ha | | |
| Rep. no: CW10/016 | detached maize leaves | Corr. Mortality [%] | Eggs/Female/Day | Hatching [%] |
| [redacted], 2010d | Control | - | 29.8 | 81.8 |
| KCP 10.3.2.2 | 375 mL product/ha | 10.5 | 19.5 | 79.5 |
| | 655 mL product/ha | 34.2 | 20.0 | 78.6 |
| | 1150 mL product/ha | 34.2 | 35.4 | 82.6 |
| | 2000 mL product/ha | 94.7 | n.a. | n.a. |
| | 3500 mL product/ha | 81.6 | n.a. | n.a. |
| *Chrysoperla carnea* | BIX+FXA+PTZ EC 190 | | | |
| M-389548-01-1 | Aged residue spray | | | |
| Rep. no: CW10/026 | deposits on maize plants, 2 | | | |
| [redacted], 2010 | appl. of 1.75 L product/ha | | | |
| KCP 10.3.2.2 | (spray interval of 14 d) | Corr. Mortality [%] | Eggs/Female/Day | Hatching [%] |
| | Residues aged for 0 d: | 7.7 | 27.2 | 81.4 |
| | Residues aged for 14 d: | -2.9[C] | 33.3 | 75.4 |
| | Residues aged for 28 d: | -2.8[C] | n.a. | n.a. |

[A]: A negative value indicates a higher reproduction rate in the treatment than in the control.
[B]: A negative value indicates a higher percentage of wasps found on plants in the treatment than in the control.
[C]: A negative value indicates a lower mortality in the treatment than in the control.
n.a.: Not assessed.
sign.: statistically significant at 5%-level.
n.sign.: not statistically significant.

The extended laboratory data clearly indicate that *C. carnea* was the most sensitive non-target arthropod species tested with Bixafen + Fluoxastrobin + Prothioconazole EC 190 ($LR_{50}$ 1107 mL product/ha).

**Risk assessment**

Since extended laboratory studies are for 4 non-target arthropod species available no tier 1 laboratory studies were conducted. Therefore, the tier 1 risk assessment has been skipped and a tier 2 risk assessment based on the extended lab data is provided below.

**Potential exposure**

The exposure scenario is based on the intended use in cereals with an application rate of 2 x 1750 mL prod./ha, at a minimum interval of 14 days. The exposure assessment for 2 x 1750 mL prod./ha covers also as worst case scenario the use rate of 2 x 1500 mL prod./ha.

According to ESCORT2 and the Terrestrial Guidance Document the exposure is calculated as:

In-field: Application rate * MAF

Off-field: Application rate * MAF * (drift factor / VDF) *correction factor

Application rate: 2 x 1750 mL/ha (cereals)

Drift factor = 2.38% (field crops, 1 m distance, 2 applications, 82nd percentile, ESCORT2)

MAF (multiple application factor) = 1.7 for cereals (default value for 2 applications; ESCORT2)

VDF (vegetation distribution factor) = 10 (default value as recommended by the Terrestrial Guidance Document, to take into account the 3-dimensional structure of the off-field vegetation; in can only be applied in the context of 2D test systems)

Correction factor = 5 (default value for tier 2 risk assessment according to the Terrestrial Guidance Document)

**Table CP 10.3.2- 2: Exposure calculation for in-field assessment**

| Crop / no. of applications | Appl. rate [mL/ha] | MAF | in-field $PEC_{max.}$ [mL/ha] |
|---|---|---|---|
| Cereals / 2 | 1750 | 1.7 | 2975 |

**Table CP 10.3.2- 3: Corrected exposure for off-field risk assessment**

| Crop | Appl. rate [mL/ha] | MAF | Drift [%] | Veg. distr. factor | Correction factor | off-field $PEC_{max.}$ [mL/ha] | Remark |
|---|---|---|---|---|---|---|---|
| Cereals | 1750 | 1.7 | 2.38 | - | 5 | 354.0 | in case of 3-D study design |
| Cereals | 1500 | 1.7 | 2.38 | 10 | 5 | 35.4 | in case of 2-D study design |

## Tier 2 in-field risk assessment

**Table CP 10.3.2- 4: In-field risk assessment based on study results from extended laboratory studies**

| Crop | Test Species | in-field $PEC_{max.}$, [mL/ha] | $LR_{50}$; $ER_{50}$ [mL/ha] | Trigger | Refinement required? |
|---|---|---|---|---|---|
| Cereals | *A. rhopalosiphi* | 2975 | > 2500 | Effects are < 50% | **yes** |
| | *T. pyri* | 2975 | >2000 | Effects are < 50% | **yes** |
| | *C. septempunctata* | 2975 | 2867 | Effects are < 50% | **yes** |
| | *C. carnea* | 2975 | 1107 | Effects are < 50% | **yes** |

The higher tier in-field risk assessment for *A. rhopalosiphi, T. pyri, C. septempunctata* and *C. carnea* indicates that initial effects in the in-field area cannot be excluded. Therefore, further refinement is needed.

**Refined in-field risk assessment**

The results of the tier 2 risk assessment based on the extended laboratory studies indicate that initial effects on non-target arthropod species with sensitivity similar *A. rhopalosiphi, T. pyri, C. septempunctata* and *C. carnea* cannot be excluded. According to the Terrestrial Guidance Document the potential for recovery needs to be demonstrated. For this purpose an aged residue study with *Chrysoperla carnea* ([redacted],; 2010; M-389548-01-1) was conducted, as this species has been identified as most sensitive species compared to the other tested non-target arthropods (*A. rhopalosiphi, T. pyri, C. septempunctata*). The results of the aged residue study indicated that under the more realistic exposure conditions (treatment of whole plants, application of 2 x 1750 ml prod./ha with a 14-day interval) no relevant adverse effects on mortality or reproduction are observed. Since *C. carnea* is the most sensitive species from the tested non-target arthropod species this covers also *A. rhopalosiphi*, *T. pyri*, and *C. septempunctata*.
The data indicate that that no unacceptable adverse effects on non-target arthropods are expected in the in-field area from the applications of BIX + FXA + PTZ EC 190 according to the proposed use pattern.

**Tier 2 off-field risk assessment**

**Table CP 10.3.2- 5: Off-field risk assessment based on study results from extended laboratory studies**

| Crop | Test Species | off-field $PEC_{max.}$, [mL/ha] | $LR_{50}$; $ER_{50}$ [mL/ha] | Trigger | Refinement required? |
|---|---|---|---|---|---|
| Cereals | *A. rhopalosiphi* | 354* | > 2500 | Effects are < 50% | no |
| | *T. pyri* | 35.4 | ≥2000 | Effects are < 50% | no |
| | *C. septempunctata* | 35.4 | 2867 | Effects are < 50% | no |
| | *C. carnea* | 35.4 | 1107 | Effects are < 50% | no |

* Off-field PEC for 3D study design

For *T. pyri*, *A. rhopalosiphi*, *C. septempunctata*, and *C. carnea* no effects > 50% neither on mortality nor on reproduction were observed in extended laboratory studies on natural substrate at exposure rates relevant for the off-crop risk assessment (see Table CP 10.3.2- 4). Therefore, it can be concluded that no unacceptable risks for non-target arthropods in the off-field area is to be expected from the use of the product according to the proposed use patterns.

## CP 10.3.2.1 Standard laboratory testing for non-target arthropods

No tier 1 standard laboratory studies were performed. Extended laboratory studies are reported below.

## CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

| | |
|---|---|
| **Report:** | KCP 10.3.2.2/01 [redacted],; 2010; M-370506-01-1 |
| Title: | Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using an extended laboratory test on barley; Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) |
| Report No.: | CW10/013 |
| Document No.: | M-370506-01-1 |
| Guideline(s): | [redacted] ET AL. (2000), [redacted] ET AL. (2009), [redacted] ET AL. (2001) |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The objective of this extended laboratory study was to investigate the lethal and sublethal toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the parasitoid wasp *Aphidius rhopalosiphi* when exposed on a plant surface.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX 08908-00; Specification No.: 102000023924-NN; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL (20°C).

The test item was applied on barley seedlings at rates of 250, 445, 790, 1400 and 2500 mL product/ha and the effects on the parasitoid wasp *Aphidius rhopalosiphi* were compared to those of a deionised water treated control. A toxic reference (active substance: dimethoate) applied at 7.2 mL product/ha (3 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system. Mortality of 30 females (6 replicates with 5 wasps per group) was assessed 2, 24 and 48 hours after exposure. Repellency of the test item was assessed during the initial 3 hours after the release of the females. Five separate observations were made at 30 minutes intervals starting 15 minutes after the introduction of all wasps. From the water control and all test item rates 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated barley seedling infested with *Rhopalosiphum padi* for a period of 24 hours. The number of mummies was assessed 11 days later.
The climatic test conditions during the study were 18.0 – 21.5 °C temperature and 60 – 90% relative humidity (with short decrease < 2 h down to 53 %). The light / dark cycle was 16:8 h with a light intensity range of 425 – 1114 Lux in the mortality phase, 856 – 3420 Lux in the parasitation phase and 7370 - 16940 Lux in the reproduction phase of the study.

**Dates of experimental work:** March 15, 2010 to March 29, 2010

## Findings:

Validity criteria:

| | Validity criteria | Finding |
|---|---|---|
| Mortality in water control | ≤ 10% | 0% |
| Corrected mortality reference item | ≥ 50% | 86.7% |
| Mean reproduction per female in water control | ≥ 5 | 22.0 |
| No more than 2 wasps producing zero reproduction in water control | ≤ 2 | 1 |

The results of this study can be considered as valid.

Biological findings:
Mortality, reproduction and repellency in each treatment are summarized below.

**Table CP 10.3.2.2- 1: Effects of BIX+FXA+PTZ EC 190 on *Aphidius rhopalosiphi***

| Test item | | Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Test organism | | *Aphidius rhopalosiphi* | | | | | | |
| Exposure on: | | Barley seedlings | | | | | | |
| | | Mortality after 48 h [%] | | | Reproduction | | Repellency | |
| Treatment | mL Prod./ha | Uncorr. | Corr. | P-Value(*) | Rate (mummies per female) | Red. rel. to Control [%] P-Value(#) | % Wasps on plant | Red. rel. to Control [%] P-Value(#) |
| Control | 0 | 0.0 | | | 22.0 | | 46.7 | |
| Test item | 250 | 0.0 | 0.0 | 1.000 n.sign. | 26.3 | -19.7 0.836 n.sign. | 50.5 | -8.2 0.263 n.sign. |
| Test item | 445 | 6.7 | 6.7 | 0.983 n.sign. | 19.6 | 10.9 0.378 n.sign. | 59.7 | -27.9 0.093 n.sign. |
| Test item | 790 | 0.0 | 0.0 | 1.000 n.sign. | 30.2 | -37.3 0.427 n.sign. | 61.3 | -31.4 0.086 n.sign. |
| Test item | 1400 | 10.0 | 10.0 | 0.593 n.sign. | 24.6 | -11.7 0.585 n.sign. | 53.8 | -15.2 0.248 n.sign. |
| Test item | 2500 | 0.0 | 0.0 | 1.000 n.sign. | 25.7 | -17.0 0.645 n.sign. | 32.8 | 29.6 0.174 n.sign. |
| Reference item | 7.2 | 86.7 | 86.7 | | n.a. | | 58.8 | -26.1 |

$LR_{50}$: > 2500 mL product/ha
$ER_{50}$: > 2500 mL product/ha
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed n.sign. not significant sign. Significant

## Conclusion:

The $LR_{50}$ was estimated to be > 2500 mL product/ha. The $ER_{50}$ was estimated to be > 2500 mL product/ha. No statistically significant repellent effect of the test item was observed.
The figures obtained fulfil the validity criteria of the extended laboratory method (MEAD-BRIGGS ET AL., 2009).

| | |
|---|---|
| **Report:** | KCP 10.3.2.2/02 [redacted]s; 2010; M-389537-01-1 |
| Title: | Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) using an extended laboratory test on zea mays; Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L) |
| Report No.: | CW10/014 |
| Document No.: | M-389537-01-1 |
| Guideline(s): | [redacted] ET AL. (2000) modified: Use of natural substrate (detached maize leaves) instead of glass plate; [redacted] ET AL. (2001) |
| Guideline deviation(s): | Use of natural substrate (detached maize leaves) instead of glass plate |
| **GLP/GEP:** | **yes** |

**Objective:**

The objective of this study was to investigate the lethal and sublethal toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 applied onto detached leaves to the predatory mite *Typhlodromus pyri*.

**Material and methods:**

Test tem: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848; Sample Description: TOX08908-00; Specification No.: 102000023924-NN; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

The test item was applied onto detached leaves of *Zea mays* at rates of 375, 655, 1150, 2000 and 3500 mL product/ha and the effects on the predatory mite *Typhlodromus pyri* were compared to those of a deionised water treated control. A toxic reference (active substance: dimethoate) applied at 96.5 mL product/ha (40 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system. Mortality of 100 mites (5 replicates with 20 individuals per test group) was assessed 1, 4, 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed. The reproduction rate of surviving mites was then evaluated from day 7 until day 14 after treatment by counting the total number of offspring (eggs and larvae) produced.
The experiment was performed at a temperature range of 24.0 – 25.0 °C temperature and a relative humidity range of 60 – 70% (with very short deviations < 2 h down to 59.8 %). The light / dark cycle was 16:8 h with a light intensity range of 596 – 1394 Lux.

**Dates of experimental work:** March 25, 2010 to July 08, 2010

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| MortEsc.-rate in the control group on day 7 | ≤ 20% | 13.0% |
| Average corr. mortality in the reference item | ≥ 50% | 100% |
| Average number of eggs/female (calculated as sum of 4 assessment dates – from day 7 on) in the control group | ≥ 4 | 4.3 |

The results of this study can be considered as valid.

Biological findings:

At the test rates of 375, 655, 1150, 2000 and 3500 mL product/ha a corrected mortality of 3.4%, 14.9%, 21.8%, 26.4% and 70.1% has been observed, respectively.
At 375, 655, 1150 and 2000 mL product/ha the reproduction was reduced by 28.5%, 0.3%, 21.3% and 43.7%, respectively.
The mortality / escaping rate in the control exposure units up to day 7 after treatment was 13.0%. The mean corrected mortality of the mites and the mean reproduction rate of the surviving females exposed to the test item and the toxic reference is given below:

**Table CP 10.3.2.2- 2 Effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on *Typhlodromus pyri***

| Test item | | Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L) | | | | | |
|---|---|---|---|---|---|---|---|
| Test organism | | *Typhlodromus pyri* | | | | | |
| Exposure on: | | Detached maize leaves | | | | | |
| | | Mortality after 7 days [%] | | | Reproduction | | |
| Treatment | mL product/ha | Uncorr. | Corr. | P-Value(*) | Rate (eggs per female) | Red. rel. to Control [%] | P-Value (#) |
| Control | 0 | 13.0 | | | 4.3 | | |
| Test item | 375 | 16.0 | 3.4 | 0.344 n.sign. | 3.1 | 28.5 | 0.180 n.sign. |
| Test item | 655 | 26.0 | 14.9 | 0.031 sign. | 4.3 | 0.3 | 0.215 n.sign. |
| Test item | 1150 | 32.0 | 21.8 | 0.003 sign. | 3.4 | 21.3 | 0.230 n.sign. |
| Test item | 2000 | 36.0 | 26.4 | <0.001 sign. | 2.4 | 43.7 | 0.238 n.sign. |
| Test item | 3500 | 74.0 | 70.1 | <0.001 sign. | n.a. | n.a. | |
| Reference item | 96.5 | 100.0 | 100.0 | | n.a. | n.a. | |

**$LR_{50}$: 2668 mL product/ha**; 95 % Confidence Interval: (1634 – 3679), calculated with Probit analysis
**$ER_{50}$: >2000 mL product/ha**
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
\# Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed n.sign. not significant sign. Significant

**Conclusion:**

The $LR_{50}$ was calculated to be 2668 mL product/ha. The $ER_{50}$ was estimated to be >2000 mL product/ha.
The figures obtained fulfil the validity criteria of the laboratory method for

**Report:** KCP 10.3.2.2/03 [redacted].; 2010; M-370455-01-1
Title: Toxicity to the ladybird beetle Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test on Zea mays; Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L)
Report No.: CW10/015
Document No.: M-370455-01-1
Guideline(s): [redacted] ET AL. (2000) modified
[redacted] ET AL. (2001)
Guideline deviation(s): Use of natural substrate (maize leaves) instead of glass plate
**GLP/GEP:** **yes**

**Objective:**

The objective of this laboratory study was to investigate the lethal and sublethal toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 to the ladybird beetle *Coccinella septempunctata* when exposed to treated leaf surfaces.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000023924-NN; Master recipe ID: 0106974-001; Analysed content of active ingredients: 3.90 % w/w bixafen (BYF 00587) (equivalent to 41.50 g/L), 4.86 % w/w fluoxastrobin (HEC 5725 E-ISO) (equivalent to 51.71 g/L), 9.59 % w/w prothioconazole (JAU 6476) (equivalent to 102.0 g/L); Density: 1.064 g/mL(20°C).

The test item was applied to detached leaves of *Zea mays* at rates of 350, 600, 1025, 1750 and 3000 mL product/ha and the effects on the ladybird beetle *Coccinella septempunctata* were compared to those of a deionised water treated control. A toxic reference (active substance: dimethoate) applied at 26.5 mL product/ha (11 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system. The preimaginal mortality of 40 larvae was assessed till the hatch of the imagines (up to 16 days) .The fertility and fecundity of the surviving hatched adults were then evaluated over the period of 17 days.
The climatic test conditions during the study were 23.5 – 26.0 °C temperature and 66.0 – 80.5% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1141 - 6366 Lux.

**Dates of experimental work:** March 25, 2010 to May 05, 2010

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| Mortality in water control | ≤ 30% | 27.5% |
| Corrected mortality reference item | ≥ 40% | 100% |
| Mean number of fertile eggs per female and day in water control | ≥ 2 | 10.1 |

The results of this study can be considered as valid.

Biological findings:

Mortality and reproduction in each of the treatments are summarized below.

**Table CP 10.3.2.2- 3: Effects of the test item on *Coccinella septempunctata***

| Test item | | Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) | | | | |
|---|---|---|---|---|---|---|
| Test organism | | *Coccinella septempunctata* | | | | |
| Exposure on: | | Detached maize leaves | | | | |
| | | Mortality [%] | | | Reproduction | |
| Treatment | mL product/ha | Uncorr. | Corr. | P-Value(*) | Fertile eggs per female and day | Fertility [hatching rate in %] |
| Control | 0 | 27.5 | | | 10.1 | 85.8 |
| Test item | 350 | 30.0 | 3.4 | 1.000 n.sign. | 6.8 | 83.4 |
| Test item | 600 | 30.0 | 3.4 | 1.000 n.sign. | 9.6 | 88.3 |
| Test item | 1025 | 27.5 | 0.0 | 1.000 n.sign. | 9.8 | 86.7 |
| Test item | 1750 | 47.5 | 27.6 | 0.211 n.sign. | 14.7 | 81.7 |
| Test item | 3000 | 65.0 | 51.7 | 0.004 sign. | 21.7 | 87.6 |
| Reference item | 26.5 | 100.0 | 100.0 | | n.a. | n.a. |

$LR_{50}$: 2867 mL product/ha; 95 % Confidence Interval: (2036 - 6769) (calculated with Probit analysis)
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed
n.sign. not significant
sign. Significant

**Conclusion:**

The $LR_{50}$ was estimated to be 2867 mL product/ha. No adverse effect on reproduction was observed up to and including 3000 mL product/ha.
The figures obtained fulfil the validity criteria of the laboratory method using glass plates.

| | |
|---|---|
| **Report:** | KCP 10.3.2.2/04 [redacted],; 2010; M-384778-01-1 |
| Title: | Toxicity to the green lacewing Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) using an extended laboratory test on Zea mays; Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) |
| Report No.: | CW10/016 |
| Document No.: | M-384778-01-1 |
| Guideline(s): | [redacted] ET AL. (2000) modified, [redacted] ET AL. (2001) |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The purpose of this extendend laboratory study was to investigate the lethal and sublethal toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 to the green lacewing *Chrysoperla carnea* when exposed to treated leaf surfaces.

**Material and methods:**

Test tem: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 40+50+100 G; Batch ID.: 2010-000848, Sample Description: TOX 08908-00; Specification No.: 102000023924-NN; Material No.: 79969775; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/cm$^3$.

The test item was applied to detached leaves of *Zea mays* at rates of 375, 655, 1150, 2000 and 3500 mL product/ha and the effects on the green lacewing *Chrysoperla carnea* were compared to those of a deionised water treated control. A toxic reference (active substance: dimethoate) applied at 38.6 mL product/ha (16 g a.s./ha) was included to indicate the relative susceptibility of the test organisms and the test system.
The preimaginal mortality of 40 larvae was assessed till the hatch of the imagines (up to 22 days) .The fertility and fecundity of the surviving hatched adults were then evaluated over the period of one week.
The climatic test conditions during the study were 24.0 – 25.5 °C temperature and 65 – 76% relative humidity (with a short decline < 2 h to 57 %). The light / dark cycle was 16:8 h with a light intensity range of 1998 - 3894 Lux during the mortality phase and 2498 - 2732 Lux during the reproduction phase.

**Dates of experminental work:** April 15, 2010 to May 19, 2010

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| Mortality in water control | ≤ 20% | 5.0% |
| Corrected mortality reference item | ≥ 50% | 86.8% |
| Mean number of eggs per female and day in water control | ≥ 15 | 29.8 |
| Mean Hatching Rate of the eggs (fertility) in water control | ≥ 70% | 81.8% |

The mean number of eggs/female/day was above the lower limit given as validity criterion for the glass plate method (mean number of eggs/female/day: ≥ 15, mean hatching rate: ≥ 70 %) according to the historical database of the ring testing group (VOGT, H. et al., 2000). Therefore, the results of this study can be considered as valid.

Biological findings:

Mortality and reproduction in each of the treatments are summarized below.

**Table CP 10.3.2.2- 4: Effects of the test item on *Chrysoperla carnea***

| Test item | | Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) | | | | |
|---|---|---|---|---|---|---|
| Test organism | | *Chrysoperla carnea* | | | | |
| Exposure on: | | Detached maize leaves | | | | |
| | | Mortality [%] | | | Reproduction | |
| Treatment | mL product/ha | Uncorr. | Corr. | P-Value(*) | Eggs per female and day | Fertility [hatching rate in %] |
| Control | 0 | 5.0 | | | 29.8 | 81.8 |
| Test item | 375 | 15.0 | 10.5 | 0.132 n.sign. | 19.5 | 79.5 |
| Test item | 655 | 37.5 | 34.2 | 0.001 sign. | 20.0 | 78.6 |
| Test item | 1150 | 37.5 | 34.2 | 0.001 sign. | 35.4 | 82.6 |
| Test item | 2000 | 95.0 | 94.7 | <0.001 sign. | n.a. | n.a. |
| Test item | 3500 | 82.5 | 81.6 | <0.001 sign. | n.a. | n.a. |
| Reference item | 38.6 | 87.5 | 86.8 | | n.a. | n.a. |

$LR_{50}$: 1107 mL product/ha; calculated with Probit analysis (95 % confidence interval could not be determined)
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed
n.sign. not significant
sign. significant

There were no adverse effects of the test item on the reproductive performance at the rates of 375, 655 and 1150 mL product/ha.

**Conclusion:**

The $LR_{50}$ was estimated to be 1107 mL product/ha. The figures obtained fulfil the validity criteria of the laboratory method using glass plates. No adverse effect on reproduction was observed up to and including 1150 mL product/ha.

| | |
|---|---|
| **Report:** | KCP 10.3.2.2/05 [redacted] H; 2010; M-389548-01-1 |
| Title: | Toxicity to the green lacewing Chrysoperla carnea STEPH. (Neuroptera, Chrysopidae) using an extended laboratory test (under semi-field conditions aged residues on Zea mays); Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) |
| Report No.: | CW10/026 |
| Document No.: | M-389548-01-1 |
| Guideline(s): | [redacted] ET AL. (2000) modified, [redacted] ET AL. (2001) |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The objective of this extended laboratory study was to investigate the lethal and sublethal toxicity of Bixafen + Fluoxastrobin + Prothioconazole EC 190 to the green lacewing *Chrysoperla carnea* when exposed to aged residues of the test item on maize.

**Material and methods:**

Test tem: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000023924-NN; Master recipe ID: 0106974-001; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

The test item was applied twice with 1.75 L product/ha in 400 L water/ha on potted maize plants with an application interval of 14 days. The control was treated with deionised water in the same way as the test item. The toxic reference dimethoate was applied at 0.0386 L product/ha (16 g a.s./ha) in 400 L water/ha on the day of the second application on potted maize plants as well. For the further exposure dates it was applied directly on the maize leaves (with 0.0386 L product/ha in 200 L water/ha). It was included to indicate the relative susceptibility of the test organisms and the test system.
Aging of the spray residues of the test item on the potted maize plants took place under natural semi-field conditions with rain protection during the whole study. Larvae of the green lacewing (*Chrysoperla carnea*) were exposed to these residues on the treated leaf surfaces.
Three bioassays were conducted. In the first one, the exposure started at day 0 after the last application and was evaluated up to 18 days. In the second one, exposure started on day 14 after the last application and was assessed up to 19 days and in the third bioassay, the exposure started 28 days after the last application and was assessed up to 20 days. In all bioassays, the preimaginal mortality of 40 larvae was assessed till the hatch of the imagines. The fertility and fecundity of the surviving hatched adults were then evaluated over the period of one week in the bioassay started on the day of the second application and in the bioassay started 14 days later.
In the outdoor area the temperature ranged from 8.5 to 35 °C and the relative humidity from 22 to 100% during the aging time of the maize plants.
In the laboratory phase the temperature was 25 ± 2 °C, and the relative humidity was 60 - 90%. The light / dark cycle was 16:8 h and the light intensity range during the mortality phase was 1438 – 2590 Lux. During the reproduction phase, the light intensity was 1893 - 3506 Lux.

**Dates of experimental work:** May 18, 2010 to July 19, 2010

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained | | |
|---|---|---|---|---|
| | | Start of bioassay | | |
| | | 0 DAA[a] | 14 DAA[a] | 28 DAA[a] |
| Mortality in water control | ≤ 20% | 2.5% | 15.0% | 10.0% |
| Corrected mortality reference item | ≥ 50% | 69.2% | 97.1% | 75.0% |
| Mean number of eggs per female and day in water control | ≥ 15 | 29.0 | 32.1 | n.a. |
| Mean hatching rate of the eggs (fertility) in water control | ≥ 70% | 79.3% | 84.2% | n.a. |

n.a. not assessed
[a] Days after the second application

The results of this study can be considered as valid.

Biological findings:

In the first bioassay (0 DAA), the preimaginal mortality in the control group was 2.5 % and in the test item group the corrected mortality was 7.7% which was not statistically significant different compared to the control. In the reference item group the corrected mortality was 69.2 %.
In the second bioassay (14 DAA), the preimaginal mortality in the control group was 15.0 %. No corrected mortality (-2.9 %) resulted in the test item group. In the reference item group the corrected mortality was 97.1 %.
In the control group of the third bioassay (28 DAA) the preimaginal mortality was10.0 %. No corrected mortality (-2.8 %) resulted in the test item group. In the reference item group the corrected mortality was 75.0 %.

The results are shown in the following table.

**Table CP 10.3.2.2- 5: Effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on *Chrysoperla carnea***

| | | | |
|---|---|---|---|
| Test item: | Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40 + 50 + 100 g/L) | | |
| Application rate: | 2 x 1.75 L product/ha | | |
| Test organism: | *Chrysoperla carnea* | | |
| Exposure on: | Dried spray deposits on maize leaves (from treated maize plants) | | |
| Start of bioassay: | 0 DAA[a] | 14 DAA[a] | 28 DAA[a] |
| | Preimaginal Mortality (%) | | |
| Control: | 2.5 | 15.0 | 10.0 |
| Test item: | 10.0 | 12.5 | 7.5 |
| Reference item: | 70.0 | 97.5 | 77.5 |
| | Corrected Preimaginal Mortality (%) | | |
| Test item: | 7.7 (p-value 0.179, not significant[b]) | -2.9 (p-value 0.741, not significant[b]) | -2.8 (p-value 0.784, not significant[b]) |
| Reference item: | 69.2 | 97.1 | 75.0 |
| | Reproduction | | |
| | Number of eggs per female and day | | |
| Control: | 29.0 | 32.1 | n.a. |
| Test item: | 27.7 | 33.3 | n.a. |
| | Fertility (hatching rate in %) | | |
| Control: | 79.3 | 84.2 | n.a. |
| Test item: | 81.4 | 75.4 | n.a. |

n.a. not assessed
[a] Days after the second application
[b] Fisher´s Exact test, one-sided, p-values adjusted according to Bonferroni-Holm

**Conclusion:**

In this study 7.7% corrected preimaginal mortality of the test item was found in the first bioassay started on the day of the second application. A second bioassay was started 14 days after the last application which showed no corrected mortality (-2.9%). A third bioassay was initiated 28 days after the last application and showed no corrected mortality (-2.8%) as well.
There were no adverse effects of the test item on the reproductive performance in the first and second bioassay (0 and 14 DAA). For the third bioassay (28 DAA) the reproduction was not assessed as both earlier bioassays indicated no adverse effect on reproduction.

## CP 10.3.2.3 Semi-field studies with non-target arthropods

Semi-field studies are not required for non-target arthropods.

## CP 10.3.2.4 Field studies with non-target arthropods

Field studies are not required for non-target arthropods.

## CP 10.3.3 Other routes of exposure for non-target arthropods

The exposure of non-target arthropod as assessed in chapter CP 10.3.2 is considered the main route of exposure for non-target arthropods.

## CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the EU Regulation 1107/2009 and the Guidance Document on Terrestrial Ecotoxicology.

### Predicted environmental concentrations used in risk assessment

Predicted environmental concentrations of the active substance and the metabolites in soil ($PEC_{soil}$) values were calculated and reported in MCP 9.1.3. The relevant PEC values considered for TER calculations are summarised in the table below. Maximum values are used for risk assessments.

**Table CP 10.4- 1: Maximum $PEC_{soil}$ values**

| Compound | Cereals, 2 × 87.5 g fluoxastrobin/ha (80% interception) $PEC_{soil}$ [mg/kg] |
|---|---|
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | **0.993**[A] |
| Fluoxastrobin (E+Z) | **0.047**[B] |
| HEC 5725-E-des-chlorophenyl | **0.011** |
| HEC 5725-carboxylic acid | **0.006** |
| 2-chlorophenol | **0.005** |

**Bold values:** worst case considered in risk assessment

[A] Based on formulation density of 1.064 g/mL and 2 applications at 14 d interval (no degradation between the 2 applications and 80% interception: worst case).

[B] Including consideration of accumulation for fluoxastrobin after long-term use considering a soil mixing depth of 20 cm

## CP 10.4.1 Earthworms

**Table CP 10.4.1- 1: Endpoints used in risk assessment**

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Earthworm, reproduction | NOEC<br>$NOEC_{corr}$ | **56 mg prod./kg dws**<br>**28[A] mg prod./kg dws** | [redacted],; 2010; M-376161-01-1 KCP 10.4.1.1 |
| Fluoxastrobin EC 100 | Earthworm, reproduction | NOEC<br>NOEC<br>$NOEC_{corr}$ | ≥ 1000 g a.s./ha<br>≥ 4.32[B] mg a.s./kg dws<br>**≥ 2.16[A,B] mg a.s./kg dws** | [redacted]; 2001; M-057395-01-1 |
| HEC 5725-E-des-chlorophenyl | Earthworm, reproduction | NOEC | **≥ 1000 mg p.m. /kg dws** | [redacted] 2002; M-058532-01-1 |
| HEC 5725-carboxylic acid | Earthworm, reproduction | NOEC | **90 mg p.m. /kg dws** | [redacted]; 2015; M-536000-01-1 KCA 8.4.1 |
| 2-chlorophenol | Earthworm, reproduction | NOEC | **≥ 0.216[C] mg a.s./kg dws** | EFSA Scientific Report 102 (2007) |

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite

[A] Endpoint corrected by a factor of 2 due to high organic matter content of test soil and log Pow of >2

[B] The endpoint of 1.33 mg as/kg dws listed in the EFSA Scientific Report 102 (2007) is based on the standard conversion. In the actual study the test material had been sprayed onto the soil, the recalculated endpoint according to the actual test conditions is calculated based on the actually applied test rate of 1090 g a.s./ha, test vessel surface of 198 $cm^2$ and test substrate of 500 g dws per test vessel

[C] for the metabolite 2-chlorophenol, in the absence of earthworm reproduction data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))

**Bold values:** endpoints used for risk assessment

### Risk assessment for earthworms

Based on the endpoints in the table above the TER values are calculated using the following equations:

$TER_{LT} = NOEC / PEC_{soil}$

The risk is considered acceptable if the $TER_{LT}$ is >5.

For lipophilic substances (log $P_{OW}$ > 2) all results from the laboratory studies are corrected by a factor 2 even when the organic matter is less than 10%.
This was applied to fluoxastrobin ($logP_{ow}$ = 2.86, refer to Section 2 of the MCA document, CA 2.7).

**Table CP 10.4.1- 2: TER calculations for earthworms**

| Compound | Species | Endpoint [mg/kg] | | $PEC_{soil,max}$ [mg/kg] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Cereals** | | | | | | |
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Earthworm, reproduction | NOEC | 28 | 0.993 | 28.2 | 5 |
| Fluoxastrobin (E+Z)[A] | Earthworm, reproduction | NOEC | ≥ 2.16 | 0.047 | ≥ 46 | 5 |
| HEC 5725-E-des-chlorophenyl | Earthworm, reproduction | NOEC | ≥ 1000 | 0.011 | ≥ 90909 | 5 |
| HEC 5725-carboxylic acid | Earthworm, reproduction | NOEC | 90 | 0.006 | 15000 | 5 |
| 2-chlorophenol | Earthworm, reproduction | NOEC | ≥ 0.216[B] | 0.005 | ≥ 43.2 | 5 |

[A] conducted with the formulation Fluoxastrobin EC 100

[B] for the metabolite 2-chlorophenol, in the absence of earthworm reproduction data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))

All TER values calculated with the worst case $PEC_{soil,\ max}$ values exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

## CP 10.4.1.1 Earthworms sub-lethal effects

### Terrestrial Risk Assessment

No study on the chronic toxicity of 2-chlorophenol to earthworms is available, but some information can be taken from the chronic earthworm study with the Fluoxastrobin EC 100 formulation presented in Annex II. In this study the application of 1.0 kg a.s./ha fluoxastrobin had no influence on mortality, weight development, and reproduction of earthworms after 56 days. The NOEC (28 days) based on mortality and weight of adult earthworms is 1.0 kg a.s/ha. Additionally it is a NOEC and not an $LC_{50}$. Assuming that 2-chlorophenol is formed and reaches its maximum between about 15 to 23 days (see Document MCA7, Point 7.1.2), the effects of this metabolite on mortality and weight of adult earthworms can be considered to be covered up to an application of 1.0 kg fluoxastrobin/ha. Since this application rate is more than 28 times higher than the actual highest use rate (cereals (80% interception): 35 g fluoxastrobin/ha) it can be assumed that higher amounts of the metabolite were present in the study than would occur under practical field conditions.

Additionally, for the purpose of the earthworm risk assessment the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007)).

| | |
|---|---|
| **Report:** | KCP 10.4.1.1/01 [redacted],; 2010; M-376161-01-1 |
| Title: | Bixafen + fluoxastrobin + prothioconazole EC 190 (040+050+100) G: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil with 5 % peat |
| Report No.: | 10 10 48 027 S |
| Document No.: | M-376161-01-1 |
| Guideline(s): | OECD Guideline 222:, Earthworm Reproduction Test (Eisenia fetida / Eisenia andrei) (April 2004); ISO 11268-2: 1998(E): „Soil quality - Effects of pollutants on earthworms (Eisenia fetida) – Part 2: Determination of effects on reproduction", July 1998. |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The purpose of this study was to determine the sublethal effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on reproduction, mortality and growth of the earthworm *Eisenia fetida* by dermal and alimentary uptake using an artificial soil in a laboratory test. The test was performed according to the recommendations of the OECD Guideline 222 (2004) and the International Standard ISO 11268-2 (1998).

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (040+050+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000023924-NN; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL (20°C). Water solubility: dispersible.

10 Adult *Eisenia fetida andrei* (about 3 months old) per replicate (8 control replicates and 4 replicates per treatment level) were exposed to an untreated control and 10 – 18 – 32 – 56 - 100 mg test item/kg soil dry weight (d.w.) containing 74.7 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.3 % $CaCO_3$, at 18.5 – 21.5 °C and a photoperiod: light : dark = 16 h : 8 h (620 lx). During the test, the adult earthworms were fed with air-dried and finely ground horse manure. Mortality and biomass change were determined after 4 weeks and reproduction was determined after 8 weeks.

Toxic standard: 5 and 10 mg Nufdazim 50 FLOW/kg soil dry weight; control: deionised water, solvent control: none.

**Dates of work:** March 29, 2010 to May 24, 2010.

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| Adult mortality after 4 weeks | ≤ 10 % | 0 % |
| Number of juvenile per replicate | ≥ 30 | 102, 69, 72, 84, 110, 89, 92, 103 |
| Coefficient of variation of reproduction | ≤ 30 % | 16.3 % |

All validity criteria were met. Therefore this study is valid.

Reference test:
In the most recent study (BioChem project No. TER-R 09 10 48 001, dated July 17, 2009) the reference item Nutdazim 50 FLOW (Carbendazim, SC 500) was tested at concentrations of 5 and 10 mg product/kg soil dry weight. The number of juveniles was reduced by 65 and 92 % (mean number of juveniles = 51 and 11) after 8 weeks of test duration when compared to control (mean number of juveniles = 143). Therefore, the observed effects assure a high sensitivity of the test system.

Biological findings:
The test item caused no mortality at concentrations of 10, 56 and 100 mg test item/kg soil dry weight. 2.5 and 5.0 % mortality were found at 18 and 32 g test item/kg soil dry weight, respectively. No mortality (0 %) occurred in the control group.
No effects on behaviour (including feeding activity) of the worms were observed during the test.
The test item caused no statistically significant change in biomass (change in fresh weight after 4 weeks relative to initial fresh weight) compared to the control treatment, i.e. a weight increase of 26.6, 26.2, 25.4, 24.1, 25.0 and 21.4 % in the control group and at concentrations of 10, 18, 32, 56 and 100 mg test item/kg soil dry weight, respectively.
Statistically significant effects on number of juveniles compared to the control group were recorded at the concentration of 100 mg test item/kg soil dry weight.

The results are summarised in the table below.

**Table CP 10.4.1.1- 1: Effects of the test item on mortality, growth and reproduction of *Eisenia fetida***

| Bixafen + Fluoxastrobin + Prothioconazole EC 190 (040+050+100) G [mg test item/kg d.w.] | | | | | | |
|---|---|---|---|---|---|---|
| | Control | 10 | 18 | 32 | 56 | 100 |
| *Mortality of adult worms after 4 weeks* | | | | | | |
| Mortality (%) | 0 | 0 | 2.5 | 5.0 | 0 | 0 |
| *Biomass change (change in fresh weight after 4 weeks relative to initial fresh weight )* | | | | | | |
| Mean (mg) | 99.9 | 98.7 | 96.1 | 91.4 | 94.2 | 80.8 |
| Mean (%) | 26.6 | 26.2 | 25.4 | 24.1 | 25.0 | 21.4 |
| *Number of juveniles per surviving adult worm after 8 weeks* | | | | | | |
| Mean | 9.0 | 8.6 | 9.6 | 9.4 | 8.4 | 6.5 |
| *Number of juveniles per replicate after 8 weeks* | | | | | | |
| Mean | 90.1 | 86.3 | 94.3 | 90.3 | 83.5 | 65.0* |
| *Reduction of reproduction per treatment (%)* | | | | | | |
| % to control | | -4.3 | 4.6 | 0.1 | -7.4 | -27.9 |

* statistically significantly different compared to control (Dunnett-t-test, one-sided smaller, $p \leq 0.05$)

**Conclusion:**

Bixafen + Fluoxastrobin + Prothioconazole EC 190 showed no statistically significantly adverse effects on mortality and growth of the earthworm *Eisenia fetida* in artificial soil up to 100 mg test item/kg soil dry weight, i.e. the highest concentration tested. The test item showed statistically significantly adverse effects on reproduction at 100 mg test item/kg soil dry weight. Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined to be 56 mg test item/kg soil dry weight, and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be 100 mg test item/kg soil dry weight. The $EC_{50}$ could not be calculated, but it can be concluded that the $EC_{50}$ is higher than 100 mg test item/kg soil dry weight, the highest tested concentration.

## CP 10.4.1.2 Earthworms field studies

Not required as the risk to earthworms is acceptable.

## CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

**Table CP 10.4.2- 1: Endpoints used in risk assessment**

| Test substance | Test species | Endpoint | | Reference |
|---|---|---|---|---|
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | *Folsomia candida* | NOEC<br>$NOEC_{corr}$ | 562 mg prod./kg dws<br>**281 mg prod./kg dws[1)]** | [redacted] (2010)<br>M-375964-01-1<br>KCP 10.4.2.1 |
| | *Hypoaspis aculeifer* | NOEC<br>$NOEC_{corr}$ | 562 mg prod./kg dws<br>**281 mg prod./kg dws[1)]** | [redacted] (2010)<br>M-372844-01-1<br>KCP 10.4.2.1 |
| Fluoxastrobin | *Folsomia candida* | NOEC<br>$NOEC_{corr}$ | 10 mg a.s./kg dws<br>**5 mg a.s./kg dws[1)]** | [redacted] (2001)<br>M-081095-01-1 |
| | *Hypoaspis aculeifer*[2)] | NOEC | **10 mg a.s./ kg dws[3)]** | [redacted] (2002)<br>M-039155-01-1 |
| HEC 5725-E-des-chlorophenyl | *Folsomia candida* | NOEC | **≥ 100 mg p.m./kg dws** | [redacted] (2001)<br>M-033640-01-1 |
| | *Hypoaspis aculeifer* | NOEC | **≥ 100 mg p.m./kg dws** | [redacted] (2013)<br>M-475673-01-1<br>KCA 8.4.2.1 |
| HEC 5725-carboxylic acid | *Folsomia candida* | NOEC | **≥ 100 mg p.m.//kg dws** | [redacted] (2014)<br>M-479456-01-1<br>KCA 8.4.2.1 |
| | *Hypoaspis aculeifer* | NOEC | **≥ 100 mg p.m./kg dws** | [redacted] (2014)<br>M-484792-01-1<br>KCA 8.4.2.1 |
| 2-chlorophenol | *Folsomia candida* | NOEC<br>$NOEC_{corr}$ | 10 mg p.m./kg dws<br>**5 mg p.m./kg dws[1)]** | [redacted] (2013)<br>M-472327-01-1<br>KCA 8.4.2.1 |
| | *Hypoaspis aculeifer* | NOEC<br>$NOEC_{corr}$ | 56 mg p.m./kg dws<br>**28 mg p.m./kg dws[1)]** | [redacted] (2013)<br>M-475688-01-1<br>KCA 8.4.2.1 |

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
**Bold values:** endpoints used for risk assessment
1) Corrected endpoint due to lipophilic substance (log $P_{ow}$ > 2)
2) Endpoint derived from EC 100 formulation
3) not corrected due to low organic matter content in test substrate LUFA 2.1

**Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)**

Ecotoxicological endpoints and $PEC_{soil}$ values used for TER calculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation:

$TER = NOEC / PEC_{soil}$

The risk is considered acceptable if the TER is >5.

**Table CP 10.4.2- 2: TER calculations for other non-target soil meso- and macrofauna**

| Compound | Species | Endpoint [mg/kg] | | $PEC_{soil,max}$ [mg/kg] | $TER_{LT}$ | Trigger |
|---|---|---|---|---|---|---|
| **Cereals** | | | | | | |
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | *Folsomia candida* | NOEC | 281 | 0.993 | 283 | 5 |
| | *Hypoaspis aculeifer* | NOEC | 281 | 0.993 | 283 | 5 |
| Fluoxastrobin (E+Z) | *Folsomia candida* | NOEC | 5.0 | 0.047 | 106.4 | 5 |
| | *Hypoaspis aculeifer* | NOEC | 10 | 0.047 | 212.8 | 5 |
| HEC 5725-E-des-chlorophenyl | *Folsomia candida* | NOEC | ≥ 100 | 0.011 | ≥ 9091 | 5 |
| | *Hypoaspis aculeifer* | NOEC | ≥ 100 | 0.011 | ≥ 9091 | 5 |
| HEC 5725-carboxylic acid | *Folsomia candida* | NOEC | ≥ 100 | 0.006 | ≥ 16667 | 5 |
| | *Hypoaspis aculeifer* | NOEC | ≥ 100 | 0.006 | ≥ 16667 | 5 |
| 2-chlorophenol | *Folsomia candida* | NOEC | 5 | 0.005 | 1000 | 5 |
| | *Hypoaspis aculeifer* | NOEC | 28 | 0.005 | 5600 | 5 |

All TER values calculated with the worst case $PEC_{soil,max}$ values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product.

## CP 10.4.2.1 Species level testing

**Report:** KCP 10.4.2.1/01, [redacted].; 2010; M-375964-01-1
Title: Bixafen + fluoxastrobin + prothioconazole EC 190 (040+050+100) G: Effects on the reproduction of the collembolans Folsomia candida
Report No.: 10 10 48 028 S
Document No.: M-375964-01-1
Guideline(s): OECD 232 (2009): OECD Guideline for testing of chemicals No. 232 (adopted 7 September 2009): Collembolan reproduction test in soil
ISO 11267 (1999): Soil quality - Inhibition of reproduction of Collembola (Folsomia candida) by soil pollutants
Guideline deviation(s): none
**GLP/GEP:** **yes**

**Objective:**

The purpose of this study was to determine effects of different concentrations of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the reproductive output of the collembolans *Folsomia candida* as a representative of soil micro-arthropods during a test period of 28 days. After 4 weeks the number of offspring (juveniles) and surviving parental collembolans were counted. EC50 and NOEC/LOEC were determined.
The test was performed in accordance with the OECD Guideline 232 (2009) and the International Standard ISO 11267 (1999).

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (040+050+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000023924-NN; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL (20°C). Water solubility: dispersible.

Ten juvenile collembolans *Folsomia candida* (9-12 days old) per replicate (8 control replicates and 4 replicates per treatment level) were exposed to control (deionised water) and 100 - 177 - 316 - 562 - 1000 mg test item/kg dry weight soil. During the test, they were fed with granulated dry yeast, supplied twice a week. During the study a temperature of 18.5 - 21.1 °C and light regime of 630 Lux, 16 h light:8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 74.7% industrial quartz sand, 5% sphagnum peat, dried and finely ground, 20% kaolin clay and 0.3% Calcium carbonate ($CaCO_3$). Mortality and reproduction were determined after 28 days.

Toxic standard 44 – 67 – 100 - 150 - 225 mg boric acid/ kg dry weight soil; control: deionised water; solvent control: none.

**Dates of work:** April 28, 2010 to May 26, 2010

**Findings:**

Validity Criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| Mean mortality of adults | ≤ 20 % | 6.3 % |
| Mean number of juvenile per test vessel | ≥ 100 | Average of 1524.5/vessel |
| Coefficient of variation (mean number of juveniles) | ≤ 30 % | 12.2 % |

All validity criteria were met. Therefore this study is valid.

Reference test:

In a separate study (BioChem project No. R 10 10 48 006 S, dated April 15, 2010), the $EC_{50}$ (reproduction) of the reference item boric acid was calculated to be 108.6 mg product/kg soil dry weight. Therefore, the observed effects assure a high sensitivity of the test system.

Biological findings:

*Mortality*

The test item caused 7.5, 7.5, 10.0, 10.0 and 10.0 % parental mortality at the test concentrations of 100, 177, 316, 562 and 1000 mg test item/kg dry weight soil, respectively. 6.3 % parental mortality was observed in the control. No statistically significant effect on parental mortality was found for any concentration tested.

No effects on behaviour of the collembolans were observed during the test.

*Reproduction*

The number of juvenile springtails counted four weeks after having introduced the parental collembolans into the test vessels was on average 1524.5 in the control and 1637.0, 1530.5, 1463.0, 1417.5 and 830.8 at the test concentrations 100, 177, 316, 562 and 1000 mg test item/kg dry weight soil, respectively. The test item concentration of 1000 mg test item/kg dry weight soil resulted in a statistically significant decrease in the number of juvenile collembolans compared to the control after 4 weeks.

The results are summarised in the tables below.

**Table CP 10.4.2.1- 1: Effects of the test item on mortality and reproduction of *Folsomia candida***

| Endpoint | Bixafen + fluoxastrobin + prothioconazole EC 190 (040+050+100) G (mg test item/kg dry weight soil) | | | | | |
|---|---|---|---|---|---|---|
| | **control** | **100** | **177** | **316** | **562** | **1000** |
| Mortality of parental collembolans after 4 weeks (%) | 6.3 | 7.5 | 7.5 | 10.0 | 10.0 | 10.0 |
| ± SD | 0.7 | 1.0 | 1.0 | 0.8 | 0.8 | 0.8 |
| Mean number of juveniles after 4 weeks | 1524.5 | 1637.0 | 1530.5 | 1463.0 | 1417.5 | 830.8* |
| ± SD | 186.2 | 240.2 | 120.5 | 89.4 | 161.7 | 49.2 |
| CV % | 12.2 | 14.7 | 7.9 | 6.1 | 11.4 | 5.9 |
| % Reduction of reproduction compared to control | - | -7.4 | -0.4 | 4.0 | 7.0 | 45.5 |

* statistically significantly different from control (Dunnett-t-test, one-sided smaller, $p \leq 0.05$)
SD: standard deviation, CV: coefficient of variation
Percent reduction: $(1-R_t/R_c) * 100$ %
$R_t$ = the reproduction observed in the treated groups
$R_c$ = the reproduction observed in the control group
Negative values indicate a higher reproductive performance compared to the control.

### Conclusion:

Bixafen + Fluoxastrobin + Prothioconazole EC 190 showed no statistically significantly adverse effects on the adult mortality of the collembolans *Folsomia candida* in artificial soil up to 1000 mg test item/kg dry weight soil. The test item caused a significant reduction of reproduction of the collembolans *Folsomia candida* in artificial soil at 1000 mg test item/kg soil dry weight, i.e. the highest concentration tested. Therefore, the overall No-Observed-Effect-Concentration (NOEC) was determined to be 562 mg test item/kg soil dry weight, and the Lowest-Observed-Effect-Concentration (LOEC) was determined to be 1000 mg test item/kg soil dry weight.
The $EC_{50}$ for number of juveniles was calculated to be 1051 mg test item/kg soil dry weight with 95 % confidence limits ranging from 977 to 1180 mg test item/kg soil dry weight.

| | |
|---|---|
| **Report:** | KCP 10.4.2.1/02 [redacted]; 2010; M-372844-01-1 |
| Title: | Bixafen + fluoxastrobin + prothioconazole EC 190 (040+050+100) G: Effects on the reproduction of the predatory mite Hypoaspis aculeifer |
| Report No.: | 10 10 48 026 S |
| Document No.: | M-372844-01-1 |
| Guideline(s): | OECD 226 (2008): Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

### Objective:

The purpose of this study was to determine potential effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the mortality and reproductive output of the soil mite species *Hypoaspis aculeifer* (CANESTRINI) as a representative of soil micro-arthropods during a test period of 14 days. A concentration-response relationship was established from which NOEC/LOEC and $EC_{50}$ were determined. The test was performed according to the guideline 226 (2008).

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000023924-NN; Material No.: 79969775; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL (20°C).

Ten adult, female *Hypoaspis aculeifer* per replicate (8 control replicates and 4 replicates per treatment level) were exposed to control (deionised water) and 100 - 178 - 316 - 562 - 1000 mg test item/kg dry weight soil. In each test vessel 20 g dry weight artificial soil were weighed in. The *Hypoaspis aculeifer* were taken from a synchronised culture with an age difference of two days. During the test, they were fed every 2 days with *Tyrophagus putrescentiae* (SCHRANK). During the study a temperature of 19.7 - 21.8 °C and light regime of 471 Lux, 16 h light : 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 74.7% industrial quartz sand, 5% sphagnum peat, 20% kaolin clay and approximately 0.3% calcium carbonate ($CaCO_3$).
After a period of 14 days mortality and reproduction were determined. The surviving mites and juveniles of *Hypoaspis aculeifer* were extracted from each test replicate using a MacFadyen high-gradient. Extracted juveniles and adults were collected in a fixing solution and being afterwards counted.

Toxic standard (Dimethoate EC 400): 4.10 - 5.12 - 6.40 - 8.00 - 10.00 mg a.s./ kg dry weight soil; control: deionised water; solvent control: none.

**Dates of work:** April 22, 2010 to May 19, 2010

**Findings:**

Validity criteria:

| Validity criteria | Recommended | Obtained |
|---|---|---|
| Mean mortality of adult females | ≤ 20 % | 1.3 % |
| Mean number of juvenile per replicate | ≥ 50 | 268.3 |
| Coefficient of variation (mean number of juveniles per replicate) | ≤ 30 % | 5.9 % |

All validity criteria were met. Therefore this study is valid.

Reference test:
In a separate study (BioChem project No. R 10 10 48 003 S, dated March 24, 2010), the $EC_{50}$ (reproduction) of the reference item Dimethoate EC 400 was calculated to be 6.6 mg a.s./ kg soil dry weight. The results of the reference test demonstrate the sensitivity of the test system.

Biological results:
*Mortality*
Bixafen + Fluoxastrobin + Prothioconazole EC 190 caused no statistically significant mortality of adult mites up to a test concentration of 562 mg/kg soil dry weight at the end of the 14-day exposure period. At the tested concentration of 1000 mg test item/kg soil dry weight a statistically significant mortality of adult mites of 15 % was observed.
In the control group a parental mortality of 1.3 % observed. The mortality in the test item treatment groups ranged between 0 and 15.0 %.

*Reproduction*

The number of juveniles 14 days after having introduced the parental mites into the test vessels was on average 268.3 in the control and 275.8, 289.3, 263.5, 245.3 and 80.8 at the test concentrations of 100, 178, 316, 562 and 1000 mg test item/kg soil dry weight. The test item caused no statistically significant reduction of reproduction up to a test concentration of 562 mg/kg soil dry weight. At the tested concentration of 1000 mg test item/kg soil dry weight a statistically significant reduction of 69.9 % was observed.

The results are summarised in the tables below.

**Table CP 10.4.2.1- 2: Summary of the effects of the test item on *Hypoaspis aculeifer* mortality and reproduction**

| Endpoint | Bixafen + Fluoxastrobin + Prothioconazole EC 190 (040+050+100) G (mg test item/kg soil dry weight) | | | | | |
|---|---|---|---|---|---|---|
| | Control | 100 | 178 | 316 | 562 | 1000 |
| Mortality of soil mites after 14 days (%) | 1.3 | 2.5 | 0.0 | 2.5 | 7.5 | 15.0* |
| Mean number of juveniles after 14 days | 268.3 | 275.8 | 289.3 | 263.5 | 245.3 | 80.8* |
| CV (%) | 5.9 | 5.0 | 2.6 | 6.2 | 13.2 | 43.5 |
| Reduction of reproduction (% to control) | - | -2.8 | -7.8 | 1.8 | 8.6 | 69.9 |

* statistically significant difference compared to control (Fisher`s Exact Binomial Test for mortality, $p \leq 0.05$; Dunnett's t-test for reproduction; $p \leq 0.05$)
Calculations were done using non-rounded values
Percent reduction: $(1 - R_t / R_c) * 100$ %
$R_t$ = the reproduction observed in the treated group(s)
$R_c$ = the reproduction observed in the control group
Negative values indicate a higher reproductive performance compared to control

**Conclusion:**

Bixafen + Fluoxastrobin + Prothioconazole EC 190 showed no statistically significantly adverse effects on adult mortality and reproduction up to a test concentration of 562 mg/kg soil dry weight. Therefore, NOEC and LOEC for mortality and reproduction were determined to be 562 mg test item/kg soil dry weight and 1000 mg test item/kg soil dry weight, respectively.
The $EC_{50}$ was calculated to be 844.6 mg test item/kg soil dry weight (95 % confidence limits: 789.5 - 897.6 mg test item/kg soil dry weight).

## CP 10.4.2.2 Higher tier testing

No higher tier testing was performed or is required.

## CP 10.5 Effects on soil nitrogen transformation

**Table CP 10.5- 1: Endpoints used in risk assessment**

| Test substance | Test design | Endpoint | | Reference |
|---|---|---|---|---|
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Nitrogen transformation, 28 d | no unacceptable effects | ≥ 24.83 mg prod./kg dws (= 17.5 L prod./ha) | [redacted].; 2010; M-369853-01-1 KCP 10.5 |
| Fluoxastrobin | Nitrogen transformation, 28 d | no unacceptable effects | ≥ 2.83 mg a.s./kg dws | [redacted] 1999; M-024686-01-1 |
| HEC 5725-E-des-chlorophenyl | | no unacceptable effects | ≥ 2.73 mg p.m./kg dws | [redacted] 2000; M-026016-01-1 |
| HEC 5725-carboxylic acid | | no unacceptable effects | ≥ 1.27 mg p.m./kg dws | [redacted]; 2001; M-033474-01-1 |
| 2-chlorophenol | | no unacceptable effects | ≥ 0.283 mg p.m./kg dws* | EFSA Scientific Report 102 (2007) |

a.s. = active substance, p.m. = pure metabolite, prod. = product, dws = dry weight soil
* for the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))
**Bold values:** endpoints used for risk assessment

### Risk assessment for Soil Nitrogen Transformation

**Table CP 10.5- 2: Risk Assessment for soil micro-organisms**

| Compound | Species | Endpoint [mg/kg] | $PEC_{soil,max}$ [mg/kg] | Refinement required |
|---|---|---|---|---|
| **Cereals** | | | | |
| Bixafen + Fluoxastrobin + Prothioconazole EC 190 | Soil micro-organisms | ≥ 24.83 mg prod./kg dws | 0.993 | No |
| Fluoxastrobin (E+Z) | Soil micro-organisms | ≥ 2.83 mg a.s./kg dws | 0.047 | No |
| HEC 5725-E-des-chlorophenyl | Soil micro-organisms | ≥ 2.73 mg p.m./kg dws | 0.011 | No |
| HEC 5725-carboxylic acid | Soil micro-organisms | ≥ 1.27 mg p.m./kg dws | 0.006 | No |
| 2-chlorophenol | Soil micro-organisms | ≥ 0.283 mg p.m./kg dws* | 0.005 | No |

a.s. = active substance, p.m. = pure metabolite, prod. = product, dws = dry weight soil
* for the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007))

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a compound/product is ≤ 25% after 100 days.

For the metabolite 2-chlorophenol, in the absence of nitrogen transformation data the conservative assumption has been made that the metabolite is 10 times more toxic than the parent a.s. (EFSA conclusion 102 (2007)). It is assumed that no influence occurs up to a concentration of 0.283 mg 2-chlorophenol/kg soil. This is conspicuously higher than the worst case $PEC_{soil}$.

In no case did deviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This indicates acceptable risk to soil micro-organisms for the intended uses.

| | |
|---|---|
| **Report:** | KCP 10.5/01 [redacted]T; 2010; M-369853-01-1 |
| Title: | Bixafen + fluoxastrobin + prothioconazole EC 190 (040+050+100) G: Effects on the activity of soil microflora (nitrogen transformation test) |
| Report No.: | 10 10 48 020 N |
| Document No.: | M-369853-01-1 |
| Guideline(s): | OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation. |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The purpose of this study was to determine the effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

**Materials and Methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100) G; Short code: BIX+FXA+PTZ EC 190 (40+50+100) G, Batch ID.: 2010-000848, Sample Description: TOX08908-00; Specification No.: 102000023924 - NN; Master recipe ID: 0106974-001; Analysed content of active ingredients: 3.90 % w/w bixafen (BYF 00587) (equivalent to 41.50 g/L), 4.86 % w/w fluoxastrobin (HEC 5725 E-ISO) (equivalent to 51.71 g/L), 9.59 % w/w prothioconazole (JAU 6476) (equivalent to 102.0 g/L); Density: 1.064 g/mL (20°C).

A loamy sand soil (DIN 4220) was exposed for 28 days to 2.48 and 24.83 mg test item/kg soil dry weight. Application rates were equivalent to 1.75 and 17.5 L test item/ha. The nitrogen transformation ($NO_3$-nitrogen production) was determined in soil enriched with lucerne meal (concentration in soil 0.5 %). $NH_4$-nitrogen, $NO_3$- and $NO_2$-nitrogen were determined using the Autoanalyzer II (BRAN+LUEBBE) at different sampling intervals (0, 7, 14 and 28 days after treatment).

**Dates of work:** April 12, 2010 to May 10, 2010

**Findings:**

<u>Validity criteria:</u>
The coefficients of variation in the control ($NO_3$-N) were maximum 8 % and thus fulfilled the demanded range (≤15 %).

<u>Reference test:</u>
In a separate study (dated 07.01.2010 to 18.02.2010) the reference item Dinoterb caused a stimulation of nitrogen transformation of +37.6 %, +51.4 % and +27.1 % at 6.80 mg, 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, 28 days after application, and thus demonstrates the sensitivity of the test system.

Biological findings:

No adverse effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on nitrogen transformation in soil were observed in both test concentrations (2.48 mg/kg dry soil and 24.83 mg/kg dry soil) after 28 days. Only a negligible deviation from the control of -9 % (test concentration 2.48 mg/kg dry soil) and -3 % (test concentration 24.83 mg/kg dry soil) were measured at the end of the 28-day incubation period.

**Table CP 10.5- 3: Effects on nitrogen transformation in soil after treatment with Bixafen + Fluoxastrobin + Prothioconazole EC 190**

| Time Interval (days) | Applications rates | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Control | | | [BIX+FXA+PTZ EC 190 (040+050+100) G] 2.48 mg/kg dry weight soil | | | | 24.83 mg/kg dry weight soil | | | | |
| | Nitrate-N[1)] | | | Nitrate-N[1)] | | | % difference to control | Nitrate-N[1)] | | | % difference to control |
| 0-7 | 2.05 | ± | 0.16 | 1.74 | ± | 0.18 | -15 n.s. | 2.53 | ± | 0.08 | +23 * |
| 7-14 | 0.50 | ± | 0.24 | 1.20 | ± | 0.09 | +142 * | 0.50 | ± | 0.11 | +1 n.s. |
| 14-28 | 0.93 | ± | 0.09 | 0.84 | ± | 0.06 | -9 n.s. | 0.90 | ± | 0.18 | -3 n.s. |

The calculations were performed with unrounded values

1) Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation

n.s. = No statistically significant difference to the control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

* = statistically significantly different to control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

**Conclusion:**

Bixafen + Fluoxastrobin + Prothioconazole EC 190 caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (measured as $NO3-N$ production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 24.83 mg test item/kg soil, which is equivalent up to an application rate of 17.5 L test item/ha.

# CP 10.6 Effects on terrestrial non-target higher plants

**Risk assessment for Terrestrial Non-Target Higher Plants**
The risk assessment for non-target terrestrial plants is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are defined as non-crop plants located outside the treated area. Spray drift from the treated areas may produce residues of a product in adjacent off-crop areas.

In the case of a non-herbicide, screening results and/or Tier 1 studies give first information about the likelihood for effects on terrestrial plants. The risk can be considered acceptable if there are no data indicating more than 50% phytotoxicity effect at the maximum application rate. Where a ≥50% effect is identified in one or more species in the Tier 1 studies, Tier 2 dose response studies are triggered to identify the respective $ER_{50}$ values. These endpoints are used to determine if mitigation measures (in-crop buffers and/or drift reduction technology) are necessary. Mitigation measures may be refined by the results of Higher Tier semi-field or field studies.

**Table CP 10.6- 1: Survey of non-target terrestrial plant tests performed with the formulated product**

| Test organism | Study type, tested rate | Effects | Most sensitive species | References |
|---|---|---|---|---|
| Terrestrial non-target plants; 10 species | Seedling emergence, Tier 1 single dose, 3000 mL product/ha | 58.7% reduction of shoot dry weight | *Lycopersicon esculentum* | [redacted],; 2010; M-386729-02-1 KCP 10.6.2/01 |
| Terrestrial non-target plants; 1 species | Tier 2 dose response Seedling emergence, 188, 375, 750, 1500 and 3000 mL product/ha | $ER_{50}$ emergence, survival, shoot dry weight (biomass): > 3000 mL product/ha | *Lycopersicon esculentum* | [redacted]; 2010; M-390280-01-1 |
| Terrestrial non-target plants; 10 species | Vegetative vigour, Tier 1 single dose, 3000 mL product/ha | 55.5% reduction of shoot dry weight | *Fagopyrum esculentum* | [redacted],; 2010; M-386731-01-1 |
| Terrestrial non-target plants; 1 species | Tier 2 dose response,Vegetative vigour, 188, 375, 750, 1500 and 3000 mL product/ha | $ER_{50}$ shoot dry weight (biomass): 2858 mL product/ha | *Fagopyrum esculentum* | [redacted],; 2010; M-390282-01-1 |

A Tier 1 seedling emergence test ([redacted],; 2010; M-386729-02-1) with the formulation showed effects > 50% at a dose rate of 3000 mL product/ha only for the test species *Lycopersicon esculentum* (58.7% reduction of shoot dry weight). Concerning the Tier 1 vegetative vigour test ([redacted]; 2010; M-386731-01-1) effects > 50% were only found in the test species *Fagopyrum esculentum* at a dose rate of 3000 mL product/ha. Therefore a seedling emergence and vegetative vigour Tier 2 test were triggered for the affected species. In the seedling emergence Tier 2 test ([redacted]; 2010; M-390280-01-1) the $ER_{50}$ for *Lycopersicon esculentum* was determined to be > 3000 mL product/ha, while in the vegetative vigour Tier 2 test with *Fagopyrum esculentum* ([redacted]; 2010; M-390282-01-1), an $ER_{50}$ of 2858 mL product/ha was determined. Since the Tier 1 seedling emergence study and the Tier 1 vegetative vigour study showed phytotoxic effects > 50% at the tested rate of 3 L prod./ha for at least one tested species and endpoints from Tier 2 tests are available, the risk assessment will be based on the vegetative vigour and seedling emergence Tier 2 endpoints.

## Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 82nd percentile estimates derived by the *BBA (2000)*[1] from the spray-drift predictions of [redacted] *(2000)*[2]. For two applications to cereals, 2.38% of the application rate was assumed to reach areas at the edge of the crop (0 meter buffer zone; worst-case scenario). For a 5 m buffer zone a drift rate of 0.47% is assumed. The highest application rate of Bixafen + Fluoxastrobin + Prothioconazole EC 190 is 2 x 1750 mL product/ha.

## Deterministic Risk assessment

According to the Terrestrial Guidance Document[3], the risk to non-target plants is evaluated by comparing the lowest $ER_{50}$ observed in the laboratory studies with the drift rates ($PER_{off\text{-}field}$) inclosing a safety factor of 5.

**Table CP 10.6- 2: Deterministic risk assessment for worst case use of the product based on the $ER_{50}$ > 3000 mL prod./ha (seedling emergence)**

| arable field crops, two applications, 2 x 1750 mL product/ha; lowest $ER_{50}$ = > 3000 mL product/ha | | | | |
|---|---|---|---|---|
| Distance | Drift | MAF | PER* | **TER (Trigger = 5)** |
| [m] | (%) | - | no drift reduction [mL product/ha] | No drift reduction |
| 1 | 2.38 ¹⁾ | 1.4 ²⁾ | 58.31 | > 51 |
| 5 | 0.47 ¹⁾ | | 11.52 | > 260 |

* Predicted environmental rate
1) Basic drift value for two applications in field crops
2) Considering MAF = 1.4 from EFSA GD Birds & Mammals (2009)

**Table CP 10.6- 3: Deterministic risk assessment for worst case use of the product based on the $ER_{50}$ 2858 mL prod./ha (vegetative vigour)**

| arable field crops, two applications, 2 x 1750 mL product/ha; lowest $ER_{50}$ = 2858 mL product/ha | | | | |
|---|---|---|---|---|
| Distance | Drift | MAF | PER* | **TER (Trigger = 5)** |
| [m] | (%) | - | no drift reduction [mL product/ha] | No drift reduction |
| 1 | 2.38 ¹⁾ | 1.4 ²⁾ | 58.31 | 49 |

* Predicted environmental rate
1) Basic drift value for two applications in field crops
2) Considering MAF = 1.4 from EFSA GD Birds & Mammals (2009)

From the calculations above, it is concluded that the product poses no unacceptable risk to non-target terrestrial plants in off crop areas.

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1 BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

2 [redacted]. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

3 Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under council directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

## CP 10.6.1 Summary of screening data

As full GLP studies are available (see CP 10.6.2 below), screening data were not generated.

## CP 10.6.2 Testing on non-target plants

| | |
|---|---|
| **Report:** | KCP 10.6.2/01 [redacted] Y; 2010; M-386729-02-1 |
| Title: | BIX + FXA + PTZ EC 40 + 50 + 100 G, Effects on the seedling emergence and growth of ten species of non-target terrestrial plants (Tier 1) |
| Report No.: | SE10/007 |
| Document No.: | M-386729-02-1 |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestrial Plant Test<br>OECD 208: Seedling emergence and seedling growth Test, July 2006 |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **no** |

**Objective:**

The purpose of this specific study was to evaluate the phytotoxic effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the <u>seedling emergence and growth</u> of ten non-target terrestrial plant species following a pre-emergence 3000 mL product/ha application of the product onto the soil surface.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID: 2010-000848; Tox No.: 08908-00; Specification No.: 102000023924-NN; Material No.: 79969775; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

A total of ten non-target plant species were tested in this seedling emergence and growth test including seven dicotyledonous and three monocotyledonous species representing nine plant families. The following species were treated: *Beta vulgaris*, *Brassica napus*, *Cucumis sativus*, *Fagopyrumesculentum*, *Glycine max*, *Helianthus annuus*, *Lycopersicon esculentum*, *Allium cepa*, *Avena sativa* and *Zea mays*.

Five seeds of each species were sown in 10.5 cm pots in the glasshouse. The soil surface of the pots was treated with Bixafen + Fluoxastrobin + Prothioconazole EC 190 after sowing of the seeds using a laboratory track sprayer applying a test rate of 3000 mL product/ha at a volume rate of 200 L/ha. Each pot (replicate) contained 5 seeds and a total of 20 seeds were treated i.e. 4 replicates. Control pots were treated with deionised water only.

Following application, pots were maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod. Emergence was assessed daily until 70% emergence of control seedlings was reached. Emergence, survival and phytotoxicity were then recorded for the replicates at each application rate 7 and 14 days after the emergence of 70% of the seeds in the water treated controls. In addition, plant growth stage and shoot dry weight were determined at the final assessment date 14 days after 70% emergence of the seeds in the water treated controls of each species.

Statistical analysis of data was performed to obtain significance for shoot dry weight effects, carried out using the Pairwise Mann-Whitney-U-Test (one side smaller; $p \leq 0.05$) by ToxRat statistics.

**Findings:**

Validity criteria:
This study can be considered valid as the validity criteria of at least 70% emergence and at least 90% survival of the emerged seedlings during the study period was achieved for the water treated controls of all species tested.

Biological findings:
A summary of the findings from a single application of 3000 mL product/ha to the 10 plant species tested is summarised in the following table:

**Table CP 10.6- 4: Summary of the effects after single application of 3000 mL Bixafen + Fluoxastrobin + Prothioconazole EC 190/ha on terrestrial plants**

| Plant species | Emergence (% inhibition) | Survival* (% inhibition) | Phytotoxicity** | Shoot Dry Weight*** (% inhibition) |
|---|---|---|---|---|
| **Dicotyledonae** | | | | |
| *Beta vulgaris* | (5.6) | 0 | A - $B^{ef}$ | 14.9 |
| *Brassica napus* | 0 | 0 | 0 - $B^{ef}$ | **33.7** |
| *Cucumis sativus* | 15.8 | 0 | $A^{f}$ | 21.7 |
| *Fagopyrum esculentum* | 5.3 | 0 | 0 - $A^{ef}$ | (4.1) |
| *Glycine max* | 21.1 | 0 | 0 - $B^{f}$ | 11.0 |
| *Helianthus annuus* | (11.1) | 0 | 0 | (3.4) |
| *Lycopersicon esculentum* | 5.9 | 0 | B - $C^{aef}$ | **58.7** |
| **Monocotyledonae** | | | | |
| *Allium cepa* | 0 | 0 | 0 | (26.5) |
| *Avena sativa* | 5.0 | 0 | 0 | (2.9) |
| *Zea mays* | (5.3) | 0 | 0 | (8.5) |

* survival is a measure of treated plants that survived at the end of the study and is expressed as an inhibition compared to the untreated control

** description of the phytotoxicity rating:

Description of symptoms assessed:
*a* = chlorosis (yellowing of green shoot tissue)
*b* = necrosis (brown shoot tissue)
*c* = bleaching (shoot tissue without pigmentation)
*d* = wilting (loss of turgor of shoot tissue)
*e* = leaf deformation (leaf curl, abnormal leaf shape)
*f* = stunting (plant height reduced with shorter internode length)

Rating system for recording the severity of phytotoxic symptoms:
*0 = no injury or effect*
*A = slight symptom (s)*
*B = moderate symptom (s)*
*C = severe symptom (s)*
*D = total plant symptom (s)*
*E = moribund*

*** inhibition or reduction is expressed on a per plant basis

( ) figures in parentheses indicate that there was an increase when compared to the untreated control

**Bold figures for shoot dry weight are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller; p ≤ 0.05).**

Emergence of *Brassica napus* and *Allium cepa* was not affected. The emergence was increased in comparison to the untreated control in *Beta vulgaris*, *Helianthus annuus*, and *Zea mays* by 5.6, 11.1 and 5.3%, respectively. The emergence was reduced in *Cucumis sativus, Fagopyrum esculentum, Glycine max, Lycopersicon esculentum and Avena sativa* by 15.8, 5.3, 21.1, 5.9 and 5.0%, respectively.
There were no effects in survival for all tested species.

Slight to severe phytotoxic symptoms were observed as chlorosis, leaf deformation and stunting in all dicotyledonous tested species, except *Helianthus annuus*.
Shoot dry weight was increased in *Fagopyrum esculentum*, *Helianthus annuus*, *Allium cepa*, *Avena sativa* and *Zea mays* by 4.1, 3.4, 26.5, 2.9 and 8.5%, respectively.
Pre-emergence treatment of *Beta vulgaris*, *Brassica napus*, *Cucumis sativus*, *Glycine max*, and *Lycopersicon esculentum* resulted in shoot dry weight reductions of 14.9, 33.7, 21.7, 11.0 and 58.7%, respectively. Only the reductions in *Brassica napus* and *Lycopersicon esculentum* were statistically significant.

**Conclusion:**

Following a soil surface application of Bixafen + Fluoxastrobin + Prothioconazole EC 190 applied at 3000 mL product/ha to ten terrestrial plant species, no adverse effects on emergence, survival and shoot dry weight exceeding 50% effect were observed in this seedling emergence study for nine non-target plant species. Shoot dry weight of *Lycopersicon esculentum* was reduced by 58.7%.

| | |
|---|---|
| **Report:** | KCP 10.6.2/02 [redacted]; 2010; M-386731-01-1 |
| Title: | BIX + FXA + PTZ EC 40 + 50 + 100 G, Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 1) |
| Report No.: | VV 10/008 |
| Document No.: | M-386731-01-1 |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestrial Plant Test OECD 227: Vegetative Vigour Test, July 2006 |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **no** |

**Objective:**

The purpose of this specific study was to evaluate the phytotoxic effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the vegetative vigour of ten non-target terrestrial plant species following a post-emergence 3000 mL product/ha application of the product onto the foliage of plants at the 2-4 leaf stage.

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848; Tox No.: 08908-00; Specification No.: 102000023924-NN; Material No.: 79969775; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

A total of ten non-target plant species were tested in this vegetative vigour test including seven dicotyledonous and three monocotyledonous species representing nine plant families. The following species were treated: *Beta vulgaris*, *Brassica napus*, *Cucumis sativus*, *Fagopyrum esculentum*, *Glycine max*, *Helianthus annuus*, *Lycopersicon esculentum*, *Allium cepa*, *Avena sativa* and *Zea mays*.
At the 2-4 leaf stage plants were treated with Bixafen + Fluoxastrobin + Prothioconazole EC 190 using a laboratory track sprayer applying a test rate of 3000 mL product/ha at a volume rate of 200 L/ha. Each pot (replicate) contained 4 plants and a total of 20 plants were treated, i.e. 5 replicates. Control pots were treated with deionised water. Pots were maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod. Survival and visual phytotoxicity were then recorded 7, 14 and 21 days after application and assessments were made against the deionised water treated controls. The study was terminated 21 days after application. Parameters measured at the final assessment were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain significance for shoot dry weight effects, carried out using the Pairwise Mann-Whitney-U-Test (one sided smaller; $p \leq 0.05$) by ToxRat statistics.

**Material and methods:**

**Findings:**

Validity criteria:
This study can be considered valid as the validity criterion of at least 90% survival throughout the study period in the water treated controls was achieved for all species.

Biological findings:
A summary of the findings from a single application of 3000 mL product/ha to the 10 plant species tested is summarised in the following table:

**Table CP 10.6- 5: Summary of the effects after single application of 3000 mL Bixafen + Fluoxastrobin + Prothioconazole EC 190/ha on terrestrial plants**

| **Plant species** | **Survival*** (% inhibition) | **Phytotoxicity**** | **Shoot Dry Weight***** (% inhibition) |
|---|---|---|---|
| **Dicotyledonae** | | | |
| *Beta vulgaris* | 0 | A - B$^{abef}$ | 10.7 |
| *Brassica napus* | 0 | B - C$^{abef}$ | **37.6** |
| *Cucumis sativus* | 0 | B - C$^{abf}$ | **20.2** |
| *Fagopyrum esculentum* | 0 | B - C$^{abef}$ | **55.5** |
| *Glycine max* | 0 | B$^{bef}$ | **20.4** |
| *Helianthus annuus* | 0 | A - B$^{ab}$ | **15.8** |
| *Lycopersicon esculentum* | 0 | B$^{ab}$ | **11.4** |
| **Monocotyledonae** | | | |
| *Allium cepa* | 0 | 0 | **12.0** |
| *Avena sativa* | 0 | 0 | 6.6 |
| *Zea mays* | 0 | A$^{abef}$ | 4.3 |

* survival is a measure of treated plants that survived at the end of the study and is expressed as an inhibition compared to the untreated control

** description of the phytotoxicity rating

Description of symptoms assessed:
*a* = chlorosis (yellowing of green shoot tissue)
*b* = necrosis (brown shoot tissue)
*c* = bleaching (shoot tissue without pigmentation)
*d* = wilting (loss of turgor of shoot tissue)
*e* = leaf deformation (leaf curl, abnormal leaf shape)
*f* = stunting (plant height reduced with shorter internode length)

Rating system for recording the severity of phytotoxic symptoms:
*0 = no injury or effect*
*A = slight symptom (s)*
*B = moderate symptom (s)*
*C = severe symptom (s)*
*D = total plant symptom (s)*
*E = moribund*

*** inhibition or reduction is expressed on a per plant basis

( ) figures in parentheses indicate that there was an increase when compared to the untreated control

**Bold figures for shoot dry weight are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller; p ≤ 0.05).**

There were no effects on survival of all tested species. Slight to severe phytotoxicity symptoms were observed as chlorosis, necrosis, leaf deformation and stunting in all tested species, except *Allium cepa* and *Avena sativa*. *Brassica napus, Cucumis sativus, Glycine max, Helianthus annuus, Lycopersicon esculentum and Allium cepa* resulted in shoot dry weight reductions of 37.6, 20.2, 20.4, 15.8, 11.4 and 12.0%, respectively, which were statistically significant. *Fagopyrum esculentum* was the most sensitive species for shoot dry weight, with a 55.5% reduction which was statistically significant.

**Conclusion:**

Following a foliar application of Bixafen + Fluoxastrobin + Prothioconazole EC 190 applied at 3000 mL product/ha to ten terrestrial plant species at the 2 to 4 leaf stage, no adverse effects on survival and shoot dry weight exceeding 50% effect were observed in this vegetative vigour study for nine non-target plant species.
Shoot dry weight of *Fagopyrum esculentum* was reduced by 55.5%.

| | |
|---|---|
| **Report:** | KCP 10.6.2/03 [redacted],; 2010; M-390280-01-1 |
| Title: | BIX + FXA + PTZ EC 40 + 50 + 100 G, Effects on the seedling emergence and growth of the of non-target terrestrial plant species Lycopersicon esculentum (Tier 2) |
| Report No.: | SE10/067 |
| Document No.: | M-390280-01-1 |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestrial Plant Test OECD 208: Seedling emergence and seedling growth Test, July 2006 |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The purpose of this specific study was to evaluate the phytotoxicity effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the seedling emergence and seedling growth of the non-target terrestrial plant species *Lycopersicon esculentum* following a pre-emergence application of the product onto the soil surface.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848; Tox No.: 08908-00; Specification No.: 102000023924-NN; Material No.: 79969775 Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

One dicotyledonous species *Lycopersicum esculentum*, representing the plant family Solanaceae, was tested in this seedling emergence and growth test. Five seeds were sown in 10.5 cm pots in the glasshouse and a total of 8 replicate pots per treatment were prepared. Five application rates (188, 375, 750, 1500 and 3000 mL product/ha) plus an untreated control were applied to the bare soil surface after sowing of the seeds as a pre-emergence treatment. The serial dilutions of Bixafen + Fluoxastrobin + Prothioconazole EC 190 were sprayed onto the soil surface using a laboratory track sprayer at a volume rate of 200 L/ha. The control pots were sprayed with 200 L/ha deionised water.
Following application, pots were maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod. Emergence was assessed daily until 70% emergence of control seedlings was reached. Emergence, survival and phytotoxicity were recorded 7 and 14 days after the emergence of 70% of the seeds in the water treated control.
In addition, plant growth stage and shoot dry weight were determined at the final assessment date 14 days after 70% emergence of the seeds in the water treated control.
Statistical analysis of data was performed to obtain $ER_{50}$ values for emergence, survival and shoot dry weight, using ToxRat statistical software.

**Findings:**

Validity criteria:
This study can be considered valid as the validity criteria of at least 70% emergence and at least 90% survival of the emerged seedlings during the study period was achieved for the water treated controls of the species tested.

Analytical findings:
Analysis of Fluoxastrobin in the highest tested application rate revealed it to 101% of nominal.

Biological findings:
The effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the seedling emergence, survival of emerged seedlings, visible phytotoxicity, growth stage and shoot dry weight during the study period are shown in the following table:

**Table CP 10.6- 6: Summary of the effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on *Lycopersiconesculentum***

| mL product/ha | Emergence | | | Survival | | | Shoot dry weight (g) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | No. | % | Sign. | No. | % | Sign. | Mean | SD | %CV | %Red | Sign. |
| control | 34 | 85.0 | | 34 | 100 | | 0.171 | 0.0254 | 14.9 | | |
| 188 | 33 | 82.5 | - | 33 | 100 | - | 0.191 | 0.0151 | 7.9 | -12.0 | - |
| 375 | 35 | 87.5 | - | 35 | 100 | - | 0.189 | 0.0239 | 12.7 | -10.6 | - |
| 750 | 36 | 90.0 | - | 36 | 100 | - | 0.169 | 0.0345 | 20.4 | 0.8 | - |
| 1500 | 31 | 77.5 | - | 31 | 100 | - | 0.143 | 0.0433 | 30.2 | 16.0 | + |
| 3000 | 32 | 80.0 | - | 32 | 100 | - | 0.102 | 0.0269 | 26.3 | 39.9 | + |
| $ER_{50}$ | >3000¤ | | | >3000¤ | | | >3000# | | | | |
| Lower 95% c.l. | n.d. | | | n.d. | | | >3000# | | | | |
| Upper 95% c.l. | n.d. | | | n.d. | | | >3000# | | | | |

No. = the total number of plants at test termination
NOER, $ER_{25}$ and $ER_{50}$ (where valid) endpoints are calculated
% = surviving plants at test termination respectively % cv = coefficient of variation
+ in column "Sign." = statistically significant different from the control
- in column "Sign." = not statistically significant different from the control
c.l. = confidence limit
n.d. = not determined
¤ not statistical determined and there were no effects observed up to the highest application rate
# highest test rate, calculated values above the highest rate tested

*Emergence and survival*
An application of Bixafen + Fluoxastrobin + Prothioconazole EC 190 to the soil surface in which *Lycopersicon esculentum* seeds had been sown resulted in no significant impact on the emergence and survival. The $ER_{50}$ for these endpoints was > 3000 mL product/ha.

*Shoot dry weight*
Shoot dry weight (biomass) was significantly reduced at applications including and above 1500 mL product/ha. The $ER_{50}$ for biomass was >3000 mL product/ha.

*Phytotoxicity symptoms*
Phytotoxicity symptoms visualised as slight to severe leaf deformation and stunting were observed at application rates including and above 750 mL product/ha. Chlorosis was observed in a single pot at 3000 mL product/ha on test day 7.

*Effects on growth stage*
There were slight effects on growth stage of emerged seedlings in comparison to the untreated control at 1500 mL product/ha.

**Conclusion:**

This Tier 2 seedling emergence and growth study in which the effect of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the non-target terrestrial plant species *Lycopersicon esculentum* was tested under glasshouse conditions resulted in an $ER_{50}$ >3000 mL product/ha for emergence, survival and shoot dry weight.

| | |
|---|---|
| **Report:** | KCP 10.6.2/04 [redacted] G; 2010; M-390282-01-1 |
| Title: | BIX + FXA + PTZ EC 40 + 50 + 100 G, Effects on the vegetative vigour of the of non-target terrestrial plant species Fagopyrum esculentum (Tier 2) |
| Report No.: | VV 10/068 |
| Document No.: | M-390282-01-1 |
| Guideline(s): | OECD Guideline for the testing of Chemicals, Terrestrial Plant Test OECD 227: Vegetative vigour Test, July 2006 |
| Guideline deviation(s): | none |
| **GLP/GEP:** | **yes** |

**Objective:**

The purpose of this specific study was to evaluate the phytotoxicity effect of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the vegetative vigour of the non-target terrestrial plant species *Fagopyrum esculentum* following a post-emergence application of the product onto the foliage of plants at the 2-4 leaf stage.

**Material and methods:**

Test item: Bixafen + Fluoxastrobin + Prothioconazole EC 190 (40+50+100 g/L); Short code: BIX+FXA+PTZ EC 190 (40+50+100) G; Batch ID.: 2010-000848; Tox No.: 08908-00; Specification No.: 102000023924-NN; Material No.: 79969775; Analysed content of active ingredients: 3.90 % w/w (41.50 g/L) bixafen (BYF 00587), 4.86 % w/w (51.71 g/L) fluoxastrobin (HEC 5725 E-ISO), 9.59 % w/w (102.0 g/L) prothioconazole (JAU 6476); Density: 1.064 g/mL.

One dicotyledonous species *Fagopyrum esculentum*, representing the plant family Polygonaceae, was tested in this vegetative vigour test. Plants were grown in a glasshouse in 13 cm pots and were treated at the 2-4 leaf stage. There were 4 plants per pot and 8 replicate pots per treatment. Plants were treated with 5 application rates (188, 375, 750, 1500 and 3000 mL product/ha) plus an untreated control. The serial dilutions of Bixafen + Fluoxastrobin + Prothioconazole EC 190 were sprayed onto the foliage of plants using a laboratory track sprayer at a volume rate of 200 L/ha. The control plants were sprayed with 200 L/ha deionised water.
Following application, pots were maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod. Assessments were made 7, 14 and 21 days after application against the water treated control. The study was terminated 21 days after application. The parameters measured at the final assessment were survival, visual phytotoxicity, plant growth stage and shoot dry weight.
Statistical analysis of data was performed to obtain $ER_{50}$ values for survival and shoot dry weight, using ToxRat statistical software.

**Findings:**

Validity criteria:
This study can be considered valid as the validity criteria of at least 90% survival throughout the study period was achieved for the water treated controls of the species tested.

Analytical findings:
Analysis of Fluoxastrobin in the highest tested application rate revealed it to 101% of nominal.

Biological findings:
The effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the vegetative vigour, survival, visible phytotoxicity, growth stage and shoot dry weight during the study period are shown in the following table:

**Table CP 10.6- 7: Summary of the effects of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on *Fagopyrum esculentum***

| mL product/ha | Survival | | | Shoot dry weight (g) | | | | |
|---|---|---|---|---|---|---|---|---|
| | No. | % | Sign. | Mean | SD | %CV | %Red | Sign. |
| control | 32 | 100 | | 4.500 | 0.7540 | 16.8 | | |
| 188 | 32 | 100 | - | 4.166 | 1.1359 | 27.3 | 7.4 | - |
| 375 | 32 | 100 | - | 4.498 | 0.4432 | 9.9 | 0 | - |
| 750 | 32 | 100 | - | 4.161 | 0.4777 | 11.5 | 7.5 | - |
| 1500 | 32 | 100 | - | 3.742 | 0.6706 | 17.9 | 16.8 | + |
| 3000 | 32 | 100 | - | 2.096 | 0.4320 | 20.6 | 53.4 | + |
| $ER_{50}$ | >3000¤ | | | 2857.54 | | | | |
| Lower 95% c.l. | n.d. | | | 2235.74 | | | | |
| Upper 95% c.l. | n.d. | | | >3000 | | | | |

No. = the total number of plants at test termination
NOER, $ER_{25}$ and $ER_{50}$ (where valid) endpoints are calculated
% = surviving plants at test termination respectively % cv = coefficient of variation
+ in column "Sign." = statistically significant different from the control
- in column "Sign." = not statistically significant different from the control
c.l. = confidence limit
n.d. = not determined
¤ not statistical determined and there were no effects observed up to the highest application rate

*Survival*
The foliar application of Bixafen + Fluoxastrobin + Prothioconazole EC 190 had no significant impact on the survival of treated *Fagopyrum esculentum* plants. The $ER_{50}$ for this endpoint was > 3000 mL product/ha.

*Shoot dry weight*
Shoot dry weight (biomass) was significantly reduced at application rates including and above 1500 mL product/ha. The $ER_{50}$ value for biomass was 2857.54 mL product/ha.

*Phytotoxicity symptoms*
Phytotoxicity symptoms visualized as slight to severe chlorosis, necrosis and stunting were observed at all application rates.

*Effects on growth stage*
There were no effects on growth stage development of treated plants in comparison with the untreated controls at all application rates.

**Conclusion:**

This Tier 2 vegetative vigour study in which the effect of Bixafen + Fluoxastrobin + Prothioconazole EC 190 on the non-target terrestrial plant species *Fagopyrum esculentum* was tested under glasshouse conditions resulted in an $ER_{50}$ of 2858 mL product/ha for shoot dry weight.

## CP 10.6.3 Extended laboratory studies on non-target plants

In view of the results presented above under CP 10.6.2, extended laboratory studies are not deemed necessary.

## CP 10.6.4 Semi-field and field tests on non-target plants

In view of the results presented above under CP 10.6.2, semi-field laboratory studies are not deemed necessary.

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

No studies are required.

## CP 10.8 Monitoring data

No monitoring data are available or required.