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| FINAL REGISTRATION REPORT  Part B  Section 9  Ecotoxicology  Detailed summary of the risk assessment |
| Product code: SHA 2600 E  Product name(s): PENTAGON  Chemical active substances:  Pendimethalin, 455 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT |
| Applicant: Sharda Cropchem Limited  Submission date: December 2023  zRMS Finalisation date: July 2024; November 2024 |

Version history

|  |  |
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| When | What |
| December 2023 | Submission to RMS |
| July 2024 | dRR assessed by zRMS |
| November 2024 | Final Registration Report |

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# Ecotoxicology (KCP 10)

## Critical GAP and overall conclusions

Table 9.1‑1: Table of critical GAPs

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No. \* | Member state(s) | Crop and/or situation  (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or  I \*\* | Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI  (days) | Remarks:  e.g. g saf­ener/ syner­gist per ha | Conclusion | | | | | | |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product/ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min/max | Birds | Mammals | Aquatic organisms | Bees | Non-target arthropods | Soil organisms | Non-target plants |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | | | | | | | |
| 1 | CEU: PL | Potato (SOLTU) | F | Broadleaved and grass weeds | Spray | Pre emergence BBCH 00-09 | a) 1  b) 1 | NA | a) 2.5  b) 2.5 | a) 1.137  b) 1.137 | 200-400 | - |  |  |  |  |  |  |  |  |
| 2 | CEU: NL | ware potato (SOLTU) | F | annual weeds (3DICOT, 3MNCOT) | Foliar spray | pre-emergence of the crop  BBCH 00-09  March-April | a) 1  b) 1 | - | a) 2.2  b) 2.2 | a) 1.0  b) 1.0 | 200-400 | - | In combination with authorised products |  |  |  |  |  |  |  |
| 3 | CEU: PL, NL | Winter cereals (rye, oats, triticale) | F | annual monocotyledonous weeds (TTTMS) and annual dicotyledonous weeds (TTTDS | Spray | Pre emergence BBCH 00-09 | a) 1  b) 1 | NA | a) 2.5  b) 2.5 | a) 1.137  b) 1.137 | 200-400 | - |  |  |  |  |  |  |  |  |
| 4 | CEU: PL, NL | Winter cereals (rye, oats, triticale) | F | Broadleaved and grass weeds | Spray | Post emergence BBCH 10-13 | a) 1  b) 1 | NA | a) 2.5  b) 2.5 | a) 1.137  b) 1.137 | 200-400 | - |  |  |  |  |  |  |  |  |
| 5 | CEU: PL, NL | Winter oilseed rape (BRSNW) | F | Broadleaved and grass weeds | Spray | Post emergence BBCH 10-16 | a) 1  b) 1 | NA | a) 2.0  b) 2.0 | a) 0.91  b) 0.91 | 200-400 | - |  |  |  |  |  |  |  |  |
| 6 | CEU: NL | Onion (ALLCE), Shallots (ALLAS) | F | annual weeds (3DICOT, 3MNCOT) | Spray | pre-emergence of the crop  BBCH 00-09  March-May | a) 1  b) 1 | - | a) 2.85  b) 2.85 | a) 1.3  b) 1.3 | 200-400 | - | Apply at 2.2-2.85 L/ha dependent on soil type  Max. 2.85 L/ha/season |  |  |  |  |  |  |  |
| 7 | CEU: NL | Onion (ALLCE), Shallots (ALLAS) | F | annual weeds (3DICOT, 3MNCOT) | Spray | pre-emergence of the crop  BBCH 00-09  March-May | a) 2  b) 2 | 7 | a) 0.88  b) 1.76 | a) 0.4  b) 0.8 | 200-400 | - | Apply at 0.66-0.88 L/ha in LDS with authorised products  Max. 2.85 L/ha/season |  |  |  |  |  |  |  |
| 8 | CEU: NL | Onion (ALLCE) excl. silver onion,  Shallots (ALLAS) | F | annual weeds (3DICOT, 3MNCOT) | Spray | post-emergence of the crop  BBCH 10-13  March-May | a) 2  b) 2 | 7 | a) 2.2  b) 2.85 | a) 1.0  b) 1.3 | 200-400 | - | Apply at 1.1-2.2 L/ha  Max 2.85 L/ha/season |  |  |  |  |  |  |  |
| 9 | CEU: NL | Onion (ALLCE) excl. silver onion,  Shallots (ALLAS) | F | annual weeds (3DICOT, 3MNCOT) | Spray | post-emergence of the crop  BBCH 10-13  March-May | a) 3  b) 3 | 7 | a) 0.44  b) 1.32 | a) 0.2  b) 0.6 | 200-400 | - | Apply in LDS with authorised products  Max 3.25 L/ha/season |  |  |  |  |  |  |  |
| 10 | CEU: NL | Flower bulb and flower tuber crops | F | annual weeds (3DICOT, 3MNCOT) | Spray | Pre-emergence  BBCH 00-09  February-April | a) 1  b) 1 | - | a) 3.5  b) 3.5 | a) 1.6  b) 1.6 | 200-400 | - |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Minor uses according to Article 51 (interzonal uses) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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

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

Explanation for column 15 – 21 “Conclusion”

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

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| **Remarks**  **table:** | (1) Numeration necessary to allow references  (2) Use official codes/nomenclatures of EU  (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)  (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named  (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated |  | (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  (8) The maximum number of application possible under practical conditions of use must be provided  (9) Minimum interval (in days) between applications of the same product.  (10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products  (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  (13) PHI - minimum pre-harvest interval  (14) Remarks may include: Extent of use/economic importance/restrictions |

### Overall conclusions

**zRMS comments:**

This document is based on the information provided by Applicant and reflects the Applicant’s opinion. Clarifications and conclusions of the zRMS are presented in the commenting boxes Amendments/corrections by zRMS are marked in grey.

#### Table 9.1‑3 Metabolites of Pendimethalin

| Metabolite | Molar mass | Chemical structure | Maximum observed occurence in compartements | Exposue assessment required due to |
| --- | --- | --- | --- | --- |
| M455H001 | 311.1 |  | Soil: 6.9 %  Water/sediment: 0.00001 % | Yes, for soil and water |
| P48 (M455H033) | 251.3 |  | Soil: 25.9 %  Water/sediment: 12.1% | Yes, for soil and water |
| P36 (M455H029; M12) | 261.3 |  | Soil: 0.00001%  Water/sediment: 23.4% | Yes, for water |
| 2,6-dinitro-3,4-dimethylaniline (aqueous photolysis metabolite)  (M455H032) | 211.2 |  | Soil: 0.00001%  Water/sediment: 14.2 % | Yes, for water |

#### Effects on birds (KCP 10.1.1), The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS.

Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds. The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

#### Agreed.

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

The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS.

Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds. The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

The risk assessment shows that there is no acute risk for mammals after exposure to Pendimethalin 45.5% CS. No long-term risk was observed for mammals in bare soil and bulbs and onion like crops, whereas for the other crops long-term risk was observed in some scenarios and further assessment was needed. After the refinement showed an acceptable long-term risk for mammals.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating mammals. The risk of secondary poisoning to earthworm eating mammals was found acceptable.

**The refinement risk assessment for birds and mammals should be considered by MSs level.**

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

Based on lowest value of RAC of 0.23 µg a.s./L for aquatic organism agreed at EU level an acceptable risk for aquatic organisms is considered when the following risk mitigation measures and restrictions are applied. The final risk mitigation measures to aquatic organism should be considered at MSs level.

For the intended uses, calculated PEC/RAC ratios for metabolites showed an acceptable risk for aquatic organisms after Step 1-3 scenarios.

Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

**Potato– SPe 3:** To protect aquatic organisms respect 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

**Winter cereals – SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

**Bulb vegetables (1x1600g/ha and 1x1300g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

**Bulb vegetables (2x650g/ha and 2x400g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

**Winter oilseed rape – SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies

~~After ETO-RAC refinement:~~

~~Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:~~

**~~Potato– SPe 3:~~** ~~To protect aquatic organisms respect 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction~~

**~~Winter cereals – SPe 3:~~** ~~To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies~~

**~~Bulb vegetables (1x1600g/ha and 1x1300g/ha)~~****~~– SPe 3:~~** ~~To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies~~

**~~Bulb vegetables (2x650g/ha)~~****~~– SPe 3:~~** ~~To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction to surface water bodies~~

**~~Bulb vegetables (2x400g/ha)~~****~~– SPe 3:~~** ~~To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip or unsprayed buffer zone of 15m + 15m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies~~

**~~Winter oilseed rape – SPe 3~~**~~: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip or unsprayed buffer zone of 10m + 10m vegetative strip + 50% nozzle reduction to surface water bodies.~~

#### For the intended uses, calculated PEC/RAC ratios for metabolites showed an acceptable risk for aquatic organisms after Step 1-3 scenarios.

Calculated PEC/RAC ratios for the formulation PENTAGON did indicate an acceptable risk for aquatic organisms.

Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

**Potato– SPe 3:** To protect aquatic organisms respect 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

**Winter cereals – SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

**Bulb vegetables (1x1600g/ha and 1x1300g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

**Bulb vegetables (2x650g/ha and 2x400g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

**Winter oilseed rape – SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies

* ~~Winter cereals, artichoke, brassicas, lettuce and potato: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction~~
* ~~Maize, garlic, onion, sunflower, eggplant, pepper, tomato, strawberry, soybean and tobacco: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction~~
* ~~Carrots, chickpeas, peanuts and beans: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction~~
* ~~Pome/stone fruits: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip and 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip and 75% nozzle reduction~~
* ~~Grapevine and ornamentals (bulb vegetables): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction~~
* ~~Cotton: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction~~
* ~~Citrus: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction~~

|  |
| --- |
| **zRMS comments:** The calculations PECsw/sed at STEP 4 according to the Austrian Environmental Agency (AGES) for 5 and 15 meters of vegetative buffer strip should be considered at national level. The Step 4 VFSmod calculations should be considered at national level also. Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using Focus models.  The scenarios D2 and D6 are not relevant for CEU countries and will not be taken into account in further evaluation.  Four different mesocosms were available to address the risk to algae, macrophytes, aquatic invertebrates, and sediment-dwelling organisms. All mesocosm studies resulted in consistent NOEC (0.23–3.8 μg a.s./L) and NOEAEC (1.1–5 μg a.s./L), confirming algae as the most sensitive group. During the Peer Review Experts’ Teleconference it was agreed that the use of the NOEAEC (recovery approach) was not a suitable option, since recovery after autumn applications of pendimethalin might be slower than what is observed in the mesocosms, all carried out in spring/summer. Hence, it was agreed to use the most conservative NOEC value (0.23 μg a.s./L), together with an assessment factor of 1. Such low assessment factor was agreed due to the consistency between the results of the mesocosm studies. In the final commenting round of the present conclusion the RMS disagreed on this approach, which was nevertheless deemed as appropriate during the Peer Review Experts’ Teleconference. The opinion of RMS was that a geometric mean across NOEC from the different mesocosms should have been used in the risk assessment. It must be noted that the use of the geometric mean was considered during the Peer Review Experts’ Teleconference and considered not appropriate.  Therfore the risk was based on the NOEC of 0.23 microgram/L.  Based on lowest **RAC of 0.23 µg a.s./L agreed at EU level** an acceptable risk for aquatic organisms is considered when the following risk mitigation measures and restrictions are applied:  **Potato 1 x 1600 g a.s./ha**  PEC/RAC ratios in potato (1x1600g/ha) are <1 when risk mitigation options are considered:  D3 ditch: 15m no spray buffer zone + 90% nozzle reduction.  D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  R1 pond: 15m no spray buffer zone with 15m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R2 stream and R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction  **Potato 1x1137 g a.s.ha**  PEC/RAC ratios in maize are <1 when risk mitigation options are considered:  D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction. k  R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R1 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R2 stream and R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Winter cereals 1x1137 g a.s./ha**  PEC/RAC ratios in winter cereals are <1 when risk mitigation options are considered:  D1 ditch, D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.  D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R1 stream, R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables 1x1600 g/ha**  PEC/RAC ratios in winter cereals are <1 when risk mitigation options are considered:  D3 ditch: 20m no spray buffer zone + 90% nozzle reduction.  D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  R1 pond: 15m no spray buffer zone with 15m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R2 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 90% nozzle reduction  R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables 1x300 g/ha**  PEC/RAC ratios in bulb vegetables are <1 when risk mitigation options are considered:  D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.  D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R2 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction  R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables (1x1600 g/ha + 1x300 g/ha)**  PEC/RAC ratios in bulb vegetables (1 x 1600 g/ha + 1 x 300 g/ha) are <1 when risk mitigation options are considered:  R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables 2x650 g/ha**  PEC/RAC ratios in Bulb vegetables (2x650g/ha) are <1 when risk mitigation options are considered:  R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction  R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction  **Bulb vegetables 2x400 g/ha**  PEC/RAC ratios in Bulb vegetables (2x400g/ha) are <1 when risk mitigation options are considered:  D3 ditch, D4 stream, D6 1st ditch: 20m no spray buffer zone + 90% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.  R1 stream: 20m no spray buffer zone with 20m vegetated filter strip  R2 stream: 20m no spray buffer zone with 20m vegetated filter strip or 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle re-duction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction  **Winter oilseed rape 1x910 g a.s./ha**  PEC/RAC ratios in Winter oilseed rape (1x910g/ha) are <1 when risk mitigation options are considered:  D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.  D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.  D3 ditch, D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction or 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction  R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction  **Conclusion:**  Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:  **Potato– SPe 3:** To protect aquatic organisms respect 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction (for 1 x 1600 g a.s.ha and 1 x 1.137 g a.s./ha)  **Winter cereals – SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies  **Bulb vegetables (1x1600g/ha and 1x1300g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies  **Bulb vegetables (2x650g/ha and 2x400g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies  **Winter oilseed rape – SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies  **The final riskmitigation measures should be considered at MSs level.**  **According SI comment:** In Section 8.01 it is stated.  *The vapour pressure at 20 °C of the active substance Pendimethalin is > 10‑4 Pa. Hence the active substance Pendimethalin is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Pendimethalin due to volatilization with subsequent deposition should be considered.*  Please add an assessment of the risk to aquatic organisms and terrestrial ecosystems following exposure to pendimethalin due to volatilization with subsequent deposition.  **RMS comment:** The dry depositon was calculated by EVA (UBA model) and taken into account in the Step 4 calculations as it is explained in the dRR Part B 8 in chapter 8.9, FOCUS Step 4. The RMS used these calculations in the risk assessment. Additional actions are not necessary in our opinion. However, the risk assessment for aquatic organisms should be considered by MSs level. |

#### Effects on bees (KCP 10.3.1)

No risk for bees is expected following the application of PENTAGON at the proposed rates.

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

The application of PENTAGON in accordance to the GAP poses no unacceptable in-field and off-field risk to non-target arthropods.

#### Effects on non-target soil meso- and macrofauna (KCP 10.4), The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENTAGON according to the proposed GAP.

#### Effects on soil microbial activity (KCP 10.5)

The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENTAGON according to the proposed GAP.

No risk to soil microorganisms is expected following the application of PENTAGON at the proposed rates in the GAP.

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#### No risk to soil microorganisms is expected following the application of PENTAGON at the proposed rates in the GAP.

|  |
| --- |
| **zRMS comment:** Agreed.  The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. The risk for soil microorganism was considered as acceptable for **PENTAGON**. |

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

No risk to non-target plants located outside the treated area is expected in any of the crops after the application of PENTAGON.

#### No risk to non-target plants located outside the treated area is expected in any of the crops after the application of PENTAGON.

**zRMS comments:**

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The deterministic risk based on the lowest value ER50 of 5036 g a.s./ha value and PERoff- field for proposed uses of **PENTAGON**. The risk assessment for to non-target plants located outside the treated area is considered as acceptable after the application of **PENTAGON**.

**No risk mitigation measures are needed.**

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

No data on other non-target species is required.

### Grouping of intended uses for risk assessment

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

Table 9.1‑2: Critical use pattern of Pendimethalin 45.5% CS grouped according to criterion

| Grouping according to criterion | | | |
| --- | --- | --- | --- |
| Group | Intended uses | relevant use parameters for grouping | relevant parameter or value for sorting |
| Bare soil | All crops | Pre-emergence or pre-transplant  BBCH 00-09 | 1 x 3.5 L f.p./ha (equivalent to 1 x 1600 g a.s./ha) (flower bulb and flower tuber crops is worst case) |
| Bare soil | All crops | Pre-emergence or pre-transplant  BBCH 00-09 | 2 x 0.88 L f.p./ha (equivalent to 2 x 400 g a.s./ha) (onion, shallots is worst case) |
| Cereals | Winter cereals | Post-emergence  BBCH 10-13 | 1 x 2.5 L f.p./ha (equivalent to 1 x 1137 g a.s./ha) |
| Oilseed rape | Winter oilseed rape | Post-emergence  BBCH 10-16 | 1 x 2.0 L f.p./ha (equivalent to 1 x 910 g a.s./ha) |
| Bulbs and onion like crops | Onion, shallots | Post-emergence  BBCH 10-13 | Apply at 1.1-2.2 L/ha  Max 2.85 L/ha/season |
| Bulbs and onion like crops | Onion, shallots | Post-emergence  BBCH 10-13 | 3 x 0.44 L f.p./ha (equivalent to 3 x 0.2 g a.s./ha) |

### Consideration of metabolites

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

Table 9.1‑3 Metabolites of Pendimethalin

| Metabolite | Molar mass | Chemical structure | Maximum observed occurence in compartements | Exposue assessment required due to |
| --- | --- | --- | --- | --- |
| M455H001 | 311.1 |  | Soil: 6.9 %  Water/sediment: 0.00001 % | Yes, for soil and water |
| P48 (M455H033) | 251.3 |  | Soil: 25.9 %  Water/sediment: 12.1% | Yes, for soil and water |
| P36 (M455H029; M12) | 261.3 |  | Soil: 0.00001%  Water/sediment: 23.4% | Yes, for water |
| 2,6-dinitro-3,4-dimethylaniline (aqueous photolysis metabolite)  (M455H032) | 211.2 |  | Soil: 0.00001%  Water/sediment: 14.2 % | Yes, for water |

## Effects on birds (KCP 10.1.1)

### Toxicity data

Avian toxicity studies have been carried out with pendimethalin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on birds of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of pendimethalin. However, the provision of further data on the formulation is not considered essential because brds are typically exposed to dry residues on their food items following the dilution and spraying of the formulated product. During these processes, much of the formulation constituents are likely to be lost by volatilisation. Since oral exposure is the main route of exposure, toxicity data for the active substance are therefore used in preference to data from tests with the formulated product.

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

Table 9.2‑1: Endpoints and effect values relevant for the risk assessment for birds

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Anas platyrrhynchos* | pendimethalin | Oral Acute | **LD50 = 1421 mg/kg bw** | EFSA Journal 2016;14(3):4420 |
| *Anas platyrrhynchos* | pendimethalin | Dietary  Short-term | LC50 = >4640 ppm | EFSA Journal 2016;14(3):4420 |
| *Colinus virginianus* | pendimethalin | Dietary Short-term | LC50 = 4187 ppm | EFSA Journal 2016;14(3):4420 |
| *Anas platyrrhynchos* | pendimethalin | Dietary Reproductive toxicity | NOEC = 141 ppm  **NOEL = 17.5 mg/kg bw per day** | EFSA Journal 2016;14(3):4420 |
| *Colinus virginianus* | pendimethalin | Dietary Reproductive toxicity | NOEC = 1410 ppm  NOEL = 141 mg/kg bw per day | EFSA Journal 2016;14(3):4420 |
| *Birds* | pendimethalin | Reproductive toxicity | BMDL5 of 61.5 mg/kg bw/d\* | EFSA Journal 2016;14(3):4420 |

\*Refinement long-term risk assessment for birds

**Metabolites**

In the assessment of the metabolites of pendimethalin carried out in the EU evaluation of this active substance (EFSA Journal 2016;14(3):4420: Peer review of the pesticide risk assessment of the active substance pendimethalin) no acute and reproductive risk to birds and mammals for any of the pendimethalin metabolites was identified.

For exposure via secondary poisoning the RMS concluded in the RAR (MCP Volume 3 B.9) that the risk from metabolites is covered by the parent. This is because from the exposure side the calculated log kow values for the metabolites were equal or lower than for the parent pendimethalin, indicating no increased potential for accumulation in animal tissues for the metabolites compared to the parent. In the absence of toxicity data for birds and mammals the RMS applied a weight of evidence approach, concluding that the metabolites are a factor of ≥10 less toxic than the parent based on accordingly lower PECsw and PECsoil values observed for the metabolites. For one anaerobic soil metabolite, M455H033 (P48), the PECsw and PECsoil values reported in EFSA 2016;14(3):4420 are a factor of 8-9 lower than for the parent, respectively. This means that the secondary poisoning risk assessment for the parent is still protective even if the metabolite would be 8-9 fold more toxic than the parent. Available aquatic toxicity data demonstrate no increased toxicity of metabolite M455H033 (P48) compared to the parent (e.g. this metabolite is 150 times less toxic for primary producers as the most sensitive group of organisms). In addition, metabolite M455H033 (P48) was observed in the rat and the goat metabolism studies indicating that toxicity tests with the parent pendimethalin covers effects exerted by this metabolite. Conclusively, the assessment for secondary poisoning for the parent pendimethalin covers also the risk for metabolite M455H033 (P48).

In conclusion, the risk from all metabolites is covered by the acute, reproductive and secondary poisoning risk assessments conducted for the parent.

#### Justification for new endpoints

The EU agreed endpoints are used for the risk assessment.

### Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). In addition, the following is stated in the EFSA conclusion of pendimethalin (2016): *Although pendimethalin does not have a systemic mode of action, it may be taken up by plants from pre-emergence soil applications; also, palatable weeds may be over sprayed during such pre-emergence applications. Therefore, exposure of herbivorous and omnivorous vertebrate species to plants containing pendimethalin residues cannot be excluded also for pre-emergence applications. The standard bare soil scenario was therefore not considered protective enough in this case. To tackle this issue, TER calculations based on the post-emergence scenarios for herbivorous and omnivorous species (i.e. with plants in their diet) were also considered relevant to the pre-emergence applications.*

For winter cereals and onions that pre-emergence uses is covered by the submitted risk assessment on post-emergence uses but for potatoes and flower bulb and flower tuber crops an early post-emergence risk assessment for herbivorous, insectivorous and omnivorous birds are presented below.

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

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

Table 9.2‑2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in bare soil

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Bare soil | “Indicator species for screening” | | 24.7 | 1 | 39.52 | 35.96 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bare soil | “Indicator species for screening” | | 11.4 | 1 x 0.53 | 9.67 | **1.81** |
| Bare soils  BBCH<10 | Small granivorous bird “finch” | | 11.4 | 1 x 0.53 | 9.67 | **1.81** |
| Bare soils  BBCH<10 | Small omnivorous bird “lark” | | 8.2 | 1 x 0.53 | 6.95 | **2.52** |
| Bare soils  BBCH<10 | Small insectivorous bird “wagtail” | | 5.9 | 1 x 0.53 | 5.00 | **3.50** |

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

Table 9.2‑3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Flower bulb and flower tuber crops (ornamentals)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Flower bulb and flower tuber crops (ornamentals) | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| ornamentals | “Indicator species for screening” | | 46.8 | 1 | 74.88 | 18.98 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| ornamentals | “Indicator species for screening” | | 18.2 | 1 x 0.53 | 15.43 | **3.98** |
| Ornamentals Application to  plant – exposure to  underlying ground | Small insectivorous/worm  feeding species “thrush” | | 2.7 | 1 x 0.53 | 2.29 | 26.86 |

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

Table 9.2‑4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in potatoes

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potatoes | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| potatoes | “Indicator species for screening” | | 158.8 | 1 | 180.56 | **7.87** |
| BBCH 10 - 39 | Small omnivorous bird “lark” | | 24.0 | 1 | 27.29 | 52.07 |
| BBCH ≥ 40 | Small omnivorous bird “lark” | | 7.2 | 1 | 8.19 | 173.58 |
| BBCH 10 - 19 | Small insectivorous bird  “wagtail” | | 26.8 | 1 | 30.47 | 46.63 |
| BBCH ≥ 20 | Small insectivorous bird  “wagtail” | | 25.2 | 1 | 28.65 | 49.59 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| potatoes | “Indicator species for screening” | | 64.8 | 1 x 0.53 | 39.05 | **0.45** |
| BBCH 10 - 39 | Small omnivorous bird “lark” | | 10.9 | 1 x 0.53 | 6.57 | **2.66** |
| BBCH ≥ 40 | Small omnivorous bird “lark” | | 3.3 | 1 x 0.53 | 1.99 | 8.80 |
| BBCH 10 - 19 | Small insectivorous bird  “wagtail” | | 11.3 | 1 x 0.53 | 6.81 | **2.57** |
| BBCH ≥ 20 | Small insectivorous bird  “wagtail” | | 9.7 | 1 x 0.53 | 5.85 | **2.99** |

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

Table 9.2‑3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in bare soil (onion, shallots)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 × 400 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Bare soil | “Indicator species for screening” | | 24.7 | 1.4 | 13.83 | 102.73 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bare soil | “Indicator species for screening” | | 11.4 | 1.6 x 0.53 | 3.87 | **4.53** |
| Bare soils  BBCH<10 | Small granivorous bird “finch” | | 11.4 | 1.6 x 0.53 | 3.87 | **4.53** |
| Bare soils  BBCH<10 | Small omnivorous bird “lark” | | 8.2 | 1.6 x 0.53 | 2.78 | 6.29 |
| Bare soils  BBCH<10 | Small insectivorous bird “wagtail” | | 5.9 | 1.6 x 0.53 | 2.00 | 8.74 |
| Bulbs & onion like crops  BBCH 10 - 39 | Small omnivorous bird “lark” | | 10.9 | 1.6 x 0.53 | 3.70 | **4.73** |
| Bulbs & onion like crops  BBCH 10 - 19 | Small insectivorous bird  “wagtail” | | 11.3 | 1.6 x 0.53 | 3.83 | **4.57** |

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

Table 9.2‑4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in Cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals | “Indicator species for screening” | | 158.8 | 1 | 180.56 | **7.87** |
| Cereals  Early (shoots) autumn-winter BBCH 10-29 | Large herbivorous bird "goose" | | 30.5 | 1 | 34.68 | 40.98 |
| Cereals  BBCH 10 - 29 | Small omnivorous bird “lark” | | 24 | 1 | 27.29 | 52.07 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | “Indicator species for screening” | | 64.8 | 1 x 0.53 | 39.05 | **0.45** |
| Cereals  Early (shoots) autumn-winter BBCH 10-29 | Large herbivorous bird “goose” | | 16.2 | 1 x 0.53 | 9.76 | **1.79** |
| Cereals  BBCH 10-29 | Small omnivorous bird “lark” | | 10.9 | 1 x 0.53 | 6.57 | **2.66** |

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

Table 9.2‑5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in winter oilseed rape

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter oilseed rape | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 910 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| oilseed rape | “Indicator species for screening” | | 158.8 | 1 | 144.51 | **9.83** |
| oilseed rape Early (shoots) BBCH 10-19 | Large herbivorous bird “goose” | | 39.0 | 1 | 35.49 | 40.04 |
| oilseed rape  BBCH 10-19 | Small omnivorous bird  “lark” | | 24 | 1 | 21.84 | 65.06 |
| oilseed rape  BBCH 10-19 | medium  herbivorous/grani vorous  bird "pigeon" | | 55.6 | 1 | 50.60 | 28.09 |
| oilseed rape  BBCH 10-19 | Small insectivorous bird  “wagtail” | | 10.9 | 1 | 9.92 | 143.26 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| oilseed rape | “Indicator species for screening” | | 64.8 | 1 x 0.53 | 31.25 | **0.56** |
| oilseed rape Early (shoots) BBCH 10-19 | Large herbivorous bird “goose” | | 15.9 | 1 x 0.53 | 7.67 | **2.28** |
| oilseed rape  BBCH 10-19 | Small omnivorous bird  “lark” | | 10.9 | 1 x 0.53 | 5.26 | **3.33** |
| oilseed rape  BBCH 10-19 | medium  herbivorous/grani vorous  bird "pigeon" | | 22.7 | 1 x 0.53 | 10.95 | **1.60** |
| oilseed rape  BBCH 10-19 | Small insectivorous bird  “wagtail” | | 5.9 | 1 x 0.53 | 2.85 | 6.15 |

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

Table 9.2‑6: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in bulbs and onion like crops

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | bulbs and onion like crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 3 × 200 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| bulbs and onion like crops | “Indicator species for screening” | | 158.8 | 1.6 | 50.82 | 27.96 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| bulbs and onion like crops | “Indicator species for screening | | 64.8 | 2.0 x 0.53 | 13.74 | **1.27** |
| bulbs and onion like crops BBCH 10-39 | Small granivoruos bird “finch” | | 11.4 | 2.0 x 0.53 | 2.42 | 7.24 |
| bulbs and onion like crops BBCH 10-39 | Small omnivorous bird  “lark” | | 10.9 | 2.0 x 0.53 | 2.31 | 7.57 |
| bulbs and onion like crops BBCH 10-19 | Small insectivorous bird  “wagtail” | | 11.3 | 2.0 x 0.53 | 2.40 | 7.31 |

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

Table 9.2‑6: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of pendimethalin 45.5% CS in bulbs and onion like crops

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | bulbs and onion like crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 × 1000 | | | | |
| Acute toxicity (mg/kg bw) | | 1421 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| bulbs and onion like crops | “Indicator species for screening” | | 158.8 | 1.4 | 222.32 | 6.39 |
| bulbs and onion like crops BBCH 10-39 | Small granivoruos bird “finch” | | 24.7 | 1.4 | 34.58 | 41.09 |
| bulbs and onion like crops BBCH 10-39 | Small omnivorous bird  “lark” | | 24.0 | 1.4 | 33.60 | 42.29 |
| bulbs and onion like crops BBCH 10-19 | Small insectivorous bird  “wagtail” | | 26.8 | 1.4 | 37.52 | 37.78 |
| Reprod. toxicity (mg/kg bw/d) | | 17.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| bulbs and onion like crops | “Indicator species for screening | | 64.8 | 1.6 x 0.53 | 54.95 | **0.32** |
| bulbs and onion like crops BBCH 10-39 | Small granivoruos bird “finch” | | 11.4 | 1.6 x 0.53 | 9.67 | **1.81** |
| bulbs and onion like crops BBCH 10-39 | Small omnivorous bird  “lark” | | 10.9 | 1.6 x 0.53 | 9.24 | **1.89** |
| bulbs and onion like crops BBCH 10-19 | Small insectivorous bird  “wagtail” | | 11.3 | 1.6 x 0.53 | 9.58 | **1.83** |

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

After the First-tier assessment, no acute risk was observed for birds in any of the crops, whereas long-term risk was observed in most of the crops and further assessment will be needed.

|  |
| --- |
| **zRMS comment:**  We agree with Tier 1 risk assessment provided by the applicant.  No acute risk was observed for birds in any of the crops, whereas long-term risk was observed in most of the crops and further assessment was needed. |

#### Higher-tier risk assessment

*Refinement of toxicity endpoint*

The value of 17.5 mg/kg bw/d is based on a 10% reduced bodyweight of 14-d old survivors and that this effect was only seen for one of the species and their hatchling weight did not differ from the controls (*Anas platyrhynchos* and not *Colinus virginianus*). Moreover, no other effects on mortality in ovo, egg shell strength, development, fertilisation rate and fecundity, were seen in the next treatment group of 181 mg/kg bw/d. Since growth of chicks is dependent on a variety of factors besides food, it is assumed that a dose of 181 mg/kg bw/d does not adversely affect population development. Therefore, it became evident that the long-term EU-agreed endpoint of 141 ppm (=17.5 mg/kg bw/d) is apparently not ecotoxicologically relevant and, as such, use of this endpoint leads to too conservative and overestimating assessment.

In the EFSA Journal 2016;14(3):4420, EFSA agreed with the refinement of the long-term endpoint for birds by using a BMDL5 of 61.5 mg/kg bw/d.

Therefore, the reproductive risk was refined using the NOEL of 61.5 mg as/kg bw/d for birds.

The resulting TER values are given in Tables below.

Table 9.2‑5: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in bare soil – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5\* | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bare soils  BBCH<10 | Small granivorous bird “finch” | | 11.4 | 1 x 0.53 | 9.67 | 6.36 |
| Bare soils  BBCH<10 | Small omnivorous bird “lark” | | 8.2 | 1 x 0.53 | 6.95 | 8.84 |
| Bare soils  BBCH<10 | Small insectivorous bird “wagtail” | | 5.9 | 1 x 0.53 | 5.00 | 12.29 |

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

Table 9.2‑8: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in Flower bulb and flower tuber crops (ornamentals) – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Flower bulb and flower tuber crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Ornamentals  Application to  plant – exposure to  underlying ground | Small insectivorous/worm  feeding species “thrush” | | 2.7 | 1 x 0.53 | 2.29 | 26.86 |

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

Table 9.2‑9: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in potatoes – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potatoes | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| potatoes | “Indicator species for screening” | | 64.8 | 1 x 0.53 | 39.05 | **1.57** |
| BBCH 10 - 39 | Small omnivorous bird “lark” | | 10.9 | 1 x 0.53 | 6.57 | 9.36 |
| BBCH ≥ 40 | Small omnivorous bird “lark” | | 3.3 | 1 x 0.53 | 1.99 | 30.93 |
| BBCH 10 - 19 | Small insectivorous bird  “wagtail” | | 11.3 | 1 x 0.53 | 6.81 | 9.03 |
| BBCH ≥ 20 | Small insectivorous bird  “wagtail” | | 9.7 | 1 x 0.53 | 5.85 | 10.52 |

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

Table 9.2‑10: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in bare soil (onion, shallots) – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 × 400 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5\* | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bare soils  BBCH<10 | Small granivorous bird “finch” | | 11.4 | 1.6 x 0.53 | 3.87 | 15.90 |
| Bulbs & onion like crops  BBCH 10 - 39 | Small omnivorous bird “lark” | | 10.9 | 1.6 x 0.53 | 3.70 | 16.63 |
| Bulbs & onion like crops  BBCH 10 - 19 | Small insectivorous bird  “wagtail” | | 11.3 | 1.6 x 0.53 | 3.83 | 16.05 |

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

Table 9.2‑11: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5\* | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals  Early (shoots) autumn-winter BBCH 10-29 | Large herbivorous bird “goose” | | 16.2 | 1 x 0.53 | 9.76 | 6.30 |
| Cereals  BBCH 10-29 | Small omnivorous bird “lark” | | 10.9 | 1 x 0.53 | 6.57 | 9.36 |

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

Table 9.2‑12: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in winter oilseed rape – refined parameters (\*) are further described and justified in the text winter oilseed rape

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter oilseed rape | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 910 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5\* | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| oilseed rape Early (shoots) BBCH 10-19 | Large herbivorous bird “goose” | | 15.9 | 1 x 0.53 | 7.67 | 8.02 |
| oilseed rape  BBCH 10-19 | Small omnivorous bird  “lark” | | 10.9 | 1 x 0.53 | 5.26 | 11.70 |
| oilseed rape  BBCH 10-19 | medium  herbivorous/grani vorous  bird "pigeon" | | 22.7 | 1 x 0.53 | 10.95 | 5.62 |

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

Table 9.2‑13: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Pendimethalin 45.5% CS in bulbs and onion like crops – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | bulbs and onion like crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 × 1000 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 61.5\* | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| bulbs and onion like crops BBCH 10-39 | Small granivoruos bird “finch” | | 11.4 | 1.6 x 0.53 | 9.67 | 6.36 |
| bulbs and onion like crops BBCH 10-39 | Small omnivorous bird  “lark” | | 10.9 | 1.6 x 0.53 | 9.24 | 6.65 |
| bulbs and onion like crops BBCH 10-19 | Small insectivorous bird  “wagtail” | | 11.3 | 1.6 x 0.53 | 9.58 | 6.42 |

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

No further refinement will be needed.

|  |
| --- |
| **zRMS comment:** Agreed. The TERlt value is above the trigger of 5 for all the following scenarios. No further refinement will be needed. The refinement risk assessment for birds should be considered by MSs level. |

#### Drinking water exposure

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

Leaf scenario

Since Pendimethalin 45.5% CS is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

With a K(f)oc of 13792 (EFSA Journal 2016;14(3):4420), pendimethalin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use cotton also covers the risk for birds from all other intended uses (see 9.1.1).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 1600 |  |  |
| Acute toxicity (mg/kg bw) = | 1421 | quotient = | 1.13 |
| Reprod. toxicity (mg/kg bw/d) = | 17.5 | quotient = | 91.43 |

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary.

|  |
| --- |
| **zRMS comment:**  We agree that since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary. |

#### Effects of secondary poisoning

The log Pow of pendimethalin amounts to 5.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required

Risk assessment for earthworm-eating birds via secondary poisoning

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group flower bulb and flower tuber crops also covers the risk for birds from all other intended uses (see 9.1.1)

Table 9.2‑14: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in cotton

| Parameter | pendimethalin | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 2.133 | Section 8, Chapter 8.7.2 |
| log Pow / Pow | 5.4 | EFSA Journal 2016;14(3):4420 |
| Koc | 13792 | EFSA Journal 2016;14(3):4420 |
| foc | 0.02 | Default |
| BCFworm | 10.93 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 23.32 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 22.48 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | 17.5 | EFSA Journal 2016;14(3):4420 |
| TERlt | **0.71** | Risk (TERlt<5) |

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger, further assessment with refined BMDL5 value of 61.5 mg/kg bw/d was conducted

Table 9.2‑15: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in cotton

| Parameter | pendimethalin | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 2.133 | Section 8, Chapter 8.7.2 |
| log Pow / Pow | 5.4 | EFSA Journal 2016;14(3):4420 |
| Koc | 13792 | EFSA Journal 2016;14(3):4420 |
| foc | 0.02 | Default |
| BCFworm | 10.93 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 21.38 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 22.45 | DDD = PECworm × 1.05 |
| BMDL5 (mg/kg bw/d) | 61.5 | EFSA Journal 2016;14(3):4420 |
| TERlt | **2.51** | Risk (TERlt<5) |

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger, further assessment is needed. A mean BCF of 0.81 is used in the refined risk assessment for earthworm-eating mammals, based on the study *Bioaccumulation in earthworms (laboratory study)* (Garret, 2000) (*Data from old dossier (Addendum B-8 Ecotoxicology, February 2002).*According to the *Conclusions of the* *peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420), the BCF is derived from the most reliable study and EFSA agrees on the use of this endpoint in the refinement.

Table 9.2‑16: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in cotton

| Parameter | pendimethalin | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 2.133 | Section 8, Chapter 8.7.2 |
| log Pow / Pow | 5.4 | EFSA Journal 2016;14(3):4420 |
| Koc | 13792 | EFSA Journal 2016;14(3):4420 |
| foc | 0.02 | Default |
| BCFworm | 0.81 | Study from RAR of bioaccumulation on earthworms (Garret, 2000) |
| PECworm | 1.73 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 1.81 | DDD = PECworm × 1.05 |
| BMDL5 (mg/kg bw/d) | 61.5 | EFSA Journal 2016;14(3):4420 |
| TERlt | 33.90 | No risk, TERlt>5 |

TER values shown in bold fall below the relevant trigger

Since the TERlt is above the trigger, the long-term risk of secondary poisoning to earthworm eating birds from the use of Pendimethalin 45.5% CS is acceptable.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comment:**  zRMS verified the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) taking into account the highest available BAF applied as a refined worst-case approach and PECsaccum.   | Parameter | Pendimethalin | Comments | | --- | --- | --- | | PECsoil accumulation, (mg/kg soil) | 2.877 | PECsoil accumulation (PECact + PECsoil plateau) | | log POW; POW | 5.4\*; 251188 | - | | KOC | 13792 | Arithmetic mean (n = 9) | | fOC | 0.02 | Default | | BAFWorm | 0.81\* |  | | PECWorm | 2.877 x 0.81=2.33 | PECworm = PECsoil × BAFworm/soil | | Daily dietary dose (mg/kg bw/d) | 2.33x1.05=2.44 | DDD = PECworm × 1.05 | | NOEL (mg/kg bw/d) | 61.5 | Refined endpoint: BMDL5 | | TERLT | 25.20 | TERLT = NOEL / DDD |   TER values shown in bold fall below the relevant trigger.  \* EFSA Journal 2016;14(3):4420  The risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable with BAF =0.81. |

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Table 9.2‑17: Assessment of the risk for fish-eating birds due to exposure to pendimethalin via bioaccumulation in fish (secondary poisoning) for the intended use in cotton

| Parameter | pendimethalin | comments |
| --- | --- | --- |
| PECsw (twa = 21 d) (mg/L) | 0.01471 | Section 8, point 8.9.2 (PECsw twa 21d, step 2; appln.hand crop < 50cm) |
| BCFfish | 931 | EFSA Journal 2016;14(3):4420 (most reliable endpoint) |
| BMF | CT50=5.1 days, 1.34 d ; 2.5 – 4.4 d  CT90: 87% depuration in 14 d; -; 96-97% clearance within 21 d (CT90 8.3-15 d)  Two outdoor mesocosm studies with a.s. pedimethalin targeted at bioconcentration are available:  *Lepomis macrochirus*, BMFKGL= 0.1054  *Oncorhynchus mykiss*  BMFKGL= 0.0402  BMFKGL= 0.0423  Outdoor mesocosms  *Leuciscus idus melanotus*  mean BCFactual conc = 199  aquatic community in outdoor mesocosms including fish  No evidence of biomagnification of either pendimethalin, its metabolites or equivalent radioactivity within the aquatic food chain.  NOEC fish: 0.0050 mg a.s./L | biomagnification factor (relevant for BCF ≥ 2000)  EFSA Journal 2016;14(3):4420 |
| PECfish | 7.258 | PECfish = PECwater × BCFfish × twa |
| Daily dietary dose (mg/kg bw/d) | 1.154 | DDD = PECfish × 0.159 |
| NOEL (mg/kg bw/d) | 17.5 | EFSA Journal 2016;14(3):4420 |
| TERlt | 15.16 | No risk, TER > 5 |

TER values shown in bold fall below the relevant trigger.

The TER is above the trigger, showing no risk for birds of secondary poisoning via fish.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comment:**  zRMS verified the risk for fish-eating birds due to exposure to pendimethalin via  bioaccumulation in fish (secondary poisoning) taking into account the lowest and the highest available  BCF values applied as a refined worst-case approach and max PECsw (Step 2).   | Parameter | Pendimethalin | Comments | | --- | --- | --- | | PECSW (mg/L) | 0.01471 | FOCUS Step 2, max PECSW | | BCFFish | 931 / 3300\* | Lowest and highest available BCF values | | PECFish | 13.69/48.54 | PECfish = PECwater × BCFfish | | Daily dietary dose (mg/kg bw/d) | 1.94/6.89 | DDD = PECfish × 0.142 | | NOEL (mg/kg bw/d) | 30 | Refined endpoint: BMDL5 | | TERLT | 15.46/**4.35** | TERLT = NOEL / DDD |   TER values shown in bold fall below the relevant trigger.  \* Highest and lowest BCF values available from EFSA Journal 2016;14(3):4420  The risk for fish -eating mammals due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is below trigger value. The 21d- PECsw,twa was used in risk assessment by zRMS.   | Parameter | Pendimethalin | Comments | | --- | --- | --- | | PECSW (mg/L) | 0.00965 | 21d- PECsw,twa | | BCFFish | 931 / 3300\* | Lowest and highest available BCF values | | PECFish | 8.98/31.845 | PECfish = PECwater × BCFfish | | Daily dietary dose (mg/kg bw/d) | 1.27/4.52 | DDD = PECfish × 0.142 | | NOEL (mg/kg bw/d) | 30 | Refined endpoint: BMDL5 | | TERLT | 23.62/7.05 | TERLT = NOEL / DDD |   TER values shown in bold fall below the relevant trigger.  \* Highest and lowest BCF values available from EFSA Journal 2016;14(3):4420  The risk for fish -eating mammals due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable. |

#### Biomagnification in terrestrial food chains

According to *Peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420):*“studies on three different species were available for assessing the bioconcentration factor (BCF) of pendimethalin in fish. The kinetic BCF ranged from 931 L/kg to 3,300 L/kg. The study providing the lowest BCF value was considered reliable, while the other two had some methodological flaws. However, the large difference between BCFs indicated that the bioconcentration of pendimethalin might be species-dependent, with higher bioconcentration for bluegill sunfish. This is consistent with the finding of the two available biomagnification (BMF) studies. These BMF studies were very much comparable (same protocol, author, laboratory, year, and tested batch) and showed that the BMF calculated for rainbow trout was less than a half of the BMF calculated for bluegill sunfish”*

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

Not relevant. Pendimethalin 45.5% CS is not intended for use as a bait, it is not a pellet, granule or prill, nor is it used for seed treatment.

### Overall conclusions

The risk assessment shows that there is no acute risk for birds after exposure to Pendimethalin 45.5% CS.

Most of the crops failed at Tier I for long-term exposure. The refinement of the chronic endpoint showed an acceptable long-term risk for birds.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating birds. The risk of secondary poisoning to earthworm eating birds was found acceptable after refinement.

Agreed.

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

### Toxicity data

Mammalian toxicity studies have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on mammals of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin.

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

Table 9.3‑1: Endpoints and effect values relevant for the risk assessment for mammals

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Mouse | Pendimethalin | Acute | LD50 (male) = 3399 mg/kg bw  LD50 (female) = 2899 mg/kg bw  LD50 (combined) = 3189 mg/kg bw | EFSA Journal 2016;14(3):4420 |
| Rat | Pendimethalin | Acute | LD50 (male) > 5000 mg/kg bw/d  LD50 (female) > 5000 mg/kg bw/d  LD50 (combined) > 5000 mg/kg bw/d | EFSA Journal 2016;14(3):4420 |
| Rat | Pendimethalin | Acute | LD50 (male) = 4665 mg/kg bw/d  LD50 (female) = 5000 mg/kg bw/d  LD50 (combined) = 4830 mg/kg bw/d | EFSA Journal 2016;14(3):4420 |
|  | Pendimethalin | Acute | Overall geomean LD50 = **3927** mg/kg bw/d | EFSA Journal 2016;14(3):4420 |
| Rat | Pendimethalin | Long-term  2-generation | NOAEL (parental and pup effects) = **30** mg/kg bw/d | EFSA Journal 2016;14(3):4420 |
| Rat | Pendimethalin | Long-term  Developmental | NOAELdevelopmental = 500 mg/kg bw/d | EFSA Journal 2016;14(3):4420 |
| Rabbit | Pendimethalin | Long-term  Developmental | NOAELdevelopmental = 30 mg/kg bw/d | EFSA Journal 2016;14(3):4420 |

**Metabolites**

See section 9.2.1. In conclusion, the risk from all metabolites is covered by the acute, reproductive and secondary poisoning risk assessments conducted for the parent.

#### Justification for new endpoints

The used endpoints are the EU agreed ones.

### Risk assessment for spray applications

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

In addition, the following is stated in the EFSA conclusion of pendimethalin (2016): *Although pendimethalin does not have a systemic mode of action, it may be taken up by plants from pre-emergence soil applications; also, palatable weeds may be over sprayed during such pre-emergence applications. Therefore, exposure of herbivorous and omnivorous vertebrate species to plants containing pendimethalin residues cannot be excluded also for pre-emergence applications. The standard bare soil scenario was therefore not considered protective enough in this case. To tackle this issue, TER calculations based on the post-emergence scenarios for herbivorous and omnivorous species (i.e. with plants in their diet) were also considered relevant to the pre-emergence applications.*

For winter cereals and onions that pre-emergence uses is covered by the submitted risk assessment on post-emergence uses but for potatoes and flower bulb and flower tuber crops an early post-emergence risk assessment for herbivorous, insectivorous and omnivorous mammals are presented below.

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

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

Table 9.3‑2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bare soil

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Bare soil | “Indicator species for screening” | | 14.4 | 1 | 23.04 | 170.44 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bare soil | “Indicator species for screening” | | 6.6 | 1 x 0.53 | 5.60 | 5.36 |

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

Table 9.3‑3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Flower bulb and flower tuber crops

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Flower bulb and flower tuber crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| ornamentals | “Indicator species for screening” | | 136,4 | 1 | 218.24 | 17.99 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| ornamentals | “Indicator species for screening” | | 72,3 | 1 x 0.53 | 61.31 | **0.49** |
| Application to  plant – exposure to  underlying ground | Small insectivorous mammal  “shrew” | | 1.9 | 1 x 0.53 | 1.61 | 18.62 |
| Application crop  directed BBCH 10 - 49 | Small omnivorous mammal  “mouse” | | 7.8 | 1 x 0.53 | 6.61 | **4.54** |

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

Table 9.3‑4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in potatoes

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potatoes | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| potatoes | “Indicator species for screening” | | 118.4 | 1 | 134.62 | 29.17 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| potatoes | “Indicator species for screening” | | 48.3 | 1 x 0.53 | 29.11 | **1.03** |
| BBCH 10 - 19 | Small insectivorous mammal  “shrew” | | 4.2 | 1 x 0.53 | 2.53 | 11.85 |
| BBCH 10 - 40 | Large herbivorous mammal  “lagomorph” | | 14.3 | 1 x 0.53 | 8.62 | **3.48** |
| BBCH 10 - 39 | Small omnivorous mammal  “mouse” | | 7.8 | 1 x 0.53 | 4.70 | 6.38 |

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

Table 9.3‑3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in bare soil (onion, shallots)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 × 400 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Bare soil | “Indicator species for screening” | | 14.4 | 1.4 | 8.06 | 487.22 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bare soil | “Indicator species for screening” | | 6.6 | 1.6 x 0.53 | 2.24 | 13.40 |

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

Table 9.3‑4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals | “Indicator species for screening” | | 118.4 | 1 | 134.62 | 29.17 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | “Indicator species for screening” | | 48.3 | 1 x 0.53 | 29.11 | **1.03** |
| Cereals  BBCH 10-19 | Small insectivorous mammal “shrew” | | 4.2 | 1x 0.53 | 2.53 | 11.85 |
| Cereals  Early (shoots) | Large herbivorous mammal “lagomorph” | | 22.3 | 1 x 0.53 | 13.44 | **2.23** |
| Cereals  BBCH 10-29 | Small omnivorous mammal “mouse” | | 7.8 | 1 x 0.53 | 4.70 | 6.38 |

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

Table 9.3‑5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in winter oilseed rape

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter oilseed rape | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 910 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Oilseed rape | “Indicator species for screening” | | 118.4 | 1 | 107.74 | 36.45 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Oilseed rape | “indicator species for screening” | | 48.3 | 1 x 0.53 | 23.30 | **1.29** |
| Oilseed rape BBCH 10-19 | Small insectivorous mammal “shrew” | | 4.2 | 1 x 0.53 | 2.03 | 14.81 |
| Oilseed rape All season | Large herbivorous mammal “lagomorph” | | 14.3 | 1 x 0.53 | 6.90 | **4.35** |
| Oilseed rape BBCH 10-29 | Small omnivorous mammal “mouse” | | 7.8 | 1 x 0.53 | 3.76 | 7.97 |

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

Table 9.3‑5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulbs and onion like crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 3 × 200 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Bulbs and onion like crops | “Indicator species for screening” | | 118.4 | 1.6 | 37.89 | 103.64 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bulbs and onion like crops | “indicator species for screening” | | 48.3 | 2.0 x 0.53 | 6.14 | **4.88** |
| Bulbs and onion like crops  BBCH 10-19 | Small insectivorous mammal “shrew” | | 4.2 | 2.0 x 0.53 | 0.53 | 56.18 |
| Bulbs and onion like crops  BBCH 10-39 | Small omnivorous mammal “mouse” | | 7.8 | 2.0 x 0.53 | 0.99 | 30.24 |

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

Table 9.3‑6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Bulbs and onion like crops

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulbs and onion like crops | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 × 1000 | | | | |
| Acute toxicity (mg/kg bw) | | 3927 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Bulbs and onion like crops | “Indicator species for screening” | | 118.4 | 1.4 | 165.75 | 23.69 |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Bulbs and onion like crops | “indicator species for screening” | | 48.3 | 1.6 x 0.53 | 24.58 | **1.22** |
| Bulbs and onion like crops  BBCH 10-19 | Small insectivorous mammal “shrew” | | 4.2 | 1.6 x 0.53 | 2.14 | 14.04 |
| Bulbs and onion like crops  BBCH 10-39 | Small omnivorous mammal “mouse” | | 7.8 | 1.6 x 0.53 | 3.97 | 7.56 |

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

After the first-tier risk assessment, no acute risk was observed for mammals in any of the crops. No long-term risk was observed for mammals in bare soil and bulbs, whereas for the other crops long-term risk was observed in some scenarios and then further assessment will be needed.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comment:**  After the first-tier risk assessment, the acute risk for mammals is considered as acceptable.  The acceptable long-term risk was observed for mammals in bare soil ( 2x 400 g pendimethalin/ha) and and bulbs and onion like crops (3 x 200 g/ha and 2 x 1000 g/ha), whereas for the other crops long-term risk was observed in some scenarios and then further assessment was needed for scenarios summerised in the table below:   |  |  |  | | --- | --- | --- | | Crop scenario  Growth stage | Indicator/generic focal species | TERlt | | Flower bulb and flower tuber crops  1 x 1600 g pendimethalin/ha | Small omnivorous mammal  “mouse”  application crop direct  BBCH 10-49 | **4.54** | | Potatoes  1 x 1137 g pendimethalin/ha | Large herbivorous mammal “lagomorph”  BBCH 10-40 | **3.48** | | Cereals 1 x 1137 g pendimethalinha | Cerels early shoots large herbivorous mammals  “lagomorph” | **2.23** | | Winter oilseed rape  1 x 910 g pendimethalin/ha | Oilseed rape all season  Large herbivorous mammal “lagomorph” | **4.35** | |

#### Higher-tier risk assessment

**DF refinement**

*Deposition factor (DF)*

PENTAGON will be applied directly to crop. Since grass will be covered by the crop, an interception by the crop has to be taken into account. Therefore, the Applicant considers that a deposition factor for the refinement is justified.

According to the interception values of EFSA Journal 2014;12(5):3662[[1]](#footnote-1), for winter oilseed rape, an interception factor 0.4 should be considered in used stage of growth (BBCH 10-19). Therefore, for the refinement of the risk a deposition factor 0.6 should be applied.

Table 9.3‑7: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in winter oilseed rape

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter oilseed rape | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 910 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA × DF | DDDm  (mg/kg bw/d) | TERlt |
| Oilseed rape All season | Large herbivorous mammal “lagomorph” | | 14.3 | 1 x 0.53×0.6 | 4.14 | 7.25 |

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

According to the interception values of EFSA Journal 2014;12(5):3662[[2]](#footnote-2), for flower, an interception factor 0.2 should be considered in used stage of growth (BBCH 10-19). Therefore, for the refinement of the risk a deposition factor 0.8 should be applied.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comments:**  The long-term risk is corrected in winter oilseed rape. The risk assessments should be as precise as possible to ensure effective protection. A DF of 0.8 might be a general estimate that lacks the precision needed for accurate risk assessment for lagomorphs in this specific context. In summary, while a DF of 0.8 might be a default value used in some contexts, it’s important to consider species-specific, ecological, and situational factors that could justify a different approach or a more tailored risk assessment for winter oilseed rape and lagomorphs. There might be insufficient empirical data to justify a DF of 0.8. Without robust data specifically related to lagomorphs in winter oilseed rape fields, using a default value could be misleading. More research or refined data might be needed to establish a more accurate risk assessment. Winter oilseed rape fields can vary in their ecological characteristics, such as the presence of cover or availability of food resources, which can affect lagomorph exposure and risk. A single DF may not account for this variability and could lead to over- or underestimations of risk. Lagomorphs can vary significantly in their sensitivity to pesticides and environmental factors. A DF of 0.8 might not accurately reflect the specific risks to the species of interest in winter oilseed rape fields. More precise risk factors tailored to the species’ biology and behavior might be needed.  The refinement risk assessment was performad by zRMS. Further, zRMS used for non-grass herbs the DT50 of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement.  Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of PENTAGON in winter oilseed rape – refined parameters (\*) are further described and justified in the text   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Intended use | | Winter oilseed rape | | | | | | | | Active substance/product | | Pendimethalin | | | | | | | | Application rate (g/ha) | | 1 × 910 | | | | | | | | Reprod. toxicity (mg/kg bw/d) | | 30 | | | | | | | | TER criterion | | 5 | | | | | | | | Focal species | Food category,  % in diet | | FIR/bw | RUDm × DF  (mg/kg food) | MAFm × TWA\* | PT | DDDm  (mg/kg bw/d) | TERlt | | Rabbit (*Oryctolagus cuniculus*) | 100% non-grass herbs. | | 0.50 | 28.7 x 1 | 1 x 0.20\* | 1 | 2.61 | 11.5 |   FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.  The TER is above the trigger showing no risk after the application of **PENTAGON**.  The long-term risk is considered as acceptable for rabbit in winter oilseed rape.  The refinement risk assessment should be considered by MSs level. |

Table 9.3‑7: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in Flower bulb and flower tuber crops (ornamentals)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Flower bulb and flower tuber crops (ornamentals) | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA×DF | DDDm  (mg/kg bw/d) | TERlt |
| Application crop  directed BBCH 10 - 49 | Small omnivorous mammal  “mouse” | | 7.8 | 1 × 0.53 × 0.8 | 6.61 | 5.67 |

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

According to the interception values of EFSA Journal 2014;12(5):3662[[3]](#footnote-3), for potatoes, an interception factor 0.5 should be considered in used stage of growth (BBCH 20-39). Therefore, for the refinement of the risk a deposition factor 0.5 should be applied.

|  |
| --- |
| **zRMS comments:** The trigger value at the 1 tier level is only slight below trigger of 5 (**4.54**) the risk can be considered as an acceptable. It should be noted that in the GAP the application of PPP PENTAGON in flower bulb and flower tuber crops is **BBCH 00-09 – pre emergence** not BBCH 10-49. Therefore, in our opinion in refinement risk assessment based on DF value is not needed. The risk assessment for mammals should be considered by MSs level. |

Table 9.3‑8: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of pendimethalin 45.5% CS in potatoes

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potatoes | | | | |
| Active substance/product | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA×DF | DDDm  (mg/kg bw/d) | TERlt |
| BBCH 10 - 40 | Large herbivorous mammal  “lagomorph” | | 14.3 | 1 × 0.53 × 0.5 | 8.62 | 6.96 |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comments:**  The long-term risk is corrected in potatoes.   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Intended use | | potatoes | | | | | | | | Active substance/product | | pendimethalin | | | | | | | | Application rate (g/ha) | | 1 × 1137 | | | | | | | | Reprod. toxicity (mg/kg bw/d) | | 30 | | | | | | | | TER criterion | | 5 | | | | | | | | Focal species | Food category,  % in diet | | FIR/bw | RUDm × DF  (mg/kg food) | MAFm × TWA\* | PT | DDDm  (mg/kg bw/d) | TERlt | | Rabbit (*Oryctolagus cuniculus*) | 100% non-grass herbs. | | 0.50 | 28.7 x 1 | 1 x 0.20 | 1 | 3.26 | 9.2 |   FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.  The refinement risk assessment was performad by zRMS. Further, zRMS used for non-grass herbs the DT50 of 3 days (from dicot plants, EFSA Conclusion) in the risk assessment, giving an ftwa of 0.2, which was also used in the higher tier refinement.  The TER is above the trigger showing no risk after the application of **PENTAGON**.  The refinement risk assessment should be considered by MSs level. |

**Refinement:**

***PT***

There are two available sources of PT data for hares. Prosser (2010[[4]](#footnote-4)) provides a 90th percentile estimate of PT of 0.69 for consumers only (*n* = 15) for winter cereals (September—November) in the UK. Grimm & Katzschner (2019) reported a generic ecological study to define PT in brown hares in early maize crops (BBCH growth stages 09 to 19) in Hungary and Germany. 24 hour observations of *n* = 21 individuals resulted in a 90th percentile PT estimate of 0.62. Therefore, the two estimates of activity of hares in early monocotyledonous crops are in accordance, providing some certainty that a PT in this range represents a reliable estimate of worst-case usage of an early growth stage cereal crop. A PT of 0.69 is used in the risk assessment for autumn uses as the worst-case value from the available studies.

|  |
| --- |
| **zRMS comment:** For further refinement PT value by Prosser, 2010 for brownhare was proposed by the applicant. zRMS is in the opinion that PT= 0.69 value, 90th percentile by Prosser 2010 for brown hare (consumer only) is accepted by zRMS to use in the risk assessment and may be considered at MSs level. |

***DT50 and twa***

In the first tier risk assessment a default foliar DT50 value of 10 days was considered. Sharda has conducted 3 residue decline studies in wheat in CEU countries to refine the DT50 value. The below table summarize the information of the trials as well as the calculated foliar DT50 values.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **Trial** | **BBCH** | **Application rate** | **Analyzed** | **Residues**  **(mg /kg)** | **Days** | **DT50 (days)** |
| Wheat | BPL17-010-03/Poland/N-EU/2017 | BBCH 25-30 | 1498 g a.s./ha | Whole plant | 6.79 | 0 | 5.73 |
| 2.80 | 1 |
| 3.19 | 2 |
| 2.68 | 3 |
| 1.19 | 4 |
| 1.16 | 5 |
| 1.15 | 6 |
| 1.22 | 7 |
| 1.34 | 8 |
| 1.49 | 9 |
| 1.46 | 10 |
| 0.68 | 13 |
| 0.78 | 14 |
| Wheat | CT17-1-47DE1/Germany/N-EU/2018 | BBCH 30 | 1498.6 g a.s./ha | Whole plant | 81 | 0 | 1.81 |
| 3.69 | 1 |
| 3.42 | 2 |
| 1.39 | 3 |
| 1.19 | 4 |
| 1.21 | 5 |
| 0.31 | 6 |
| 0.34 | 7 |
| 0.21 | 8 |
| 0.03 | 9 |
| 0.19 | 10 |
| 0.07 | 12 |
| 0.12 | 14 |
| Wheat | SRHU19-207-034HR/  Hungary/  NEU/  2019 | BBCH 30 | 1635.399 g a.s./ha | Whole plant | 146.48 | 0 | 2.79 |
| 102.99 | 1 |
| 90.25 | 2 |
| 83.17 | 3 |
| 27.51 | 4 |
| 17.14 | 5 |
| 27.56 | 6 |
| 26.83 | 7 |
| 16.54 | 8 |
| 31.34 | 9 |
| 13.47 | 10 |
| 11.03 | 12 |
| 2.91 | 14 |

The DT50 values have been calculated according to the formula given in Appendix H of the EFSA Journal 2009; 7(12):1438:

DT50 = - (t x ln2) / ln (Cfinal/Cmax)

Being:

t = time interval between sampling dates

Cmax: maximum residue level

Cfinal: last measured residue level

The resulting DT50 values were 5.73, 1.81 and 2.79 days. Based on those values, the geometric mean DT50 resulted to be 3.07 days. This DT50 value was used to refine the ftwa value and the resulting Twa value was 0.21.

The highest DT50 value of 5.73 d obtained from kinetic, which results in a MAFxTwa of 0.36 will be used in calculations belowe.

**zRMS comment:** The new value of DT50 = 5.73 d was not considered by zRMS-PL for using in refined risk assessment for mammals for cereals. The minimum requirement in order to have a reliable refinement of the dissipation as defined by the EFSA (four sites per regulatory zone) is also not fulfilled. As **PENTAGON** is intended for a use in central Europe and for a growth stage of winter cereals including pre-emergence and post emergence application (BBCH 00-9 and BBCH 10-13), the refinement based on DT50 of 5.73 d is only applicable for post-emergence applications (BBCH 25-30) but mostly **in spring cereals** for Central Zone. No spring cerelas are included in the GAP table. The refinement risk assessment should be considered by MSs level.

**In conclusion:**

The defult value of DT50 for winter cereals/weeds should be used. However, it should be noted that DT50 seems to be less than 10 days.

For non-grass herbs the DT50 of 3 days (from dicot plants, EFSA Conclusion) was used by zRMS in the risk assessment. The refinement risk assessment should be considered by MSs level.

*Consideration of focal species*

Large herbivorous

In cereals the generic focal species for large herbivorous is lagomorph. Both the rabbit and the hare can be present in all crops but its presence or absence can depend upon the surrounding habitat suitability rather that the crop itself. In the Northern Zone guidance for selection of species and scenarios for higher tier risk assessment (version 2.1; Northern Zone, 2020[[5]](#footnote-5)) the brown Hare *Lepus europaeus* is suggested as a focal species for winter and spring cereals at BBCH growth stage 10-29. The hare is considered to be more vulnerable species than the rabbit at population level either in abundance and/or distribution (Topping & Weyman 2017) and hence it is more relevant for the risk assessment.

Therefore, for the refined risk assessment of the large herbivorous mammal, the European hare (*Lepus europaeus*) will be used. A body weight of 3800 g and a FIR/bw of 0.32 (as given in EFSA guideline for grassland) will be considered since in this case it is assumed the conservative case of eating 100% grass (grass+cereals).

Table 9.3‑8: Higher-tier assessment of the long-term risk for mammals due to the use of Pendimethalin 45.5% CS in cereals – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | | | |
| Active substance/product | | pendimethalin | | | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | 30 | | | | | | |
| TER criterion | | 5 | | | | | | |
| Crop scenario  Growth stage | Focal species | | RUD | FIR/bw | MAF × fTWA | PT | DDDm  (mg/kg bw/d) | TERlt |
| Cereals early shoots | European hare | | 54.2 | 0.32 \* | ~~0.36~~  1 x 0.53 | 0.69 | ~~4.90~~  7.21 | ~~6.12~~  **4.1** |

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

Pre-emergence applications in cereals were covered by scenario bare soil and the risk was acceptable. For post-emergence applications the TER values are above the trigger after refinement, showing no risk.

**zRMS comment:** The risk for large herbivorous needs further refinement. The zRMS performed the refinement risk assessment for rabbit winter cereals (BBCH 10-13). For refinement risk assessment for cereals the PD 50/50 % value by Zoerner (1989) and FIR/bw=0.45 were considered by zRMS. This refinement value was accepted in report for **PENSHUI** (2022). Penshui is a plant protection product similar to Pentagon (it contains the same active substance content in the product, Applicant: Sharda Cropchem España SL). The ecotoxicology assessment report of this product is available on the CIRCA website. Zoerner (1989) [Zoerner, H. (1989): Lepus europaeus (Pallas), 286-321. In: Stubble, M. Buch der Hege Band 1 Haarwild. Deutscher Landwirtschaftsverlag, Berlin] summarises data from a study by Onder-scheka, et al., (1981) looking at hare diet from analysis of botanical composition of stomach contents (366 hares in 8 regions of Austria). This study showed that the average percentage stomach content of beet ranged from 0.0 to 9.1% and that cereals and grasses dominate the diet of hares (about 50% to 70%) which is supplemented by beets, alfalfa, red clover and various plants that often occur only individually.In a study by **Reitz & Léonard (1994)** [Reitz, F., Leonard, Y. (1994) characteristics of European hare Lepus europaeus use of space in a French agricultural region of intensive farming. Acta Theriologica 39 (2): 143-157] French hares were monitored for at least one month by radio-tracking in an intensely farmed landscape. The mean home range size was about 100 ha and the associated crops within the monitored area were wheat (47% of the area), sugar beet (19%), peas (11%), maize (5%) and potatoes (4%). According to above, it is considered that the same approach is adequate to assess the risk following application to cereals: the proportion of diet obtained from the treated area could be as high as 54% (crop leaves) to 72% (non-crop leaves). A generic PD value for rabbit should be 0.5 for non-grass herbs and 0.5 of grasses. The PD value should be considered by MSs level.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Intended use** | | | Winter cereals, BBCH 10-13 | | | | | | | |
| **Active substance/product** | | | Pendimethalin | | | | | | | |
| **Application rate (g/ha)** | | | 1 × 1137 | | | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | | | 30 | | | | | | | |
| **TER criterion** | | | 5 | | | | | | | |
| **Focal species** | **Food category,**  **% in diet** | **FIR/bw\*** | | **RUDm × DF**  **(mg/kg food)** | **MAFm × TWA** | **PT** | **PD** | **DDDm**  **(mg/kg bw/d)** | | **TERlt** |
| Rabbit (*Oryctolagus cuniculus*) | Cereals and grasses | 0.45 | | 54.2 x 1 | 0.53 | 1 | 0.5 | 7.34 | 8.8 | **3.41** |
| Non-grass herbs | 0.45 | | 28.7 x 1 | 0.2 | 1 | 0.5 | 1.47 |

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

TERLT is below the trigger of 5 when default value of DT50 =10 d for grasses/cereals is taken into consideration as the most conservative approach in case of pendimethalin.

For further refinement PT value by Prosser, 2010 for brownhare was proposed by the applicant. zRMS is in the opinion that PT= 0.69 value, 90th percentile by Prosser 2010 for brown hare (consumer only) is appropriate to use in the risk assessment and may be considered at MSs level, if relevant.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | | Winter cereals, BBCH 10-13 | | | | | | | |
| Active substance/product | | | Pendimethalin | | | | | | | |
| Application rate (g/ha) | | | 1 × 1137 | | | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | | 30 | | | | | | | |
| TER criterion | | | 5 | | | | | | | |
| Focal species | Food category,  % in diet | FIR/bw\* | | RUDm × DF  (mg/kg food) | MAFm × TWA | PT | PD | DDDm  (mg/kg bw/d) | | TERlt |
| Rabbit (*Oryctolagus cuniculus*) | Cereals and grasses | 0.45 | | 54.2 x 1 | 0.53 | 0.69 | 0.5 | 5.07 | 6.08 | **4.93** |
| Non-grass herbs | 0.45 | | 28.7 x 1 | 0.2 | 0.69 | 0.5 | 1.01 |

The trigger value at the higher tier is only slight below trigger of 5 (**4.93**) the risk can be considered as an acceptable. However, it should be noted that DT50 seems to be less than 10 days. For non-grass herbs the DT50 of 3 days (from dicot plants, EFSA Conclusion) was used by zRMS in the risk assessment.

**Updated November 2024**

According NL comment: The PT from a study with hares cannot be used for rabbit. Any justification is missing. Please remove.

RMS comment: We agree that using PT data from hares in risk assessments for rabbits may have some uncertainties. However, in our opinion in this case it is valid.

Justification:

1. **Similar Behavioral Ecology**

Hares and rabbits have overlapping behavioral patterns, such as grazing and resting in open fields. Although hares tend to range farther than rabbits, their activity patterns within similar habitats make their PT values comparable, especially in agricultural landscapes.

1. **Shared Habitat Use**

Both species often inhabit similar environments, such as farmland, grasslands, and forest edges. This shared habitat use suggests that their field exposure to pesticides will overlap in terms of time spent in treated areas.

1. **Dietary Overlap**

Hares and rabbits consume similar vegetation, including crops often treated with pesticides. Their foraging behaviors, particularly in agricultural fields, lead to comparable risks, making hare PT data relevant to rabbit exposure assessment.

1. **Conservation of Risk Factors**

The factors influencing PT—such as food availability, predator presence, and shelter—are broadly conserved between hares and rabbits, making data transferable between these species for risk modeling.

1. **Empirical Comparisons**

Studies on PT for hares and rabbits in shared environments often show similar exposure patterns, especially in areas with consistent agricultural practices. This empirical evidence supports the use of hare PT data as a proxy.

The using PT data from hares in risk assessments for rabbits should be considered by MSs level.

The risk assessment for mammals should be considered by MSs level.

#### Drinking water exposure

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

**Puddle scenario**

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

With a K(f)oc of 13792 (EFSA Journal 2016;14(3):4420), pendimethalin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cotton also covers the risk for mammals from all other intended uses (see 9.1.1).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 1600 |  |  |
| Acute toxicity (mg/kg bw) = | 3927 | quotient = | 0.41 |
| Reprod. toxicity (mg/kg bw/d) = | 30 | quotient = | 53.33 |

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary.

|  |
| --- |
| **zRMS comments:**  We agree that since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000 a quantitative risk assessment (calculation of TER values) is not necessary. |

#### Effects of secondary poisoning

The log Pow of pendimethalin amounts to 5.4 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required

Risk assessment for earthworm-eating mammals via secondary poisoning

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

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

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

| Parameter | Pendimethalin | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 1.956 | Section 8, Chapter 8.7.2 (cotton was worst case) |
| log Pow / Pow | 5.4 | EFSA Journal 2009;7(12):1438 |
| Koc | 13792 | Mean |
| foc | 0.02 | Default |
| BCFworm | 10.93 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 21.38 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 27.37 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 30 | EFSA Journal 2009;7(12):1438 |
| TERlt | **1.10** | Risk, TERlt<5 |

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger value, a mean BCF of 0.81 is used in the refined risk assessment for earthworm-eating mammals, based on the study *Bioaccumulation in earthworms (laboratory study)* (Garret, 2000) (*Data from old dossier (Addendum B-8 Ecotoxicology, February 2002).* According to the *Conclusions of the* *peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420), it is derived from the most reliable study and EFSA agrees on the use of this endpoint in the refinement.

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

| Parameter | Pendimethalin | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) | 2.133 | Section 8, Chapter 8.7.2 |
| log Pow / Pow | 5.4 | EFSA Journal 2016;14(3):4420 |
| Koc | 13792 | EFSA Journal 2016;14(3):4420 |
| foc | 0.02 | Default |
| BCFworm | 0.81 | Study from RAR of bioaccumulation on earthworms (Garret, 2000) |
| PECworm | 1.73 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 2.21 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 30 | EFSA Journal 2016;14(3):4420 |
| TERlt | 13.57 | No risk, TERlt>5 |

TER values shown in bold fall below the relevant trigger.

Since the TERlt is above the trigger, the long-term risk of secondary poisoning to earthworm eating mammals from the use of Pendimethalin 45.5% CS is acceptable.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comment:**  zRMS verified the risk for earthworm-eating mammals due to exposure to pendimethalin via  bioaccumulation in earthworms (secondary poisoning) taking into account the highest available  BAF applied as a refined worst-case approach and PECsaccum.   | Parameter | Pendimethalin | Comments | | --- | --- | --- | | PECsoil accumulation, (mg/kg soil) | 2.877 | PECsoil accumulation (PECact + PECsoil plateau) | | log POW; POW | 5.4\*; 251188 | - | | KOC | 13792 | Arithmetic mean (n = 9) | | fOC | 0.02 | Default | | BAFWorm | 0.81 | Refined BAF; worst-case approach | | PECWorm | 2.877 x 0.81 = 2.33 | PECworm = PECsoil × BAFworm/soil | | Daily dietary dose (mg/kg bw/d) | 2.33 x 1.28 = 2.98 | DDD = PECworm × 1.28 | | NOEL (mg/kg bw/d) | 30 | Refined endpoint: BMDL5 | | TERLT | 10.06 | TERLT = NOEL / DDD |   TER values shown in bold fall below the relevant trigger.  \* EFSA Journal 2016;14(3):4420  The risk for earthworm-eating mammals due to exposure to pendimethalin via bioaccumulation in  earthworms (secondary poisoning) is considered as acceptable. |

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Table 9.3‑11: Assessment of the risk for fish-eating mammals due to exposure to Pendimethalin via bioaccumulation in fish (secondary poisoning) for the intended use in cotton

|  |  |  |
| --- | --- | --- |
| Parameter | Pendimethalin | comments |
| PECsw (~~twa = 21 d~~) (mg/L) | 0.01471 | Section 8, point 8.9.2 ~~(PECsw twa 21d, step 2; appln.hand crop < 50cm)~~  FOCUS Step 2, max PECSW |
| BCFfish | 931 | EFSA Journal 2016;14(3):4420 (most reliable endpoint) |
| BMF | CT50=5.1 days, 1.34 d ; 2.5 – 4.4 d  CT90: 87% depuration in 14 d; -; 96-97% clearance within 21 d (CT90 8.3-15 d)  Two outdoor mesocosm studies with a.s. pedimethalin targeted at bioconcentration are available:  *Lepomis macrochirus*, BMFKGL= 0.1054  *Oncorhynchus mykiss*  BMFKGL= 0.0402  BMFKGL= 0.0423  Outdoor mesocosms  *Leuciscus idus melanotus*  mean BCFactual conc = 199  aquatic community in outdoor mesocosms including fish  No evidence of biomagnification of either pendimethalin, its metabolites or equivalent radioactivity within the aquatic food chain.  NOEC fish: 0.0050 mg a.s./L | biomagnification factor (relevant for BCF ≥ 2000)  EFSA Journal 2016;14(3):4420 |
| PECfish | 7.258 | PECfish = PECwater × BCFfish × twa |
| Daily dietary dose (mg/kg bw/d) | 1.154 | DDD = PECfish × 0.142 |
| NOEL (mg/kg bw/d) | 30 | EFSA Journal 2016;14(3):4420 |
| TERlt | 25.99 | No risk, TER > 5 |

TER values shown in bold fall below the relevant trigger.

The TER is above the trigger, showing no risk for mammals of secondary poisoning by fish.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comment:**  zRMS verified the risk for fish-eating birds due to exposure to pendimethalin via  bioaccumulation in fish (secondary poisoning) taking into account the lowest and the highest available  BCF values applied as a refined worst-case approach and max PECsw (Step 2).   | Parameter | Pendimethalin | Comments | | --- | --- | --- | | PECSW (mg/L) | 0.01471 | FOCUS Step 2, max PECSW | | BCFFish | 931 / 3300\* | Lowest and highest available BCF values | | PECFish | 13.69/48.54 | PECfish = PECwater × BCFfish | | Daily dietary dose (mg/kg bw/d) | 2.17/7.72 | DDD = PECfish × 0.159 | | NOEL (mg/kg bw/d) | 30 | Refined endpoint: BMDL5 | | TERLT | 13.82/**3.89** | TERLT = NOEL / DDD |   TER values shown in bold fall below the relevant trigger.  \* Highest and lowest BCF values available from EFSA Journal 2016;14(3):4420  The risk for fish -eating mammals due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is below trigger value. The 21d- PECsw,twa was used in risk assessment by zRMS.   | Parameter | Pendimethalin | Comments | | --- | --- | --- | | PECSW (mg/L) | 0.00965 | 21d- PECsw,twa | | BCFFish | 931 / 3300\* | Lowest and highest available BCF values | | PECFish | 8.98/31.85 | PECfish = PECwater × BCFfish | | Daily dietary dose (mg/kg bw/d) | 1.43/5.06 | DDD = PECfish × 0.159 | | NOEL (mg/kg bw/d) | 30 | Refined endpoint: BMDL5 | | TERLT | 20.98/5.93 | TERLT = NOEL / DDD |   TER values shown in bold fall below the relevant trigger.  \* Highest and lowest BCF values available from EFSA Journal 2016;14(3):4420  The risk for fish -eating mammals due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable. |

#### Biomagnification in terrestrial food chains

According to *Peer review of the pesticide risk assessment of the active substance pendimethalin* (EFSA Journal 2016;14(3):4420):*“studies on three different species were available for assessing the bioconcentration factor (BCF) of pendimethalin in fish. The kinetic BCF ranged from 931 L/kg to 3,300 L/kg. The study providing the lowest BCF value was considered reliable, while the other two had some methodological flaws. However, the large difference between BCFs indicated that the bioconcentration of pendimethalin might be species-dependent, with higher bioconcentration for bluegill sunfish. This is consistent with the finding of the two available biomagnification (BMF) studies. These BMF studies were very much comparable (same protocol, author, laboratory, year, and tested batch) and showed that the BMF calculated for rainbow trout was less than a half of the BMF calculated for bluegill sunfish”.*

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

Not relevant. Pendimethalin 45.5% CS is not a granule, nor is it intended for use as a bait or as seed treatment

### Overall conclusions

The risk assessment shows that there is no acute risk for mammals after exposure to Pendimethalin 45.5% CS. No long-term risk was observed for mammals in bare soil and bulbs and onion like crops, whereas for the other crops long-term risk was observed in some scenarios and further assessment was needed. After the refinement showed an acceptable long-term risk for mammals.

No unacceptable risk is expected from exposure to via drinking water and via secondary poisoning from fish-eating mammals. The risk of secondary poisoning to earthworm eating mammals was found acceptable.

The refinement risk assessment should be considered by MSs level.

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

According to EFSA Journal 2016;14(3):4420 for Pendimethalin: “*Based on information from the public literature, RMS concludes that the available data indicate that the risk for amphibians and reptiles is covered by the risk assessments for birds and mammals and aquatic organisms.*

## Effects on aquatic organisms (KCP 10.2)

### Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Pendimethalin and its relevant metabolties. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on aquatic organisms of Pendimethalin 45.5% SC were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Table 9.5‑1: Endpoints and effect values relevant for the risk assessment for aquatic organisms regarding Pendimethalin and relevant metabolites

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| **Fish** | | | | |
| *Oncorhynchus mykiss* | Pendimethalin | Acute 96 hr (static, with and without sediment) | Without sediment:  LC50 = **0.196** mg a.s./L mm  LC50 = 0.283 mg a.s./L mm | EFSA Journal 2016;14(3):4420 |
| *Pimephales promelas* | Pendimethalin | Acute 96 hr (flow-through) | LC50 > 0.240 mg a.s./L mm | EFSA Journal 2016;14(3):4420 |
| *Oncorhynchus mykiss* | BAS 455 48 H | Acute 96 hr (static) | LC50 = 8.427 mg prep./L  (3.263 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
| *Cyprinus carpio* | BAS 455 48 H | Acute 96 hr (static) | LC50 = 27.8 mg prep./L  (10.6 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
| *Oncorhynchus mykiss* | AG-P4-400-SC | Acute 96 hr (semi-static) | LC50 = 41.1 mg prep./L  (14.7 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
| *Oncorhynchus mykiss* | M455H001 (P44) | Acute 96 hr (static) | LC50 = 8.28 mg/L(nom) | EFSA Journal 2016;14(3):4420 |
| *Danio rerio* | Pendimethalin | Chronic (ELS) (static, in presence of sediment\*) | NOEC (growth) = 0.108 mg a.s./L(nom)  NOEAEC (35 d) = 0.300 mg a.s./L(nom) | EFSA Journal 2016;14(3):4420 |
| *Pimephales promelas* | Pendimethalin | Chronic (FFLC) (flow-through) | Reproduction NOEC = **0.0063 mg a.s./L(mm)**  BCF = 1810 L/Kg | EFSA Journal 2016;14(3):4420 |
| *Danio rerio* | Pendimethalin | Chronic (FFLC) (static, with sediment – exposure profile considered realistic to worst case) | NOEC (survival) = 20 µg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
| *Danio rerio* | Pendimethalin | Chronic (FFLC) (static, with sediment – exposure profile considered realistic to worst case) | NOEC (highest test concentration) = 50 µg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
|  |  |  | **Geomean *D. rerio* FFLC: 32 µg a.s./L (nom)\***  **\* nominal endpoint applicable for single peak exposure scenario’s only** | EFSA Journal 2016;14(3):4420 |
| **Aquatic invertebrates** | | | | |
| *Daphnia magna* | Pendimethalin | 48 h, s | EC50 = **0.147** mg a.s./L mm | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | Pendimethalin | 48 h (static, with and without sediment\*) | Without sediment:  EC50> 1.0 mg a.s./L (nom) / 0.701 (mm)  With sediment :  EC50> 1.0 mg a.s./L (nom) / 0.606 (mm) | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | BAS 455 48 H | 48 h, s | EC50 > 41.6 mg prep./L  (> 16.1 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | AG-P4-400-SC | 48 h (semi-static) | EC50 = 6.55 mg prep./L  (2.33 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | M455H033 (P48) | 48 h, s | EC50 = 0.613 mg/L(mm) | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | M455H001 (P44) | 48 h, s | EC50 = 7.73 mg/L(nom) | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | Pendimethalin | 21 d, f | NOEC(reproduction) = **0.0145 mg a.s./L nom** | EFSA Journal 2016;14(3):4420 |
| *Daphnia magna* | Pendimethalin | 21 d (semi-static) | NOEC(reproduction) = 0.0173 mg a.s./L nom | EFSA Journal 2016;14(3):4420 |
| **Sediment-dwelling organisms** | | | | |
| *Chironomus riparius* | Pendimethalin | 30 d, s, spiked water | NOEC = **0.082 mg a.s./l**  (219 mg a.s./kg sed dw (mm)) | EFSA Journal 2016;14(3):4420 |
| *Chironomus riparius* | Pendimethalin | 28 d (static, spiked water) | NOEC ≥0.0011 mg a.s./L (mm) | EFSA Journal 2016;14(3):4420 |
| *Chironomus riparius* | Pendimethalin | 28 d (static, spiked sediment) | NOEC = **227.3 mg a.s./kg dry sediment** **(im)**  (0.1099 mg a.s./L (im). 0.080 mg a.s./L(mm)) | EFSA Journal 2016;14(3):4420 |
| **Algae** | | | | |
| *Selenastrum capricornutum (syn. Pseudokirchneriella subcapitata)*  (freshwater green algae) | Pendimethalin | 72 h (static) | EbC50 = 0.0041 mg a.s./L (mm)  **ErC50 = 0.0093 mg a.s./L (mm)**  EyC50 = 0.0038 mg a.s./L (mm) | EFSA Journal 2016;14(3):4420 |
| Pendimethalin | 72 h (static) | ErC50 >0.055 mg a.s./L (mm)  EyC50 = 0.0043 mg a.s./L (mm) | EFSA Journal 2016;14(3):4420 |
| Pendimethalin | 72 h (static) | ErC50 = 0.0243 mg a.s./L (mm)  EyC50 = 0.0127 mg a.s./L (mm)  72 h + 7 d recovery period NOEC = > 0.050 (nom) | EFSA Journal 2016;14(3):4420 |
| *Anabaena flos-aquae*  (blue green algae) | Pendimethalin | 120 h (static) | EyC50 > 0.174 (mm) | EFSA Journal 2016;14(3):4420 |
| *Pseudokirchneriella subcapitata* | BAS 455 48 H | 72 h (static) | ErC50 = 1.13 mg prep./L (0.438 mg a.s./L (mm))  EyC50 = 0.164 mg prep./L (0.0635 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
| *Pseudokirchneriella subcapitata* | AG-P4-400-SC | 72 h (static) | ErC50 = 0.120 mg prep./L (0.0429 mg a.s./L (mm))  EyC50 = 0.0256 mg prep./L (0.00915 mg a.s./L (mm)) | EFSA Journal 2016;14(3):4420 |
|  | M455H033 (P48) | 72 h (static) | ErC50 > 1.45 mg/L(mm)  EyC50 = 0.498 mg/L(mm) | EFSA Journal 2016;14(3):4420 |
|  | M455H001 (P44) | 72 h (static) | ErC50 > 2.5 mg/L(nom)  EyC50 > 2.5 mg/L(nom) | EFSA Journal 2016;14(3):4420 |
|  | M455H032 | 72 h (static) | ErC50 = 1.48 mg/L(nom)  EbC50 = 0.90 mg/L(nom) | EFSA Journal 2016;14(3):4420 |
| **Higher plant** | | | | |
| *Lemna gibba* | Pendimethalin | 14 d, s | Frond number  ErC50 = 0.022 mg a.s./L (mm)  EyC50 = 0.0084 mg a.s./L mm) | EFSA Journal 2016;14(3):4420 |
| *Lemna gibba* | Pendimethalin | 7 d, s | Frond number  **ErC50 = 0.0156 mg a.s./L (im)/ 0.012 mg a.s./L (mm)**  EyC50 = 0.0064 mg a.s./L (im) /0.0049 mg a.s./L (mm) | EFSA Journal 2016;14(3):4420 |
| *Lemna gibba* | BAS 455 48 H | 7 d, ss | Frond number  ErC50 = 7.55 mg a.s./L (nom)  EyC50 = 1.74 mg a.s./L (nom)  Dry weight  ErC50 >39.2 mg a.s./L (nom)  EyC50 = 23.2 mg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
| *Lemna gibba* | AG-P4-400-SC | 7 d, ss | Frond number  ErC50 = 0.0366 mg a.s./L (nom)  EyC50 = 0.0122 mg a.s./L (nom)  Dry weight  ErC50 >0.263 mg a.s./L (nom)  EyC50 = 0.0366 mg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
| Further testing on aquatic organisms | | | | |
| In total 4 mesocosms are available. Since the representative formulations from both notifiers do not indicate a higher toxicity than the a.s. and the mesocosms show consistent results, it is considered acceptable to combine all mesocoms for the current risk assessment. However, it is noted that the study of Kubitza (2004) used a formulation containing pendimethanil together with picolinafen and therefore this study is considered as supportive information (agreement TC123).  In the study with Pendimethalin 330 EC the NOEAEC was determined in a range from 4 to 16 µg a.s./L (within the most sensitive groups phytoplankton and zooplankton). Taking into account however that the number of endpoints showing a class 3A effect was considerably lower in the 4 μg a.s./L treatment than in the 16 μg a.s./L treatment, and that in the study with the formulation BAS 455 48 H there were clear effects at 8.5 and 18.5 µg a.s./L, including class 5A effects, RMS derived an overall NOEAC for all available mesocosms of 5 µg a.s./L.  In TC 123 it was discussed if NOEAEC values can be used for risk assessment, since the applications may be in autumn, while all studies have been performed in spring/summer. If effects occur as result of the applications in autumn, then recovery may not be possible because of different climatic and ecological circumstances. Therefore it was agreed by the participants of the TC to use the NOEC values from the mesocosm studies for risk assessment.  Furthermore it was not agreed by the TC participants to take a geomean of the available mesocosm endpoints given that they are not equivalent endpoints and based on different ecological thresholds. It was agreed to take the lowest NOEC value of the studies and to lower the safety factor to take into account that several mesocosm studies are available.  Hence, based on all available information and the agreements from TC123 the NOEC of 0.23 μg as/L from the study of Ebke (2001) together with a safety factor of 1 should be used for risk assessment. This endpoint covers the higher tier risk assessment for all aquatic organisms groups, including sediment dwellers, except fish.  The exposure profiles in the mesocosms were checked by RMS and the use of nominal concentrations was considered acceptable.  However, looking at the RAC of 0.23 μg as/L based on the mesocosm studies, it appears that this value is lower than the lowest RAC based on tier 1 laboratory studies (0.38 μg as/L based on an algae study together with a safety factor of 10). Hence, the lowest NOEC form the mesocosm study with an SF of 1 is too much worst-case. It could be that this low value is the consequence of dose spacing in the study of Ebke (2001). Therefore Applicant proposes in this case to take the geomean of the NOEC values of the three valid mesocosm studies together with a safety factor of 2. The geomean value is 0.96 μg as/Land the **RAC is 0.48 μg as/L.** | | | | |
| Aquatic community in outdoor mesocosms; single treatment.  Endpoints:  Impact on pelagic and bentic species, phytoplankton and peryphyton, macrophytes. | BAS 455 24 H (400 g/L pendimethalin SC) | 128 d | NOEC = 0.00023 mg a.s./L (nom)  NOEAEC = 0.0011 mg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
| Aquatic community in outdoor mesocosms; single treatment..  Endpoints:  -macrophytes  -phytoplankton  -periphyton  -zooplankton  -functional pa-  rameters  (only supportive information) | BAS 701 00H (320 g/L pendimethalin + 16 g/L picolinafen) | 70 d | NOECpop = 0.0012 mg a.s./L (nom)  NOECcom = 0.0012 mg a.s./L (nom)  NOEAEC = 0.005 mg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
| Aquatic community in outdoor mesocosms; single treatment.  Endpoints:  macrophytes; phytoplankton  periphyton;  zooplankton;  macorzoobenthos. | Pendimethalin 330 EC | 84 d | NOECpop = 0.001 mg a.s./L (nom)  NOECcom = 0.001 mg a.s./L (nom)  NOEAEC = 0.004 to 0.016 mg a.s./L (nom) | EFSA Journal 2016;14(3):4420 |
| Aquatic community in outdoor mesocosms; single treatment.  Endpoints:  -macrophytes  -phytoplankton  -periphyton  -zooplankton  -functional pa-  rameters | BAS 455 48 H | 140 d | NOEC = 0.0038 mg a.s./L  NOEAEC = 0.0038 mg a.s./L | EFSA Journal 2016;14(3):4420 |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3)  Fish full life cycle (FFLC) testing with zebrafish suggest a weak estrogenic or anti-androgenic effects. Adult male zebrafish exposed to pendimethalin at levels <10μ/L showed increased vitellogenin and decreased 11-keto-testosterone levels. Adult male fish are most sensitive to this category of subsances and changes in these two biomarkers are commonly used to indicate substances which may interact with the estrogen receptor. In vitro assays and one modified uterotrophic assay from the literature, along with data from ToxCast indicate a potential interaction with ERα and/or ERβ. No effects upon reproduction (number, quality or survival of offspring) were seen in either the FFLCs nor the mammalian toxicology section that would indicate an ecological relevance of this potential interaction.  The results taken together indicate that pendimethalin interacts with the endocrine system in fish. In order to determine if this interaction leads to adverse effects on the population level, effects on population relevant endocrine related parameters need to be considered (i.e. growth, reproduction, sex ratio). The lowest concentration where such effects were observed in the two higher tier FFLC tests with D. rerio was: 80 μg/L (F1 single fish weight group A). This endpoint is higher than the lowest endpoint used in the long-term risk assessment for fish (i.e. NOEC 20 μg/L, based on day 28 F1 survival group B ), indicating that toxicity is driving the aquatic risk assessment. | | | | |

(nom) nominal concentration; (mm) mean measured concentration; prep: preparation; a.s.: active substance

\* Exposure profile in the study in presence of sediment was not considered realistic to worst case by RMS and therefore the use of the endpoint based nominal concentration as included in the study report is not justified. The study report contains analytical measurements, which can be used for a higher tier endpoint based on geomean measured concentrations if necessary at member state level.

Table 9.5‑2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Pendimethalin 45.5% CS

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Oncorhynchus mykiss* | Pendimethalin 45.5% CS | 96 h, static | LC50 = 9.24 mg f.p./L (3.57 mg a.s./L) | KCP 10.2.1-01  Murali, K. 2020  7887/2020 |
| *Daphnia magna* | Pendimethalin 45.5% CS | 48 h, static | EC50 = 47.16 mg f.p./L (18.22 mg a.s./L) | KCP 10.2.1-02  Rajeshwari, K. 2021  9010/2021 |
| *Raphidocelus subcapitata* | Pendimethalin 45.5% CS | 72 h | ErC50 = 1.233 mg f.p./L (0.476 mg a.s./L)  EyC50 = 0.386 mg f.p./L (0.149 mg a.s./L) | KCP 10.2.1-03  Radha, S. 2021  9008/2021 |
| *Lemna gibba* | Pendimethalin 45.5% CS | 7 d | ErC50 = 19.271 mg f.p./L (7.4 mg a.s./L)  EyC50 > 100 mg f.p./L (> 38.64 mg a.s./L) | KCP 10.2.1-04  Radha, S. 2021  9009/2021 |
| Higher-tier studies (micro- or mesocosm studies) | | | | |
| None | | | | |

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

#### Justification for new endpoints

Except for the formulation, the used endpoints are the EU agreed ones. However, for algae and aquatic macrophytes, the endpoints considered for the risk assessment were the ErC50 instead of EyC50, since according to the EFSA Journal 2013;11(/):3290, for algae and macrophytes, *growth rate is the preferred endpoint to be used*.

Applicant has conducted studies with the formulation Pendimethalin 45.5% CS and the endpoints of these studies were also used in the risk assessment.

### Risk assessment

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

The relevant global maximum FOCUS Step 1, 2 and 3 PECSW for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below.

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

Table 9.5‑3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Potato (1 x 1600 g as/ha)

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| **Step 1** | | | | | | | | | | | |
|  | 43.93 | **22.413** | **69.730** | **13.728** | **29.884** | **30.297** | **47.237** | **5.357** | **36.608** | 3800 | 0.167 |
| **Step 2** | | | | | | | | | | | |
| S-Europe (March-May) | 14.71 | **7.230** | **22.492** | **4.428** | **9.639** | **9.772** | **15.237** | **1.728** | **11.808** | 1580 | 0.070 |
| S-Europe (June-Sept) | 1210 | 0.053 |
| N-Europe  (March-May) | 838.08 | 0.034 |
| N-Europe  (June-Sept) |

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

Table 9.5‑4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of PENTAGON to Potato (1 x 1600 g as/ha)

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D3 ditch | 8.524 | 8.289 | **4.229** | **13.157** | **2.590** | **5.639** | **5.717** | **8.913** | **1.011** | 5.412 | 0.0002 |
| D4 pond | 0.294 | 0.334 | 0.170 | 0.530 | 0.104 | 0.227 | 0.230 | 0.359 | 0.041 | 1.654 | 0.0001 |
| D4 stream | 7.389 | 6.842 | **3.491** | **10.860** | **2.138** | **4.654** | **4.719** | **7.357** | 0.834 | 0.316 | 0.0000 |
| D6 1st ditch | 7.972 | 8.197 | **4.182** | **13.011** | **2.562** | **5.576** | **5.653** | **8.814** | **1.000** | 2.724 | 0.0001 |
| D6 2nd ditch | 8.617 | 8.332 | **4.251** | **13.225** | **2.604** | **5.668** | **5.746** | **8.959** | **1.016** | 7.270 | 0.0003 |
| R1 pond | 0.300 | 0.357 | 0.182 | 0.567 | 0.112 | 0.243 | 0.246 | 0.384 | 0.044 | 3.901 | 0.0002 |
| R1 stream | 5.616 | 5.727 | **2.922** | **9.090** | **1.790** | **3.896** | **3.950** | **6.158** | 0.698 | 7.532 | 0.0003 |
| R2 stream | 7.798 | 7.584 | **3.869** | **12.038** | **2.370** | **5.159** | **5.230** | **8.155** | 0.925 | 131.2 | 0.0058 |
| R3 stream | 5.651 | 8.063 | **4.114** | **12.798** | **2.520** | **5.485** | **5.561** | **8.670** | 0.983 | 8.541 | 0.0004 |

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

Table 9.5‑5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 3 calculations for the use of PENTAGON to Potato (1 x 1600 g as/ha) as refinement

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D3 ditch | 5.890 | **3.005** | **9.349** | **1.841** | **4.007** | **4.062** | **6.333** | 0.718 | **4.908** | 3.849 | 0.0002 |
| D4 pond | 0.237 | 0.121 | 0.376 | 0.074 | 0.161 | 0.163 | 0.255 | 0.029 | 0.198 | 1.180 | 0.0001 |
| D4 stream | 4.861 | **2.480** | **7.716** | **1.519** | **3.307** | **3.352** | **5.227** | 0.593 | **4.051** | 0.224 | 0.0000 |
| D6 1st ditch | 5.824 | **2.971** | **9.244** | **1.820** | **3.962** | **4.017** | **6.262** | 0.710 | **4.853** | 1.936 | 0.0001 |
| D6 2nd ditch | 5.920 | **3.020** | **9.397** | **1.850** | **4.027** | **4.083** | **6.366** | 0.722 | **4.933** | 5.172 | 0.0002 |
| R1 pond | 0.254 | 0.130 | 0.403 | 0.079 | 0.173 | 0.175 | 0.273 | 0.031 | 0.212 | 2.763 | 0.0001 |
| R1 stream | 4.069 | **2.076** | **6.459** | **1.272** | **2.768** | **2.806** | **4.375** | 0.496 | **3.391** | 5.462 | 0.0002 |
| R2 stream | 5.389 | **2.749** | **8.554** | **1.684** | **3.666** | **3.717** | **5.795** | 0.657 | **4.491** | 94.02 | 0.0041 |
| R3 stream | 5.729 | **2.923** | **9.094** | **1.790** | **3.897** | **3.951** | **6.160** | 0.699 | **4.774** | 6.135 | 0.0003 |

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

Table 9.5‑6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Winter cereals (1 x 1137 g as/ha)

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| **Step 1** | | | | | | | | | | | |
|  | 31.22 | **15.929** | **49.556** | **9.756** | **21.238** | **21.531** | **33.570** | **3.807** | **26.017** | 2700 | 0.119 |
| **Step 2** | | | | | | | | | | | |
| S-Europe (June-Sept) | 10.46 | **5.337** | **16.603** | **3.269** | **7.116** | **7.214** | **11.247** | **1.276** | **8.717** | 860.19 | **0.038** |
| S-Europe (Oct-Feb) | 1120 | **0.049** |
| N-Europe  (June-Sept) | 595.56 | **0.026** |
| N-Europe  (Oct-Feb) | 11.12 | **5.673** | **17.651** | **3.475** | **7.565** | **7.669** | **11.957** | **1.356** | **9.267** | 1390 | **0.061** |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D1 ditch | 7.201 | **3.674** | **11.430** | **2.250** | **4.899** | **4.966** | **7.743** | 0.878 | **6.001** | 14.88 | 0.0007 |
| D1 stream | 6.298 | **3.213** | **9.997** | **1.968** | **4.284** | **4.343** | **6.772** | 0.768 | **5.248** | 3.687 | 0.0002 |
| D2 ditch | 7.208 | **3.678** | **11.441** | **2.253** | **4.903** | **4.971** | **7.751** | 0.879 | **6.007** | 15.41 | 0.0007 |
| D2 stream | 6.413 | **3.272** | **10.179** | **2.004** | **4.363** | **4.423** | **6.896** | 0.782 | **5.344** | 13.72 | 0.0006 |
| D3 ditch | 7.099 | **3.622** | **11.268** | **2.218** | **4.829** | **4.896** | **7.633** | 0.866 | **5.916** | 3.890 | 0.0002 |
| D4 pond | 0.245 | 0.125 | 0.389 | 0.077 | 0.167 | 0.169 | 0.263 | 0.030 | 0.204 | 1.146 | 0.0001 |
| D4 stream | 6.154 | **3.140** | **9.768** | **1.923** | **4.186** | **4.244** | **6.617** | 0.750 | **5.128** | 1.303 | 0.0001 |
| D5 pond | 0.245 | 0.125 | 0.389 | 0.077 | 0.167 | 0.169 | 0.263 | 0.030 | 0.204 | 1.449 | 0.0001 |
| D5 stream | 6.640 | **3.388** | **10.540** | **2.075** | **4.517** | **4.579** | **7.140** | 0.810 | **5.533** | 1.845 | 0.0001 |
| D6 ditch | 7.177 | **3.662** | **11.392** | **2.243** | **4.882** | **4.950** | **7.717** | 0.875 | **5.981** | 15.00 | 0.0007 |
| R1 pond | 0.249 | 0.127 | 0.395 | 0.078 | 0.169 | 0.172 | 0.268 | 0.030 | 0.208 | 3.052 | 0.0001 |
| R1 stream | 4.678 | **2.387** | **7.425** | **1.462** | **3.182** | **3.226** | **5.030** | 0.570 | **3.898** | 9.833 | 0.0004 |
| R3 stream | 6.495 | **3.314** | **10.310** | **2.030** | **4.418** | **4.479** | **6.984** | 0.792 | **5.413** | 346.4 | 0.0152 |
| R4 stream | 4.707 | **2.402** | **7.471** | **1.471** | **3.202** | **3.246** | **5.061** | 0.574 | **3.923** | 3.625 | 0.0002 |

Table 9.5‑7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1600 g as/ha)

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| **Step 1** | | | | | | | | | | | |
|  | 43.93 | **22.413** | **69.730** | **13.728** | **29.884** | **30.297** | **47.237** | **5.357** | **36.608** | 3800 | 0.167 |
| **Step 2** | | | | | | | | | | | |
| S-Europe (June-Sept) | 14.71 | **7.505** | **23.349** | **4.597** | **10.007** | **10.145** | **15.817** | **1.794** | **12.258** | 1580 | 0.070 |
| S-Europe (Oct-Feb) |
| N-Europe  (June-Sept) | 15.64 | **7.980** | **24.825** | **4.888** | **10.639** | **10.786** | **16.817** | **1.907** | **13.033** | 1960 | 0.086 |
| N-Europe  (Oct-Feb) | 14.71 | **7.505** | **23.349** | **4.597** | **10.007** | **10.145** | **15.817** | **1.794** | **12.258** | 838.08 | 0.037 |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D3 ditch | 10.01 | **5.107** | **15.889** | **3.128** | **6.810** | **6.903** | **10.763** | **1.221** | **8.342** | 6.158 | 0.0003 |
| D4 pond | 0.345 | 0.176 | 0.548 | 0.108 | 0.235 | 0.238 | 0.371 | 0.042 | 0.288 | 2.050 | 0.0001 |
| D4 stream | 7.642 | **3.899** | **12.130** | **2.388** | **5.199** | **5.270** | **8.217** | 0.932 | **6.368** | 0.277 | 0.0000 |
| D6 1st ditch | 9.862 | **5.032** | **15.654** | **3.082** | **6.709** | **6.801** | **10.604** | **1.203** | **8.218** | 2.500 | 0.0001 |
| D6 2nd ditch | 10.10 | **5.153** | **16.032** | **3.156** | **6.871** | **6.966** | **10.860** | **1.232** | **8.417** | 14.30 | 0.0006 |
| R1 pond | 0.367 | 0.187 | 0.583 | 0.115 | 0.250 | 0.253 | 0.395 | 0.045 | 0.306 | 3.863 | 0.0002 |
| R1 stream | 6.598 | **3.366** | **10.473** | **2.062** | **4.488** | **4.550** | **7.095** | 0.805 | **5.498** | 8.996 | 0.0004 |
| R2 stream | 8.656 | **4.416** | **13.740** | **2.705** | **5.888** | **5.970** | **9.308** | **1.056** | **7.213** | 27.60 | 0.0012 |
| R3 stream | 9.338 | **4.764** | **14.822** | **2.918** | **6.352** | **6.440** | **10.041** | **1.139** | **7.782** | 3.027 | 0.0001 |
| R4 stream | 6.624 | **3.380** | **10.514** | **2.070** | **4.506** | **4.568** | **7.123** | 0.808 | **5.520** | 14.44 | 0.0006 |

Table 9.5‑8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1300 g as/ha) as first refinement

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D3 ditch | 8.129 | **4.147** | **12.903** | **2.540** | **5.530** | **5.606** | **8.741** | 0.991 | **6.774** | 5.005 | 0.0002 |
| D4 pond | 0.280 | 0.143 | 0.444 | 0.088 | 0.190 | 0.193 | 0.301 | 0.034 | 0.233 | 1.669 | 0.0001 |
| D4 stream | 6.209 | **3.168** | **9.856** | **1.940** | **4.224** | **4.282** | **6.676** | 0.757 | **5.174** | 0.225 | 0.0000 |
| D6 1st ditch | 8.012 | **4.088** | **12.717** | **2.504** | **5.450** | **5.526** | **8.615** | 0.977 | **6.677** | 2.030 | 0.0001 |
| D6 2nd ditch | 8.209 | **4.188** | **13.030** | **2.565** | **5.584** | **5.661** | **8.827** | **1.001** | **6.841** | 11.63 | 0.0005 |
| R1 pond | 0.298 | 0.152 | 0.473 | 0.093 | 0.203 | 0.206 | 0.320 | 0.036 | 0.248 | 3.133 | 0.0001 |
| R1 stream | 5.360 | **2.735** | **8.508** | **1.675** | **3.646** | **3.697** | **5.763** | 0.654 | **4.467** | 7.398 | 0.0003 |
| R2 stream | 7.032 | **3.588** | **11.162** | **2.198** | **4.784** | **4.850** | **7.561** | 0.858 | **5.860** | 22.68 | 0.0010 |
| R3 stream | 7.587 | **3.871** | **12.043** | **2.371** | **5.161** | **5.232** | **8.158** | 0.925 | **6.323** | 2.463 | 0.0001 |
| R4 stream | 5.381 | **2.745** | **8.541** | **1.682** | **3.661** | **3.711** | **5.786** | 0.656 | **4.484** | 11.83 | 0.0005 |

Table 9.5‑9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1000 g/ha + 1 x 300 g/ha) as second refinement

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D4 pond | 0.215/0.176 | 0.11/0.09 | 0.341/0.279 | 0.067/0.055 | 0.146/0.12 | 0.148/0.121 | 0.231/0.189 | 0.026/0.021 | 0.179/0.147 | 1.288/1.188 | <0.001/<0.001 |
| D4 stream | 4.775/4.129 | **2.436/2.107** | **7.579/6.554** | **1.492/1.29** | **3.248/2.809** | **3.293/2.848** | **5.134/4.44** | 0.582/0.504 | **3.979/3.441** | 0.173/0.186 | <0.001/<0.001 |
| D6 1st ditch | 6.162/5.385 | **3.144/2.747** | **9.781/8.548** | **1.926/1.683** | **4.192/3.663** | **4.25/3.714** | **6.626/5.79** | 0.751/0.657 | **5.135/4.488** | 1.561/1.924 | <0.001/<0.001 |
| D6 2nd ditch | 6.313/5.517 | **3.221/2.815** | **10.021/8.757** | **1.973/1.724** | **4.295/3.753** | **4.354/3.805** | **6.788/5.932** | 0.77/0.673 | **5.261/4.598** | 8.959/8.936 | <0.001/<0.001 |
| R1 pond | 0.229/0.210 | 0.117/0.107 | 0.363/0.333 | 0.072/0.066 | 0.156/0.143 | 0.158/0.145 | 0.246/0.226 | 0.028/0.026 | 0.191/0.175 | 2.404/3.133 | <0.001/<0.001 |
| R1 stream | 4.123/3.565 | **2.104/1.819** | **6.544/5.659** | **1.288/1.114** | **2.805/2.425** | **2.843/2.459** | **4.433/3.833** | 0.503/0.435 | **3.436/2.971** | 5.777/7.938 | <0.001/<0.001 |
| R3 stream | 5.835/5.046 | **2.977/2.574** | **9.262/8.01** | **1.823/1.577** | **3.969/3.433** | **4.024/3.48** | **6.274/5.426** | 0.712/0.615 | **4.862/4.205** | 1.898/2.381 | <0.001/<0.001 |
| R4 stream | 4.139/3.579 | **2.112/1.826** | **6.57/5.681** | **1.293/1.118** | **2.816/2.435** | **2.854/2.468** | **4.451/3.848** | 0.505/0.436 | **3.449/2.983** | 9.199/12.65 | <0.001/0.001 |

Table 9.5‑10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Bulb vegetables (2 x 650 g as/ha) as third refinement

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D4 stream | 2.700 | **1.378** | **4.286** | 0.844 | **1.837** | **1.862** | **2.903** | 0.329 | **2.250** | 0.187 | **<0.0001** |
| D6 1st ditch | 3.557 | **1.815** | **5.646** | **1.112** | **2.420** | **2.453** | **3.825** | 0.434 | **2.964** | 2.920 | **0.0001** |
| D6 2nd ditch | 3.768 | **1.922** | **5.981** | **1.178** | **2.563** | **2.599** | **4.052** | 0.460 | **3.140** | 9.217 | **0.0004** |
| R1 stream | 2.317 | **1.182** | **3.678** | 0.724 | **1.576** | **1.598** | **2.491** | 0.283 | **1.931** | 8.602 | **0.0004** |
| R3 stream | 3.280 | **1.673** | **5.206** | **1.025** | **2.231** | **2.262** | **3.527** | 0.400 | **2.733** | 2.405 | **0.0001** |
| R4 stream | 2.326 | **1.187** | **3.692** | 0.727 | **1.582** | **1.604** | **2.501** | 0.284 | **1.938** | 13.61 | **0.0006** |

Table 9.5‑11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Bulb vegetables (2 x 400 g as/ha) as fourth refinement

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D3 ditch | 2.500/2.188 | **1.276/1.116** | **3.968/3.473** | 0.781/0.684 | **1.701/1.488** | **1.724/1.509** | **2.688/2.353** | 0.305/0.267 | **2.083/1.823** | 1.543/2.366 | <0.001/<0.001 |
| D4 pond | 0.086/0.088 | 0.044/0.045 | 0.137/0.14 | 0.027/0.027 | 0.059/0.06 | 0.059/0.061 | 0.092/0.095 | 0.01/0.011 | 0.072/0.073 | 0.521/0.710 | <0.001/<0.001 |
| D4 stream | 1.909/1.661 | 0.974/0.847 | **3.03/2.637** | 0.597/0.519 | **1.299/1.13** | **1.317/1.146** | **2.053/1.786** | 0.233/0.203 | **1.591/1.384** | 0.069/0.109 | <0.001/<0.001 |
| D6 1st ditch | 2.464/2.188 | **1.257/1.116** | **3.911/3.473** | 0.77/0.684 | **1.676/1.488** | **1.699/1.509** | **2.649/2.353** | 0.3/0.267 | **2.053/1.823** | 0.623/1.800 | <0.001/<0.001 |
| D6 2nd ditch | 2.524/2.317 | **1.288/1.182** | **4.006/3.678** | 0.789/0.724 | **1.717/1.576** | **1.741/1.598** | **2.714/2.491** | 0.308/0.283 | **2.103/1.931** | 3.601/5.692 | <0.001/<0.001 |
| R1 pond | 0.092/0.128 | 0.047/0.065 | 0.146/0.203 | 0.029/0.04 | 0.063/0.087 | 0.063/0.088 | 0.099/0.138 | 0.011/0.016 | 0.077/0.107 | 0.954/1.929 | <0.001/<0.001 |
| R1 stream | 1.648/1.425 | 0.841/0.727 | **2.616/2.262** | 0.515/0.445 | **1.121/0.969** | **1.137/0.983** | **1.772/1.532** | 0.201/0.174 | **1.373/1.188** | 2.436/5.435 | <0.001/<0.001 |
| R2 stream | 2.162/1.999 | **1.103/1.02** | **3.432/3.173** | 0.676/0.625 | **1.471/1.36** | **1.491/1.379** | **2.325/2.149** | 0.264/0.244 | **1.802/1.666** | 7.445/103.7 | <0.001/0.005 |
| R3 stream | 2.333/2.018 | **1.19/1.03** | **3.703/3.203** | 0.729/0.631 | **1.587/1.373** | **1.609/1.392** | **2.509/2.17** | 0.285/0.246 | **1.944/1.682** | 0.765/1.491 | <0.001/<0.001 |
| R4 stream | 1.655/1.431 | 0.844/0.73 | **2.627/2.271** | 0.517/0.447 | **1.126/0.973** | **1.141/0.987** | **1.78/1.539** | 0.202/0.175 | **1.379/1.193** | 3.822/8.533 | <0.001/<0.001 |

Table 9.5‑12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1-2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1600 g as/ha)

| Group |  | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher plant |  | Sed. dweller prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *O. mykiss* | *P.promelas* | *Danio rerio* | *Daphnia magna* | *Daphnia magna* | *P. subcapitata* | *C. riparius* | *Lemna gibba* |  | *C. riparius* |
| Endpoint |  | LC50 | NOEC | NOEC geomean | EC50 | NOEC | ErC50 | NOEC | ErC50 |  | NOEC |
| (µg/L) |  | 196 | 6.3 | 32 | 147 | 14.5 | 9.3 | 82 | 12 |  | 227300 |
| AF |  | 100 | 10 | 10 | 100 | 10 | 10 | 10 | 10 |  | 10 |
| RAC (µg/L) |  | 1.96 | 0.63 | 3.2 | 1.47 | 1.45 | 0.93 | 8.2 | 1.2 |  | 22730 |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  |  | PEC gl-max (µg/kg) |  |
| **Step 1** | | | | | | | | | | | |
|  | 24.98 | **12.745** | **39.651** | **7.806** | **16.993** | **17.228** | **26.860** | **3.046** | **20.817** | 2160 | 0.095 |
| **Step 2** | | | | | | | | | | | |
| S-Europe (June-Sept) | 8.37 | **4.270** | **13.286** | **2.616** | **5.694** | **5.772** | **9.000** | **1.021** | **6.975** | 434.30 | 0.019 |
| S-Europe (Oct-Feb) | 561.38 | 0.025 |
| N-Europe  (June-Sept) | 307.22 | 0.014 |
| N-Europe  (Oct-Feb) | 688.45 | 0.030 |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |
| D2 ditch | 5.769 | **2.943** | **9.157** | **1.803** | **3.924** | **3.979** | **6.203** | 0.704 | **4.808** | 12.46 | 0.0005 |
| D2 stream | 5.132 | **2.618** | **8.146** | **1.604** | **3.491** | **3.539** | **5.518** | 0.626 | **4.277** | 11.10 | 0.0005 |
| D3 ditch | 5.719 | **2.918** | **9.078** | **1.787** | **3.890** | **3.944** | **6.149** | 0.697 | **4.766** | 5.199 | 0.0002 |
| D4 pond | 0.196 | 0.100 | 0.311 | 0.061 | 0.133 | 0.135 | 0.211 | 0.024 | 0.163 | 0.920 | <0.0001 |
| D4 stream | 4.925 | **2.513** | **7.817** | **1.539** | **3.350** | **3.397** | **5.296** | 0.601 | **4.104** | 1.043 | <0.0001 |
| D5 pond | 0.196 | 0.100 | 0.311 | 0.061 | 0.133 | 0.135 | 0.211 | 0.024 | 0.163 | 0.808 | <0.0001 |
| D5 stream | 5.314 | **2.711** | **8.435** | **1.661** | **3.615** | **3.665** | **5.714** | 0.648 | **4.428** | 1.429 | 0.0001 |
| R1 pond | 0.198 | 0.101 | 0.314 | 0.062 | 0.135 | 0.137 | 0.213 | 0.024 | 0.165 | 1.599 | 0.0001 |
| R1 stream | 3.765 | **1.921** | **5.976** | **1.177** | **2.561** | **2.597** | **4.048** | 0.459 | **3.138** | 2.617 | 0.0001 |
| R3 stream | 5.265 | **2.686** | **8.357** | **1.645** | **3.582** | **3.631** | **5.661** | 0.642 | **4.388** | 26.47 | 0.0012 |

For the all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PECSW considering reduced exposure of surface water bodies and the the endpoint of 0.23 µg a.s./L (mesocosms) with an AF of 1 as requested by the zRMS, resulting a RAC of 0.23 µg a.s./L Furthermore, VFSMOD calculation have been done as refinement for all R scenarios.

Table 9.5‑13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Potato (1 x 1600 g/ha)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Potato | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D3 ditch | 2.715 | 1.439 | 0.983 | 0.747 | - | - | - | - |
| 50% | 1.357 | 0.755 | 0.526 | 0.400 | - | - | - | - |
| 75% | 0.760 | 0.463 | 0.332 | 0.252 | - | - | - | - |
| 90% | 0.464 | 0.310 | 0.228 | 0.173 | - | - | - | - |
| None | D4 pond | 0.334 | 0.245 | 0.195 | - | - | - | - | - |
| 50% | 0.202 | 0.148 | - | - | - | - | - | - |
| 75% | - | - | - | - | - | - | - | - |
| None | D4 stream | 2.937 | 1.571 | 1.076 | 0.818 | - | - | - | - |
| 50% | 1.497 | 0.807 | 0.555 | 0.422 | - | - | - | - |
| 75% | 0.777 | 0.425 | 0.319 | 0.319 | - | - | - | - |
| 90% | 0.345 | 0.319 | 0.319 | 0.319 | - | - | - | - |
| None | D6 1st ditch | 2.685 | 1.423 | 0.972 | 0.739 | - | - | - | - |
| 50% | 1.342 | 0.711 | 0.563 | 0.563 | - | - | - | - |
| 75% | 0.698 | 0.563 | 0.563 | 0.563 | - | - | - | - |
| 90% | 0.563 | 0.563 | - | - | - | - | - | - |
| None | D6 2nd ditch | 2.729 | 1.447 | 0.988 | 0.751 | - | - | - | - |
| 50% | 1.364 | 0.701 | 0.724 | 0.724 | - | - | - | - |
| 75% | 0.758 | 0.724 | 0.724 | 0.724 | - | - | - | - |
| 90% | 0.724 | 0.724 | - | - | - | - | - | - |
| None | R1 pond | - | - | - | - | 0.356 | 0.259 | 0.204 | - |
| 50% | - | - | - | - | 0.217 | 0.159 | - | - |
| 75% | - | - | - | - | - | - | - | - |
| None | R1 stream | - | - | - | - | 2.484 | 1.340 | 0.923 | 0.702 |
| 50% | - | - | - | - | 1.298 | 0.737 | 0.565 | 0.385 |
| 75% | - | - | - | - | 1.058 | 0.737 | 0.565 | 0.385 |
| 90% | - | - | - | - | 1.058 | - | - | - |
| None | R2 stream | - | - | - | - | 3.282 | 1.761 | 1.208 | 0.919 |
| 50% | - | - | - | - | 1.686 | 0.915 | 0.630 | 0.479 |
| 75% | - | - | - | - | 0.888 | 0.492 | 0.341 | 0.260 |
| 90% | - | - | - | - | 0.409 | 0.238 | 0.183 | 0.128 |
| None | R3 stream | - | - | - | - | 3.434 | 1.845 | 1.269 | 0.965 |
| 50% | - | - | - | - | 1.784 | 0.983 | 0.681 | 0.518 |
| 75% | - | - | - | - | 1.122 | 0.783 | 0.601 | 0.410 |
| 90% | - | - | - | - | 1.122 | 0.783 | 0.601 | 0.410 |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D3 ditch | **11.804** | **6.257** | **4.274** | **3.248** | **-** | **-** | **-** | **-** |
| 50% | **5.900** | **3.283** | **2.287** | **1.739** | **-** | **-** | **-** | **-** |
| 75% | **3.304** | **2.013** | **1.443** | **1.096** | **-** | **-** | **-** | **-** |
| 90% | **2.017** | **1.348** | 0.991 | 0.752 | **-** | **-** | **-** | **-** |
| None | D4 pond | **1.452** | **1.065** | 0.848 | **-** | **-** | **-** | **-** | **-** |
| 50% | 0.878 | 0.643 | **-** | **-** | **-** | **-** | **-** | **-** |
| 75% | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D4 stream | **12.77** | **6.830** | **4.678** | **3.557** | **-** | **-** | **-** | **-** |
| 50% | **6.509** | **3.509** | **2.413** | **1.835** | **-** | **-** | **-** | **-** |
| 75% | **3.378** | **1.848** | **1.387** | **1.387** | **-** | **-** | **-** | **-** |
| 90% | **1.5** | **1.387** | **1.387** | **1.387** | **-** | **-** | **-** | **-** |
| None | D6 1st ditch | **11.674** | **6.187** | **4.226** | **3.213** | **-** | **-** | **-** | **-** |
| 50% | **5.835** | **3.091** | **2.448** | **2.448** | **-** | **-** | **-** | **-** |
| 75% | **3.035** | **2.448** | **2.448** | **2.400** | **-** | **-** | **-** | **-** |
| 90% | **2.448** | **2.448** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 2nd ditch | **11.865** | **6.291** | **4.296** | **3.265** | **-** | **-** | **-** | **-** |
| 50% | **5.93** | **3.048** | **3.148** | **3.148** | **-** | **-** | **-** | **-** |
| 75% | **3.296** | **3.148** | **3.148** | **3.148** | **-** | **-** | **-** | **-** |
| 90% | **3.148** | **3.148** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | R1 pond | **-** | **-** | **-** | **-** | **1.548** | **1.126** | 0.887 | **-** |
| 50% | **-** | **-** | **-** | **-** | 0.943 | 0.691 | **-** | **-** |
| 75% | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | R1 stream | **-** | **-** | **-** | **-** | **10.8** | **5.826** | **4.013** | **3.052** |
| 50% | **-** | **-** | **-** | **-** | **5.643** | **3.204** | **2.457** | **1.674** |
| 75% | **-** | **-** | **-** | **-** | **4.6** | **3.204** | **2.457** | **1.674** |
| 90% | **-** | **-** | **-** | **-** | **4.6** | **-** | **-** | **-** |
| None | R2 stream | **-** | **-** | **-** | **-** | **14.27** | **7.657** | **5.252** | **3.996** |
| 50% | **-** | **-** | **-** | **-** | **7.33** | **3.978** | **2.739** | **2.083** |
| 75% | **-** | **-** | **-** | **-** | **3.861** | **2.139** | **1.483** | **1.13** |
| 90% | **-** | **-** | **-** | **-** | **1.778** | **1.035** | 0.796 | 0.557 |
| None | R3 stream | **-** | **-** | **-** | **-** | **14.93** | **8.022** | **5.517** | **4.196** |
| 50% | **-** | **-** | **-** | **-** | **7.757** | **4.274** | **2.961** | **2.252** |
| 75% | **-** | **-** | **-** | **-** | **4.878** | **3.404** | **2.613** | **1.783** |
| 90% | **-** | **-** | **-** | **-** | **4.878** | **3.404** | **2.613** | **1.783** |

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

Table 9.5‑14: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Potato (1 x 1600 g/ha) VFSmod

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potato | | | | | | |
| Active substance | | pendimethalin | | | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | | | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | | | 20 |
| R1 pond | R1 pond | 0.344 | 0.250 | | 0.197 | | | - |
| 50% | 0.205 | 0.150 | | - | | | - |
| 75% | - | - | | - | | | - |
| R1 stream | R1 stream | 2.484 | 1.340 | | 0.923 | | | 0.702 |
| 50% | 1.298 | 0.716 | | 0.497 | | | 0.378 |
| 75% | 0.710 | 0.404 | | 0.284 | | | 0.216 |
| 90% | 0.357 | 0.217 | | 0.156 | | | - |
| R2 stream | R2 stream | 3.282 | 1.761 | | 1.208 | | | 0.919 |
| 50% | 1.686 | 0.915 | | 0.630 | | | 0.479 |
| 75% | 0.888 | 0.492 | | 0.341 | | | 0.260 |
| 90% | 0.409 | 0.238 | | 0.168 | | | 0.128 |
| R3 stream | R3 stream | 3.433 | 1.845 | | 1.269 | | | 0.965 |
| 50% | 1.784 | 0.983 | | 0.681 | | | 0.518 |
| 75% | 0.972 | 0.552 | | 0.388 | | | 0.295 |
| 90% | 0.502 | 0.312 | | 0.226 | | | 0.172 |
| RAC (µg/L) | | PEC/RAC ratio | | | | | | |
| 0.23 | |
| None | R1 pond | **1.496** | **1.087** | | | 0.857 | **-** | |
| 50% | 0.891 | 0.652 | | | **-** | **-** | |
| 75% | **-** | **-** | | | **-** | **-** | |
| None | R1 stream | **10.8** | **5.826** | | | **4.013** | **3.052** | |
| 50% | **5.643** | **3.113** | | | **2.161** | **1.643** | |
| 75% | **3.087** | **1.757** | | | **1.235** | 0.939 | |
| 90% | **1.552** | 0.943 | | | 0.678 | **-** | |
| None | R2 stream | **14.27** | **7.657** | | | **5.252** | **3.996** | |
| 50% | **7.33** | **3.978** | | | **2.739** | **2.083** | |
| 75% | **3.861** | **2.139** | | | **1.483** | **1.13** | |
| 90% | **1.778** | **1.035** | | | 0.73 | 0.557 | |
| None | R3 stream | **14.926** | **8.022** | | | **5.517** | **4.196** | |
| 50% | **7.757** | **4.274** | | | **2.961** | **2.252** | |
| 75% | **4.226** | **2.4** | | | **1.687** | **1.3** | |
| 90% | **2.183** | **1.357** | | | 0.983 | 0.748 | |

PEC/RAC ratios in potato (1x1600g/ha) are <1 when risk mitigation options are considered:

D3 ditch: 15m no spray buffer zone + 90% nozzle reduction.

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.

R1 pond: 15m no spray buffer zone with 15m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction

R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

R2 stream and R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction

Table 9.5‑15: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Potato (1 x 1137 g/ha) as refinement

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potato | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D3 ditch | 1.929 | 1.023 | 0.698 | 0.531 | - | - | - | - |
| 50% | 0.965 | 0.537 | 0.373 | 0.283 | - | - | - | - |
| 75% | 0.541 | 0.329 | 0.239 | 0.179 | - | - | - | - |
| 90% | 0.331 | 0.221 | 0.163 | - | - | - | - | - |
| None | D4 pond | 0.242 | 0.175 | - | - | - | - | - | - |
| 50% | 0.144 | - | - | - | - | - | - | - |
| None | D4 stream | 2.087 | 1.116 | 0.764 | 0.581 | - | - | - | - |
| 50% | 1.064 | 0.573 | 0.394 | 0.299 | - | - | - | - |
| 75% | 0.552 | 0.302 | 0.220 | 0.220 | - | - | - | - |
| 90% | 0.246 | 0.220 | - | - |  |  |  |  |
| None | D6 1st ditch | 1.908 | 1.011 | 0.691 | 0.525 | - | - | - | - |
| 50% | 0.953 | 0.505 | 0.386 | 0.386 | - | - | - | - |
| 75% | 0.496 | 0.386 | 0.386 | 0.386 | - | - | - | - |
| 90% | 0.386 | 0.386 | - | - |  |  |  |  |
| None | D6 2nd ditch | 1.939 | 1.028 | 0.702 | 0.534 | - | - | - | - |
| 50% | 0.969 | 0.537 | 0.495 | 0.495 | - | - | - | - |
| 75% | 0.540 | 0.495 | 0.495 | 0.495 | - | - | - | - |
| 90% | 0.495 | 0.495 | - | - |  |  |  |  |
| None | R1 pond | - | - | - | - | 0.253 | 0.183 | - | - |
| 50% | - | - | - | - | 0.155 | - | - | - |
| None | R1 stream | - | - | - | - | 1.765 | 0.953 | 0.655 | 0.498 |
| 50% | - | - | - | - | 0.923 | 0.517 | 0.396 | 0.270 |
| 75% | - | - | - | - | 0.742 | 0.517 | 0.396 | 0.270 |
| 90% | - | - | - | - | 0.742 | - | - | - |
| None | R2 stream | - | - | - | - | 2.332 | 1.251 | 0.858 | 0.652 |
| 50% | - | - | - | - | 1.198 | 0.650 | 0.447 | 0.340 |
| 75% | - | - | - | - | 0.631 | 0.350 | 0.242 | 0.184 |
| 90% | - | - | - | - | 0.291 | 0.169 | 0.128 | - |
| None | R3 stream | - | - | - | - | 2.440 | 1.311 | 0.901 | 0.685 |
| 50% | - | - | - | - | 1.268 | 0.699 | 0.484 | 0.367 |
| 75% | - | - | - | - | 0.785 | 0.548 | 0.421 | 0.287 |
| 90% | - | - | - | - | 0.785 | 0.548 | 0.421 | 0.287 |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D3 ditch | **8.387** | **4.448** | **3.035** | **2.309** | **-** | **-** | **-** | **-** |
| 50% | **4.196** | **2.335** | **1.622** | **1.23** | **-** | **-** | **-** | **-** |
| 75% | **2.352** | **1.43** | **1.039** | 0.778 | **-** | **-** | **-** | **-** |
| 90% | **1.439** | 0.961 | 0.709 | **-** | **-** | **-** | **-** | **-** |
| None | D4 pond | **1.052** | 0.761 | - | **-** | **-** | **-** | **-** | **-** |
| 50% | 0.626 | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D4 stream | **9.074** | **4.852** | **3.322** | **2.526** | **-** | **-** | **-** | **-** |
| 50% | **4.626** | **2.491** | **1.713** | **1.3** | **-** | **-** | **-** | **-** |
| 75% | **2.4** | **1.313** | 0.957 | 0.957 | **-** | **-** | **-** | **-** |
| 90% | **1.07** | 0.957 | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 1st ditch | **8.296** | **4.396** | **3.004** | **2.283** | **-** | **-** | **-** | **-** |
| 50% | **4.143** | **2.196** | **1.678** | **1.678** | **-** | **-** | **-** | **-** |
| 75% | **2.157** | **1.678** | **1.678** | **1.678** | **-** | **-** | **-** | **-** |
| 90% | **1.678** | **1.678** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 2nd ditch | **8.43** | **4.47** | **3.052** | **2.322** | **-** | **-** | **-** | **-** |
| 50% | **4.213** | **2.335** | **2.152** | **2.152** | **-** | **-** | **-** | **-** |
| 75% | **2.348** | **2.152** | **2.152** | **2.152** | **-** | **-** | **-** | **-** |
| 90% | **2.152** | **2.152** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | R1 pond | **-** | **-** | **-** | **-** | **1.1** | 0.796 | **-** | **-** |
| 50% | **-** | **-** | **-** | **-** | 0.674 | **-** | **-** | **-** |
| None | R1 stream | **-** | **-** | **-** | **-** | **7.674** | **4.143** | **2.848** | **2.165** |
| 50% | **-** | **-** | **-** | **-** | **4.013** | **2.248** | **1.722** | **1.174** |
| 75% | **-** | **-** | **-** | **-** | **3.226** | **2.248** | **1.722** | **1.174** |
| 90% | **-** | **-** | **-** | **-** | **3.226** | **-** | **-** | **-** |
| None | R2 stream | **-** | **-** | **-** | **-** | **10.139** | **5.439** | **3.73** | **2.835** |
| 50% | **-** | **-** | **-** | **-** | **5.209** | **2.826** | **1.943** | **1.478** |
| 75% | **-** | **-** | **-** | **-** | **2.743** | **1.522** | **1.052** | 0.8 |
| 90% | **-** | **-** | **-** | **-** | **1.265** | 0.735 | 0.557 | **-** |
| None | R3 stream | **-** | **-** | **-** | **-** | **10.609** | **5.7** | **3.917** | **2.978** |
| 50% | **-** | **-** | **-** | **-** | **5.513** | **3.039** | **2.104** | **1.596** |
| 75% | **-** | **-** | **-** | **-** | **3.413** | **2.383** | **1.83** | **1.248** |
| 90% | **-** | **-** | **-** | **-** | **3.413** | **2.383** | **1.83** | **1.248** |

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

Table 9.5‑16: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Potato (1 x 1137 g/ha) as refinement VFSmod

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | potato | | | | | | |
| Active substance | | pendimethalin | | | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | | | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | | | 20 |
| R1 pond | R1 pond | 0.245 | 0.177 | | - | | | - |
| 50% | 0.146 | - | | - | | | - |
| 75% | - | - | | - | | | - |
| R1 stream | R1 stream | 1.765 | 0.953 | | 0.655 | | | 0.498 |
| 50% | 0.923 | 0.509 | | 0.353 | | | 0.268 |
| 75% | 0.505 | 0.288 | | 0.201 | | | 0.153 |
| 90% | 0.254 | 0.155 | | - | | | - |
| R2 stream | R2 stream | 2.332 | 1.251 | | 0.858 | | | 0.652 |
| 50% | 1.198 | 0.650 | | 0.447 | | | 0.340 |
| 75% | 0.631 | 0.349 | | 0.242 | | | 0.184 |
| 90% | 0.291 | 0.169 | | 0.119 | | | - |
| R3 stream | R3 stream | 2.440 | 1.311 | | 0.901 | | | 0.685 |
| 50% | 1.268 | 0.699 | | 0.484 | | | 0.367 |
| 75% | 0.691 | 0.393 | | 0.276 | | | 0.209 |
| 90% | 0.357 | 0.223 | | 0.160 | | | - |
| RAC (µg/L) | | PEC/RAC ratio | | | | | | |
| 0.23 | |
| None | R1 pond | **1.065** | 0.77 | | | **-** | **-** | |
| 50% | 0.635 | **-** | | | **-** | **-** | |
| 75% | **-** | **-** | | | **-** | **-** | |
| None | R1 stream | **7.674** | **4.143** | | | **2.848** | **2.165** | |
| 50% | **4.013** | **2.213** | | | **1.535** | **1.165** | |
| 75% | **2.196** | **1.252** | | | 0.874 | 0.665 | |
| 90% | **1.104** | 0.674 | | | **-** | **-** | |
| None | R2 stream | **10.139** | **5.439** | | | **3.73** | **2.835** | |
| 50% | **5.209** | **2.826** | | | **1.943** | **1.478** | |
| 75% | **2.743** | **1.517** | | | **1.052** | 0.8 | |
| 90% | **1.265** | 0.735 | | | 0.517 | **-** | |
| None | R3 stream | **10.609** | **5.7** | | | **3.917** | **2.978** | |
| 50% | **5.513** | **3.039** | | | **2.104** | **1.596** | |
| 75% | **3.004** | **1.709** | | | **1.2** | 0.9 | |
| 90% | **1.552** | 0.97 | | | 0.696 | **-** | |

PEC/RAC ratios in maize are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.

D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction

R1 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

R2 stream and R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

Table 9.5‑17: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals (1 x 1137 g/ha)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter cereals | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D1 ditch | 1.966 | 1.070 | 0.741 | 0.562 | - | - | - | - |
| 50% | 1.064 | 0.615 | 0.433 | 0.328 | - | - | - | - |
| 75% | 0.644 | 0.402 | 0.291 | 0.221 | - | - | - | - |
| 90% | 0.420 | 0.269 | 0.210 | - | - | - | - | - |
| None | D1 stream | 2.303 | 1.222 | 0.835 | 0.635 | - | - | - | - |
| 50% | 1.153 | 0.612 | 0.418 | 0.318 | - | - | - | - |
| 75% | 0.580 | 0.342 | 0.244 | 0.185 | - | - | - | - |
| 90% | 0.346 | 0.237 | 0.176 | - | - | - | - | - |
| None | D2 ditch | 1.973 | 1.074 | 0.745 | 0.565 | - | - | - | - |
| 50% | 1.071 | 0.619 | 0.436 | 0.330 | - | - | - | - |
| 75% | 0.652 | 0.407 | 0.295 | 0.223 | - | - | - | - |
| 90% | 0.424 | 0.286 | 0.212 | - | - | - | - | - |
| None | D2 stream | 2.345 | 1.244 | 0.850 | 0.646 | - | - | - | - |
| 50% | 1.174 | 0.623 | 0.426 | 0.324 | - | - | - | - |
| 75% | 0.589 | 0.313 | 0.214 | 0.163 | - | - | - | - |
| 90% | 0.238 | 0.131 | - | - | - | - | - | - |
| None | D3 ditch | 1.923 | 1.019 | 0.696 | 0.530 | - | - | - | - |
| 50% | 0.964 | 0.537 | 0.373 | 0.283 | - | - | - | - |
| 75% | 0.540 | 0.323 | 0.231 | 0.175 | - | - | - | - |
| 90% | 0.323 | 0.215 | 0.159 | - | - | - | - | - |
| None | D4 pond | 0.240 | 0.174 | - | - | - | - | - | - |
| 50% | 0.143 | - | - | - | - | - | - | - |
| None | D4 stream | 2.252 | 1.197 | 0.820 | 0.623 | - | - | - | - |
| 50% | 1.144 | 0.624 | 0.431 | 0.327 | - | - | - | - |
| 75% | 0.611 | 0.342 | 0.239 | 0.182 | - | - | - | - |
| 90% | 0.305 | 0.189 | 0.178 | - | - | - | - | - |
| None | D5 pond | 0.245 | 0.178 | - | - | - | - | - | - |
| 50% | 0.146 | - | - | - | - | - | - | - |
| None | D5 stream | 2.429 | 1.288 | 0.880 | 0.669 | - | - | - | - |
| 50% | 1.223 | 0.666 | 0.459 | 0.349 | - | - | - | - |
| 75% | 0.651 | 0.370 | 0.260 | 0.197 | - | - | - | - |
| 90% | 0.336 | 0.212 | 0.155 | - | - | - | - | - |
| None | D6 ditch | 1.971 | 1.077 | 0.748 | 0.568 | - | - | - | - |
| 50% | 1.076 | 0.621 | 0.438 | 0.331 | - | - | - | - |
| 75% | 0.659 | 0.411 | 0.305 | 0.305 | - | - | - | - |
| 90% | 0.429 | 0.305 | 0.305 | 0.305 | - | - | - | - |
| None | R1 pond | - | - | - | - | 0.249 | 0.180 | - | - |
| 50% | - | - | - | - | 0.151 | - | - | - |
| None | R1 stream | - | - | - | - | 1.766 | 0.952 | 0.654 | 0.497 |
| 50% | - | - | - | - | 0.917 | 0.575 | 0.441 | 0.301 |
| 75% | - | - | - | - | 0.826 | 0.575 | 0.441 | 0.301 |
| 90% | - | - | - | - | 0.826 | - | - | - |
| None | R3 stream | - | - | - | - | 2.438 | 1.313 | 0.902 | 0.685 |
| 50% | - | - | - | - | 1.263 | 0.690 | 0.478 | 0.363 |
| 75% | - | - | - | - | 0.794 | 0.554 | 0.425 | 0.290 |
| 90% | - | - | - | - | 0.794 | 0.554 | 0.425 | 0.290 |
| None | R4 stream | - | - | - | - | 1.773 | 0.959 | 0.660 | 0.501 |
| 50% | - | - | - | - | 1.012 | 0.703 | 0.539 | 0.367 |
| 75% | - | - | - | - | 1.012 | 0.703 | 0.539 | 0.367 |
| 90% | - | - | - | - | - | - | - | - |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D1 ditch | **8.548** | **4.652** | **3.222** | **2.443** | **-** | **-** | **-** | **-** |
| 50% | **4.626** | **2.674** | **1.883** | **1.426** | **-** | **-** | **-** | **-** |
| 75% | **2.8** | **1.748** | **1.265** | 0.961 | **-** | **-** | **-** | **-** |
| 90% | **1.826** | **1.17** | 0.913 | **-** | **-** | **-** | **-** | **-** |
| None | D1 stream | **10.013** | **5.313** | **3.63** | **2.761** | **-** | **-** | **-** | **-** |
| 50% | **5.013** | **2.661** | **1.817** | **1.383** | **-** | **-** | **-** | **-** |
| 75% | **2.522** | **1.487** | **1.061** | 0.804 | **-** | **-** | **-** | **-** |
| 90% | **1.504** | **1.03** | 0.765 | **-** | **-** | **-** | **-** | **-** |
| None | D2 ditch | **8.578** | **4.67** | **3.239** | **2.457** | **-** | **-** | **-** | **-** |
| 50% | **4.657** | **2.691** | **1.896** | **1.435** | **-** | **-** | **-** | **-** |
| 75% | **2.835** | **1.77** | **1.283** | 0.97 | **-** | **-** | **-** | **-** |
| 90% | **1.843** | **1.243** | 0.922 | **-** | **-** | **-** | **-** | **-** |
| None | D2 stream | **10.196** | **5.409** | **3.696** | **2.809** | **-** | **-** | **-** | **-** |
| 50% | **5.104** | **2.709** | **1.852** | **1.4** | **-** | **-** | **-** | **-** |
| 75% | **2.561** | **1.361** | 0.93 | 0.709 | **-** | **-** | **-** | **-** |
| 90% | **1.035** | 0.57 | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D3 ditch | **8.361** | **4.43** | **3.026** | **2.304** | **-** | **-** | **-** | **-** |
| 50% | **4.191** | **2.335** | **1.622** | **1.23** | **-** | **-** | **-** | **-** |
| 75% | **2.348** | **1.404** | **1.004** | 0.761 | **-** | **-** | **-** | **-** |
| 90% | **1.404** | 0.935 | 0.691 | **-** | **-** | **-** | **-** | **-** |
| None | D4 pond | **1.043** | 0.757 | - | **-** | **-** | **-** | **-** | **-** |
| 50% | 0.622 | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D4 stream | **9.791** | **5.204** | **3.565** | **2.709** | **-** | **-** | **-** | **-** |
| 50% | **4.974** | **2.713** | **1.874** | **1.422** | **-** | **-** | **-** | **-** |
| 75% | **2.657** | **1.487** | **1.039** | 0.791 | **-** | **-** | **-** | **-** |
| 90% | **1.326** | 0.822 | 0.774 | **-** | **-** | **-** | **-** | **-** |
| None | D5 pond | **1.065** | 0.774 | - | **-** | **-** | **-** | **-** | **-** |
| 50% | 0.635 | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D5 stream | **10.561** | **5.6** | **3.826** | **2.909** | **-** | **-** | **-** | **-** |
| 50% | **5.317** | **2.896** | **1.996** | **1.517** | **-** | **-** | **-** | **-** |
| 75% | **2.83** | **1.609** | **1.13** | 0.857 | **-** | **-** | **-** | **-** |
| 90% | **1.461** | 0.922 | 0.674 | **-** | **-** | **-** | **-** | **-** |
| None | D6 ditch | **8.57** | **4.683** | **3.252** | **2.47** | **-** | **-** | **-** | **-** |
| 50% | **4.678** | **2.7** | **1.904** | **1.439** | **-** | **-** | **-** | **-** |
| 75% | **2.865** | **1.787** | **1.326** | **1.326** | **-** | **-** | **-** | **-** |
| 90% | **1.865** | **1.326** | **1.326** | **1.326** | **-** | **-** | **-** | **-** |
| None | R1 pond | **-** | **-** | **-** | **-** | **1.083** | 0.783 | **-** | **-** |
| 50% | **-** | **-** | **-** | **-** | 0.657 | **-** | **-** | **-** |
| None | R1 stream | **-** | **-** | **-** | **-** | **7.678** | **4.139** | **2.843** | **2.161** |
| 50% | **-** | **-** | **-** | **-** | **3.987** | **2.5** | **1.917** | **1.309** |
| 75% | **-** | **-** | **-** | **-** | **3.591** | **2.5** | **1.917** | **1.309** |
| 90% | **-** | **-** | **-** | **-** | **3.591** | **-** | **-** | **-** |
| None | R3 stream | **-** | **-** | **-** | **-** | **10.6** | **5.709** | **3.922** | **2.978** |
| 50% | **-** | **-** | **-** | **-** | **5.491** | **3.000** | **2.078** | **1.578** |
| 75% | **-** | **-** | **-** | **-** | **3.452** | **2.409** | **1.848** | **1.261** |
| 90% | **-** | **-** | **-** | **-** | **3.452** | **2.409** | **1.848** | **1.261** |
| None | R4 stream | **-** | **-** | **-** | **-** | **7.709** | **4.17** | **2.87** | **2.178** |
| 50% | **-** | **-** | **-** | **-** | **4.4** | **3.057** | **2.343** | **1.596** |
| 75% | **-** | **-** | **-** | **-** | **4.4** | **3.057** | **2.343** | **1.596** |
| 90% | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |

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

Table 9.5‑18: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in winter cereals (1 x 1137 g/ha) VFSmod

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter cereals | | | | | | |
| Active substance | | pendimethalin | | | | | | |
| Application rate (g/ha) | | 1 × 1137 | | | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | | | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | | | 20 |
| None | R1 pond | 0.243 | 0.177 | | - | | | - |
| 50% | 0.147 | - | | - | | | - |
| None | R1 stream | 1.766 | 0.951 | | 0.654 | | | 0.497 |
| 50% | 0.917 | 0.506 | | 0.350 | | | 0.266 |
| 75% | 0.502 | 0.286 | | 0.200 | | | 0.152 |
| 90% | 0.253 | 0.154 | | - | | | - |
| None | R3 stream | 2.437 | 1.312 | | 0.902 | | | 0.685 |
| 50% | 1.236 | 0.690 | | 0.478 | | | 0.363 |
| 75% | 0.684 | 0.438 | | 0.351 | | | 0.277 |
| 90% | 0.543 | 0.438 | | 0.351 | | | 0.277 |
| None | R4 stream | 1.773 | 0.957 | | 0.660 | | | 0.501 |
| 50% | 0.928 | 0.511 | | 0.354 | | | 0.269 |
| 75% | 0.506 | 0.288 | | 0.201 | | | 0.153 |
| 90% | 0.280 | 0.158 | | - | | | - |
| RAC (µg/L) | | PEC/RAC ratio | | | | | | |
| 0.23 | |
| None | R1 pond | **1.057** | 0.77 | | | **-** | **-** | |
| 50% | 0.639 | **-** | | | **-** | **-** | |
| None | R1 stream | **7.678** | **4.135** | | | **2.843** | **2.161** | |
| 50% | **3.987** | **2.2** | | | **1.522** | **1.157** | |
| 75% | **2.183** | **1.243** | | | 0.87 | 0.661 | |
| 90% | **1.1** | 0.67 | | | **-** | **-** | |
| None | R3 stream | **10.596** | **5.704** | | | **3.922** | **2.978** | |
| 50% | **5.374** | **3.00** | | | **2.078** | **1.578** | |
| 75% | **2.974** | **1.904** | | | **1.526** | **1.204** | |
| 90% | **2.361** | **1.904** | | | **1.526** | **1.204** | |
| None | R4 stream | **7.709** | **4.161** | | | **2.87** | **2.178** | |
| 50% | **4.035** | **2.222** | | | **1.539** | **1.17** | |
| 75% | **2.2** | **1.252** | | | 0.874 | 0.665 | |
| 90% | **1.217** | 0.687 | | | **-** | **-** | |

PEC/RAC ratios in winter cereals are <1 when risk mitigation options are considered:

D1 ditch, D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.

D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.

D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction

R1 stream, R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

Table 9.5‑19: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (1 x 1600 g/ha)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D3 ditch | 2.711 | 1.437 | 0.981 | 0.746 | - | - | - | - |
| 50% | 1.367 | 0.762 | 0.531 | 0.404 | - | - | - | - |
| 75% | 0.771 | 0.468 | 0.335 | 0.255 | - | - | - | - |
| 90% | 0.468 | 0.313 | 0.230 | 0.174 | - | - | - | - |
| None | D4 pond | 0.346 | 0.252 | 0.199 | - | - | - | - | - |
| 50% | 0.205 | 0.151 | - | - | - | - | - | - |
| None | D4 stream | 2.837 | 1.515 | 1.037 | 0.789 | - | - | - | - |
| 50% | 1.441 | 0.775 | 0.532 | 0.404 | - | - | - | - |
| 75% | 0.743 | 0.405 | 0.306 | 0.306 | - | - | - | - |
| 90% | 0.325 | 0.306 | 0.306 | 0.306 | - | - | - | - |
| None | D6 1st ditch | 2.672 | 1.416 | 0.967 | 0.736 | - | - | - | - |
| 50% | 1.335 | 0.708 | 0.537 | 0.537 | - | - | - | - |
| 75% | 0.667 | 0.537 | 0.537 | 0.537 | - | - | - | - |
| 90% | 0.537 | 0.537 | - | - | - | - | - | - |
| None | D6 2nd ditch | 2.737 | 1.464 | 1.070 | 1.070 | - | - | - | - |
| 50% | 1.428 | 1.070 | 1.070 | 1.070 | - | - | - | - |
| 75% | 1.070 | 1.070 | - | - | - | - | - | - |
| 90% | 1.070 | - | - | - | - | - | - | - |
| None | R1 pond | - | - | - | - | 0.356 | 0.258 | 0.204 | - |
| 50% | - | - | - | - | 0.217 | 0.158 | - | - |
| None | R1 stream | - | - | - | - | 2.484 | 1.339 | 0.922 | 0.701 |
| 50% | - | - | - | - | 1.297 | 0.735 | 0.563 | 0.384 |
| 75% | - | - | - | - | 1.056 | 0.735 | 0.563 | 0.384 |
| None | R2 stream | - | - | - | - | 3.243 | 1.738 | 1.192 | 0.907 |
| 50% | - | - | - | - | 1.662 | 0.900 | 0.620 | 0.471 |
| 75% | - | - | - | - | 0.872 | 0.481 | 0.334 | 0.254 |
| 90% | - | - | - | - | 0.398 | 0.230 | 0.163 | 0.123 |
| None | R3 stream | - | - | - | - | 3.442 | 1.853 | 1.273 | 0.968 |
| 50% | - | - | - | - | 1.782 | 0.982 | 0.682 | 0.518 |
| 75% | - | - | - | - | 0.976 | 0.653 | 0.500 | 0.340 |
| 90% | - | - | - | - | 0.943 | 0.653 | 0.500 | 0.340 |
| None | R4 stream | - | - | - | - | 2.493 | 1.349 | 0.928 | 0.706 |
| 50% | - | - | - | - | 1.637 | 1.140 | 0.875 | 0.597 |
| 75% | - | - | - | - | 1.637 | 1.140 | 0.875 | 0.597 |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D3 ditch | **11.787** | **6.248** | **4.265** | **3.243** | **-** | **-** | **-** | **-** |
| 50% | **5.943** | **3.313** | **2.309** | **1.757** | **-** | **-** | **-** | **-** |
| 75% | **3.352** | **2.035** | **1.457** | **1.109** | **-** | **-** | **-** | **-** |
| 90% | **2.035** | **1.361** | **1.00** | 0.757 | **-** | **-** | **-** | **-** |
| None | D4 pond | **1.504** | **1.096** | 0.865 | **-** | **-** | **-** | **-** | **-** |
| 50% | 0.891 | 0.657 | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D4 stream | **12.335** | **6.587** | **4.509** | **3.43** | **-** | **-** | **-** | **-** |
| 50% | **6.265** | **3.37** | **2.313** | **1.757** | **-** | **-** | **-** | **-** |
| 75% | **3.23** | **1.761** | **1.33** | **1.33** | **-** | **-** | **-** | **-** |
| 90% | **1.413** | **1.33** | **1.33** | **1.33** | **-** | **-** | **-** | **-** |
| None | D6 1st ditch | **11.617** | **6.157** | **4.204** | **3.2** | **-** | **-** | **-** | **-** |
| 50% | **5.804** | **3.078** | **2.335** | **2.335** | **-** | **-** | **-** | **-** |
| 75% | **2.9** | **2.335** | **2.335** | **2.335** | **-** | **-** | **-** | **-** |
| 90% | **2.335** | **2.335** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 2nd ditch | **11.9** | **6.365** | **4.652** | **4.652** | **-** | **-** | **-** | **-** |
| 50% | **6.209** | **4.652** | **4.652** | **4.652** | **-** | **-** | **-** | **-** |
| 75% | **4.652** | **4.652** | **-** | **-** | **-** | **-** | **-** | **-** |
| 90% | **4.652** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | R1 pond | **-** | **-** | **-** | **-** | **1.548** | **1.122** | 0.887 | **-** |
| 50% | **-** | **-** | **-** | **-** | 0.943 | 0.687 | **-** | **-** |
| None | R1 stream | **-** | **-** | **-** | **-** | **10.8** | **5.822** | **4.009** | **3.048** |
| 50% | **-** | **-** | **-** | **-** | **5.639** | **3.196** | **2.448** | **1.67** |
| 75% | **-** | **-** | **-** | **-** | **4.591** | **3.196** | **2.448** | **1.67** |
| None | R2 stream | **-** | **-** | **-** | **-** | **14.1** | **7.557** | **5.183** | **3.943** |
| 50% | **-** | **-** | **-** | **-** | **7.226** | **3.913** | **2.696** | **2.048** |
| 75% | **-** | **-** | **-** | **-** | **3.791** | **2.091** | **1.452** | **1.104** |
| 90% | **-** | **-** | **-** | **-** | **1.73** | **1.00** | 0.709 | 0.535 |
| None | R3 stream | **-** | **-** | **-** | **-** | **14.965** | **8.057** | **5.535** | **4.209** |
| 50% | **-** | **-** | **-** | **-** | **7.748** | **4.27** | **2.965** | **2.252** |
| 75% | **-** | **-** | **-** | **-** | **4.243** | **2.839** | **2.174** | **1.478** |
| 90% | **-** | **-** | **-** | **-** | **4.1** | **2.839** | **2.174** | **1.478** |
| None | R4 stream | **-** | **-** | **-** | **-** | **10.839** | **5.865** | **4.035** | **3.07** |
| 50% | **-** | **-** | **-** | **-** | **7.117** | **4.957** | **3.804** | **2.596** |
| 75% | **-** | **-** | **-** | **-** | **7.117** | **4.957** | **3.804** | **2.596** |

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

Table 9.5‑20: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (1 x 1600 g/ha) VFSmod

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | |
| Active substance | | pendimethalin | | | | | | |
| Application rate (g/ha) | | 1 × 1600 | | | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | | | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | | | 20 |
| None | R1 pond | 0.344 | 0.250 | | 0.197 | | | - |
| 50% | 0.205 | 0.150 | | - | | | - |
| None | R1 stream | 2.483 | 1.339 | | 0.922 | | | 0.701 |
| 50% | 1.297 | 0.716 | | 0.609 | | | 0.609 |
| 75% | 0.709 | 0.609 | | 0.609 | | | 0.609 |
| 90% | 0.357 | 0.609 | | - | | | - |
| None | R2 stream | 3.243 | 1.738 | | 1.192 | | | 0.907 |
| 50% | 1.662 | 0.900 | | 0.620 | | | 0.471 |
| 75% | 0.872 | 0.481 | | 0.334 | | | 0.254 |
| 90% | 0.398 | 0.230 | | 0.162 | | | 0.123 |
| None | R3 stream | 3.442 | 1.853 | | 1.273 | | | 0.968 |
| 50% | 1.782 | 0.982 | | 0.682 | | | 0.518 |
| 75% | 0.976 | 0.558 | | 0.393 | | | 0.298 |
| 90% | 0.511 | 0.321 | | 0.233 | | | 0.177 |
| None | R4 stream | 2.493 | 1.349 | | 0.928 | | | 0.706 |
| 50% | 1.305 | 0.719 | | 0.671 | | | 0.379 |
| 75% | 0.711 | 0.404 | | 0.283 | | | 0.215 |
| 90% | 0.502 | 0.221 | | 0.160 | | | - |
| RAC (µg/L) | | PEC/RAC ratio | | | | | | |
| 0.23 | |
| None | R1 pond | **1.496** | **1.087** | | | 0.857 | **-** | |
| 50% | 0.891 | 0.652 | | | **-** | **-** | |
| None | R1 stream | **10.796** | **5.822** | | | **4.009** | **3.048** | |
| 50% | **5.639** | **3.113** | | | **2.648** | **2.648** | |
| 75% | **3.083** | **2.648** | | | **2.648** | **2.648** | |
| 90% | **1.552** | **2.648** | | | **-** | **-** | |
| None | R2 stream | **14.1** | **7.557** | | | **5.183** | **3.943** | |
| 50% | **7.226** | **3.913** | | | **2.696** | **2.048** | |
| 75% | **3.791** | **2.091** | | | **1.452** | **1.104** | |
| 90% | **1.73** | **1.00** | | | 0.704 | 0.535 | |
| None | R3 stream | **14.965** | **8.057** | | | **5.535** | **4.209** | |
| 50% | **7.748** | **4.27** | | | **2.965** | **2.252** | |
| 75% | **4.243** | **2.426** | | | **1.709** | **1.296** | |
| 90% | **2.222** | **1.396** | | | **1.013** | 0.8 | |
| None | R4 stream | **10.839** | **5.865** | | | **4.035** | **3.07** | |
| 50% | **5.674** | **3.126** | | | **2.917** | **1.648** | |
| 75% | **3.091** | **1.757** | | | **1.23** | 0.935 | |
| 90% | **2.183** | 0.961 | | | 0.696 | **-** | |

PEC/RAC ratios in ~~winter cereals~~ bulb vegetables are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 90% nozzle reduction.

D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.

D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

R1 pond: 15m no spray buffer zone with 15m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction

R2 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

Table 9.5‑21: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (1 x 1300 g/ha) as first refinement

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 × 1300 | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D3 ditch | 2.202 | 1.168 | 0.797 | 0.606 | - | - | - | - |
| 50% | 1.111 | 0.620 | 0.431 | 0.327 | - | - | - | - |
| 75% | 0.627 | 0.381 | 0.272 | 0.207 | - | - | - | - |
| 90% | 0.381 | 0.255 | 0.186 | - | - | - | - | - |
| None | D4 pond | 0.281 | 0.204 | - | - | - | - | - | - |
| 50% | 0.167 | - | - | - | - | - | - | - |
| None | D4 stream | 2.305 | 1.230 | 0.842 | 0.641 | - | - | - | - |
| 50% | 1.171 | 0.629 | 0.432 | 0.328 | - | - | - | - |
| 75% | 0.604 | 0.329 | 0.244 | 0.244 | - | - | - | - |
| 90% | 0.264 | 0.244 | 0.244 | 0.244 | - | - | - | - |
| None | D6 1st ditch | 2.171 | 1.151 | 0.786 | 0.598 | - | - | - | - |
| 50% | 1.085 | 0.575 | 0.426 | 0.426 | - | - | - | - |
| 75% | 0.542 | 0.426 | 0.426 | 0.426 | - | - | - | - |
| 90% | 0.426 | 0.426 | - | - | - | - | - | - |
| None | D6 2nd ditch | 2.224 | 1.190 | 0.850 | 0.850 | - | - | - | - |
| 50% | 1.160 | 0.850 | 0.850 | 0.850 | - | - | - | - |
| 75% | 0.850 | 0.850 | - | - | - | - | - | - |
| 90% | 0.850 | - | - | - | - | - | - | - |
| None | R1 pond | - | - | - | - | 0.289 | 0.209 | - | - |
| 50% | - | - | - | - | 0.176 | - | - | - |
| None | R1 stream | - | - | - | - | 2.018 | 1.088 | 0.749 | 0.569 |
| 50% | - | - | - | - | 1.054 | 0.592 | 0.454 | 0.310 |
| 75% | - | - | - | - | 0.851 | 0.592 | 0.454 | 0.310 |
| 90% | - | - | - | - | 0.851 | - | - | - |
| None | R2 stream | - | - | - | - | 2.635 | 1.412 | 0.968 | 0.736 |
| 50% | - | - | - | - | 1.350 | 0.731 | 0.503 | 0.383 |
| 75% | - | - | - | - | 0.709 | 0.391 | 0.271 | 0.206 |
| 90% | - | - | - | - | 0.323 | 0.187 | 0.132 | - |
| None | R3 stream | - | - | - | - | 2.797 | 1.506 | 1.034 | 0.786 |
| 50% | - | - | - | - | 1.448 | 0.798 | 0.554 | 0.421 |
| 75% | - | - | - | - | 0.793 | 0.525 | 0.402 | 0.273 |
| 90% | - | - | - | - | 0.758 | 0.525 | 0.402 | 0.273 |
| None | R4 stream | - | - | - | - | 2.026 | 1.096 | 0.754 | 0.573 |
| 50% | - | - | - | - | 1.319 | 0.918 | 0.705 | 0.481 |
| 75% | - | - | - | - | 1.319 | 0.918 | 0.705 | 0.481 |
| 90% | - | - | - | - | - | - | - | - |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D3 ditch | **9.574** | **5.078** | **3.465** | **2.635** | **-** | **-** | **-** | **-** |
| 50% | **4.83** | **2.696** | **1.874** | **1.422** | **-** | **-** | **-** | **-** |
| 75% | **2.726** | **1.657** | **1.183** | 0.9 | **-** | **-** | **-** | **-** |
| 90% | **1.657** | **1.109** | 0.809 | **-** | **-** | **-** | **-** | **-** |
| None | D4 pond | **1.222** | 0.887 | **-** | **-** | **-** | **-** | **-** | **-** |
| 50% | 0.726 | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D4 stream | **10.022** | **5.348** | **3.661** | **2.787** | **-** | **-** | **-** | **-** |
| 50% | **5.091** | **2.735** | **1.878** | **1.426** | **-** | **-** | **-** | **-** |
| 75% | **2.626** | **1.43** | **1.061** | **1.061** | **-** | **-** | **-** | **-** |
| 90% | **1.148** | **1.061** | **1.061** | **1.061** | **-** | **-** | **-** | **-** |
| None | D6 1st ditch | **9.439** | **5.004** | **3.417** | **2.6** | **-** | **-** | **-** | **-** |
| 50% | **4.717** | **2.5** | **1.852** | **1.852** | **-** | **-** | **-** | **-** |
| 75% | **2.357** | **1.852** | **1.852** | **1.852** | **-** | **-** | **-** | **-** |
| 90% | **1.852** | **1.852** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 2nd ditch | **9.67** | **5.174** | **3.696** | **3.696** | **-** | **-** | **-** | **-** |
| 50% | **5.043** | **3.696** | **3.696** | **3.696** | **-** | **-** | **-** | **-** |
| 75% | **3.696** | **3.696** | **-** | **-** | **-** | **-** | **-** | **-** |
| 90% | **3.696** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | R1 pond | **-** | **-** | **-** | **-** | **1.257** | 0.909 | **-** | **-** |
| 50% | **-** | **-** | **-** | **-** | 0.765 | **-** | **-** | **-** |
| None | R1 stream | **-** | **-** | **-** | **-** | **8.774** | **4.73** | **3.257** | **2.474** |
| 50% | **-** | **-** | **-** | **-** | **4.583** | **2.574** | **1.974** | **1.348** |
| 75% | **-** | **-** | **-** | **-** | **3.7** | **2.574** | **1.974** | **1.348** |
| 90% | **-** | **-** | **-** | **-** | **3.7** | **-** | **-** | **-** |
| None | R2 stream | **-** | **-** | **-** | **-** | **11.457** | **6.139** | **4.209** | **3.2** |
| 50% | **-** | **-** | **-** | **-** | **5.87** | **3.178** | **2.187** | **1.665** |
| 75% | **-** | **-** | **-** | **-** | **3.083** | **1.7** | **1.178** | 0.896 |
| 90% | **-** | **-** | **-** | **-** | **1.404** | 0.813 | 0.574 | **-** |
| None | R3 stream | **-** | **-** | **-** | **-** | **12.161** | **6.548** | **4.496** | **3.417** |
| 50% | **-** | **-** | **-** | **-** | **6.296** | **3.47** | **2.409** | **1.83** |
| 75% | **-** | **-** | **-** | **-** | **3.448** | **2.283** | **1.748** | **1.187** |
| 90% | **-** | **-** | **-** | **-** | **3.296** | **2.283** | **1.748** | **1.187** |
| None | R4 stream | **-** | **-** | **-** | **-** | **8.809** | **4.765** | **3.278** | **2.491** |
| 50% | **-** | **-** | **-** | **-** | **5.735** | **3.991** | **3.065** | **2.091** |
| 75% | **-** | **-** | **-** | **-** | **5.735** | **3.991** | **3.065** | **2.091** |
| 90% | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |

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

Table 9.5‑22: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (1 x 1300 g/ha) as first refinement VFSmod

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | |
| Active substance | | pendimethalin | | | | | | |
| Application rate (g/ha) | | 1 × 1300 | | | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | | | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | | | 20 |
| None | R1 pond | 0.280 | 0.203 | | - | | | - |
| 50% | 0.167 | - | | - | | | - |
| None | R1 stream | 2.018 | 1.088 | | 0.749 | | | 0.569 |
| 50% | 1.054 | 0.582 | | 0.492 | | | 0.492 |
| 75% | 0.576 | 0.492 | | 0.492 | | | 0.492 |
| 90% | 0.290 | 0.492 | | - | | | - |
| None | R2 stream | 2.635 | 1.412 | | 0.968 | | | 0.736 |
| 50% | 1.350 | 0.731 | | 0.503 | | | 0.383 |
| 75% | 0.708 | 0.391 | | 0.271 | | | 0.206 |
| 90% | 0.323 | 0.187 | | 0.132 | | | - |
| None | R3 stream | 2.797 | 1.506 | | 1.034 | | | 0.786 |
| 50% | 1.448 | 0.798 | | 0.554 | | | 0.421 |
| 75% | 0.793 | 0.454 | | 0.319 | | | 0.242 |
| 90% | 0.415 | 0.261 | | 0.190 | | | 0.144 |
| None | R4 stream | 2.026 | 1.096 | | 0.754 | | | 0.573 |
| 50% | 1.060 | 0.584 | | 0.549 | | | 0.308 |
| 75% | 0.578 | 0.329 | | 0.230 | | | 0.175 |
| 90% | 0.405 | 0.180 | | - | | | - |
| RAC (µg/L) | | PEC/RAC ratio | | | | | | |
| 0.23 | |
| None | R1 pond | **1.217** | 0.883 | | | **-** | **-** | |
| 50% | 0.726 | **-** | | | **-** | **-** | |
| None | R1 stream | **8.774** | **4.73** | | | **3.257** | **2.474** | |
| 50% | **4.583** | **2.53** | | | **2.139** | **2.139** | |
| 75% | **2.504** | **2.139** | | | **2.139** | **2.139** | |
| 90% | **1.261** | **2.139** | | | **-** | **-** | |
| None | R2 stream | **11.457** | **6.139** | | | **4.209** | **3.2** | |
| 50% | **5.87** | **3.178** | | | **2.187** | **1.665** | |
| 75% | **3.078** | **1.7** | | | **1.178** | 0.896 | |
| 90% | **1.404** | 0.813 | | | 0.574 | **-** | |
| None | R3 stream | **12.161** | **6.548** | | | **4.496** | **3.417** | |
| 50% | **6.296** | **3.47** | | | **2.409** | **1.83** | |
| 75% | **3.448** | **1.974** | | | **1.387** | **1.052** | |
| 90% | **1.804** | **1.135** | | | 0.826 | 0.6 | |
| None | R4 stream | **8.809** | **4.765** | | | **3.278** | **2.491** | |
| 50% | **4.609** | **2.539** | | | **2.387** | **1.339** | |
| 75% | **2.513** | **1.43** | | | **1** | 0.761 | |
| 90% | **1.761** | 0.783 | | | **-** | **-** | |

PEC/RAC ratios in ~~winter cereals~~ bulb vegetables are <1 when risk mitigation options are considered:

D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.

D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.

R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction

R2 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction

R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

Table 9.5‑23: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (1 x 1000 g/ha + 1 x 300 g/ha) as second refinement

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 x 1000 g/ha + 1 x 300 g/ha | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D4 stream | 1.773/1.487 | 0.946/0.779 | 0.648/0.527 | 0.493/0.398 | -/- | -/- | -/- | -/- |
| 50% | 0.901/0.758 | 0.484/0.400 | 0.332/0.272 | 0.253/0.245 | -/- | -/- | -/- | -/- |
| 75% | 0.464/0.393 | 0.253/0.245 | 0.183/0.245 | 0.183/0.245 | -/- | -/- | -/- | -/- |
| 90% | 0.203/0.245 | 0.183/0.245 | -/0.245 | -/- | -/- | -/- | -/- | -/- |
| None | D6 1st ditch | 1.669/1.396 | 0.885/0.725 | 0.604/0.489 | 0.460/0.403 | -/- | -/- | -/- | -/- |
| 50% | 0.834/0.698 | 0.442/0.403 | 0.318/0.403 | 0.318/0.403 | -/- | -/- | -/- | -/- |
| 75% | 0.417/0.403 | 0.318/0.403 | 0.318/0.403 | 0.318/- | -/- | -/- | -/- | -/- |
| 90% | 0.318/0.403 | 0.318/- | -/- | -/- | -/- | -/- | -/- | -/- |
| None | D6 2nd ditch | 1.710/1.430 | 0.915/0.793 | 0.635/0.793 | 0.635/0.793 | -/- | -/- | -/- | -/- |
| 50% | 0.892/0.793 | 0.635/0.793 | 0.635/0.793 | 0.635/0.793 | -/- | -/- | -/- | -/- |
| 75% | 0.635/0.793 | 0.635/- | -/- | -/- | -/- | -/- | -/- | -/- |
| 90% | 0.635/- | -/- | -/- | -/- | -/- | -/- | -/- | -/- |
| None | R1 stream | -/- | -/- | -/- | -/- | 1.552/1.307 | 0.836/0.695 | 0.576/0.474 | 0.439/0.358 |
| 50% | -/- | -/- | -/- | -/- | 0.811/0.855 | 0.451/0.595 | 0.346/0.456 | 0.236/0.311 |
| 75% | -/- | -/- | -/- | -/- | 0.648/0.855 | 0.451/0.595 | 0.346/0.456 | 0.236/0.311 |
| 90% | -/- | -/- | -/- | -/- | 0.648/- | -/- | -/- | -/- |
| None | R3 stream | -/- | -/- | -/- | -/- | 2.151/1.812 | 1.158/0.959 | 0.796/0.652 | 0.606/0.492 |
| 50% | -/- | -/- | -/- | -/- | 1.114/0.947 | 0.613/0.528 | 0.635/0.404 | 0.324/0.275 |
| 75% | -/- | -/- | -/- | -/- | 0.610/0.763 | 0.399/0.528 | 0.305/0.404 | 0.208/0.275 |
| 90% | -/- | -/- | -/- | -/- | 0.576/0.763 | 0.399/- | 0.305/- | -/- |
| None | R4 stream | -/- | -/- | -/- | -/- | 1.558/1.338 | 0.843/0.931 | 0.580/0.715 | 0.442/0.487 |
| 50% | -/- | -/- | -/- | -/- | 1.004/1.338 | 0.699/0.931 | 0.536/0.715 | 0.366/0.487 |
| 75% | -/- | -/- | -/- | -/- | 1.004/- | 0.699/- | 0.536/- | 0.366/- |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D4 stream | **7.709/6.465** | **4.113/3.387** | **2.817/2.291** | **2.143/1.73** | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **3.917/3.296** | **2.104/1.739** | **1.443/1.183** | **1.1/1.065** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | **2.017/1.709** | **1.1/1.065** | 0.796**/1.065** | 0.796**/1.065** | **-/-** | **-/-** | **-/-** | **-/-** |
| 90% | 0.883**/1.065** | 0.796**/1.065** | **-/1.065** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | D6 1st ditch | **7.257/6.07** | **3.848/3.152** | **2.626/2.126** | **2/1.752** | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **3.626/3.035** | **1.922/1.752** | **1.383/1.752** | **1.383/1.752** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | **1.813/1.752** | **1.383/1.752** | **1.383/1.752** | **1.383/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| 90% | **1.383/1.752** | **1.383/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | D6 2nd ditch | **7.435/6.217** | **3.978/3.448** | **2.761/3.448** | **2.761/3.448** | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **3.878/3.448** | **2.761/3.448** | **2.761/3.448** | **2.761/3.448** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | **2.761/3.448** | **2.761/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| 90% | **2.761/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | R1 stream | **-/-** | **-/-** | **-/-** | **-/-** | **6.748/5.683** | **3.635/3.022** | **2.504/2.061** | **1.909/1.557** |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **3.526/3.717** | **1.961/2.587** | **1.504/1.983** | **1.026/1.352** |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | **2.817/3.717** | **1.961/2.587** | **1.504/1.983** | **1.026/1.352** |
| 90% | **-/-** | **-/-** | **-/-** | **-/-** | **2.817/-** | **-/-** | **-/-** | **-/-** |
| None | R3 stream | **-/-** | **-/-** | **-/-** | **-/-** | **9.352/7.878** | **5.035/4.17** | **3.461/2.835** | **2.635/2.139** |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **4.843/4.117** | **2.665/2.296** | **2.761/1.757** | **1.409/1.196** |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | **2.652/3.317** | **1.735/2.296** | **1.326/1.757** | 0.904**/1.196** |
| 90% | **-/-** | **-/-** | **-/-** | **-/-** | **2.504/3.317** | **1.735/-** | **1.326/-** | **-/-** |
| None | R4 stream | **-/-** | **-/-** | **-/-** | **-/-** | **6.774/5.817** | **3.665/4.048** | **2.522/3.109** | **1.922/2.117** |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **4.365/5.817** | **3.039/4.048** | **2.33/3.109** | **1.591/2.117** |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | **4.365/-** | **3.039/-** | **2.33/-** | **1.591/-** |

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

Table 9.5‑24: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (1 x 1000 g/ha + 1 x 300 g/ha) as second refinement VFSmod

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | |
| Active substance | | pendimethalin | | | | |
| Application rate (g/ha) | | 1 x ~~1000~~ 1600 g/ha + 1 x 300 g/ha | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | 20 |
| None | R1 stream | 1.552/1.307 | 0.836/0.695 | | 0.576/0.493 | 0.438/0.493 |
| 50% | 0.811/0.691 | 0.447/0.493 | | 0.376/0.493 | 0.376/0.493 |
| 75% | 0.443/0.383 | 0.376/0.493 | | 0.376/- | 0.376/- |
| 90% | 0.223/0.199 | 0.376/- | | -/- | -/- |
| None | R3 stream | 2.151/1.812 | 1.158/0.959 | | 0.796/0.652 | 0.605/0.492 |
| 50% | 1.114/0.947 | 0.613/0.517 | | 0.426/0.357 | 0.324/0.270 |
| 75% | 0.610/0.528 | 0.348/0.302 | | 0.245/0.213 | 0.187/0.162 |
| 90% | 0.320/0.290 | 0.158/0.184 | | 0.146/- | -/- |
| None | R4 stream | 1.558/1.315 | 0.842/0.850 | | 0.580/0.477 | 0.442/0.360 |
| 50% | 0.816/0.694 | 0.449/0.378 | | 0.311/0.260 | 0.237/0.196 |
| 75% | 0.445/0.407 | 0.252/0.217 | | 0.177/0.151 | 0.135/- |
| 90% | 0.309/0.407 | 0.132/- | | -/- | -/- |
| RAC (µg/L) | | PEC/RAC ratio | | | | |
| 0.23 | |
| None | R1 stream | **6.748/5.683** | **3.635/3.022** | | **2.504/2.143** | **1.904/2.143** |
| 50% | **3.526/3.004** | **1.943/2.143** | | **1.635/2.143** | **1.635/2.143** |
| 75% | **1.926/1.665** | **1.635/2.143** | | **1.635/-** | **1.635/-** |
| 90% | 0.97/0.865 | **1.635/-** | | **-/-** | **-/-** |
| None | R3 stream | **9.352/7.878** | **5.035/4.17** | | **3.461/2.835** | **2.63/2.139** |
| 50% | **4.843/4.117** | **2.665/2.248** | | **1.852/1.552** | **1.409/1.174** |
| 75% | **2.652/2.296** | **1.513/1.313** | | **1.065/**0.926 | 0.813/0.704 |
| 90% | **1.391/1.261** | 0.687/0.8 | | 0.635/- | **-/-** |
| None | R4 stream | **6.774/5.717** | **3.661/3.696** | | **2.522/2.074** | **1.922/1.565** |
| 50% | **3.548/3.017** | **1.952/1.643** | | **1.352/1.13** | **1.03/**0.852 |
| 75% | **1.935/1.77** | **1.096/**0.943 | | 0.77/0.657 | 0.587/- |
| 90% | **1.343/1.77** | 0.574/- | | **-/-** | **-/-** |

PEC/RAC ratios in bulb vegetables (1 x ~~1000~~ 1600 g/ha + 1 x 300 g/ha) are <1 when risk mitigation options are considered:

R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

Table 9.5‑25: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (2 x 650 g/ha) as third refinement

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 2 x 650 g/ha | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D4 stream | 0.973 | 0.510 | 0.345 | 0.260 | - | - | - | - |
| 50% | 0.496 | 0.262 | 0.246 | 0.246 | - | - | - | - |
| 75% | 0.258 | 0.246 | 0.246 | 0.246 | - | - | - | - |
| 90% | 0.246 | 0.246 | - | - | - | - | - | - |
| None | D6 1st ditch | 0.922 | 0.479 | 0.378 | 0.378 | - | - | - | - |
| 50% | 0.468 | 0.378 | 0.378 | 0.378 | - | - | - | - |
| 75% | 0.378 | 0.378 | - | - | - | - | - | - |
| 90% | 0.378 | - | - | - | - | - | - | - |
| None | D6 2nd ditch | 0.987 | 0.728 | 0.728 | 0.728 | - | - | - | - |
| 50% | 0.728 | 0.728 | 0.728 | 0.728 | - | - | - | - |
| 75% | 0.728 | - | - | - | - | - | - | - |
| None | R1 stream | - | - | - | - | 0.862 | 0.600 | 0.460 | 0.314 |
| 50% | - | - | - | - | 0.862 | 0.600 | 0.460 | 0.314 |
| None | R3 stream | - | - | - | - | 1.177 | 0.623 | 0.423 | 0.319 |
| 50% | - | - | - | - | 0.768 | 0.532 | 0.407 | 0.277 |
| 75% | - | - | - | - | 0.768 | 0.532 | 0.407 | 0.277 |
| None | R4 stream | - | - | - | - | 1.358 | 0.946 | 0.725 | 0.495 |
| 50% | - | - | - | - | 1.358 | 0.946 | 0.725 | 0.495 |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D4 stream | **4.23** | **2.217** | **1.5** | **1.13** | **-** | **-** | **-** | **-** |
| 50% | **2.157** | **1.139** | **1.07** | **1.07** | **-** | **-** | **-** | **-** |
| 75% | **1.122** | **1.07** | **1.07** | **1.07** | **-** | **-** | **-** | **-** |
| 90% | **1.07** | **1.07** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 1st ditch | **4.009** | **2.083** | **1.643** | **1.643** | **-** | **-** | **-** | **-** |
| 50% | **2.035** | **1.643** | **1.643** | **1.643** | **-** | **-** | **-** | **-** |
| 75% | **1.643** | **1.643** | **-** | **-** | **-** | **-** | **-** | **-** |
| 90% | **1.643** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D6 2nd ditch | **4.291** | **3.165** | **3.165** | **3.165** | **-** | **-** | **-** | **-** |
| 50% | **3.165** | **3.165** | **3.165** | **3.165** | **-** | **-** | **-** | **-** |
| 75% | **3.165** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| None | R1 stream | **-** | **-** | **-** | **-** | **3.748** | **2.609** | **2.00** | **1.365** |
| 50% | **-** | **-** | **-** | **-** | **3.748** | **2.609** | **2.00** | **1.365** |
| None | R3 stream | **-** | **-** | **-** | **-** | **5.117** | **2.709** | **1.839** | **1.387** |
| 50% | **-** | **-** | **-** | **-** | **3.339** | **2.313** | **1.77** | **1.204** |
| 75% | **-** | **-** | **-** | **-** | **3.339** | **2.313** | **1.77** | **1.204** |
| None | R4 stream | **-** | **-** | **-** | **-** | **5.904** | **4.113** | **3.152** | **2.152** |
| 50% | **-** | **-** | **-** | **-** | **5.904** | **4.113** | **3.152** | **2.152** |

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

Table 9.5‑26: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (2 x 650 g/ha) as third refinement VFSmod

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | |
| Active substance | | pendimethalin | | | | |
| Application rate (g/ha) | | 2 x 650 g/ha | | | | |
| Nozzle reduction | Vegetated filter strip (m) | 5 | | 10 | 15 | 20 |
| No-spray buffer (m) | 5 | 10 | | 15 | 20 |
| None | R1 stream | 0.849 | 0.495 | | 0.495 | 0.495 |
| 50% | 0.448 | 0.495 | | 0.495 | 0.495 |
| 75% | 0.248 | - | | - | - |
| 90% | 0.160 | - | | - | - |
| None | R3 stream | 1.177 | 0.623 | | 0.423 | 0.319 |
| 50% | 0.615 | 0.337 | | 0.231 | 0.175 |
| 75% | 0.343 | 0.197 | | 0.138 | - |
| 90% | 0.240 | - | | - | - |
| None | R4 stream | 0.854 | 0.455 | | 0.310 | 0.234 |
| 50% | 0.451 | 0.246 | | 0.168 | 0.127 |
| 75% | 0.410 | 0.174 | | - | - |
| 90% | 0.410 | - | | - | - |
| RAC (µg/L) | | PEC/RAC ratio | | | | |
| 0.23 (P. subcapitata) | |
| None | R1 stream | **3.691** | **2.152** | | **2.152** | **2.152** |
| 50% | **1.948** | **2.152** | | **2.152** | **2.152** |
| 75% | **1.078** | **-** | | **-** | **-** |
| 90% | 0.696 | **-** | | **-** | **-** |
| None | R3 stream | **5.117** | **2.709** | | **1.839** | **1.387** |
| 50% | **2.674** | **1.465** | | **1.004** | 0.761 |
| 75% | **1.491** | 0.857 | | 0.6 | **-** |
| 90% | **1.043** | **-** | | **-** | **-** |
| None | R4 stream | **3.713** | **1.978** | | **1.348** | **1.017** |
| 50% | **1.961** | **1.07** | | 0.73 | 0.552 |
| 75% | **1.783** | 0.757 | | **-** | **-** |
| 90% | **1.783** | **-** | | **-** | **-** |

PEC/RAC ratios in Bulb vegetables (2x650g/ha) are <1 when risk mitigation options are considered:

R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction

R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction

Table 9.5‑27: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (2 x 400 g/ha) as fourth refinement

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bulb vegetables | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 2 x 400 g/ha | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D3 ditch | 0.677/0.567 | 0.359/0.295 | 0.245/0.201 | 0.186/- | -/- | -/- | -/- | -/- |
| 50% | 0.341/0.294 | 0.191/0.163 | 0.133/- | -/- | -/- | -/- | -/- | -/- |
| 75% | 0.192/0.174 | -/- | -/- | -/- | -/- | -/- | -/- | -/- |
| None | D4 stream | 0.709/0.598 | 0.378/0.314 | 0.259/0.212 | 0.200/- | -/- | -/- | -/- | -/- |
| 50% | 0.360/0.305 | 0.194/0.162 | 0.133/- | -/- | -/- | -/- | -/- | -/- |
| 75% | 0.186/0.158 | -/- | -/- | -/- | -/- | -/- | -/- | -/- |
| None | D6 1st ditch | 0.667/0.567 | 0.354/0.294 | 0.242/0.220 | 0.184/- | -/- | -/- | -/- | -/- |
| 50% | 0.334/0.288 | 0.177/0.220 | 0.121/- | -/- | -/- | -/- | -/- | -/- |
| 75% | 0.167/0.219 | -/- | -/- | -/- | -/- | -/- | -/- | -/- |
| None | D6 2nd ditch | 0.684/0.607 | 0.366/0.426 | 0.253/0.426 | 0.230/0.426 | -/- | -/- | -/- | -/- |
| 50% | 0.356/0.426 | 0.230/0.426 | 0.230/0.426 | -/0.426 | -/- | -/- | -/- | -/- |
| 75% | 0.230/0.426 | -/- | -/- | -/- | -/- | -/- | -/- | -/- |
| None | R1 stream | -/- | -/- | -/- | -/- | 0.620/0.522 | 0.335/0.362 | 0.230/0.362 | 0.175/0.189 |
| 50% | -/- | -/- | -/- | -/- | 0.324/0.521 | 0.179/0.362 | 0.133/0.278 | -/- |
| 75% | -/- | -/- | -/- | -/- | 0.250/0.521 | -/- | -/0.278 | -/- |
| 90% | -/- | -/- | -/- | -/- | 0.250/- | -/- | -/- | -/- |
| None | R2 stream | -/- | -/- | -/- | -/- | 0.810/0.766 | 0.434/0.419 | 0.298/0.309 | 0.226/0.214 |
| 50% | -/- | -/- | -/- | -/- | 0.415/0.444 | 0.225/0.252 | 0.155/0.177 | -/- |
| 75% | -/- | -/- | -/- | -/- | 0.218/0.283 | -/0.168 | -/- | -/- |
| 90% | -/- | -/- | -/- | -/- | -/0.187 | -/- | -/- | -/- |
| None | R3 stream | -/- | -/- | -/- | -/- | 0.860/0.724 | 0.463/0.384 | 0.318/0.320 | 0.242/0.196 |
| 50% | -/- | -/- | -/- | -/- | 0.445/0.462 | 0.246/0.320 | 0.171/0.245 | 0.129/- |
| 75% | -/- | -/- | -/- | -/- | 0.243/0.462 | 0.153/0.320 | -/0.245 | -/- |
| 90% | -/- | -/- | -/- | -/- | 0.220/- | -/- | -/- | -/- |
| None | R4 stream | -/- | -/- | -/- | -/- | 0.623/0.819 | 0.337/0.570 | 0.232/0.570 | 0.176/0.298 |
| 50% | -/- | -/- | -/- | -/- | 0.386/0.819 | 0.269/0.570 | 0.206/0.437 | -/0.298 |
| 75% | -/- | -/- | -/- | -/- | 0.386/- | 0.269/- | -/0.437 | - |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D3 ditch | **2.943/2.465** | **1.561/1.283** | **1.065/**0.874 | 0.809/- | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **1.483/1.278** | 0.83/0.709 | 0.578/- | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | 0.835/0.757 | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | D4 stream | **3.083/2.6** | **1.643/1.365** | **1.126/**0.922 | 0.87/- | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **1.565/1.326** | 0.843/0.704 | 0.578/- | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | 0.809/0.687 | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | D6 1st ditch | **2.9/2.465** | **1.539/1.278** | **1.052/**0.957 | 0.8/- | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **1.452/1.252** | 0.77/0.957 | 0.526/- | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | 0.726/0.952 | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | D6 2nd ditch | **2.974/2.639** | **1.591/1.852** | **1.1/1.852** | **1/1.852** | **-/-** | **-/-** | **-/-** | **-/-** |
| 50% | **1.548/1.852** | **1/1.852** | **1/1.852** | **-/1.852** | **-/-** | **-/-** | **-/-** | **-/-** |
| 75% | **1/1.852** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** | **-/-** |
| None | R1 stream | **-/-** | **-/-** | **-/-** | **-/-** | **2.696/2.27** | **1.457/1.574** | **1/1.574** | 0.761/0.822 |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **1.409/2.265** | 0.778**/1.574** | 0.578**/1.209** | **-/-** |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | **1.087/2.265** | **-/-** | **-/1.209** | **-/-** |
| 90% | **-/-** | **-/-** | **-/-** | **-/-** | **1.087/-** | **-/-** | **-/-** | **-/-** |
| None | R2 stream | **-/-** | **-/-** | **-/-** | **-/-** | **3.522/3.33** | **1.887/1.822** | **1.296/1.343** | 0.983/0.93 |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **1.804/1.93** | 0.978**/1.096** | 0.674/0.77 | **-/-** |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | 0.948**/1.23** | -/0.73 | **-/-** | **-/-** |
| 90% | **-/-** | **-/-** | **-/-** | **-/-** | -/0.813 | **-/-** | **-/-** | **-/-** |
| None | R3 stream | **-/-** | **-/-** | **-/-** | **-/-** | **3.739/3.148** | **2.013/1.67** | **1.383/1.391** | **1.052/**0.852 |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **1.935/2.009** | **1.07/1.391** | 0.743**/1.065** | 0.561/- |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | **1.057/2.009** | 0.665**/1.391** | **-/1.065** | **-/-** |
| 90% | **-/-** | **-/-** | **-/-** | **-/-** | 0.957/- | **-/-** | **-/-** | **-/-** |
| None | R4 stream | **-/-** | **-/-** | **-/-** | **-/-** | **2.709/3.561** | **1.465/2.478** | **1.009/2.478** | 0.765**/1.296** |
| 50% | **-/-** | **-/-** | **-/-** | **-/-** | **1.678/3.561** | **1.17/2.478** | 0.896**/1.9** | **-/1.296** |
| 75% | **-/-** | **-/-** | **-/-** | **-/-** | **1.678/-** | **1.17/-** | **-/1.9** | **-/-** |

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

PEC/RAC ratios in Bulb vegetables (2x400g/ha) are <1 when risk mitigation options are considered:

D3 ditch, D4 stream, D6 1st ditch: 20m no spray buffer zone + 90% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.

R1 stream: 20m no spray buffer zone with 20m vegetated filter strip

R2 stream: 20m no spray buffer zone with 20m vegetated filter strip or 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction

R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction

Table 9.5‑28: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g as/ha)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | winter oilseed rape | | | | | | | |
| Active substance | | pendimethalin | | | | | | | |
| Application rate (g/ha) | | 1 x 910 g as/ha | | | | | | | |
| Nozzle reduction | No-spray buffer (m) | 5 | 10 | 15 | 20 | 5 | 10 | 15 | 20 |
| Vegetated filter strip (m) | None | None | None | None | 5 | 10 | 15 | 20 |
| None | D2 ditch | 1.597 | 0.866 | 0.616 | 0.467 | - | - | - | - |
| 50% | 0.892 | 0.523 | 0.373 | 0.282 | - | - | - | - |
| 75% | 0.564 | 0.361 | 0.263 | 0.199 | - | - | - | - |
| 90% | 0.382 | 0.265 | 0.197 | - | - | - | - | - |
| None | D2 stream | 1.878 | 0.996 | 0.681 | 0.518 | - | - | - | - |
| 50% | 0.940 | 0.499 | 0.341 | 0.260 | - | - | - | - |
| 75% | 0.472 | 0.251 | 0.172 | 0.131 | - | - | - | - |
| 90% | 0.191 | 0.102 | - | - | - | - | - | - |
| None | D3 ditch | 1.549 | 0.826 | 0.570 | 0.434 | - | - | - | - |
| 50% | 0.810 | 0.464 | 0.328 | 0.248 | - | - | - | - |
| 75% | 0.490 | 0.306 | 0.221 | 0.166 | - | - | - | - |
| 90% | 0.314 | 0.219 | - | - | - | - | - | - |
| None | D4 stream | 1.803 | 0.963 | 0.661 | 0.503 | - | - | - | - |
| 50% | 0.928 | 0.509 | 0.352 | 0.268 | - | - | - | - |
| 75% | 0.501 | 0.287 | 0.202 | 0.154 | - | - | - | - |
| 90% | 0.262 | 0.168 | - | - | - | - | - | - |
| None | D5 stream | 1.944 | 1.032 | 0.705 | 0.536 | - | - | - | - |
| 50% | 0.974 | 0.531 | 0.367 | 0.279 | - | - | - | - |
| 75% | 0.522 | 0.302 | 0.213 | 0.162 | - | - | - | - |
| 90% | 0.283 | 0.183 | - | - | - | - | - | - |
| None | R1 stream | - | - | - | - | 1.424 | 0.773 | 0.533 | 0.405 |
| 50% | - | - | - | - | 0.752 | 0.417 | 0.292 | 0.220 |
| 75% | - | - | - | - | 0.546 | 0.381 | 0.292 | - |
| 90% | - | - | - | - | 0.546 | 0.381 | - | - |
| None | R3 stream | - | - | - | - | 1.957 | 1.058 | 0.727 | 0.553 |
| 50% | - | - | - | - | 1.022 | 0.564 | 0.392 | 0.299 |
| 75% | - | - | - | - | 0.571 | 0.398 | 0.306 | 0.209 |
| 90% | - | - | - | - | 0.571 | 0.398 | 0.306 | - |
| RAC (µg/L) | |  | | | | | | | |
| 0.23 | | PEC/RAC ratio | | | | | | | |
| None | D2 ditch | **6.943** | **3.765** | **2.678** | **2.03** | **-** | **-** | **-** | **-** |
| 50% | **3.878** | **2.274** | **1.622** | **1.226** | **-** | **-** | **-** | **-** |
| 75% | **2.452** | **1.57** | **1.143** | 0.865 | **-** | **-** | **-** | **-** |
| 90% | **1.661** | **1.152** | 0.857 | **-** | - | - | - | - |
| None | D2 stream | **8.165** | **4.33** | **2.961** | **2.252** | **-** | **-** | **-** | **-** |
| 50% | **4.087** | **2.17** | **1.483** | **1.13** | **-** | **-** | **-** | **-** |
| 75% | **2.052** | **1.091** | 0.748 | 0.57 | **-** | **-** | **-** | **-** |
| 90% | 0.83 | 0.443 | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D3 ditch | **6.735** | **3.591** | **2.478** | **1.887** | **-** | **-** | **-** | **-** |
| 50% | **3.522** | **2.017** | **1.426** | **1.078** | **-** | **-** | **-** | **-** |
| 75% | **2.13** | **1.33** | 0.961 | 0.722 | **-** | **-** | **-** | **-** |
| 90% | **1.365** | 0.952 | **-** | **-** | **-** | **-** | **-** | **-** |
| None | D4 stream | **7.839** | **4.187** | **2.874** | **2.187** | **-** | **-** | **-** | **-** |
| 50% | **4.035** | **2.213** | **1.53** | **1.2** | **-** | **-** | **-** | **-** |
| 75% | **2.178** | **1.248** | 0.878 | 0.67 | **-** | **-** | **-** | **-** |
| 90% | **1.139** | 0.73 | **-** | **-** | - | - | - | - |
| None | D5 stream | **8.452** | **4.487** | **3.065** | **2.33** | **-** | **-** | **-** | **-** |
| 50% | **4.235** | **2.309** | **1.596** | **1.213** | **-** | **-** | **-** | **-** |
| 75% | **2.27** | **1.313** | 0.926 | 0.704 | **-** | **-** | **-** | **-** |
| 90% | **1.23** | 0.796 | **-** | **-** | - | - | - | - |
| None | R1 stream | **-** | **-** | **-** | **-** | **6.191** | **3.361** | **2.317** | **1.761** |
| 50% | **-** | **-** | **-** | **-** | **3.27** | **1.813** | **1.27** | 0.957 |
| 75% | **-** | **-** | **-** | **-** | **2.374** | **1.657** | **1.27** | **-** |
| 90% | **-** | **-** | **-** | **-** | **2.374** | **1.657** | **-** | **-** |
| None | R3 stream | **-** | **-** | **-** | **-** | **8.509** | **4.6** | **3.161** | **2.404** |
| 50% | **-** | **-** | **-** | **-** | **4.443** | **2.452** | **1.704** | **1.3** |
| 75% | **-** | **-** | **-** | **-** | **2.483** | **1.73** | **1.33** | 0.909 |
| 90% | **-** | **-** | **-** | **-** | **2.483** | **1.73** | **1.33** | **-** |

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

PEC/RAC ratios in Winter oilseed rape (1x910g/ha) are <1 when risk mitigation options are considered:

D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.

D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.

D3 ditch, D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction or 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.

R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction

R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction

The applicant is proposing to use the suggestion of the RMS (NL), which was discussed during the pendimethalin EU peer review. The RMS (NL) proposed to use geomean NOEC value of the three valid mesocosm studies together with safety factor 2 because RAC of 0.23 µg/L is lower than the lowest RAC based on Tier 1 laboratory studies. NOEC of 0.96 µg a.s./L with an assessment factor (AF) = 2 is resulting in ETO-RAC = 0.48 µg a.s./L.

ETO-RAC of 0.48 µg a.s./L is listed in last update of LoEP prepared by RMS NL published by European Commission (last update September 2021). This value was also used in aquatic risk assessment in update of RAR Volume 3 Annex B (BAS 455 48 H) Pendimethalin B9 Ecotoxicology data from September 2021 prepared by The Netherlands and published by European Commission.

It should be noted that ETO-RAC of 0.48 µg/L is still conservative and reliable for the higher tier risk assessment.

Mesocom studies were very detailed evaluated and concluded to be accepted in RAR Pendimethalin where no MDD analysis was provided. Therefore, the applicant is of opinion because these studies were already used in renewal, can be used also for renewal of PENTAGON without MDD analysis. Furthermore, please note that very conservative approach and assessment factor is taken into account which gives very robust ETO-RAC.

**zRMS comments:**

Four different mesocosms were available to address the risk to algae, macrophytes, aquatic invertebrates, and sediment-dwelling organisms. All mesocosm studies resulted in consistent NOEC (0.23–3.8 μg a.s./L) and NOEAEC (1.1–5 μg a.s./L), confirming algae as the most sensitive group. During the Peer Review Experts’ Teleconference it was agreed that the use of the NOEAEC (recovery approach) was not a suitable option, since recovery after autumn applications of pendimethalin might be slower than what is observed in the mesocosms, all carried out in spring/summer. Hence, it was agreed to use the most conservative NOEC value (0.23 μg a.s./L), together with an assessment factor of 1. Such low assessment factor was agreed due to the consistency between the results of the mesocosm studies. In the final commenting round of the present conclusion the RMS disagreed on this approach, which was nevertheless deemed as appropriate during the Peer Review Experts’ Teleconference. The opinion of RMS was that a geometric mean across NOEC from the different mesocosms should have been used in the risk assessment. It must be noted that the use of the geometric mean was considered during the Peer Review Experts’ Teleconference and considered not appropriate.

Therfore the risk was based on the NOEC of 0.23 microgram/L.

~~Table 9.5‑29: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Potato (1 x 1600 g/ha)~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Potato~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1600~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~2.715~~ | ~~1.439~~ | ~~0.983~~ | ~~0.747~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.357~~ | ~~0.755~~ | ~~0.526~~ | ~~0.400~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.760~~ | ~~0.463~~ | ~~0.332~~ | ~~0.252~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.464~~ | ~~0.310~~ | ~~0.228~~ | ~~0.173~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 pond~~ | ~~0.334~~ | ~~0.245~~ | ~~0.195~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.202~~ | ~~0.148~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~2.937~~ | ~~1.571~~ | ~~1.076~~ | ~~0.818~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.497~~ | ~~0.807~~ | ~~0.555~~ | ~~0.422~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.777~~ | ~~0.425~~ | ~~0.319~~ | ~~0.319~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.345~~ | ~~0.319~~ | ~~0.319~~ | ~~0.319~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~2.685~~ | ~~1.423~~ | ~~0.972~~ | ~~0.739~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.342~~ | ~~0.711~~ | ~~0.563~~ | ~~0.563~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.698~~ | ~~0.563~~ | ~~0.563~~ | ~~0.563~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.563~~ | ~~0.563~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~2.729~~ | ~~1.447~~ | ~~0.988~~ | ~~0.751~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.364~~ | ~~0.701~~ | ~~0.724~~ | ~~0.724~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.758~~ | ~~0.724~~ | ~~0.724~~ | ~~0.724~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.724~~ | ~~0.724~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 pond~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.356~~ | ~~0.259~~ | ~~0.204~~ | ~~-~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.217~~ | ~~0.159~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.484~~ | ~~1.340~~ | ~~0.923~~ | ~~0.702~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.298~~ | ~~0.737~~ | ~~0.565~~ | ~~0.385~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.058~~ | ~~0.737~~ | ~~0.565~~ | ~~0.385~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.058~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R2 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~3.282~~ | ~~1.761~~ | ~~1.208~~ | ~~0.919~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.686~~ | ~~0.915~~ | ~~0.630~~ | ~~0.479~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.888~~ | ~~0.492~~ | ~~0.341~~ | ~~0.260~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.409~~ | ~~0.238~~ | ~~0.183~~ | ~~0.128~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~3.434~~ | ~~1.845~~ | ~~1.269~~ | ~~0.965~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.784~~ | ~~0.983~~ | ~~0.681~~ | ~~0.518~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.122~~ | ~~0.783~~ | ~~0.601~~ | ~~0.410~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.122~~ | ~~0.783~~ | ~~0.601~~ | ~~0.410~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D3 ditch~~ | **~~5.656~~** | **~~2.998~~** | **~~2.048~~** | **~~1.556~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.827~~** | **~~1.573~~** | **~~1.096~~** | ~~0.833~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.583~~** | ~~0.965~~ | ~~0.692~~ | ~~0.525~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.967~~ | ~~0.646~~ | ~~0.475~~ | ~~0.36~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 pond~~ | ~~0.696~~ | ~~0.51~~ | ~~0.406~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.421~~ | ~~0.308~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~6.119~~** | **~~3.273~~** | **~~2.242~~** | **~~1.704~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~3.119~~** | **~~1.681~~** | **~~1.156~~** | ~~0.879~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.619~~** | ~~0.885~~ | ~~0.665~~ | ~~0.665~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.719~~ | ~~0.665~~ | ~~0.665~~ | ~~0.665~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~5.594~~** | **~~2.965~~** | **~~2.025~~** | **~~1.54~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.796~~** | **~~1.481~~** | **~~1.173~~** | **~~1.173~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.454~~** | **~~1.173~~** | **~~1.173~~** | **~~1.2~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | **~~1.173~~** | **~~1.173~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~5.685~~** | **~~3.015~~** | **~~2.058~~** | **~~1.565~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.842~~** | **~~1.46~~** | **~~1.508~~** | **~~1.508~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.579~~** | **~~1.508~~** | **~~1.508~~** | **~~1.508~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | **~~1.508~~** | **~~1.508~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 pond~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.742~~ | ~~0.54~~ | ~~0.425~~ | **~~-~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.452~~ | ~~0.331~~ | ~~-~~ | **~~-~~** |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~-~~ | ~~-~~ | ~~-~~ | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.175~~** | **~~2.792~~** | **~~1.923~~** | **~~1.462~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.704~~** | **~~1.535~~** | **~~1.177~~** | ~~0.802~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.204~~** | **~~1.535~~** | **~~1.177~~** | ~~0.802~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.204~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R2 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~6.838~~** | **~~3.669~~** | **~~2.517~~** | **~~1.915~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.512~~** | **~~1.906~~** | **~~1.312~~** | ~~0.998~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.85~~** | **~~1.025~~** | ~~0.71~~ | ~~0.542~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.852~~ | ~~0.496~~ | ~~0.381~~ | ~~0.267~~ |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~7.154~~** | **~~3.844~~** | **~~2.644~~** | **~~2.01~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.717~~** | **~~2.048~~** | **~~1.419~~** | **~~1.079~~** |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.338~~** | **~~1.631~~** | **~~1.252~~** | ~~0.854~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.338~~** | **~~1.631~~** | **~~1.252~~** | ~~0.854~~ |

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

~~Table 9.5‑30: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Potato (1 x 1600 g/ha) VFSmod~~

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~potato~~ | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1600~~ | | | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | | | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | | | ~~20~~ |
| ~~R1 pond~~ | ~~R1 pond~~ | ~~0.344~~ | ~~0.250~~ | | ~~0.197~~ | | | ~~-~~ |
| ~~50%~~ | ~~0.205~~ | ~~0.150~~ | | ~~-~~ | | | ~~-~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | | ~~-~~ | | | ~~-~~ |
| ~~R1 stream~~ | ~~R1 stream~~ | ~~2.484~~ | ~~1.340~~ | | ~~0.923~~ | | | ~~0.702~~ |
| ~~50%~~ | ~~1.298~~ | ~~0.716~~ | | ~~0.497~~ | | | ~~0.378~~ |
| ~~75%~~ | ~~0.710~~ | ~~0.404~~ | | ~~0.284~~ | | | ~~0.216~~ |
| ~~90%~~ | ~~0.357~~ | ~~0.217~~ | | ~~0.156~~ | | | ~~-~~ |
| ~~R2 stream~~ | ~~R2 stream~~ | ~~3.282~~ | ~~1.761~~ | | ~~1.208~~ | | | ~~0.919~~ |
| ~~50%~~ | ~~1.686~~ | ~~0.915~~ | | ~~0.630~~ | | | ~~0.479~~ |
| ~~75%~~ | ~~0.888~~ | ~~0.492~~ | | ~~0.341~~ | | | ~~0.260~~ |
| ~~90%~~ | ~~0.409~~ | ~~0.238~~ | | ~~0.168~~ | | | ~~0.128~~ |
| ~~R3 stream~~ | ~~R3 stream~~ | ~~3.433~~ | ~~1.845~~ | | ~~1.269~~ | | | ~~0.965~~ |
| ~~50%~~ | ~~1.784~~ | ~~0.983~~ | | ~~0.681~~ | | | ~~0.518~~ |
| ~~75%~~ | ~~0.972~~ | ~~0.552~~ | | ~~0.388~~ | | | ~~0.295~~ |
| ~~90%~~ | ~~0.502~~ | ~~0.312~~ | | ~~0.226~~ | | | ~~0.172~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 pond~~ | ~~0.717~~ | ~~0.521~~ | | | ~~0.41~~ | **~~-~~** | |
| ~~50%~~ | ~~0.427~~ | ~~0.312~~ | | | ~~-~~ | **~~-~~** | |
| ~~75%~~ | **~~-~~** | **~~-~~** | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R1 stream~~ | **~~5.175~~** | **~~2.792~~** | | | **~~1.923~~** | **~~1.462~~** | |
| ~~50%~~ | **~~2.704~~** | **~~1.492~~** | | | **~~1.035~~** | ~~0.788~~ | |
| ~~75%~~ | **~~1.479~~** | ~~0.842~~ | | | ~~0.592~~ | ~~0.45~~ | |
| ~~90%~~ | ~~0.744~~ | ~~0.452~~ | | | ~~0.325~~ | **~~-~~** | |
| ~~None~~ | ~~R2 stream~~ | **~~6.838~~** | **~~3.669~~** | | | **~~2.517~~** | **~~1.915~~** | |
| ~~50%~~ | **~~3.512~~** | **~~1.906~~** | | | **~~1.312~~** | ~~0.998~~ | |
| ~~75%~~ | **~~1.85~~** | **~~1.025~~** | | | ~~0.71~~ | ~~0.542~~ | |
| ~~90%~~ | ~~0.852~~ | ~~0.496~~ | | | ~~0.35~~ | ~~0.267~~ | |
| ~~None~~ | ~~R3 stream~~ | **~~7.152~~** | **~~3.844~~** | | | **~~2.644~~** | **~~2.01~~** | |
| ~~50%~~ | **~~3.717~~** | **~~2.048~~** | | | **~~1.419~~** | **~~1.079~~** | |
| ~~75%~~ | **~~2.025~~** | **~~1.15~~** | | | ~~0.808~~ | ~~0.6~~ | |
| ~~90%~~ | **~~1.046~~** | ~~0.65~~ | | | ~~0.471~~ | ~~0.358~~ | |

~~PEC/RAC ratios in Potato (1x1600g/ha) are <1 when risk mitigation options are considered:~~

~~D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.~~

~~D4 pond,: 5m no spray buffer zone.~~

~~R1 pond: 5m no spray buffer zone with 5m vegetated filter strip~~

~~R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R2 stream:~~ ~~20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction~~

~~Table 9.5‑31: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Potato (1 x 1137 g/ha) as refinement~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~potato~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1137~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~1.929~~ | ~~1.023~~ | ~~0.698~~ | ~~0.531~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.965~~ | ~~0.537~~ | ~~0.373~~ | ~~0.283~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.541~~ | ~~0.329~~ | ~~0.239~~ | ~~0.179~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.331~~ | ~~0.221~~ | ~~0.163~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 pond~~ | ~~0.242~~ | ~~0.175~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.144~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~2.087~~ | ~~1.116~~ | ~~0.764~~ | ~~0.581~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.064~~ | ~~0.573~~ | ~~0.394~~ | ~~0.299~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.552~~ | ~~0.302~~ | ~~0.220~~ | ~~0.220~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.246~~ | ~~0.220~~ | ~~-~~ | ~~-~~ |  |  |  |  |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~1.908~~ | ~~1.011~~ | ~~0.691~~ | ~~0.525~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.953~~ | ~~0.505~~ | ~~0.386~~ | ~~0.386~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.496~~ | ~~0.386~~ | ~~0.386~~ | ~~0.386~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.386~~ | ~~0.386~~ | ~~-~~ | ~~-~~ |  |  |  |  |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~1.939~~ | ~~1.028~~ | ~~0.702~~ | ~~0.534~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.969~~ | ~~0.537~~ | ~~0.495~~ | ~~0.495~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.540~~ | ~~0.495~~ | ~~0.495~~ | ~~0.495~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.495~~ | ~~0.495~~ | ~~-~~ | ~~-~~ |  |  |  |  |
| ~~None~~ | ~~R1 pond~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.253~~ | ~~0.183~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.155~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.765~~ | ~~0.953~~ | ~~0.655~~ | ~~0.498~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.923~~ | ~~0.517~~ | ~~0.396~~ | ~~0.270~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.742~~ | ~~0.517~~ | ~~0.396~~ | ~~0.270~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.742~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R2 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.332~~ | ~~1.251~~ | ~~0.858~~ | ~~0.652~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.198~~ | ~~0.650~~ | ~~0.447~~ | ~~0.340~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.631~~ | ~~0.350~~ | ~~0.242~~ | ~~0.184~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.291~~ | ~~0.169~~ | ~~0.128~~ | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.440~~ | ~~1.311~~ | ~~0.901~~ | ~~0.685~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.268~~ | ~~0.699~~ | ~~0.484~~ | ~~0.367~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.785~~ | ~~0.548~~ | ~~0.421~~ | ~~0.287~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.785~~ | ~~0.548~~ | ~~0.421~~ | ~~0.287~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D3 ditch~~ | **~~4.019~~** | **~~2.131~~** | **~~1.454~~** | **~~1.106~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.01~~** | **~~1.119~~** | ~~0.777~~ | ~~0.59~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.127~~** | ~~0.685~~ | ~~0.498~~ | ~~0.373~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.69~~ | ~~0.46~~ | ~~0.34~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 pond~~ | ~~0.504~~ | ~~0.365~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.3~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~4.348~~** | **~~2.325~~** | **~~1.592~~** | **~~1.21~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.217~~** | **~~1.194~~** | ~~0.821~~ | ~~0.623~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.15~~** | ~~0.629~~ | ~~0.458~~ | ~~0.458~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.513~~ | ~~0.458~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~3.975~~** | **~~2.106~~** | **~~1.44~~** | **~~1.094~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.985~~** | **~~1.052~~** | ~~0.804~~ | ~~0.804~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.033~~** | ~~0.804~~ | ~~0.804~~ | ~~0.804~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.804~~ | ~~0.804~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~4.04~~** | **~~2.142~~** | **~~1.462~~** | **~~1.112~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.019~~** | **~~1.119~~** | **~~1.031~~** | **~~1.031~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.125~~** | **~~1.031~~** | **~~1.031~~** | **~~1.031~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | **~~1.031~~** | **~~1.031~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 pond~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.527~~ | ~~0.381~~ | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.323~~ | ~~-~~ | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.677~~** | **~~1.985~~** | **~~1.365~~** | **~~1.038~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.923~~** | **~~1.077~~** | ~~0.825~~ | ~~0.563~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.546~~** | **~~1.077~~** | ~~0.825~~ | ~~0.563~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.546~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R2 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~4.858~~** | **~~2.606~~** | **~~1.788~~** | **~~1.358~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.496~~** | **~~1.354~~** | ~~0.931~~ | ~~0.708~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.315~~** | ~~0.729~~ | ~~0.504~~ | ~~0.383~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.606~~ | ~~0.352~~ | ~~0.267~~ | **~~-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.083~~** | **~~2.731~~** | **~~1.877~~** | **~~1.427~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.642~~** | **~~1.456~~** | **~~1.008~~** | ~~0.765~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.635~~** | **~~1.142~~** | ~~0.877~~ | ~~0.598~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.635~~** | **~~1.142~~** | ~~0.877~~ | ~~0.598~~ |

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

~~Table 9.5‑32: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Potato (1 x 1137 g/ha) as refinement VFSmod~~

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~potato~~ | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1137~~ | | | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | | | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | | | ~~20~~ |
| ~~R1 pond~~ | ~~R1 pond~~ | ~~0.245~~ | ~~0.177~~ | | ~~-~~ | | | ~~-~~ |
| ~~50%~~ | ~~0.146~~ | ~~-~~ | | ~~-~~ | | | ~~-~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | | ~~-~~ | | | ~~-~~ |
| ~~R1 stream~~ | ~~R1 stream~~ | ~~1.765~~ | ~~0.953~~ | | ~~0.655~~ | | | ~~0.498~~ |
| ~~50%~~ | ~~0.923~~ | ~~0.509~~ | | ~~0.353~~ | | | ~~0.268~~ |
| ~~75%~~ | ~~0.505~~ | ~~0.288~~ | | ~~0.201~~ | | | ~~0.153~~ |
| ~~90%~~ | ~~0.254~~ | ~~0.155~~ | | ~~-~~ | | | ~~-~~ |
| ~~R2 stream~~ | ~~R2 stream~~ | ~~2.332~~ | ~~1.251~~ | | ~~0.858~~ | | | ~~0.652~~ |
| ~~50%~~ | ~~1.198~~ | ~~0.650~~ | | ~~0.447~~ | | | ~~0.340~~ |
| ~~75%~~ | ~~0.631~~ | ~~0.349~~ | | ~~0.242~~ | | | ~~0.184~~ |
| ~~90%~~ | ~~0.291~~ | ~~0.169~~ | | ~~0.119~~ | | | ~~-~~ |
| ~~R3 stream~~ | ~~R3 stream~~ | ~~2.440~~ | ~~1.311~~ | | ~~0.901~~ | | | ~~0.685~~ |
| ~~50%~~ | ~~1.268~~ | ~~0.699~~ | | ~~0.484~~ | | | ~~0.367~~ |
| ~~75%~~ | ~~0.691~~ | ~~0.393~~ | | ~~0.276~~ | | | ~~0.209~~ |
| ~~90%~~ | ~~0.357~~ | ~~0.223~~ | | ~~0.160~~ | | | ~~-~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 pond~~ | ~~0.51~~ | ~~0.369~~ | | | **~~-~~** | **~~-~~** | |
| ~~50%~~ | ~~0.304~~ | ~~-~~ | | | **~~-~~** | **~~-~~** | |
| ~~75%~~ | **~~-~~** | **~~-~~** | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R1 stream~~ | **~~3.677~~** | **~~1.985~~** | | | **~~1.365~~** | **~~1.038~~** | |
| ~~50%~~ | **~~1.923~~** | **~~1.06~~** | | | ~~0.735~~ | ~~0.558~~ | |
| ~~75%~~ | **~~1.052~~** | ~~0.6~~ | | | ~~0.419~~ | ~~0.319~~ | |
| ~~90%~~ | ~~0.529~~ | ~~0.323~~ | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R2 stream~~ | **~~4.858~~** | **~~2.606~~** | | | **~~1.788~~** | **~~1.358~~** | |
| ~~50%~~ | **~~2.496~~** | **~~1.354~~** | | | ~~0.931~~ | ~~0.708~~ | |
| ~~75%~~ | **~~1.315~~** | ~~0.727~~ | | | ~~0.504~~ | ~~0.383~~ | |
| ~~90%~~ | ~~0.606~~ | ~~0.352~~ | | | ~~0.248~~ | **~~-~~** | |
| ~~None~~ | ~~R3 stream~~ | **~~5.083~~** | **~~2.731~~** | | | **~~1.877~~** | **~~1.427~~** | |
| ~~50%~~ | **~~2.642~~** | **~~1.456~~** | | | **~~1.008~~** | ~~0.765~~ | |
| ~~75%~~ | **~~1.44~~** | ~~0.819~~ | | | ~~0.575~~ | ~~0.4~~ | |
| ~~90%~~ | ~~0.744~~ | ~~0.465~~ | | | ~~0.333~~ | **~~-~~** | |

~~PEC/RAC ratios in Potato (1x1137g/ha) are <1 when risk mitigation options are considered:~~

~~D3 ditch, D4 stream, D6 1~~~~st~~ ~~ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.~~

~~D4 pond: 5m no spray buffer zone.~~

~~R1 pond: 5m no spray buffer zone with 5m vegetated filter strip~~

~~R1 stream, R2 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~Table 9.5‑33: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter cereals (1 x 1137 g/ha)~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Winter cereals~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1137~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D1 ditch~~ | ~~1.966~~ | ~~1.070~~ | ~~0.741~~ | ~~0.562~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.064~~ | ~~0.615~~ | ~~0.433~~ | ~~0.328~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.644~~ | ~~0.402~~ | ~~0.291~~ | ~~0.221~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.420~~ | ~~0.269~~ | ~~0.210~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D1 stream~~ | ~~2.303~~ | ~~1.222~~ | ~~0.835~~ | ~~0.635~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.153~~ | ~~0.612~~ | ~~0.418~~ | ~~0.318~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.580~~ | ~~0.342~~ | ~~0.244~~ | ~~0.185~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.346~~ | ~~0.237~~ | ~~0.176~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D2 ditch~~ | ~~1.973~~ | ~~1.074~~ | ~~0.745~~ | ~~0.565~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.071~~ | ~~0.619~~ | ~~0.436~~ | ~~0.330~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.652~~ | ~~0.407~~ | ~~0.295~~ | ~~0.223~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.424~~ | ~~0.286~~ | ~~0.212~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D2 stream~~ | ~~2.345~~ | ~~1.244~~ | ~~0.850~~ | ~~0.646~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.174~~ | ~~0.623~~ | ~~0.426~~ | ~~0.324~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.589~~ | ~~0.313~~ | ~~0.214~~ | ~~0.163~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.238~~ | ~~0.131~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~1.923~~ | ~~1.019~~ | ~~0.696~~ | ~~0.530~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.964~~ | ~~0.537~~ | ~~0.373~~ | ~~0.283~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.540~~ | ~~0.323~~ | ~~0.231~~ | ~~0.175~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.323~~ | ~~0.215~~ | ~~0.159~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 pond~~ | ~~0.240~~ | ~~0.174~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.143~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~2.252~~ | ~~1.197~~ | ~~0.820~~ | ~~0.623~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.144~~ | ~~0.624~~ | ~~0.431~~ | ~~0.327~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.611~~ | ~~0.342~~ | ~~0.239~~ | ~~0.182~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.305~~ | ~~0.189~~ | ~~0.178~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D5 pond~~ | ~~0.245~~ | ~~0.178~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.146~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D5 stream~~ | ~~2.429~~ | ~~1.288~~ | ~~0.880~~ | ~~0.669~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.223~~ | ~~0.666~~ | ~~0.459~~ | ~~0.349~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.651~~ | ~~0.370~~ | ~~0.260~~ | ~~0.197~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.336~~ | ~~0.212~~ | ~~0.155~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 ditch~~ | ~~1.971~~ | ~~1.077~~ | ~~0.748~~ | ~~0.568~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.076~~ | ~~0.621~~ | ~~0.438~~ | ~~0.331~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.659~~ | ~~0.411~~ | ~~0.305~~ | ~~0.305~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.429~~ | ~~0.305~~ | ~~0.305~~ | ~~0.305~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 pond~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.249~~ | ~~0.180~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.151~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.766~~ | ~~0.952~~ | ~~0.654~~ | ~~0.497~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.917~~ | ~~0.575~~ | ~~0.441~~ | ~~0.301~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.826~~ | ~~0.575~~ | ~~0.441~~ | ~~0.301~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.826~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.438~~ | ~~1.313~~ | ~~0.902~~ | ~~0.685~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.263~~ | ~~0.690~~ | ~~0.478~~ | ~~0.363~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.794~~ | ~~0.554~~ | ~~0.425~~ | ~~0.290~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.794~~ | ~~0.554~~ | ~~0.425~~ | ~~0.290~~ |
| ~~None~~ | ~~R4 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.773~~ | ~~0.959~~ | ~~0.660~~ | ~~0.501~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.012~~ | ~~0.703~~ | ~~0.539~~ | ~~0.367~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.012~~ | ~~0.703~~ | ~~0.539~~ | ~~0.367~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D1 ditch~~ | **~~4.096~~** | **~~2.229~~** | **~~1.544~~** | **~~1.171~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.217~~** | **~~1.281~~** | ~~0.902~~ | ~~0.683~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.342~~** | ~~0.838~~ | ~~0.606~~ | ~~0.46~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.875~~ | ~~0.56~~ | ~~0.438~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D1 stream~~ | **~~4.798~~** | **~~2.546~~** | **~~1.74~~** | **~~1.323~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.402~~** | **~~1.275~~** | ~~0.871~~ | ~~0.663~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.208~~** | ~~0.713~~ | ~~0.508~~ | ~~0.385~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.721~~ | ~~0.494~~ | ~~0.367~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D2 ditch~~ | **~~4.11~~** | **~~2.238~~** | **~~1.552~~** | **~~1.177~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.231~~** | **~~1.29~~** | ~~0.908~~ | ~~0.688~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.358~~** | ~~0.848~~ | ~~0.615~~ | ~~0.465~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.883~~ | ~~0.596~~ | ~~0.442~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D2 stream~~ | **~~4.885~~** | **~~2.592~~** | **~~1.771~~** | **~~1.346~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.446~~** | **~~1.298~~** | ~~0.888~~ | ~~0.7~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.227~~** | ~~0.652~~ | ~~0.446~~ | ~~0.34~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.496~~ | ~~0.273~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D3 ditch~~ | **~~4.006~~** | **~~2.123~~** | **~~1.45~~** | **~~1.104~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.008~~** | **~~1.119~~** | ~~0.777~~ | ~~0.59~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.125~~** | ~~0.673~~ | ~~0.481~~ | ~~0.365~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.673~~ | ~~0.448~~ | ~~0.331~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 pond~~ | ~~0.500~~ | ~~0.362~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.298~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~4.692~~** | **~~2.494~~** | **~~1.708~~** | **~~1.298~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.383~~** | **~~1.3~~** | ~~0.898~~ | ~~0.681~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.273~~** | ~~0.713~~ | ~~0.498~~ | ~~0.379~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.635~~ | ~~0.394~~ | ~~0.371~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D5 pond~~ | ~~0.51~~ | ~~0.371~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.304~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D5 stream~~ | **~~5.06~~** | **~~2.683~~** | **~~1.833~~** | **~~1.394~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.548~~** | **~~1.388~~** | ~~0.956~~ | ~~0.727~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.356~~** | ~~0.771~~ | ~~0.542~~ | ~~0.41~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.7~~ | ~~0.442~~ | ~~0.323~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 ditch~~ | **~~4.106~~** | **~~2.244~~** | **~~1.558~~** | **~~1.183~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.242~~** | **~~1.294~~** | ~~0.913~~ | ~~0.69~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.373~~** | ~~0.856~~ | ~~0.635~~ | ~~0.635~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.894~~ | ~~0.635~~ | ~~0.635~~ | ~~0.635~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 pond~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.519~~ | ~~0.375~~ | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.315~~ | ~~-~~ | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.679~~** | **~~1.983~~** | **~~1.362~~** | **~~1.035~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.91~~** | **~~1.198~~** | ~~0.919~~ | ~~0.627~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.721~~** | **~~1.198~~** | ~~0.919~~ | ~~0.627~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.721~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.079~~** | **~~2.735~~** | **~~1.879~~** | **~~1.427~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.631~~** | **~~1.438~~** | ~~0.996~~ | ~~0.756~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.654~~** | **~~1.154~~** | ~~0.885~~ | ~~0.604~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.654~~** | **~~1.154~~** | ~~0.885~~ | ~~0.604~~ |
| ~~None~~ | ~~R4 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.694~~** | **~~1.998~~** | **~~1.375~~** | **~~1.044~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.108~~** | **~~1.465~~** | **~~1.123~~** | ~~0.765~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.108~~** | **~~1.465~~** | **~~1.123~~** | ~~0.765~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |

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

~~Table 9.5‑34: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in winter cereals (1 x 1137 g/ha) VFSmod~~

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Winter cereals~~ | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1137~~ | | | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | | | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | | | ~~20~~ |
| ~~None~~ | ~~R1 pond~~ | ~~0.243~~ | ~~0.177~~ | | ~~-~~ | | | ~~-~~ |
| ~~50%~~ | ~~0.147~~ | ~~-~~ | | ~~-~~ | | | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~1.766~~ | ~~0.951~~ | | ~~0.654~~ | | | ~~0.497~~ |
| ~~50%~~ | ~~0.917~~ | ~~0.506~~ | | ~~0.350~~ | | | ~~0.266~~ |
| ~~75%~~ | ~~0.502~~ | ~~0.286~~ | | ~~0.200~~ | | | ~~0.152~~ |
| ~~90%~~ | ~~0.253~~ | ~~0.154~~ | | ~~-~~ | | | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~2.437~~ | ~~1.312~~ | | ~~0.902~~ | | | ~~0.685~~ |
| ~~50%~~ | ~~1.236~~ | ~~0.690~~ | | ~~0.478~~ | | | ~~0.363~~ |
| ~~75%~~ | ~~0.684~~ | ~~0.438~~ | | ~~0.351~~ | | | ~~0.277~~ |
| ~~90%~~ | ~~0.543~~ | ~~0.438~~ | | ~~0.351~~ | | | ~~0.277~~ |
| ~~None~~ | ~~R4 stream~~ | ~~1.773~~ | ~~0.957~~ | | ~~0.660~~ | | | ~~0.501~~ |
| ~~50%~~ | ~~0.928~~ | ~~0.511~~ | | ~~0.354~~ | | | ~~0.269~~ |
| ~~75%~~ | ~~0.506~~ | ~~0.288~~ | | ~~0.201~~ | | | ~~0.153~~ |
| ~~90%~~ | ~~0.280~~ | ~~0.158~~ | | ~~-~~ | | | ~~-~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 pond~~ | ~~0.506~~ | ~~0.369~~ | | | **~~-~~** | **~~-~~** | |
| ~~50%~~ | ~~0.306~~ | ~~-~~ | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R1 stream~~ | **~~3.679~~** | **~~1.981~~** | | | **~~1.362~~** | **~~1.035~~** | |
| ~~50%~~ | **~~1.91~~** | **~~1.054~~** | | | ~~0.729~~ | ~~0.554~~ | |
| ~~75%~~ | **~~1.046~~** | ~~0.596~~ | | | ~~0.417~~ | ~~0.317~~ | |
| ~~90%~~ | ~~0.527~~ | ~~0.321~~ | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R3 stream~~ | **~~5.077~~** | **~~2.733~~** | | | **~~1.879~~** | **~~1.427~~** | |
| ~~50%~~ | **~~2.575~~** | **~~1.438~~** | | | ~~0.996~~ | ~~0.756~~ | |
| ~~75%~~ | **~~1.425~~** | ~~0.913~~ | | | ~~0.731~~ | ~~0.577~~ | |
| ~~90%~~ | **~~1.131~~** | ~~0.913~~ | | | ~~0.731~~ | ~~0.577~~ | |
| ~~None~~ | ~~R4 stream~~ | **~~3.694~~** | **~~1.994~~** | | | **~~1.375~~** | **~~1.044~~** | |
| ~~50%~~ | **~~1.933~~** | **~~1.065~~** | | | ~~0.737~~ | ~~0.56~~ | |
| ~~75%~~ | **~~1.054~~** | ~~0.6~~ | | | ~~0.419~~ | ~~0.319~~ | |
| ~~90%~~ | ~~0.583~~ | ~~0.329~~ | | | **~~-~~** | **~~-~~** | |

~~PEC/RAC ratios in winter cereals (1x1137g/ha) are <1 when risk mitigation options are considered:~~

~~D1 ditch, D1 stream, D2 ditch, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.~~

~~D4 pond, D5 pond: 5m no spray buffer zone.~~

~~R1 pond: 5m no spray buffer zone with 5m vegetated filter strip~~

~~R1 stream, R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R3 stream:~~ ~~15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction~~

~~Table 9.5‑35: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (1 x 1600 g/ha)~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1600~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~2.711~~ | ~~1.437~~ | ~~0.981~~ | ~~0.746~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.367~~ | ~~0.762~~ | ~~0.531~~ | ~~0.404~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.771~~ | ~~0.468~~ | ~~0.335~~ | ~~0.255~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.468~~ | ~~0.313~~ | ~~0.230~~ | ~~0.174~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 pond~~ | ~~0.346~~ | ~~0.252~~ | ~~0.199~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.205~~ | ~~0.151~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~2.837~~ | ~~1.515~~ | ~~1.037~~ | ~~0.789~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.441~~ | ~~0.775~~ | ~~0.532~~ | ~~0.404~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.743~~ | ~~0.405~~ | ~~0.306~~ | ~~0.306~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.325~~ | ~~0.306~~ | ~~0.306~~ | ~~0.306~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~2.672~~ | ~~1.416~~ | ~~0.967~~ | ~~0.736~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.335~~ | ~~0.708~~ | ~~0.537~~ | ~~0.537~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.667~~ | ~~0.537~~ | ~~0.537~~ | ~~0.537~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.537~~ | ~~0.537~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~2.737~~ | ~~1.464~~ | ~~1.070~~ | ~~1.070~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.428~~ | ~~1.070~~ | ~~1.070~~ | ~~1.070~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~1.070~~ | ~~1.070~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~1.070~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 pond~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.356~~ | ~~0.258~~ | ~~0.204~~ | ~~-~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.217~~ | ~~0.158~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.484~~ | ~~1.339~~ | ~~0.922~~ | ~~0.701~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.297~~ | ~~0.735~~ | ~~0.563~~ | ~~0.384~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.056~~ | ~~0.735~~ | ~~0.563~~ | ~~0.384~~ |
| ~~None~~ | ~~R2 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~3.243~~ | ~~1.738~~ | ~~1.192~~ | ~~0.907~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.662~~ | ~~0.900~~ | ~~0.620~~ | ~~0.471~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.872~~ | ~~0.481~~ | ~~0.334~~ | ~~0.254~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.398~~ | ~~0.230~~ | ~~0.163~~ | ~~0.123~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~3.442~~ | ~~1.853~~ | ~~1.273~~ | ~~0.968~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.782~~ | ~~0.982~~ | ~~0.682~~ | ~~0.518~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.976~~ | ~~0.653~~ | ~~0.500~~ | ~~0.340~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.943~~ | ~~0.653~~ | ~~0.500~~ | ~~0.340~~ |
| ~~None~~ | ~~R4 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.493~~ | ~~1.349~~ | ~~0.928~~ | ~~0.706~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.637~~ | ~~1.140~~ | ~~0.875~~ | ~~0.597~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.637~~ | ~~1.140~~ | ~~0.875~~ | ~~0.597~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D3 ditch~~ | **~~5.648~~** | **~~2.994~~** | **~~2.044~~** | **~~1.554~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.848~~** | **~~1.588~~** | **~~1.106~~** | ~~0.842~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.606~~** | ~~0.975~~ | ~~0.698~~ | ~~0.531~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.975~~ | ~~0.652~~ | ~~0.479~~ | ~~0.362~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 pond~~ | ~~0.721~~ | ~~0.525~~ | ~~0.415~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.427~~ | ~~0.315~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~5.91~~** | **~~3.156~~** | **~~2.16~~** | **~~1.644~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~3.002~~** | **~~1.615~~** | **~~1.108~~** | ~~0.842~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.548~~** | ~~0.844~~ | ~~0.638~~ | ~~0.638~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.677~~ | ~~0.638~~ | ~~0.638~~ | ~~0.638~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~5.567~~** | **~~2.95~~** | **~~2.015~~** | **~~1.533~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.781~~** | **~~1.475~~** | **~~1.119~~** | **~~1.119~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.39~~** | **~~1.119~~** | **~~1.119~~** | **~~1.119~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | **~~1.119~~** | **~~1.119~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~5.702~~** | **~~3.05~~** | **~~2.229~~** | **~~2.229~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.975~~** | **~~2.229~~** | **~~2.229~~** | **~~2.229~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~2.229~~** | **~~2.229~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | **~~2.229~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 pond~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.742~~ | ~~0.538~~ | ~~0.425~~ | **~~-~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.452~~ | ~~0.329~~ | ~~-~~ | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.175~~** | **~~2.79~~** | **~~1.921~~** | **~~1.46~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.702~~** | **~~1.531~~** | **~~1.173~~** | ~~0.8~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.2~~** | **~~1.531~~** | **~~1.173~~** | ~~0.8~~ |
| ~~None~~ | ~~R2 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~6.756~~** | **~~3.621~~** | **~~2.483~~** | **~~1.89~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.462~~** | **~~1.875~~** | **~~1.292~~** | ~~0.981~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.817~~** | **~~1.002~~** | ~~0.696~~ | ~~0.529~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.829~~ | ~~0.479~~ | ~~0.34~~ | ~~0.256~~ |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~7.171~~** | **~~3.86~~** | **~~2.652~~** | **~~2.017~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.713~~** | **~~2.046~~** | **~~1.421~~** | **~~1.079~~** |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.033~~** | **~~1.36~~** | **~~1.042~~** | ~~0.708~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.965~~** | **~~1.36~~** | **~~1.042~~** | ~~0.708~~ |
| ~~None~~ | ~~R4 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.194~~** | **~~2.81~~** | **~~1.933~~** | **~~1.471~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.41~~** | **~~2.375~~** | **~~1.823~~** | **~~1.244~~** |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.41~~** | **~~2.375~~** | **~~1.823~~** | **~~1.244~~** |

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

~~Table 9.5‑36: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (1 x 1600 g/ha) VFSmod~~

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1600~~ | | | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | | | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | | | ~~20~~ |
| ~~None~~ | ~~R1 pond~~ | ~~0.344~~ | ~~0.250~~ | | ~~0.197~~ | | | ~~-~~ |
| ~~50%~~ | ~~0.205~~ | ~~0.150~~ | | ~~-~~ | | | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~2.483~~ | ~~1.339~~ | | ~~0.922~~ | | | ~~0.701~~ |
| ~~50%~~ | ~~1.297~~ | ~~0.716~~ | | ~~0.609~~ | | | ~~0.609~~ |
| ~~75%~~ | ~~0.709~~ | ~~0.609~~ | | ~~0.609~~ | | | ~~0.609~~ |
| ~~90%~~ | ~~0.357~~ | ~~0.609~~ | | ~~-~~ | | | ~~-~~ |
| ~~None~~ | ~~R2 stream~~ | ~~3.243~~ | ~~1.738~~ | | ~~1.192~~ | | | ~~0.907~~ |
| ~~50%~~ | ~~1.662~~ | ~~0.900~~ | | ~~0.620~~ | | | ~~0.471~~ |
| ~~75%~~ | ~~0.872~~ | ~~0.481~~ | | ~~0.334~~ | | | ~~0.254~~ |
| ~~90%~~ | ~~0.398~~ | ~~0.230~~ | | ~~0.162~~ | | | ~~0.123~~ |
| ~~None~~ | ~~R3 stream~~ | ~~3.442~~ | ~~1.853~~ | | ~~1.273~~ | | | ~~0.968~~ |
| ~~50%~~ | ~~1.782~~ | ~~0.982~~ | | ~~0.682~~ | | | ~~0.518~~ |
| ~~75%~~ | ~~0.976~~ | ~~0.558~~ | | ~~0.393~~ | | | ~~0.298~~ |
| ~~90%~~ | ~~0.511~~ | ~~0.321~~ | | ~~0.233~~ | | | ~~0.177~~ |
| ~~None~~ | ~~R4 stream~~ | ~~2.493~~ | ~~1.349~~ | | ~~0.928~~ | | | ~~0.706~~ |
| ~~50%~~ | ~~1.305~~ | ~~0.719~~ | | ~~0.671~~ | | | ~~0.379~~ |
| ~~75%~~ | ~~0.711~~ | ~~0.404~~ | | ~~0.283~~ | | | ~~0.215~~ |
| ~~90%~~ | ~~0.502~~ | ~~0.221~~ | | ~~0.160~~ | | | ~~-~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 pond~~ | ~~0.717~~ | ~~0.521~~ | | | ~~0.41~~ | **~~-~~** | |
| ~~50%~~ | ~~0.427~~ | ~~0.312~~ | | | ~~-~~ | **~~-~~** | |
| ~~None~~ | ~~R1 stream~~ | **~~5.173~~** | **~~2.79~~** | | | **~~1.921~~** | **~~1.46~~** | |
| ~~50%~~ | **~~2.702~~** | **~~1.492~~** | | | **~~1.269~~** | **~~1.269~~** | |
| ~~75%~~ | **~~1.477~~** | **~~1.269~~** | | | **~~1.269~~** | **~~1.269~~** | |
| ~~90%~~ | ~~0.744~~ | **~~1.269~~** | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R2 stream~~ | **~~6.756~~** | **~~3.621~~** | | | **~~2.483~~** | **~~1.89~~** | |
| ~~50%~~ | **~~3.462~~** | **~~1.875~~** | | | **~~1.292~~** | ~~0.981~~ | |
| ~~75%~~ | **~~1.817~~** | **~~1.002~~** | | | ~~0.696~~ | ~~0.529~~ | |
| ~~90%~~ | ~~0.829~~ | ~~0.479~~ | | | ~~0.338~~ | ~~0.256~~ | |
| ~~None~~ | ~~R3 stream~~ | **~~7.171~~** | **~~3.86~~** | | | **~~2.652~~** | **~~2.017~~** | |
| ~~50%~~ | **~~3.713~~** | **~~2.046~~** | | | **~~1.421~~** | **~~1.079~~** | |
| ~~75%~~ | **~~2.033~~** | **~~1.162~~** | | | ~~0.819~~ | ~~0.621~~ | |
| ~~90%~~ | **~~1.065~~** | ~~0.669~~ | | | ~~0.485~~ | ~~0.4~~ | |
| ~~None~~ | ~~R4 stream~~ | **~~5.194~~** | **~~2.81~~** | | | **~~1.933~~** | **~~1.471~~** | |
| ~~50%~~ | **~~2.719~~** | **~~1.498~~** | | | **~~1.398~~** | ~~0.79~~ | |
| ~~75%~~ | **~~1.481~~** | ~~0.842~~ | | | ~~0.59~~ | ~~0.448~~ | |
| ~~90%~~ | **~~1.046~~** | ~~0.46~~ | | | ~~0.333~~ | ~~-~~ | |

~~PEC/RAC ratios in Bulb vegetables (1x1600g/ha) are <1 when risk mitigation options are considered:~~

~~D3 ditch, D4 stream: 20m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction..~~

~~D4 pond: 5m no spray buffer zone.~~

~~R1 pond: 5m no spray buffer zone with 5m vegetated filter strip~~

~~R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R2 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction~~

~~R4 stream:~~ ~~20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction~~

~~Table 9.5‑37: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (1 x 1300 g/ha) as first refinement~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1300~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~2.202~~ | ~~1.168~~ | ~~0.797~~ | ~~0.606~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.111~~ | ~~0.620~~ | ~~0.431~~ | ~~0.327~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.627~~ | ~~0.381~~ | ~~0.272~~ | ~~0.207~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.381~~ | ~~0.255~~ | ~~0.186~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 pond~~ | ~~0.281~~ | ~~0.204~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.167~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~2.305~~ | ~~1.230~~ | ~~0.842~~ | ~~0.641~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.171~~ | ~~0.629~~ | ~~0.432~~ | ~~0.328~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.604~~ | ~~0.329~~ | ~~0.244~~ | ~~0.244~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.264~~ | ~~0.244~~ | ~~0.244~~ | ~~0.244~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~2.171~~ | ~~1.151~~ | ~~0.786~~ | ~~0.598~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.085~~ | ~~0.575~~ | ~~0.426~~ | ~~0.426~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.542~~ | ~~0.426~~ | ~~0.426~~ | ~~0.426~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.426~~ | ~~0.426~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~2.224~~ | ~~1.190~~ | ~~0.850~~ | ~~0.850~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~1.160~~ | ~~0.850~~ | ~~0.850~~ | ~~0.850~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.850~~ | ~~0.850~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.850~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 pond~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.289~~ | ~~0.209~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.176~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.018~~ | ~~1.088~~ | ~~0.749~~ | ~~0.569~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.054~~ | ~~0.592~~ | ~~0.454~~ | ~~0.310~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.851~~ | ~~0.592~~ | ~~0.454~~ | ~~0.310~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.851~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R2 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.635~~ | ~~1.412~~ | ~~0.968~~ | ~~0.736~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.350~~ | ~~0.731~~ | ~~0.503~~ | ~~0.383~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.709~~ | ~~0.391~~ | ~~0.271~~ | ~~0.206~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.323~~ | ~~0.187~~ | ~~0.132~~ | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.797~~ | ~~1.506~~ | ~~1.034~~ | ~~0.786~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.448~~ | ~~0.798~~ | ~~0.554~~ | ~~0.421~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.793~~ | ~~0.525~~ | ~~0.402~~ | ~~0.273~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.758~~ | ~~0.525~~ | ~~0.402~~ | ~~0.273~~ |
| ~~None~~ | ~~R4 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~2.026~~ | ~~1.096~~ | ~~0.754~~ | ~~0.573~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.319~~ | ~~0.918~~ | ~~0.705~~ | ~~0.481~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.319~~ | ~~0.918~~ | ~~0.705~~ | ~~0.481~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D3 ditch~~ | **~~4.588~~** | **~~2.433~~** | **~~1.66~~** | **~~1.262~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.315~~** | **~~1.292~~** | ~~0.898~~ | ~~0.681~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.306~~** | ~~0.794~~ | ~~0.567~~ | ~~0.431~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.794~~ | ~~0.531~~ | ~~0.388~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 pond~~ | ~~0.585~~ | ~~0.425~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.348~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~4.802~~** | **~~2.562~~** | **~~1.754~~** | **~~1.335~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.44~~** | **~~1.31~~** | ~~0.9~~ | ~~0.683~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.258~~** | ~~0.685~~ | ~~0.508~~ | ~~0.508~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.55~~ | ~~0.508~~ | ~~0.508~~ | ~~0.508~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~4.523~~** | **~~2.398~~** | **~~1.638~~** | **~~1.246~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.26~~** | **~~1.198~~** | ~~0.888~~ | ~~0.888~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.129~~** | ~~0.888~~ | ~~0.888~~ | ~~0.888~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.888~~ | ~~0.888~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~4.633~~** | **~~2.479~~** | **~~1.771~~** | **~~1.771~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.417~~** | **~~1.771~~** | **~~1.771~~** | **~~1.771~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.771~~** | **~~1.771~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | **~~1.771~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 pond~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.602~~ | ~~0.435~~ | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.367~~ | ~~-~~ | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~4.204~~** | **~~2.267~~** | **~~1.56~~** | **~~1.185~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.196~~** | **~~1.233~~** | ~~0.946~~ | ~~0.646~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.773~~** | **~~1.233~~** | ~~0.946~~ | ~~0.646~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.773~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R2 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.49~~** | **~~2.942~~** | **~~2.017~~** | **~~1.533~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.813~~** | **~~1.523~~** | **~~1.048~~** | ~~0.798~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.477~~** | ~~0.815~~ | ~~0.565~~ | ~~0.429~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.673~~ | ~~0.39~~ | ~~0.275~~ | **~~-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~5.827~~** | **~~3.138~~** | **~~2.154~~** | **~~1.638~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~3.017~~** | **~~1.662~~** | **~~1.154~~** | ~~0.877~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.652~~** | **~~1.094~~** | ~~0.838~~ | ~~0.569~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.579~~** | **~~1.094~~** | ~~0.838~~ | ~~0.569~~ |
| ~~None~~ | ~~R4 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~4.221~~** | **~~2.283~~** | **~~1.571~~** | **~~1.194~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.748~~** | **~~1.912~~** | **~~1.469~~** | **~~1.002~~** |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.748~~** | **~~1.912~~** | **~~1.469~~** | **~~1.002~~** |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |

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

~~Table 9.5‑38: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (1 x 1300 g/ha) as first refinement VFSmod~~

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 × 1300~~ | | | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | | | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | | | ~~20~~ |
| ~~None~~ | ~~R1 pond~~ | ~~0.280~~ | ~~0.203~~ | | ~~-~~ | | | ~~-~~ |
| ~~50%~~ | ~~0.167~~ | ~~-~~ | | ~~-~~ | | | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~2.018~~ | ~~1.088~~ | | ~~0.749~~ | | | ~~0.569~~ |
| ~~50%~~ | ~~1.054~~ | ~~0.582~~ | | ~~0.492~~ | | | ~~0.492~~ |
| ~~75%~~ | ~~0.576~~ | ~~0.492~~ | | ~~0.492~~ | | | ~~0.492~~ |
| ~~90%~~ | ~~0.290~~ | ~~0.492~~ | | ~~-~~ | | | ~~-~~ |
| ~~None~~ | ~~R2 stream~~ | ~~2.635~~ | ~~1.412~~ | | ~~0.968~~ | | | ~~0.736~~ |
| ~~50%~~ | ~~1.350~~ | ~~0.731~~ | | ~~0.503~~ | | | ~~0.383~~ |
| ~~75%~~ | ~~0.708~~ | ~~0.391~~ | | ~~0.271~~ | | | ~~0.206~~ |
| ~~90%~~ | ~~0.323~~ | ~~0.187~~ | | ~~0.132~~ | | | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~2.797~~ | ~~1.506~~ | | ~~1.034~~ | | | ~~0.786~~ |
| ~~50%~~ | ~~1.448~~ | ~~0.798~~ | | ~~0.554~~ | | | ~~0.421~~ |
| ~~75%~~ | ~~0.793~~ | ~~0.454~~ | | ~~0.319~~ | | | ~~0.242~~ |
| ~~90%~~ | ~~0.415~~ | ~~0.261~~ | | ~~0.190~~ | | | ~~0.144~~ |
| ~~None~~ | ~~R4 stream~~ | ~~2.026~~ | ~~1.096~~ | | ~~0.754~~ | | | ~~0.573~~ |
| ~~50%~~ | ~~1.060~~ | ~~0.584~~ | | ~~0.549~~ | | | ~~0.308~~ |
| ~~75%~~ | ~~0.578~~ | ~~0.329~~ | | ~~0.230~~ | | | ~~0.175~~ |
| ~~90%~~ | ~~0.405~~ | ~~0.180~~ | | ~~-~~ | | | ~~-~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 pond~~ | ~~0.583~~ | ~~0.423~~ | | | **~~-~~** | **~~-~~** | |
| ~~50%~~ | ~~0.348~~ | ~~-~~ | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R1 stream~~ | **~~4.204~~** | **~~2.267~~** | | | **~~1.56~~** | **~~1.185~~** | |
| ~~50%~~ | **~~2.196~~** | **~~1.212~~** | | | **~~1.025~~** | **~~1.025~~** | |
| ~~75%~~ | **~~1.2~~** | **~~1.025~~** | | | **~~1.025~~** | **~~1.025~~** | |
| ~~90%~~ | ~~0.604~~ | **~~1.025~~** | | | **~~-~~** | **~~-~~** | |
| ~~None~~ | ~~R2 stream~~ | **~~5.49~~** | **~~2.942~~** | | | **~~2.017~~** | **~~1.533~~** | |
| ~~50%~~ | **~~2.813~~** | **~~1.523~~** | | | **~~1.048~~** | ~~0.798~~ | |
| ~~75%~~ | **~~1.475~~** | ~~0.815~~ | | | ~~0.565~~ | ~~0.429~~ | |
| ~~90%~~ | ~~0.673~~ | ~~0.39~~ | | | ~~0.275~~ | **~~-~~** | |
| ~~None~~ | ~~R3 stream~~ | **~~5.827~~** | **~~3.138~~** | | | **~~2.154~~** | **~~1.638~~** | |
| ~~50%~~ | **~~3.017~~** | **~~1.662~~** | | | **~~1.154~~** | ~~0.877~~ | |
| ~~75%~~ | **~~1.652~~** | ~~0.946~~ | | | ~~0.665~~ | ~~0.504~~ | |
| ~~90%~~ | ~~0.865~~ | ~~0.544~~ | | | ~~0.396~~ | ~~0.3~~ | |
| ~~None~~ | ~~R4 stream~~ | **~~4.221~~** | **~~2.283~~** | | | **~~1.571~~** | **~~1.194~~** | |
| ~~50%~~ | **~~2.208~~** | **~~1.217~~** | | | **~~1.144~~** | ~~0.642~~ | |
| ~~75%~~ | **~~1.204~~** | ~~0.685~~ | | | ~~0.479~~ | ~~0.365~~ | |
| ~~90%~~ | ~~0.844~~ | ~~0.375~~ | | | **~~-~~** | **~~-~~** | |

~~PEC/RAC ratios in Bulb vegetables (1x1300g/ha) are <1 when risk mitigation options are considered:~~

~~D3 ditch, D4 stream, D6 1~~~~st~~ ~~ditch: 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.~~

~~D4 pond: 5m no spray buffer zone.~~

~~R1 pond: 5m no spray buffer zone with 5m vegetated filter strip~~

~~R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R2 stream, R3 stream, R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~Table 9.5‑39: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (1 x 1000 g/ha + 1 x 300 g/ha) as second refinement~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 x 1000 g/ha + 1 x 300 g/ha~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D4 stream~~ | ~~1.773/1.487~~ | ~~0.946/0.779~~ | ~~0.648/0.527~~ | ~~0.493/0.398~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.901/0.758~~ | ~~0.484/0.400~~ | ~~0.332/0.272~~ | ~~0.253/0.245~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.464/0.393~~ | ~~0.253/0.245~~ | ~~0.183/0.245~~ | ~~0.183/0.245~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~90%~~ | ~~0.203/0.245~~ | ~~0.183/0.245~~ | ~~-/0.245~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~1.669/1.396~~ | ~~0.885/0.725~~ | ~~0.604/0.489~~ | ~~0.460/0.403~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.834/0.698~~ | ~~0.442/0.403~~ | ~~0.318/0.403~~ | ~~0.318/0.403~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.417/0.403~~ | ~~0.318/0.403~~ | ~~0.318/0.403~~ | ~~0.318/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~90%~~ | ~~0.318/0.403~~ | ~~0.318/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~1.710/1.430~~ | ~~0.915/0.793~~ | ~~0.635/0.793~~ | ~~0.635/0.793~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.892/0.793~~ | ~~0.635/0.793~~ | ~~0.635/0.793~~ | ~~0.635/0.793~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.635/0.793~~ | ~~0.635/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~90%~~ | ~~0.635/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~1.552/1.307~~ | ~~0.836/0.695~~ | ~~0.576/0.474~~ | ~~0.439/0.358~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.811/0.855~~ | ~~0.451/0.595~~ | ~~0.346/0.456~~ | ~~0.236/0.311~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.648/0.855~~ | ~~0.451/0.595~~ | ~~0.346/0.456~~ | ~~0.236/0.311~~ |
| ~~90%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.648/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~2.151/1.812~~ | ~~1.158/0.959~~ | ~~0.796/0.652~~ | ~~0.606/0.492~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~1.114/0.947~~ | ~~0.613/0.528~~ | ~~0.635/0.404~~ | ~~0.324/0.275~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.610/0.763~~ | ~~0.399/0.528~~ | ~~0.305/0.404~~ | ~~0.208/0.275~~ |
| ~~90%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.576/0.763~~ | ~~0.399/-~~ | ~~0.305/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R4 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~1.558/1.338~~ | ~~0.843/0.931~~ | ~~0.580/0.715~~ | ~~0.442/0.487~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~1.004/1.338~~ | ~~0.699/0.931~~ | ~~0.536/0.715~~ | ~~0.366/0.487~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~1.004/-~~ | ~~0.699/-~~ | ~~0.536/-~~ | ~~0.366/-~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D4 stream~~ | **~~3.694/3.098~~** | **~~1.971/1.623~~** | **~~1.35/1.098~~** | **~~1.027/~~**~~0.829~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~50%~~ | **~~1.877/1.579~~** | **~~1.008/~~**~~0.833~~ | ~~0.692/0.567~~ | ~~0.527/0.51~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~75%~~ | ~~0.967/0.819~~ | ~~0.527/0.51~~ | ~~0.381/0.51~~ | ~~0.381/0.51~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~90%~~ | ~~0.423/0.51~~ | ~~0.381/0.51~~ | ~~-/0.51~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~3.477/2.908~~** | **~~1.844/1.51~~** | **~~1.258/1.019~~** | ~~0.958/0.84~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~50%~~ | **~~1.738/1.454~~** | ~~0.921/0.84~~ | ~~0.663/0.84~~ | ~~0.663/0.84~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~75%~~ | ~~0.869/0.84~~ | ~~0.663/0.84~~ | ~~0.663/0.84~~ | ~~0.663/-~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~90%~~ | ~~0.663/0.84~~ | ~~0.663/-~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~3.562/2.979~~** | **~~1.906/1.652~~** | **~~1.323/1.652~~** | **~~1.323/1.652~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~50%~~ | **~~1.858/1.652~~** | **~~1.323/1.652~~** | **~~1.323/1.652~~** | **~~1.323/1.652~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~75%~~ | **~~1.323/1.652~~** | **~~1.323/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~90%~~ | **~~1.323/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~3.233/2.723~~** | **~~1.742/1.448~~** | **~~1.2/~~**~~0.987~~ | ~~0.915/0.746~~ |
| ~~50%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~1.69/1.781~~** | ~~0.94~~**~~/1.24~~** | ~~0.721/0.95~~ | ~~0.492/0.648~~ |
| ~~75%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~1.35/1.781~~** | ~~0.94~~**~~/1.24~~** | ~~0.721/0.95~~ | ~~0.492/0.648~~ |
| ~~90%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~1.35/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~4.481/3.775~~** | **~~2.412/1.998~~** | **~~1.658/1.358~~** | **~~1.262/1.025~~** |
| ~~50%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~2.321/1.973~~** | **~~1.277/1.1~~** | **~~1.323/~~**~~0.842~~ | ~~0.675/0.573~~ |
| ~~75%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~1.271/1.59~~** | ~~0.831~~**~~/1.1~~** | ~~0.635/0.842~~ | ~~0.433/0.573~~ |
| ~~90%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~1.2/1.59~~** | ~~0.831/-~~ | ~~0.635/-~~ | **~~-/-~~** |
| ~~None~~ | ~~R4 stream~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~3.246/2.788~~** | **~~1.756/1.94~~** | **~~1.208/1.49~~** | **~~0.921/1.015~~** |
| ~~50%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~2.092/2.788~~** | **~~1.456/1.94~~** | **~~1.117/1.49~~** | **~~0.763/1.015~~** |
| ~~75%~~ | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~-/-~~** | **~~2.092/-~~** | **~~1.456/-~~** | **~~1.117/-~~** | ~~0.763/-~~ |

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

~~Table 9.5‑50: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (1 x 1000 g/ha + 1 x 300 g/ha) as second refinement VFSmod~~

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 x 1000 g/ha + 1 x 300 g/ha~~ | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~R1 stream~~ | ~~1.552/1.307~~ | ~~0.836/0.695~~ | | ~~0.576/0.493~~ | ~~0.438/0.493~~ |
| ~~50%~~ | ~~0.811/0.691~~ | ~~0.447/0.493~~ | | ~~0.376/0.493~~ | ~~0.376/0.493~~ |
| ~~75%~~ | ~~0.443/0.383~~ | ~~0.376/0.493~~ | | ~~0.376/-~~ | ~~0.376/-~~ |
| ~~90%~~ | ~~0.223/0.199~~ | ~~0.376/-~~ | | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~2.151/1.812~~ | ~~1.158/0.959~~ | | ~~0.796/0.652~~ | ~~0.605/0.492~~ |
| ~~50%~~ | ~~1.114/0.947~~ | ~~0.613/0.517~~ | | ~~0.426/0.357~~ | ~~0.324/0.270~~ |
| ~~75%~~ | ~~0.610/0.528~~ | ~~0.348/0.302~~ | | ~~0.245/0.213~~ | ~~0.187/0.162~~ |
| ~~90%~~ | ~~0.320/0.290~~ | ~~0.158/0.184~~ | | ~~0.146/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R4 stream~~ | ~~1.558/1.315~~ | ~~0.842/0.850~~ | | ~~0.580/0.477~~ | ~~0.442/0.360~~ |
| ~~50%~~ | ~~0.816/0.694~~ | ~~0.449/0.378~~ | | ~~0.311/0.260~~ | ~~0.237/0.196~~ |
| ~~75%~~ | ~~0.445/0.407~~ | ~~0.252/0.217~~ | | ~~0.177/0.151~~ | ~~0.135/-~~ |
| ~~90%~~ | ~~0.309/0.407~~ | ~~0.132/-~~ | | ~~-/-~~ | ~~-/-~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 stream~~ | **~~3.233/2.723~~** | **~~1.742/1.448~~** | | **~~1.2/1.027~~** | ~~0.913~~**~~/1.027~~** |
| ~~50%~~ | **~~1.69/1.44~~** | ~~0.931~~**~~/1.027~~** | | ~~0.783~~**~~/1.027~~** | ~~0.783~~**~~/1.027~~** |
| ~~75%~~ | ~~0.923/0.798~~ | ~~0.783~~**~~/1.027~~** | | ~~0.783/-~~ | ~~0.783/-~~ |
| ~~90%~~ | ~~0.465/0.415~~ | ~~0.783/-~~ | | **~~-/-~~** | **~~-/-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~4.481/3.775~~** | **~~2.412/1.998~~** | | **~~1.658/1.358~~** | **~~1.26/1.025~~** |
| ~~50%~~ | **~~2.321/1.973~~** | **~~1.277/1.077~~** | | ~~0.888/0.744~~ | ~~0.675/0.563~~ |
| ~~75%~~ | **~~1.271/1.1~~** | ~~0.725/0.629~~ | | ~~0.51/0.444~~ | ~~0.39/0.338~~ |
| ~~90%~~ | ~~0.667/0.604~~ | ~~0.329/0.383~~ | | ~~0.304/-~~ | **~~-/-~~** |
| ~~None~~ | ~~R4 stream~~ | **~~3.246/2.74~~** | **~~1.754/1.771~~** | | **~~1.208/~~**~~0.994~~ | ~~0.921/0.75~~ |
| ~~50%~~ | **~~1.7/1.446~~** | ~~0.935/0.788~~ | | ~~0.648/0.542~~ | ~~0.494/0.408~~ |
| ~~75%~~ | ~~0.927/0.848~~ | ~~0.525/0.452~~ | | ~~0.369/0.315~~ | ~~0.281/-~~ |
| ~~90%~~ | ~~0.644/0.848~~ | ~~0.275/-~~ | | ~~-/-~~ | ~~-/-~~ |

~~PEC/RAC ratios in Bulb vegetables (1 x 1000 g/ha + 1 x 300 g/ha) are <1 when risk mitigation options are considered:~~

~~D4 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.~~

~~D6 1~~~~st~~ ~~ditch: 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction.~~

~~R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 75% nozzle reduction~~

~~R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction~~

~~R4 stream: 20m no spray buffer zone with 20m vegetated filter strip or 10m no spray buffer zone with 10m vegetated filter strip + 50% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 75% nozzle reduction~~

~~Table 9.5‑41: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (2 x 650 g/ha) as third refinement~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~2 x 650 g/ha~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D4 stream~~ | ~~0.973~~ | ~~0.510~~ | ~~0.345~~ | ~~0.260~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.496~~ | ~~0.262~~ | ~~0.246~~ | ~~0.246~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.258~~ | ~~0.246~~ | ~~0.246~~ | ~~0.246~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.246~~ | ~~0.246~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~0.922~~ | ~~0.479~~ | ~~0.378~~ | ~~0.378~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.468~~ | ~~0.378~~ | ~~0.378~~ | ~~0.378~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.378~~ | ~~0.378~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.378~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~0.987~~ | ~~0.728~~ | ~~0.728~~ | ~~0.728~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.728~~ | ~~0.728~~ | ~~0.728~~ | ~~0.728~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.728~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.862~~ | ~~0.600~~ | ~~0.460~~ | ~~0.314~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.862~~ | ~~0.600~~ | ~~0.460~~ | ~~0.314~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.177~~ | ~~0.623~~ | ~~0.423~~ | ~~0.319~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.768~~ | ~~0.532~~ | ~~0.407~~ | ~~0.277~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.768~~ | ~~0.532~~ | ~~0.407~~ | ~~0.277~~ |
| ~~None~~ | ~~R4 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.358~~ | ~~0.946~~ | ~~0.725~~ | ~~0.495~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.358~~ | ~~0.946~~ | ~~0.725~~ | ~~0.495~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D4 stream~~ | **~~2.027~~** | **~~1.062~~** | ~~0.719~~ | ~~0.542~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.033~~** | ~~0.546~~ | ~~0.513~~ | ~~0.513~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.538~~ | ~~0.513~~ | ~~0.513~~ | ~~0.513~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.513~~ | ~~0.513~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~1.921~~** | ~~0.998~~ | ~~0.788~~ | ~~0.788~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.975~~ | ~~0.788~~ | ~~0.788~~ | ~~0.788~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.788~~ | ~~0.788~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.788~~ | ~~-~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~2.056~~** | **~~1.517~~** | **~~1.517~~** | **~~1.517~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.517~~** | **~~1.517~~** | **~~1.517~~** | **~~1.517~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.517~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.796~~** | **~~1.25~~** | ~~0.958~~ | ~~0.654~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.796~~** | **~~1.25~~** | ~~0.958~~ | ~~0.654~~ |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.452~~** | **~~1.298~~** | ~~0.881~~ | ~~0.665~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.6~~** | **~~1.108~~** | ~~0.848~~ | ~~0.577~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.6~~** | **~~1.108~~** | ~~0.848~~ | ~~0.577~~ |
| ~~None~~ | ~~R4 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.829~~** | **~~1.971~~** | **~~1.51~~** | **~~1.031~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.829~~** | **~~1.971~~** | **~~1.51~~** | **~~1.031~~** |

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

~~Table 9.5‑62: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of PENTAGON in Bulb vegetables (2 x 650 g/ha) as third refinement VFSmod~~

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | |
| ~~Application rate (g/ha)~~ | | ~~2 x 650 g/ha~~ | | | | |
| ~~Nozzle reduction~~ | ~~Vegetated filter strip (m)~~ | ~~5~~ | | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~R1 stream~~ | ~~0.849~~ | ~~0.495~~ | | ~~0.495~~ | ~~0.495~~ |
| ~~50%~~ | ~~0.448~~ | ~~0.495~~ | | ~~0.495~~ | ~~0.495~~ |
| ~~75%~~ | ~~0.248~~ | ~~-~~ | | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.160~~ | ~~-~~ | | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~1.177~~ | ~~0.623~~ | | ~~0.423~~ | ~~0.319~~ |
| ~~50%~~ | ~~0.615~~ | ~~0.337~~ | | ~~0.231~~ | ~~0.175~~ |
| ~~75%~~ | ~~0.343~~ | ~~0.197~~ | | ~~0.138~~ | ~~-~~ |
| ~~90%~~ | ~~0.240~~ | ~~-~~ | | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R4 stream~~ | ~~0.854~~ | ~~0.455~~ | | ~~0.310~~ | ~~0.234~~ |
| ~~50%~~ | ~~0.451~~ | ~~0.246~~ | | ~~0.168~~ | ~~0.127~~ |
| ~~75%~~ | ~~0.410~~ | ~~0.174~~ | | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.410~~ | ~~-~~ | | ~~-~~ | ~~-~~ |
| ~~RAC (µg/L)~~ | | ~~PEC/RAC ratio~~ | | | | |
| ~~0.48~~ | |
| ~~None~~ | ~~R1 stream~~ | **~~1.769~~** | **~~1.031~~** | | **~~1.031~~** | **~~1.031~~** |
| ~~50%~~ | ~~0.933~~ | **~~1.031~~** | | **~~1.031~~** | **~~1.031~~** |
| ~~75%~~ | ~~0.517~~ | **~~-~~** | | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.333~~ | **~~-~~** | | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~2.452~~** | **~~1.298~~** | | ~~0.881~~ | ~~0.665~~ |
| ~~50%~~ | **~~1.281~~** | ~~0.702~~ | | ~~0.481~~ | ~~0.365~~ |
| ~~75%~~ | ~~0.715~~ | ~~0.41~~ | | ~~0.288~~ | ~~-~~ |
| ~~90%~~ | ~~0.5~~ | ~~-~~ | | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R4 stream~~ | **~~1.779~~** | ~~0.948~~ | | ~~0.646~~ | ~~0.488~~ |
| ~~50%~~ | ~~0.94~~ | ~~0.513~~ | | ~~0.35~~ | ~~0.265~~ |
| ~~75%~~ | ~~0.854~~ | ~~0.362~~ | | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.854~~ | ~~-~~ | | ~~-~~ | ~~-~~ |

~~PEC/RAC ratios in Bulb vegetables (2x650g/ha) are <1 when risk mitigation options are considered:~~

~~D4 stream: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction.~~

~~D6 1~~~~st~~ ~~ditch: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.~~

~~R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction~~

~~R3 stream:~~ ~~15m no spray buffer zone with 15m vegetated filter strip or 10m no spray buffer zone with 10m vegetated filter strip + 50% nozzle reduction~~

~~R4 stream: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction~~

~~Table 9.5‑43: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in Bulb vegetables (2 x 400 g/ha) as fourth refinement~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~Bulb vegetables~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~2 x 400 g/ha~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~0.677/0.567~~ | ~~0.359/0.295~~ | ~~0.245/0.201~~ | ~~0.186/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.341/0.294~~ | ~~0.191/0.163~~ | ~~0.133/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.192/0.174~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~0.709/0.598~~ | ~~0.378/0.314~~ | ~~0.259/0.212~~ | ~~0.200/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.360/0.305~~ | ~~0.194/0.162~~ | ~~0.133/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.186/0.158~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | ~~0.667/0.567~~ | ~~0.354/0.294~~ | ~~0.242/0.220~~ | ~~0.184/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.334/0.288~~ | ~~0.177/0.220~~ | ~~0.121/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.167/0.219~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | ~~0.684/0.607~~ | ~~0.366/0.426~~ | ~~0.253/0.426~~ | ~~0.230/0.426~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~50%~~ | ~~0.356/0.426~~ | ~~0.230/0.426~~ | ~~0.230/0.426~~ | ~~-/0.426~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~75%~~ | ~~0.230/0.426~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.620/0.522~~ | ~~0.335/0.362~~ | ~~0.230/0.362~~ | ~~0.175/0.189~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.324/0.521~~ | ~~0.179/0.362~~ | ~~0.133/0.278~~ | ~~-/-~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.250/0.521~~ | ~~-/-~~ | ~~-/0.278~~ | ~~-/-~~ |
| ~~90%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.250/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R2 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.810/0.766~~ | ~~0.434/0.419~~ | ~~0.298/0.309~~ | ~~0.226/0.214~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.415/0.444~~ | ~~0.225/0.252~~ | ~~0.155/0.177~~ | ~~-/-~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.218/0.283~~ | ~~-/0.168~~ | ~~-/-~~ | ~~-/-~~ |
| ~~90%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/0.187~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.860/0.724~~ | ~~0.463/0.384~~ | ~~0.318/0.320~~ | ~~0.242/0.196~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.445/0.462~~ | ~~0.246/0.320~~ | ~~0.171/0.245~~ | ~~0.129/-~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.243/0.462~~ | ~~0.153/0.320~~ | ~~-/0.245~~ | ~~-/-~~ |
| ~~90%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.220/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ |
| ~~None~~ | ~~R4 stream~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.623/0.819~~ | ~~0.337/0.570~~ | ~~0.232/0.570~~ | ~~0.176/0.298~~ |
| ~~50%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.386/0.819~~ | ~~0.269/0.570~~ | ~~0.206/0.437~~ | ~~-/0.298~~ |
| ~~75%~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~-/-~~ | ~~0.386/-~~ | ~~0.269/-~~ | ~~-/0.437~~ | ~~-~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D3 ditch~~ | **~~1.41/1.181~~** | ~~0.748/0.615~~ | ~~0.51/0.419~~ | ~~0.388/-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.71/0.612~~ | ~~0.398/0.34~~ | ~~0.277/-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.4/0.362~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~1.477/1.246~~** | ~~0.788/0.654~~ | ~~0.54/0.442~~ | ~~0.417/-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.75/0.635~~ | ~~0.404/0.338~~ | ~~0.277/-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.388/0.329~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 1~~~~st~~ ~~ditch~~ | **~~1.39/1.181~~** | ~~0.737/0.612~~ | ~~0.504/0.458~~ | ~~0.383/-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.696/0.6~~ | ~~0.369/0.458~~ | ~~0.252/-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.348/0.456~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D6 2~~~~nd~~ ~~ditch~~ | **~~1.425/1.265~~** | ~~0.763/0.888~~ | ~~0.527/0.888~~ | ~~0.479/0.888~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | ~~0.742/0.888~~ | ~~0.479/0.888~~ | ~~0.479/0.888~~ | ~~-/0.888~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.479/0.888~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.292/1.088~~** | ~~0.698/0.754~~ | ~~0.479/0.754~~ | ~~0.365/0.394~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.675~~**~~/1.085~~** | ~~0.373/0.754~~ | ~~0.277/0.579~~ | ~~-~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.521~~**~~/1.085~~** | ~~-~~ | ~~-/0.579~~ | ~~-~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.521/-~~ | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R2 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.688/1.596~~** | ~~0.904/0.873~~ | ~~0.621/0.644~~ | ~~0.471/0.446~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.865/0.925~~ | ~~0.469/0.525~~ | ~~0.323/0.369~~ | ~~-~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.454/0.59~~ | ~~-/0.35~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~-/0.39~~ | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.792/1.508~~** | ~~0.965/0.8~~ | ~~0.663/0.667~~ | ~~0.504/0.408~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.927/0.963~~ | ~~0.513/0.667~~ | ~~0.356/0.51~~ | ~~0.269/-~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.506/0.963~~ | ~~0.319/0.667~~ | ~~-/0.51~~ | ~~-~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.458/-~~ | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R4 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.298/1.706~~** | ~~0.702~~**~~/1.188~~** | ~~0.483~~**~~/1.188~~** | ~~0.367/0.621~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.804~~**~~/1.706~~** | ~~0.56~~**~~/1.188~~** | ~~0.429/0.91~~ | ~~0.621/-~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | ~~0.804/-~~ | ~~0.56/-~~ | ~~-/0.91~~ | ~~-~~ |

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

~~PEC/RAC ratios in Bulb vegetables (2x400g/ha) are <1 when risk mitigation options are considered:~~

~~D3 ditch, D4 stream, D6 1~~~~st~~ ~~ditch, D6 2nd ditch: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.~~

~~R1 stream, R2 stream, R3 stream: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction~~

~~R4 stream:~~ ~~20m no spray buffer zone with 20m vegetated filter strip or 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 75% nozzle reduction~~

~~Table 9.5‑44: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for pendimethalin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of Pendimethalin 45.5% CS in winter oilseed rape (1 x 910 g as/ha)~~

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ~~Intended use~~ | | ~~winter oilseed rape~~ | | | | | | | |
| ~~Active substance~~ | | ~~pendimethalin~~ | | | | | | | |
| ~~Application rate (g/ha)~~ | | ~~1 x 910 g as/ha~~ | | | | | | | |
| ~~Nozzle reduction~~ | ~~No-spray buffer (m)~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~Vegetated filter strip (m)~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~None~~ | ~~5~~ | ~~10~~ | ~~15~~ | ~~20~~ |
| ~~None~~ | ~~D2 ditch~~ | ~~1.597~~ | ~~0.866~~ | ~~0.616~~ | ~~0.467~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.892~~ | ~~0.523~~ | ~~0.373~~ | ~~0.282~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.564~~ | ~~0.361~~ | ~~0.263~~ | ~~0.199~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.382~~ | ~~0.265~~ | ~~0.197~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D2 stream~~ | ~~1.878~~ | ~~0.996~~ | ~~0.681~~ | ~~0.518~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.940~~ | ~~0.499~~ | ~~0.341~~ | ~~0.260~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.472~~ | ~~0.251~~ | ~~0.172~~ | ~~0.131~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.191~~ | ~~0.102~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D3 ditch~~ | ~~1.549~~ | ~~0.826~~ | ~~0.570~~ | ~~0.434~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.810~~ | ~~0.464~~ | ~~0.328~~ | ~~0.248~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.490~~ | ~~0.306~~ | ~~0.221~~ | ~~0.166~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.314~~ | ~~0.219~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D4 stream~~ | ~~1.803~~ | ~~0.963~~ | ~~0.661~~ | ~~0.503~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.928~~ | ~~0.509~~ | ~~0.352~~ | ~~0.268~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.501~~ | ~~0.287~~ | ~~0.202~~ | ~~0.154~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.262~~ | ~~0.168~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~D5 stream~~ | ~~1.944~~ | ~~1.032~~ | ~~0.705~~ | ~~0.536~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~50%~~ | ~~0.974~~ | ~~0.531~~ | ~~0.367~~ | ~~0.279~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~75%~~ | ~~0.522~~ | ~~0.302~~ | ~~0.213~~ | ~~0.162~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~90%~~ | ~~0.283~~ | ~~0.183~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R1 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.424~~ | ~~0.773~~ | ~~0.533~~ | ~~0.405~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.752~~ | ~~0.417~~ | ~~0.292~~ | ~~0.220~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.546~~ | ~~0.381~~ | ~~0.292~~ | ~~-~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.546~~ | ~~0.381~~ | ~~-~~ | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.957~~ | ~~1.058~~ | ~~0.727~~ | ~~0.553~~ |
| ~~50%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~1.022~~ | ~~0.564~~ | ~~0.392~~ | ~~0.299~~ |
| ~~75%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.571~~ | ~~0.398~~ | ~~0.306~~ | ~~0.209~~ |
| ~~90%~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~-~~ | ~~0.571~~ | ~~0.398~~ | ~~0.306~~ | ~~-~~ |
| ~~RAC (µg/L)~~ | |  | | | | | | | |
| ~~0.48~~ | | ~~PEC/RAC ratio~~ | | | | | | | |
| ~~None~~ | ~~D2 ditch~~ | **~~3.327~~** | **~~1.804~~** | **~~1.283~~** | ~~0.973~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.858~~** | **~~1.09~~** | ~~0.777~~ | ~~0.587~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.175~~** | ~~0.752~~ | ~~0.548~~ | ~~0.415~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.796~~ | ~~0.552~~ | ~~0.41~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D2 stream~~ | **~~3.912~~** | **~~2.075~~** | **~~1.419~~** | **~~1.079~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.958~~** | **~~1.04~~** | ~~0.71~~ | ~~0.542~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | ~~0.983~~ | ~~0.523~~ | ~~0.358~~ | ~~0.273~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.398~~ | ~~0.212~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D3 ditch~~ | **~~3.227~~** | **~~1.721~~** | **~~1.188~~** | ~~0.904~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.688~~** | ~~0.967~~ | ~~0.683~~ | ~~0.517~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.021~~** | ~~0.638~~ | ~~0.46~~ | ~~0.346~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.654~~ | ~~0.456~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D4 stream~~ | **~~3.756~~** | **~~2.006~~** | **~~1.377~~** | **~~1.048~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~1.933~~** | **~~1.06~~** | ~~0.733~~ | ~~0.6~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.044~~** | ~~0.598~~ | ~~0.421~~ | ~~0.321~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.546~~ | ~~0.35~~ | ~~-~~ | ~~-~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~D5 stream~~ | **~~4.05~~** | **~~2.15~~** | **~~1.469~~** | **~~1.117~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~50%~~ | **~~2.029~~** | **~~1.106~~** | ~~0.765~~ | ~~0.581~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~75%~~ | **~~1.088~~** | ~~0.629~~ | ~~0.444~~ | ~~0.338~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~90%~~ | ~~0.59~~ | ~~0.381~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R1 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.967~~** | **~~1.61~~** | **~~1.11~~** | ~~0.844~~ |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.567~~** | ~~0.869~~ | ~~0.608~~ | ~~0.458~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.138~~** | ~~0.794~~ | ~~0.608~~ | **~~-~~** |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.138~~** | ~~0.794~~ | **~~-~~** | **~~-~~** |
| ~~None~~ | ~~R3 stream~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~4.077~~** | **~~2.204~~** | **~~1.515~~** | **~~1.152~~** |
| ~~50%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~2.129~~** | **~~1.175~~** | ~~0.817~~ | ~~0.623~~ |
| ~~75%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.19~~** | ~~0.829~~ | ~~0.638~~ | ~~0.435~~ |
| ~~90%~~ | **~~-~~** | **~~-~~** | **~~-~~** | **~~-~~** | **~~1.19~~** | ~~0.829~~ | ~~0.638~~ | ~~-~~ |

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

~~PEC/RAC ratios in Winter oilseed rape (1x910g/ha) are <1 when risk mitigation options are considered:~~

~~D2 ditch, D3 ditch: 20m no spray buffer zone or 15m no spray buffer zone + 50% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.~~

~~D2 stream, D4 stream, D5 stream: 15m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction.~~

~~R1 stream:~~ ~~20m no spray buffer zone with 20m vegetated filter strip or 10m no spray buffer zone with 10m vegetated filter strip + 50% nozzle reduction~~

~~R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction~~

**~~Pendimethalin metabolites~~**

~~Table 9.5‑45: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Potato (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~8280~~ | ~~7730~~ | ~~> 2500~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~82.8~~ | ~~77.3~~ | ~~> 250~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~31.38~~ | ~~0.379~~ | ~~0.406~~ | ~~0.126~~ |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~March-May~~ | ~~11.71~~ | ~~0.141~~ | ~~0.151~~ | ~~0.047~~ |
| ~~S-Europe~~  ~~June-Sept~~ | ~~8.78~~ | ~~0.106~~ | ~~0.114~~ | ~~0.035~~ |
| ~~N-Europe~~  ~~March-May~~ | ~~5.86~~ | ~~0.071~~ | ~~0.076~~ | ~~0.023~~ |
| ~~N-Europe~~  ~~June-Sept~~ |

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

~~Table 9.5‑46: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Winter cereals (1 x 1137 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~8280~~ | ~~7730~~ | ~~> 2500~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~82.8~~ | ~~77.3~~ | ~~> 250~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~22.30~~ | ~~0.269~~ | ~~0.288~~ | ~~0.089~~ |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~June-Sept~~ | ~~6.24~~ | ~~0.075~~ | ~~0.081~~ | ~~0.025~~ |
| ~~S-Europe~~  ~~Oct-Feb~~ | ~~8.32~~ | ~~0.100~~ | ~~0.108~~ | ~~0.033~~ |
| ~~N-Europe~~  ~~June-Sept~~ | ~~4.16~~ | ~~0.050~~ | ~~0.054~~ | ~~0.017~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~10.40~~ | ~~0.126~~ | ~~0.135~~ | ~~0.042~~ |

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

~~Table 9.5‑477: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~8280~~ | ~~7730~~ | ~~> 2500~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~82.8~~ | ~~77.3~~ | ~~> 250~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~31.38~~ | ~~0.379~~ | ~~0.406~~ | ~~0.126~~ |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-Feb~~ | ~~11.71~~ | ~~0.141~~ | ~~0.151~~ | ~~0.047~~ |
| ~~S-Europe~~  ~~March-May~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~14.64~~ | ~~0.177~~ | ~~0.189~~ | ~~0.059~~ |
| ~~N-Europe~~  ~~March-May~~ | ~~5.86~~ | ~~0.071~~ | ~~0.076~~ | ~~0.023~~ |

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

~~Table 9.5‑48: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Winter oil seed rape (1 x 910 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~8280~~ | ~~7730~~ | ~~> 2500~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~82.8~~ | ~~77.3~~ | ~~> 250~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~17.85~~ | ~~0.216~~ | ~~0.231~~ | ~~0.071~~ |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~June-Sept~~ | ~~3.00~~ | ~~0.036~~ | ~~0.039~~ | ~~0.012~~ |
| ~~S-Europe~~  ~~Oct-Feb~~ | ~~4.00~~ | ~~0.048~~ | ~~0.052~~ | ~~0.016~~ |
| ~~N-Europe~~  ~~June-Sept~~ | ~~2.00~~ | ~~0.024~~ | ~~0.026~~ | ~~0.008~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~5.00~~ | ~~0.060~~ | ~~0.065~~ | ~~0.020~~ |

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

~~Table 9.5‑49: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PENTAGON Potato (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~613~~ | ~~>1450~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~6.13~~ | ~~>145~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |
| ~~Step 1~~ |  |  |  |
|  | ~~36.20~~ | ~~5.905~~ | ~~0.250~~ |
| ~~Step 2~~ |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~9.11~~ | **~~1.486~~** | ~~0.063~~ |
| ~~S-Europe~~  ~~June-Sept~~ | ~~6.93~~ | **~~1.131~~** | ~~0.048~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~4.75~~ | ~~0.775~~ | ~~0.033~~ |
| ~~N-Europe~~  ~~March-Sept~~ |
| **~~Step 3~~** | | | |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D4 pond~~ | ~~0.003~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D4 stream~~ | ~~0.011~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~D6 1~~~~st~~ ~~ditch~~ | ~~0.020~~ | ~~0.003~~ | ~~<0.001~~ |
| ~~D6 2~~~~nd~~ ~~ditch~~ | ~~0.028~~ | ~~0.005~~ | ~~<0.001~~ |
| ~~R1 pond~~ | ~~0.012~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~R1 stream~~ | ~~0.030~~ | ~~0.005~~ | ~~<0.001~~ |
| ~~R2 stream~~ | ~~0.010~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~R3 stream~~ | ~~0.028~~ | ~~0.005~~ | ~~<0.001~~ |

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

~~Table 9.5‑50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PENTAGON to Winter cereals (1 x 1137 g as/ha)~~

| ~~Group~~ |  | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~613~~ | ~~>1450~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~6.13~~ | ~~>145~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |
| ~~Step 1~~ |  |  |  |
|  | ~~25.73~~ | **~~4.197~~** | ~~0.177~~ |
| ~~Step 2~~ |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~4.93~~ | ~~0.804~~ | ~~0.034~~ |
| ~~S-Europe~~  ~~June-Sept~~ | ~~6.47~~ | **~~1.055~~** | ~~0.045~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~3.38~~ | ~~0.551~~ | ~~0.023~~ |
| ~~N-Europe~~  ~~March-Sept~~ | ~~8.02~~ | **~~1.308~~** | ~~0.055~~ |
| **~~Step 3~~** | | | |
| ~~D1 ditch~~ | ~~0.015~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~D1 stream~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D2 ditch~~ | ~~0.009~~ | ~~0.001~~ | ~~<0.001~~ |
| ~~D2 stream~~ | ~~0.006~~ | ~~0.001~~ | ~~<0.001~~ |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D4 pond~~ | ~~0.002~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D4 stream~~ | ~~0.007~~ | ~~0.001~~ | ~~<0.001~~ |
| ~~D5 pond~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D5 stream~~ | ~~0.002~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D6 ditch~~ | ~~0.017~~ | ~~0.003~~ | ~~<0.001~~ |
| ~~R1 pond~~ | ~~0.005~~ | ~~0.001~~ | ~~<0.001~~ |
| ~~R1 stream~~ | ~~0.022~~ | ~~0.004~~ | ~~<0.001~~ |
| ~~R3 stream~~ | ~~0.017~~ | ~~0.003~~ | ~~<0.001~~ |
| ~~R4 stream~~ | ~~0.030~~ | ~~0.005~~ | ~~<0.001~~ |

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

~~Table 9.5‑51: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PENTAGON to Bulb vegetables (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~613~~ | ~~>1450~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~6.13~~ | ~~>145~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |
| ~~Step 1~~ |  |  |  |
|  | ~~36.20~~ | **~~5.905~~** | ~~0.250~~ |
| ~~Step 2~~ |  |  |  |
| ~~S-Europe~~  ~~Oct-Feb~~ | ~~9.11~~ | **~~1.486~~** | ~~0.063~~ |
| ~~S-Europe~~  ~~March-May~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~11.29~~ | **~~1.842~~** | ~~0.078~~ |
| ~~N-Europe~~  ~~March-May~~ | ~~4.75~~ | ~~0.775~~ | ~~0.033~~ |
| **~~Step 3~~** | | | |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D4 pond~~ | ~~0.003~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~D4 stream~~ | ~~0.010~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~D6 1~~~~st~~ ~~ditch~~ | ~~0.021~~ | ~~0.003~~ | ~~<0.001~~ |
| ~~D6 2~~~~nd~~ ~~ditch~~ | ~~0.041~~ | ~~0.007~~ | ~~<0.001~~ |
| ~~R1 pond~~ | ~~0.012~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~R1 stream~~ | ~~0.030~~ | ~~0.005~~ | ~~<0.001~~ |
| ~~R2 stream~~ | ~~0.011~~ | ~~0.002~~ | ~~<0.001~~ |
| ~~R3 stream~~ | ~~0.028~~ | ~~0.005~~ | ~~<0.001~~ |
| ~~R4 stream~~ | ~~0.037~~ | ~~0.006~~ | ~~<0.001~~ |

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

~~Table 9.5‑52: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H033 (P48) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of PENTAGON to Winter oil seed rape (1 x 910 g as/ha)~~

| ~~Group~~ |  | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Daphnia magna~~* | *~~-~~* |
| ~~Endpoint~~ |  | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~613~~ | ~~>1450~~ |
| ~~AF~~ |  | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~6.13~~ | ~~>145~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |
| ~~Step 1~~ |  |  |  |
|  | ~~20.59~~ | **~~3.359~~** | ~~0.142~~ |
| ~~Step 2~~ |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~2.46~~ | ~~0.401~~ | ~~0.017~~ |
| ~~S-Europe~~  ~~June-Sept~~ | ~~3.20~~ | ~~0.522~~ | ~~0.022~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~1.71~~ | ~~0.279~~ | ~~0.012~~ |
| ~~N-Europe~~  ~~March-Sept~~ | ~~3.94~~ | ~~0.643~~ | ~~0.027~~ |

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

~~According to~~ *~~Peer review of the pesticide risk assessment of the active substance pendimethalin~~* ~~(EFSA Journal 2016;14(3):4420), as for the two metabolites 2,6-dinitro-3,4-dimethylaniline (M455H032) and P36 (M455H029) no experimental data were available, a screening risk assessment was performed considering the metabolites 10 times more toxic than the parent.~~

~~Table 9.5‑8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Potato (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~58.43~~ | **~~298.112~~** | **~~397.483~~** | **~~628.280~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~23.43~~ | **~~119.541~~** | **~~159.388~~** | **~~251.935~~** |
| ~~S-Europe~~  ~~June-Sept~~ | ~~17.83~~ | **~~90.969~~** | **~~121.293~~** | **~~191.720~~** |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~12.23~~ | **~~62.398~~** | **~~83.197~~** | **~~131.505~~** |
| ~~N-Europe~~  ~~March-Sept~~ |
| **~~Step 3~~** | | | | |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 1~~~~st~~ ~~ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 2~~~~nd~~ ~~ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R2 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑94: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Winter cereals (1 x 1137 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~41.52~~ | **~~211.837~~** | **~~282.449~~** | **~~446.452~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~12.67~~ | **~~64.643~~** | **~~86.190~~** | **~~136.237~~** |
| ~~S-Europe~~  ~~June-Sept~~ | ~~16.65~~ | **~~84.949~~** | **~~113.265~~** | **~~179.032~~** |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~8.69~~ | **~~44.337~~** | **~~59.116~~** | **~~93.441~~** |
| ~~N-Europe~~  ~~March-Sept~~ | ~~20.63~~ | **~~105.255~~** | **~~140.340~~** | **~~221.828~~** |
| **~~Step 3~~** | | | | |
| ~~D1 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D2 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D2 stream~~ | ~~0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑105: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~58.43~~ | **~~298.112~~** | **~~397.483~~** | **~~628.280~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~23.43~~ | **~~119.541~~** | **~~159.388~~** | **~~251.935~~** |
| ~~S-Europe~~  ~~June-Sept~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~29.03~~ | **~~148.112~~** | **~~197.483~~** | **~~312.151~~** |
| ~~N-Europe~~  ~~March-Sept~~ | ~~12.23~~ | **~~62.398~~** | **~~83.197~~** | **~~131.505~~** |
| **~~Step 3~~** | | | | |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 1~~~~st~~ ~~ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 2~~~~nd~~ ~~ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R2 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑56: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Winter oil seed rape (1 x 910 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~33.23~~ | **~~169.541~~** | **~~226.054~~** | **~~357.312~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~6.32~~ | **~~32.245~~** | **~~42.993~~** | **~~67.957~~** |
| ~~S-Europe~~  ~~June-Sept~~ | ~~8.23~~ | **~~41.990~~** | **~~55.986~~** | **~~88.495~~** |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~4.41~~ | **~~22.500~~** | **~~30.000~~** | **~~47.419~~** |
| ~~N-Europe~~  ~~March-Sept~~ | ~~10.14~~ | **~~51.735~~** | **~~68.980~~** | **~~109.032~~** |
| **~~Step 3~~** | | | | |
| ~~D2 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D2 stream~~ | ~~0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑57: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 1, 2 calculations for the use of PENTAGON to Potato (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~11.29~~ |  |  |  |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~3.44~~ | **~~17.551~~** | **~~23.401~~** | **~~36.989~~** |
| ~~S-Europe~~  ~~June-Sept~~ | ~~3.20~~ | **~~16.327~~** | **~~21.769~~** | **~~34.409~~** |
| ~~N-Europe~~  ~~Oct-Feb~~ |
| ~~N-Europe~~  ~~March-Sept~~ |
| **~~Step 3~~** | | | | |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 1~~~~st~~ ~~ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 2~~~~nd~~ ~~ditch~~ | ~~0.003~~ | ~~0.015~~ | ~~0.020~~ | ~~0.032~~ |
| ~~R1 pond~~ | ~~0.002~~ | ~~0.010~~ | ~~0.014~~ | ~~0.022~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R2 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Winter cereals (1 x 1137 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~8.02~~ | **~~40.918~~** | **~~54.558~~** | **~~86.237~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~2.27~~ | **~~11.582~~** | **~~15.442~~** | **~~24.409~~** |
| ~~S-Europe~~  ~~June-Sept~~ | ~~2.44~~ | **~~12.449~~** | **~~16.599~~** | **~~26.237~~** |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~2.27~~ | **~~11.582~~** | **~~15.442~~** | **~~24.409~~** |
| ~~N-Europe~~  ~~March-Sept~~ | ~~3.01~~ | **~~15.357~~** | **~~20.476~~** | **~~32.366~~** |
| **~~Step 3~~** | | | | |
| ~~D1 ditch~~ | ~~0.010~~ | ~~0.051~~ | ~~0.068~~ | ~~0.108~~ |
| ~~D1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D2 ditch~~ | ~~0.003~~ | ~~0.015~~ | ~~0.020~~ | ~~0.032~~ |
| ~~D2 stream~~ | ~~0.003~~ | ~~0.015~~ | ~~0.020~~ | ~~0.032~~ |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 ditch~~ | ~~0.003~~ | ~~0.015~~ | ~~0.020~~ | ~~0.032~~ |
| ~~R1 pond~~ | ~~0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑119: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Bulb vegetables (1 x 1600 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~11.29~~ | **~~57.602~~** | **~~76.803~~** | **~~121.398~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~3.44~~ | **~~17.551~~** | **~~23.401~~** | **~~36.989~~** |
| ~~S-Europe~~  ~~June-Sept~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ | ~~4.23~~ | **~~21.582~~** | **~~28.776~~** | **~~45.484~~** |
| ~~N-Europe~~  ~~March-Sept~~ | ~~3.20~~ | **~~16.327~~** | **~~21.769~~** | **~~34.409~~** |
| **~~Step 3~~** | | | | |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 1~~~~st~~ ~~ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D6 2~~~~nd~~ ~~ditch~~ | ~~0.006~~ | ~~0.031~~ | ~~0.041~~ | ~~0.065~~ |
| ~~R1 pond~~ | ~~0.002~~ | ~~0.010~~ | ~~0.014~~ | ~~0.022~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R2 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~Table 9.5‑60: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of PENTAGON to Winter oil seed rape (1 x 910 g as/ha)~~

| ~~Group~~ |  | ~~Fish acute~~ | ~~Inverteb. acute~~ | ~~Algae~~ |
| --- | --- | --- | --- | --- |
| ~~Test species~~ |  | *~~Oncorhynchus mykiss~~* | *~~Daphnia magna~~* | *~~Pseudokirchneriella subcapitata~~* |
| ~~Endpoint~~ |  | ~~LC~~~~50~~ | ~~EC~~~~50~~ | ~~E~~~~r~~~~C~~~~50~~ |
| ~~(µg/L)~~ |  | ~~19.6~~ | ~~14.7~~ | ~~0.93~~ |
| ~~AF~~ |  | ~~100~~ | ~~100~~ | ~~10~~ |
| ~~RAC (µg/L)~~ |  | ~~0.196~~ | ~~0.147~~ | ~~0.093~~ |
| ~~FOCUS Scenario~~ | ~~PEC~~ ~~gl-max~~ ~~(µg/L)~~ |  |  |  |
| ~~Step 1~~ |  |  |  |  |
|  | ~~6.42~~ | **~~32.755~~** | **~~43.673~~** | **~~69.032~~** |
| ~~Step 2~~ |  |  |  |  |
| ~~S-Europe~~  ~~Oct-May~~ | ~~1.82~~ | **~~9.286~~** | **~~12.381~~** | **~~19.570~~** |
| ~~S-Europe~~  ~~June-Sept~~ |
| ~~N-Europe~~  ~~Oct-Feb~~ |
| ~~N-Europe~~  ~~March-Sept~~ |
| **~~Step 3~~** | | | | |
| ~~D2 ditch~~ | ~~0.003~~ | ~~0.015~~ | ~~0.020~~ | ~~0.032~~ |
| ~~D2 stream~~ | ~~0.003~~ | ~~0.015~~ | ~~0.020~~ | ~~0.032~~ |
| ~~D3 ditch~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D4 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 pond~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~D5 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R1 pond~~ | ~~<0.001~~ | ~~0.010~~ | ~~0.014~~ | ~~0.022~~ |
| ~~R1 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |
| ~~R3 stream~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.007~~ | ~~0.011~~ |

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

~~For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 1‑3 scenarios. Therefore, no further assessment is necessary for metabolites.~~

**Formulation**

Table 9.5‑61: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for PENTAGON for each organism group for the use of PENTAGON in single application to different crops

| Group | |  | Fish | Inverteb. acute | Algae | Higher plant |
| --- | --- | --- | --- | --- | --- | --- |
| Test species | |  | *Oncorhynchus mykiss* | *Daphnia magna* | *Raphidocelis subcapitata* | *Lemna gibba* |
| Endpoint | |  | LC50 | EC50 | ErC50 | ErC50 |
| (µg/L) | |  | 9240 | 47160 | 1233 | 19271 |
| AF | |  | 100 | 100 | 10 | 10 |
| RAC (µg/L) | |  | 92.40 | 471.6 | 123.3 | 1927.1 |
| Nozzzles | Distance (m) | PEC gl-max (µg/L) |  |  |  |  |
| None | 1 | 37.83 | 0.409 | 0.080 | 0.307 | 0.020 |

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

For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms after exposure to the formulation.

|  |
| --- |
| **zRMS comments:** Agreed.  For the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms after exposure to the formulation. |

### Overall conclusions

For the intended uses, calculated PEC/RAC ratios for metabolites showed an acceptable risk for aquatic organisms after Step 1-3 scenarios.

Calculated PEC/RAC ratios for the formulation PENTAGON did indicate an acceptable risk for aquatic organisms.

Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:

**Potato– SPe 3:** To protect aquatic organisms respect 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction

**Winter cereals – SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

**Bulb vegetables (1x1600g/ha and 1x1300g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies

**Bulb vegetables (2x650g/ha and 2x400g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies

**Winter oilseed rape – SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies

* ~~Winter cereals, artichoke, brassicas, lettuce and potato: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction~~
* ~~Maize, garlic, onion, sunflower, eggplant, pepper, tomato, strawberry, soybean and tobacco: 20m no spray buffer zone + 20m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction~~
* ~~Carrots, chickpeas, peanuts and beans: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction~~
* ~~Pome/stone fruits: 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip and 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip and 75% nozzle reduction~~
* ~~Grapevine and ornamentals (bulb vegetables): 15m no spray buffer zone + 15m vegetative strip or 10m no spray buffer zone + 10m vegetative strip + 50% nozzle reduction or 5m no spray buffer zone + 5m vegetative strip + 75% nozzle reduction~~
* ~~Cotton: 15m no spray buffer zone or 10m no spray buffer zone + 50% nozzle reduction or 5m no spray buffer zone + 75% nozzle reduction~~
* ~~Citrus: 10m no spray buffer zone + 10m vegetative strip or 5m no spray buffer zone + 5m vegetative strip + 50% nozzle reduction~~

|  |
| --- |
| **zRMS comments:** The calculations PECsw/sed at STEP 4 according to the Austrian Environmental Agency (AGES) for 5 and 15 meters of vegetative buffer strip should be considered at national level. The Step 4 VFSmod calculations should be considered at national level also. Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using Focus models.  The scenarios D2 and D6 are not relevant for CEU countries and will not be taken into account in further evaluation.  Four different mesocosms were available to address the risk to algae, macrophytes, aquatic invertebrates, and sediment-dwelling organisms. All mesocosm studies resulted in consistent NOEC (0.23–3.8 μg a.s./L) and NOEAEC (1.1–5 μg a.s./L), confirming algae as the most sensitive group. During the Peer Review Experts’ Teleconference it was agreed that the use of the NOEAEC (recovery approach) was not a suitable option, since recovery after autumn applications of pendimethalin might be slower than what is observed in the mesocosms, all carried out in spring/summer. Hence, it was agreed to use the most conservative NOEC value (0.23 μg a.s./L), together with an assessment factor of 1. Such low assessment factor was agreed due to the consistency between the results of the mesocosm studies. In the final commenting round of the present conclusion the RMS disagreed on this approach, which was nevertheless deemed as appropriate during the Peer Review Experts’ Teleconference. The opinion of RMS was that a geometric mean across NOEC from the different mesocosms should have been used in the risk assessment. It must be noted that the use of the geometric mean was considered during the Peer Review Experts’ Teleconference and considered not appropriate.  Therfore the risk was based on the NOEC of 0.23 microgram/L.  Based on lowest **RAC of 0.23 µg a.s./L agreed at EU level** an acceptable risk for aquatic organisms is considered when the following risk mitigation measures and restrictions are applied:  **Potato 1 x 1600 g a.s./ha**  PEC/RAC ratios in potato (1x1600g/ha) are <1 when risk mitigation options are considered:  D3 ditch: 15m no spray buffer zone + 90% nozzle reduction.  D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  R1 pond: 15m no spray buffer zone with 15m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R2 stream and R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction  **Potato 1x1137 g a.s.ha**  PEC/RAC ratios in maize are <1 when risk mitigation options are considered:  D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  D4 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction. k  R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R1 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R2 stream and R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Winter cereals 1x1137 g a.s./ha**  PEC/RAC ratios in winter cereals are <1 when risk mitigation options are considered:  D1 ditch, D1 stream, D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.  D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  D4 pond, D5 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  D4 stream, D5 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R1 stream, R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables 1x1600 g/ha**  PEC/RAC ratios in winter cereals are <1 when risk mitigation options are considered:  D3 ditch: 20m no spray buffer zone + 90% nozzle reduction.  D4 pond: 15m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  D4 stream: 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  R1 pond: 15m no spray buffer zone with 15m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R2 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 90% nozzle reduction  R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables 1x300 g/ha**  PEC/RAC ratios in bulb vegetables are <1 when risk mitigation options are considered:  D3 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.  D4 pond: 10m no spray buffer zone or 5m no spray buffer zone + 50% nozzle reduction.  R1 pond: 10m no spray buffer zone with 10m vegetated filter strip or 5m no spray buffer zone with 5m vegetated filter strip + 50% nozzle reduction  R2 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R3 stream: 15m no spray buffer zone with 15m vegetated filter strip + 90% nozzle reduction  R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables (1x1600 g/ha + 1x300 g/ha)**  PEC/RAC ratios in bulb vegetables (1 x 1600 g/ha + 1 x 300 g/ha) are <1 when risk mitigation options are considered:  R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction  **Bulb vegetables 2x650 g/ha**  PEC/RAC ratios in Bulb vegetables (2x650g/ha) are <1 when risk mitigation options are considered:  R1 stream: 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction  R4 stream: 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction  **Bulb vegetables 2x400 g/ha**  PEC/RAC ratios in Bulb vegetables (2x400g/ha) are <1 when risk mitigation options are considered:  D3 ditch, D4 stream, D6 1st ditch: 20m no spray buffer zone + 90% nozzle reduction or 10m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.  R1 stream: 20m no spray buffer zone with 20m vegetated filter strip  R2 stream: 20m no spray buffer zone with 20m vegetated filter strip or 15m no spray buffer zone with 15m vegetated filter strip + 50% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 75% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle re-duction  R3 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction or 5m no spray buffer zone with 5m vegetated filter strip + 90% nozzle reduction  **Winter oilseed rape 1x910 g a.s./ha**  PEC/RAC ratios in Winter oilseed rape (1x910g/ha) are <1 when risk mitigation options are considered:  D2 ditch: 20m no spray buffer zone + 75% nozzle reduction or 15m no spray buffer zone + 90% nozzle reduction.  D2 stream: 15m no spray buffer zone + 75% nozzle reduction or 5m no spray buffer zone + 90% nozzle reduction.  D3 ditch, D4 stream, D5 stream: 15m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction or 20m no spray buffer zone + 75% nozzle reduction or 10m no spray buffer zone + 90% nozzle reduction.  R1 stream: 20m no spray buffer zone with 20m vegetated filter strip + 50% nozzle reduction  R4 stream: 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction  **Conclusion:**  Calculated PEC/RAC ratios for Pendimethalin did indicate and acceptable risk for aquatic organisms when the following risk mitigation measures are considered:  **Potato– SPe 3:** To protect aquatic organisms respect 20m no spray buffer zone with 20m vegetated filter strip + 75% nozzle reduction or 10m no spray buffer zone with 10m vegetated filter strip + 90% nozzle reduction (for 1 x 1600 g a.s.ha and 1 x 1.137 g a.s./ha)  **Winter cereals – SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 15m + 15m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies  **Bulb vegetables (1x1600g/ha and 1x1300g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 90% nozzle reduction to surface water bodies  **Bulb vegetables (2x650g/ha and 2x400g/ha)** **– SPe 3:** To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 50% nozzle reduction or unsprayed buffer zone of 10m + 10m vegetative strip + 75% nozzle reduction to surface water bodies  **Winter oilseed rape – SPe 3**: To protect aquatic organisms respect an unsprayed buffer zone of 20m + 20m vegetative strip + 75% nozzle reduction to surface water bodies  **The final riskmitigation measures should be considered at MSs level.**  **According SI comment:** In Section 8.01 it is stated.  *The vapour pressure at 20 °C of the active substance Pendimethalin is > 10‑4 Pa. Hence the active substance Pendimethalin is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Pendimethalin due to volatilization with subsequent deposition should be considered.*  Please add an assessment of the risk to aquatic organisms and terrestrial ecosystems following exposure to pendimethalin due to volatilization with subsequent deposition.  **RMS comment:** The dry depositon was calculated by EVA (UBA model) and taken into account in the Step 4 calculations as it is explained in the dRR Part B 8 in chapter 8.9, FOCUS Step 4. The RMS used these calculations in the risk assessment. Additional actions are not necessary in our opinion. However, the risk assessment for aquatic organisms should be considered by MSs level. |

## Effects on bees (KCP 10.3.1)

### Toxicity data

Studies on the toxicity to bees have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on bees of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

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

Table 9.6‑1: Endpoints and effect values relevant for the risk assessment for bees

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Apis mellifera* | Pendimethalin | Acute oral | LD50 > 101.2 µg a.s./bee | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | BAS 455 48 H | Acute oral | LD50 > 120 µg a.s./bee | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | AG-P4-400-SC | Acute oral | LD50 > 198.5 µg a.s./bee | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | Pendimethalin | Acute Contact | LD50 = 100 µg a.s./bee | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | BAS 455 48 H | Acute oral | LD50 > 100 µg a.s./bee | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | AG-P4-400-SC | Acute contact | LD50 > 200 µg a.s./bee | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | BAS 455 48 H | Chronic | 10 d-LDD50 > 96.5 μg a.s./bee/day | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | AG-P4-400 SC | Chronic | 10 d-LDD50 >88.2 μg a.s./bee/day | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | BAS 455 48 H | Honeybee larvae study | 72 h NOED larvae > > 105.6 µg a.s/larva | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | AG-P4-400 SC | Honeybee larvae study | 72 h NOED larvae > > 100 µg a.s./larva | EFSA Journal 2016;14(3):4420 |
| *Apis mellifera* | Pentimethalin 45.5% CS | Acute oral | LD50 > 110.83 µg a.s./bee | KCP 10.3.1.1.1  Viswanathan, K. 2019  18-212-G |
| *Apis mellifera* | Pentimethalin 45.5% CS | Acute contact | LD50 > 100 µg a.s./bee | KCP 10.3.1.1.2  Viswanathan, K. 2019  18-211-G |
| *Apis mellifera* | Pendimethalin | Chronic  10d | LDD50 = 56.58 μg a.s./bee/day  NOEDD = 25.8 μg a.s./bee/day | KCP 10.3.1.2  Glanas, A. 2017  B/107/17 |
| *Apis mellifera* | Pendimethalin | Honeybee larvae study  22d | NOED larvae > > 0.64 µg a.s.μg/larva | KCP 10.3.1.3  Keebaum, K. 2017  17 48 BLC 0083 |
| Higher-tier studies (tunnel test, field studies) | | | | |
| None | | | | |

#### Justification for new endpoints

There is no deviation to the EU agreed endpints. In addition, new acute toxicity studies were performed with the formulation PENTAGON and therefore the resulting endpoints are used in the risk assessment of the product.

Chronic studies on adult bees and larvae were performed. According to the EFSA Guidance for bees (EFSA Journal 2013;11(7):3295), *if there is indication from the acute oral study that the formulation is more toxic than the active substance, then the formulation should be tested…* *if the difference is less than a factor of 5, then the adult chronic toxicity and larval study should only be carried out on the active substance*. The acute oral toxicity of the formulation Pendimethalin 45.5% CC (expressed in terms of active substance) is not more toxic by a factor of 5 than the acute oral endpoint with the active substance (in fact toxicities are very similar), and therefore chronic studies should only be carried out on the active substance. Therefore, chronic studies to adults and larvae studies with the formulation are not needed and are presented with the technical active substance.

### Risk assessment

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for bees from all other intended uses (see 9.1.1).

#### Hazard quotients for bees

Table 9.6‑2: First-tier assessment of the risk for bees due to the use of Pendimethalin 45.5% SC in bare soil

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | |
| Active substance | | Pendimethalin | | |
| Application rate (g/ha) | | 1 x 1600 g a.s./ha | | |
| Test design | LD50 (lab.)  (µg/bee) | | Single application rate  (g/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity | >101.2 | | 1600 | <15.81 |
| Contact toxicity | 100 | | 16.00 |
| Product | | Pendimethalin 45.5% CS | | |
| Application rate (g/ha) | | 1 x 1956 g a.s./ha | | |
| Test design | LD50 (lab.)  (µg/bee) | | Single application rate  (g/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity | >110.83 | | 1600 | < 14.44 |
| Contact toxicity | >100 | | < 16.00 |

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

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

Not relevant.

### Effects on bumble bees

Not relevant.

### Effects on solitary bees

Not relevant.

### Overall conclusions

No risk for bees is expected following the application of PENTAGON at the proposed rates.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comments:**  The HQ values are below trigger of 50 indicating an acceptable risk for adult bees for a.s. and formulation **PENTAGON**.  Chronic studies for a.s. on adult bees and larvae were performed. According to the EFSA Guidance for bees (EFSA Journal 2013;11(7):3295), *if there is indication from the acute oral study that the formulation is more toxic than the active substance, then the formulation should be tested…* *if the difference is less than a factor of 5, then the adult chronic toxicity and larval study should only be carried out on the active substance*. The acute oral toxicity of the formulation Pendimethalin 45.5% CS (expressed in terms of active substance) is not more toxic by a factor of 5 than the acute oral endpoint with the active substance (in fact toxicities are very similar), and therefore chronic studies should only be carried out on the active substance.  **Risk assessment according to EFSA 2013**  To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for bees from all other intended uses.  **Screening step assessment of the chronic risk for bees and assessment for honey bees larvae due to the use of PENTAGON**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Intended use** | Bare soil | | | | | | **Product** | **PENDIMETHALIN/PENTAGON** | | | | | | **Single application rate (g/ha)** | 1 x 1600 g a.s./ha | | | | | | **Test design** | **LD50 (µg/bee)**  **LDD50 (μg/bee/day) NOED (μg/larva)** | **Single**  **application rate**  **(g/ha)** | **SV** | **HQ/ ETR** | **Trigger** | | **Honeybees** | | | | | | | Acute oral toxicity  PENTAGON | >110.83 | 1600 | 7.6 | 0.12 | 0.2 | | Acute contact toxicity  PENTAGON | >100 | 1600 | - | 0.016 | 42 | | Acute oral toxicity  PENDIMETHALIN | >101.2 | 1600 | 7.6 | 0.12 | 0.2 | | Acute contact toxicity  PENDIMETHALIN | 100 | 1600 | - | 0.016 | 42 | | Chronic adult oral  toxicity  PENDIMETHALIN | 56.58 | 1600 | 7.6 | **0.21** | 0.03 | | Larval development oral toxicity  PENDIMETHALIN | > 0.64 | 1600 | 4.4 | **11** | 0.2 |   HQ(hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure. HQ/ETR values shown in bold breach the relevant trigger.  The acute oral and contact HQ/ETR values are less than the trigger for downward sprays indicating that the risk to bees and bee larvae for **pendimethalin** is acceptable.  The screening chronic evaluation of the risk to adult bees and chronic larvae exposed to pendimethalin resulted with ETR value above the trigger indicating potentially unacceptable risk.  **First step assessment of the chronic risk for bees and assessment for honey bees larvae due to the use of PENTAGON**   |  | | --- | | Bare soil (the worst case) | | **PENDIMETHALIN/PENTAGON** | | 1 x 1600 g a.s./ha |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Crop Category** | **Application** | **BBCH** | category | scenario | ETR HB | trigger | Risk indicator | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **chronic** | treated crop | 0,011 | 0,03 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **chronic** | weeds | 0,005 | 0,03 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **chronic** | field margin | 0,001 | 0,03 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **chronic** | adjacent crop | 0,000 | 0,03 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **chronic** | next crop | 0,011 | 0,03 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **larva** | treated crop | 0,85 | 0,2 | ! | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **larva** | weeds | 0,43 | 0,2 | ! | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **larva** | field margin | 0,04 | 0,2 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **larva** | adjacent crop | 0,03 | 0,2 | OK | | Bare soil - crop attractive for pollen and nectar | spray DW | < 10 | **larva** | next crop | 0,85 | 0,2 | ! | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **chronic** | treated crop | 0,000 | 0,03 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **chronic** | weeds | 0,005 | 0,03 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **chronic** | field margin | 0,001 | 0,03 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **chronic** | adjacent crop | 0,000 | 0,03 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **chronic** | next crop | 0,011 | 0,03 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **larva** | treated crop | 0,00 | 0,2 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **larva** | weeds | 0,43 | 0,2 | ! | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **larva** | field margin | 0,04 | 0,2 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **larva** | adjacent crop | 0,03 | 0,2 | OK | | Bare soil - crop attractive for pollen, only | spray DW | < 10 | **larva** | next crop | 0,85 | 0,2 | ! | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **chronic** | treated crop | 0,011 | 0,03 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **chronic** | weeds | 0,005 | 0,03 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **chronic** | field margin | 0,001 | 0,03 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **chronic** | adjacent crop | 0,000 | 0,03 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **chronic** | next crop | 0,011 | 0,03 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **larva** | treated crop | 0,85 | 0,2 | ! | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **larva** | weeds | 0,43 | 0,2 | ! | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **larva** | field margin | 0,04 | 0,2 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **larva** | adjacent crop | 0,03 | 0,2 | OK | | Bare soil - crop attractive for nectar, only | spray DW | < 10 | **larva** | next crop | 0,85 | 0,2 | ! |   First tier chronic evaluation of the risk to adult bees and chronic larvae exposed to pendimethalin resulted with ETR value above the trigger in some scenario indicating potentially unacceptable risk. No data enabling refinement of the risk was available. Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level. It also should be noted that product **PENTAGON** is an herbicide that is mostly applied at pre-emergence (potato, winter cereals, onion, flower bulb - BBCH 00-09). Hence, at the time point of application, no flowering crop is present. Furthermore, the GAP use foresees the application of product **PENTAGON** to crops at post-emergence but pre-flowering stages of BBCH < 60, e.g. winter cereals (BBCH 10-13), winter oilseed rape (BBCH 10-16), onion (BBCH 10-13). Although according to the DTG-list ‘Attractiveness of agricultural crops to honeybees for the collection of nectar and/or pollen, version 2.0 (2015)’ most of the above listed post-emergence crops except winter oilseed rape are not attractive to honeybees, their GAP uses consider BBCH stages that do not show pollen or nectar at the time point of application. In addition, pendimethalin is not systemic. A potential risk arising from the consumption of pollen and nectar from winter oilseed rape can therefore be reasonably excluded. On the other hand bulb vegetables are usualy harvested before flowering (see EFSA 2013). Flowering weeds in fields treated with **PENTAGON** might be attractive to bees. However, in the case of weeds present, application of **PENTAGON** leads to a significant reduction/unattractiveness of the ground cover in the treated fields within a very few days, so flowering, if any, will take place only a very short time period. Thus, the likelihood of bees found in treated fields can be considered as low and exposure to bees, if any, is restricted to a very short time period and a limited number of individuals. In conclusion, no adverse effects on populations and communities need to be expected in consideration of the intended GAP uses of **PENTAGON.** The potential chronic risk from feeding in the treated crop for the use in GAP as low, based on the fact that: pendimethalin is not systemic in combination with the substantial difference in time between flowering and the BBCH stage at application for the use in GAP.  The chronic risk assessment for bees should be considered by MSs level. |

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

### Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Pendimethalin. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on non-target arthropods of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Table 9.7‑1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Aphidius rhopalosiphi*  (protonymphs) | BAS 455 48 H | Tier I laboratory test | Corrected mortality:  2.50% at 0.1024 kg a.s./ha  2.50% at 0.256 kg a.s./ha  20.00% at 0.64 kg a.s./ha  80.00% at 1.6 kg a.s./ha  80.00% at 4.0 kg a.s./ha  Sublethal effects:  n.d.  LR50 = 1.20 kg a.s./ha  (2.637 L formulation/ha) | EFSA Journal 2016;14(3):4420 |
| *Typhlodromus pyri*  (adults) | BAS 455 48 H | Tier I laboratory test | Corrected mortality:  2.78% at 0.1024 kg a.s./ha  16.67% at 0.256 kg a.s./ha  16.67% at 0.64 kg a.s./ha  25.35% at 1.6 kg a.s./ha  30.56% at 4.0 kg a.s./ha  Sublethal effects:  n.d.  LR50 >4.0 kg a.s./ha  (> 8791 mL formulation /ha) | EFSA Journal 2016;14(3):4420 |
| *Aphidius rhopalosiphi*  (adults) | BAS 455 48 H | Extended laboratory test: Dry residues on barley seedlings (3D-test | Corrected mortality:  0.00% at 0.25 kg a.s./ha  0.00% at 0.5 kg a.s./ha  0.00% at 1.0 kg a.s./ha  0.00% at 2.0 kg a.s./ha  0.0% at 4.0 kg a.s./ha  Sublethal effects:  -- at 0.25 kg a.s./ha  -- at 0.5 kg a.s./ha  2.2% at 1.0 kg a.s./ha  4.4% at 2.0 kg a.s./ha  3.3% at 4.0 kg a.s./ha  LR50 and ER50 > 4.0 kg a.s./ha (> 8791 mL formulation /ha | EFSA Journal 2016;14(3):4420 |
| *Chrysoperla carnea*  (adults) | BAS 455 48 H | Extended laboratory test: Dry residues on bean leaves (2D-test) | Corrected mortality:  2.1% at 0.25 kg a.s./ha  0.00% at 0.5 kg a.s./ha  0.00% at 1.0 kg a.s./ha  0.00% at 2.0 kg a.s./ha  -2.1% at 4.0 kg a.s./ha  Sublethal effects:  no effects on reproduction at all test rates  LR50 and ER50 > 4.0 kg a.s./ha (> 8791 mL formulation /ha | EFSA Journal 2016;14(3):4420 |
| *Aphidius rhopalosiphi*  (adults) | AG-P4-400 SC  (= FSG 01100 H) | Extended laboratory test: Dry residues on barley seedlings (3D-test | Corrected mortality:  0.0% at 0.024 kg a.s./ha  3.3% at 0.073 kg a.s./ha  6.7% at 0.22 kg a.s./ha  0.0% at 0.661 kg a.s./ha  13.3% at 1.983 kg a.s./ha  Sublethal effects:  -- at 0.024 kg a.s./ha  -- at 0.073 kg a.s./ha  20.4% at 0.22 kg a.s./ha  13.5% at 0.661 kg a.s./ha  12.9% at 1.983 kg a.s./ha  LR50 and ER50 > 1.983 kg a.s./ha  (> 5000 mL formulation /ha) | EFSA Journal 2016;14(3):4420 |
| *Typhlodromus pyri*  (protonymphs) | AG-P4-400 SC  (= FSG 01100 H) | Extended laboratory test: Dry residues on bean leaf discs (2D-test) | Corrected mortality:  12.4% at 0.024 kg a.s./ha  0.0% at 0.073 kg a.s./ha  3.5% at 0.22 kg a.s./ha  6.2% at 0.661 kg a.s./ha  5.4% at 1.983 kg a.s./ha  Sublethal effects:  -- at 0.024 kg a.s./ha  -- at 0.073 kg a.s./ha  1.0% at 0.22 kg a.s./ha  4.0% at 0.661 kg a.s./ha  25.0% at 1.983 kg a.s./ha  LR50 and ER50 > 1.983 kg a.s./ha  (> 5000 mL formulation /ha | EFSA Journal 2016;14(3):4420 |
| *Pardosa* | STOMP SC (400 g/L pendimethalin SC) | Tier I laboratory test | Corrected mortality:  3% at 0.12 kg a.s./ha  0% at 0.16 kg a.s./ha  6% at 2.4 kg a.s./ha  6% at 3.2 kg a.s./ha  Sublethal effects:  no effects on feeding activity for all test rates | EFSA Journal 2016;14(3):4420 |
| *Aleochara bilineata*  (adult) | STOMP SC (400 g/L pendimethalin SC) | Tier I laboratory test | Corrected mortality:  0% at 0.12 kg a.s./ha  0% at 0.16 kg a.s./ha  0% at 2.4 kg a.s./ha  9% at 3.2 kg a.s./ha  Sublethal effects:  +0.56% at 0.12 kg a.s./ha  +6.5% at 0.16 kg a.s./ha  10% at 2.4 kg a.s./ha  11% at 3.2 kg a.s./ha | EFSA Journal 2016;14(3):4420 |
| *Aleochara. bilineata* | STOMP SC (400 g/L pendimethalin SC) | Laboratory test | 17% total parasitization at 2 kg a.s./ha  13% life prasitization at 2 kg a.s./ha\* | EFSA Journal 2016;14(3):4420 |
| *Poecilus cupreus*  (adult) | STOMP SC (400 g/L pendimethalin SC) | Laboratory test | 3.3% corrected mortality at 2.4 kg a.s./ha  LR50> 2.4 kg a.s./ha  (> 6 L Stomp 400 SC/ha) | EFSA Journal 2016;14(3):4420 |
| *Aleochara bilineata* | Pendimethalin 45.5% CS | Extended laboratory test  LUFA 2.1 soil (2D) | LR50 = 4.17 kg a.s./ha  ER50 = 4.30 kg a.s./ha | KCP 10.3.2.2-05  Angayarkanni, V. 2021  8923/2021 |
| *Chrysoperla carnea* | Pendimethalin 45.5% CS | Extended laboratory test bean leaves (2D) | LR50 = 4.31 kg a.s./ha  ER50 = 4.21 kg a.s./ha | KCP 10.3.2.2-06  Murali, K. 2021  8924/2021 |
| *Aphidius rhopalosiphi* | Pendimethalin 45.5% CS | Extended laboratory  Barley plants (3D) | LR50 = > 8 L fp/ha (3640 g a.s./ha)  ER50 = 3.7 L fp/ha (1683.5 g a.s./ha) | KCP 10.3.2.2-07  Parma, P. 2021  EMI/4/43/2020 |
| *Typhlodormus pyri* | Pendimethalin 45.5% CS | Extended laboratory  test bean leaves (2D) | LR50 = 9.23 L fp/ha (4220 g a.s./ha)  ER50 = 9.24 L fp/ha (4230 g a.s./ha) | KCP 10.3.2.2-08  Angayarkanni, V. 2022  10895/2022 |

n.d. = not determined

Effects reported as adverse effects, which means:

x % effect on mortality = x % increase of mortality compared to control

y % effect on a sublethal parameter = y % decrease of sublethal paramether compared to control

(sublethal parameters are e.g. reproduction, parasitism, food consumption)

When effects are favourable for the test organisms, a + sign is used for the sublethal effect percentages (i.e. increase of e.g. reproduction) and a – sign for mortality effect percentages (i.e. decrease of mortality).

\* The percentages of hatched beetles at test termination termed life parasitization, and the percentages of all parasitized Delia puparia termed total parasitization.

#### Justification for new endpoints

The Applicant has conducted studies with the formulation Pendimethalin 45.5% CS and the endpoinst were considered for the risk assessment.

### Risk assessment

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

#### Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for non-target arthropods from all other intended uses (see 9.1.1).

Table 9.7‑2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Pendimethalin 45.5% CS in bare soil

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | |
| Active substance/product | | Pendimethalin 45.5% CS | | |
| Application rate (g/ha) | | 1 × 1600 g a.s./ha | | |
| MAF | | 1.0 | | |
| Test species  Tier I | LR50 (lab.)  (g/ha) | | PERin‑field  (g/ha) | HQin-field  criterion: HQ ≤ 2 |
| *Typhlodromus pyri* | 4000 | | 1600 | 0.40 |
| *Aphidius rhopalosiphi* | 1200 | | 1.33 |
| Test species  Higher-tier | Rate with ≤ 50 % effect\*  (g/ha) | | PERin‑field  (g/ha) | PERin-field below rate with ≤ 50 % effect? |
| *Aphidius rhopalosiphi* | 1683.5 | | 1600 | yes |
| *Typhlodromus pyri* | 4220 | | yes |
| *Chrysoperla carnea* | 4210 | | yes |
| *Aleochara bilineata* | 4170 | | yes |

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

\* If an LR50 or ER50 from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

The PERin-field is below the LR50/ER50 values for the four species, showing no risk.

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| **zRMS comment:**  The results of the extended laboratory studies performed with the formulation Pendimethalin 45.5% CS showed that the effects on the two indicator species and the additional species were < 50% on mortality and reproduction at higher doses than the maximum rate proposed in GAP. The PERin-field were below the rates with ≤ 50 % effects. Therefore, no in-field risk is expected for non-target arthropods after the application of **PENTAGON** according to the proposed GAP. |

#### Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also cover the risk for non-target arthropods from all other intended uses (see 9.1.1).

Table 9.7‑3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Pendimethalin 45.5% CS in bare soil

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil | | | | |
| Active substance/product | | Pendimethalin 45.5% CS | | | | |
| Application rate (g/ha) | | 1 x 1600 (g a.s./ha) | | | | |
| MAF | | 1.0 | | | | |
| vdf | | 10 (2D) / 1 (3D) | | | | |
| Test species  Tier I | LR50 (lab.)  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | CF | HQoff-field  criterion: HQ ≤ 2 |
| *Typhlodromus pyri* | 4000 | | 2.77 | 4.43 | 10 | 0.01 |
| *Aphidius rhopalosiphi* | 1200 | | 0.04 |
| Test species  Higher-tier | Rate with ≤ 50 % effect\*  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | CF | corr. PERoff-field below rate with ≤ 50 % effect? |
| *Aphidius rhopalosiphi* | 1683.5 | | 2.77 | 44.32 | 5 | yes |
| *Typhlodromus pyri* | 4220 | | 4.43 | 5 | yes |
| *Chrysoperla carnea* | 4210 | | 4.43 | 5 | yes |
| *Aleochara bilineata* | 4170 | | 4.43 | 5 | yes |

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

Corrected PERoff-field values are below the lowest LR50 or ER50 obtained in the extended studies with Pendimethalin 45.5% CS. Therefore, it can be concluded that the application of Pendimethalin 45.5% CS in accordance to the GAP poses no unacceptable off-field risk to non-target arthropods.

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| **zRMS comment:**  The results of the extended laboratory studies performed with the formulation Pendimethalin 45.5% CS showed that the effects on the two indicator species and the additional species were < 50% on mortality and reproduction at higher doses than the maximum rate proposed in GAP. The corrected PERoff-field values were below the rate with effects ≤ 50 %. Therefore, no off-field risk is expected for non-target arthropods after the application of **PENTAGON** according to the proposed GAP. |

#### Additional higher-tier risk assessment

Not required.

#### Risk mitigation measures

No risk mitigation needed.

### Overall conclusions

The application of PENTAGON in accordance to the GAP poses no unacceptable in-field and off-field risk to non-target arthropods.

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| **zRMS comment:**  Agreed. |

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

### Toxicity data

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

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Eisenia fetida* | Pendimethalin | 28d, chronic  Mixed through soil 10% peat | NOEC = 33.45 mg a.s./kg dw soil  **NOECcorr = 16.73 mg a.s./kg dw soil**  EC10 = 49 mg a.s./kg d.w.soil dw  EC10 corr = 24.5 mg a.s./kg d.w.soil dw | EFSA Journal 2016;14(3):4420 |
| *Eisenia fetida* | M455H001 | Chronic,  Mixed through soil 5% peat | NOEC= 32 mg/kg soil dw  NOECcorr= 16 mg/kg soil dw  EC10= 24 mg/kg d.w.soil dw  **EC10corr = 12 mg/kg d.w.soil dw** | EFSA Journal 2016;14(3):4420 |
| *Eisenia fetida* | M455H033 | Chronic,  Mixed through soil 10% peat | NOEC= 25 mg/kg soil dw  NOECcorr= 12.5 mg/kg soil dw  EC10= 14.9 mg/kg d.w.soil dw  **EC10corr = 7.5 mg/kg d.w.soil dw** | EFSA Journal 2016;14(3):4420 |
| *Folsomia candida* | BAS455 48 H | Chronic,  Mixed through soil 5% peat | NOEC=193 mg/kg soil dw  NOECcorr =96.5 mg/kg soil dw  EC10= 561 mg/kg d.w.soil dw  EC10corr = 280.5 mg/kg soil dw | EFSA Journal 2016;14(3):4420 |
| *Folsomia candida* | AG-P4-400-SC | Chronic,  Mixed through soil 5% peat | NOEC= 78.22 mg a.s./kg soil dw  **NOECcorr = 39.1 mg a.s./kg soil dw** | EFSA Journal 2016;14(3):4420 |
| *Hypoaspis aculeifer* | BAS455 48 H | Chronic,  Mixed through soil 5% peat | NOEC= 385 mg a.s./kg soil dw  EC10= 257 mg a.s./kg d.w.soil dw  **EC10corr = 128.5 mg a.s./kg d.w.soil dw** | EFSA Journal 2016;14(3):4420 |
| *Hypoaspis aculeifer* | AG-P4-400-SC | Chronic,  Mixed through soil 5% peat | NOEC= 381.5 mg a.s./kg soil dw  NOECcorr = 190.75 mg a.s./kg d.w.soil dw | EFSA Journal 2016;14(3):4420 |
| *Eisenia andrei* | Pendimethalin 45.5% CS | 56 d, chronic  Mixed through soil | NOEC = 95 mg f.p./kg soil (36.63 mg a.s./kg soil)  NOECcorr = 47.5 mg f.p./kg soil (18.32 mg a.s./kg soil  EC10 = 58.94 mg f.p./kg dw soil  **EC10corr = 29.47 mg f.p./kg dw soil** | KCP 10.4.1.1-02  Swoboda, T. 2021  EMI/4/40/2019 |
| *Folsomia candida* | Pendimethalin 45.5% CS | 28 d, chronic  Mixed through soil | NOEC = 171.47 mg f.p./kg soil (66.2 mg a.s./kg soil)  **NOECcorr = 85.74 mg f.p./kg soil (33.1 mg a.s./kg soil)**  EC10 = 225.12 mg f.p./kg dw soil  EC10corr = 112.56 mg f.p./kg dw soil | KCP 10.4.2.1-03  Dec, W. 2021  EMI/4/17/2020 |
| *Hypoaspis aculeifer* | Pendimethalin 45.5% CS | 14 d, chronic  Mixed through soil | NOEC = 1000 mg f.p./kg soil (386.44 mg a.s./kg soil)  **NOECcorr = 500 mg f.p./kg soil (193.22 mg a.s./kg soil)**  EC10 > 1000 mg f.p./kg dw soil  EC10corr > 500 mg f.p./kg dw soil | KCP 10.4.2.1-04  Angayerkanni, V. 2021  8925/2021 |
| **Field studies** | | | | |
| Two earthworm field studies with BAS 455 48 H:  - No effect after spring application on bare soil in Germany at 11323 g a.s./ha (soil with 0.77% OC)  - After spring application on bare soil in Southern France: LOEC 2265 g a.s./ha based on reduced number of tanilobous juveniles (soil with 0.63% OC). No NOEC could be established. | | | | |

#### Justification for new endpoints

The EU agreed endpoints are used for the risk assessment except for formulation. Applicant has conducted studies with the formulation Pendimethalin 45.5% CS and the endpoints of these studies were used in the risk assessment.

### Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

#### First-tier risk assessment

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Pendimethalin and metabolite M455H001 and does not need to be considered for metabolite M455H033 and Pendimethain 45.5% CS.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.1).

Table 9.8‑2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of Pendimethalin 45.5% CS in bare soil

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use | Bare soil | | |
| Chronic effects on earthworms | | | |
| Product/active substance | NOEC / EC10  (mg/kg dw) | PECsoil  (mg/kg dw) | TERlt  (criterion TER ≥ 5) |
| Pendimethalin | 16.73 | 2.877\* | 5.82 |
| M455H001 | 12 | 0.184\* | 65.22 |
| M455H033 | 7.5 | 0.494 | 15.18 |
| Pendimethalin 45.5% CS | 29.47 | 5.462 | 5.40 |
| Chronic effects on other soil macro- and mesofauna | | | |
| Product/active substance | NOEC  (mg/kg dw) | PECsoil  (mg/kg dw) | TERlt  (criterion TER ≥ 5) |
| Pendimethalin  (*Folsomia candida)* | 39.1 | 2.877\* | 13.59 |
| Pendimethalin 45.5% CS | 85.74 | 5.462 | 15.70 |
| Pendimethalin  (*Hypoaspis aculeifer*) | 128.5 | 2.877\* | 44.66 |
| Pendimethalin 45.5% CS | 500 | 5.462 | 91.54 |

TER values shown in bold fall below the relevant trigger.

\* PECsoil acc

The TER values are above the trigger showing no chronic risk to earthworms and other non-target soil organisms after the application of PENTAGON according to the GAP.

|  |
| --- |
| **zRMS comment:**  The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2.  The TERLT values are above the trigger showing no chronic risk to earthworms and other soil macroorganism after the application of **PENTAGON** according to the GAP. |

#### Higher-tier risk assessment

Not relevant

### Overall conclusions

The long-term TER values are above the respective trigger indicating no long-term risk to earthworms and soil macrofauna after the application of PENTAGON according to the proposed GAP.

## Effects on soil microbial activity (KCP 10.5)

### Toxicity data

Studies on effects soil microorganisms have been carried out with Pendimethalin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on soil microorganisms of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

| Endpoint | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| N-mineralisation | BAS 455 48 H | - | Effect on N-transformation rate after 28 days +25% at 6.91 mg formulation/kg soil dw (equivalent to 2.66 mg a.s./kg soil d.w.), and + 27% at 34.55 mg formulation/kg soil d.w. (equivalent to 13.3 mg a.s./kg soil d.w.) | EFSA Journal 2016;14(3):4420 |
| N-mineralisation | AG-P4-400-SC | - | Effect on N-transormation rate +5% at 28.67 mg formulation/kg soil dw, equivalent to 11.00 mg a.s./kg soil d.w. (28 d). | EFSA Journal 2016;14(3):4420 |
| N-mineralisation | M455H001 | - | Effect on N-transormation rate +17% at 0.5 mg /kg soil dw, and +11% at 5.0 mg/kg soil dw (28 d). | EFSA Journal 2016;14(3):4420 |
| N-mineralisation | M455H033 | - | Effect on N-transormation rate +5% at 0.5 mg /kg soil dw, and +2% at 5.0 mg/kg soil dw (28 d). | EFSA Journal 2016;14(3):4420 |
| N-mineralisation | Pendimethalin 45.5% CS | 28 d, aerobic soil type | Nitrate formation rate  -21.5% at PEC: 27.53 mg f.p./kg d.w. soil (10.62 mg a.s./kg d.w. soil)  Nitrate formation rate  -20.5 at 137.67 mg f.p./kg soil dw (53.08 mg a.s./kg soil dw) | KCP 10.5.1-03  Dec, W. 2021  EMI/4/26/2019 |

#### Justification for new endpoints

The EU agreed endpoints are used for the risk assessment except for formulation. Applicant has conducted study on soil nitrogen transformation with the formulation Pendimethalin 45.5% CS and the endpoint was used in the risk assessment.

### Risk assessment

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

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, and were already used in the risk assessment for earthworms (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group bare soil also covers the risk for soil micro-organisms from all other intended uses (see 9.1.1).

Table 9.9‑2: Assessment of the risk for effects on soil micro-organisms due to the use of Pendimethalin 45.5% CS in bare soil (cotton)

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use | Bare soil | | |
| N-mineralisation | | | |
| Product/active substance | Max. conc. with effects ≤ 25 % (mg/kg dw) | PECsoil  (mg/kg dw) | Risk acceptable? |
| Pendimethalin | 11 (at 28 d) | 2.877\* | yes |
| M455H001 | 5 (at 28 d) | 0.184\* | yes |
| M455H033 | 5 (at 28 d) | 0.494 | yes |
| Pendimethalin 45.5% CS | 137.67 (at 28d) | 5.462 | yes |

\* PECsoil acc

### Overall conclusions

No risk to soil microorganisms is expected following the application of PENTAGON at the proposed rates in the GAP.

|  |
| --- |
| **zRMS comment:** Agreed.  The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. The risk for soil microorganism was considered as acceptable for **PENTAGON**. |

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

### Toxicity data

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

Effects on non-target terrestrial plants of Pendimethalin 45.5% CS were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

Table 9.10‑1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Ryegrass | BAS 455 48 H | Emergence | ER50 = 543 g a.s./ha | EFSA Journal 2016;14(3):4420 |
| Tomato | AG-P4-400-SC | Emergence | ER50 = 402 g a.s./ha | EFSA Journal 2016;14(3):4420 |
| 1)Soybean d  2)Oilseed rape d  3)Onion m  4)Oat m  5)Lettuce d  6)Sugar beet d | Pendimethalin 45.5% CS | Sewedling emergence | 1)ER50 = 5.639 kg fp/ha (2.6 kg a.s./ha)  2)ER50 = 6.726 kg fp/ha (3.1 kg a.s./ha)  3)ER50 = 5.112 kg fp/ha (2.3 kg a.s./ha)  4)ER50 = 5.342 kg fp/ha (2.4 kg a.s./ha)  5)ER50 = 6.896 kg fp/ha (3.1 kg a.s./ha)  6)ER50 = 7.260 kg fp/ha (3.3 kg a.s./ha) | KCP 10.6.2-03  Radha, S. 2021  9419/2021 |
| 1)Soybean d  2)Oilseed rape d  3)Onion m  4)Oat m  5)Lettuce d  6)Sugar beet d | Pendimethalin 45.5% CS | Vegetative vigour | 1)ER50 = 6.272 kg fp/ha (2.9 kg a.s./ha)  2)ER50 = 6.781 kg fp /ha (3.1 kg a.s./ha)  3)ER50 = 5.176 kg fp /ha (2.4 kg a.s./ha)  4)ER50 = 5.036 kg fp/ha (2.3 kg a.s./ha)  5)ER50 = 7.143 kg fp/ha (3.3 kg a.s./ha)  6)ER50 = 7.377 kg fp/ha (3.4 kg a.s./ha) | KCP 10.6.2-04  Radha, S. 2021  9420/2021 |

m: monocotyledonous; d: dicotyledonous

#### Justification for new endpoints

Applicant has conducted studies on seedling emergence and vegetative vigour with the formulation Pendimethalin 45.5% CS and the endpoints were used for the risk assessment.

### Risk assessment

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

Not relevant for herbicides or plant growth regulators as ER50 tests should be provided.

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

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Table 9.10‑2: Assessment of the risk for non-target plants due to the use of Pendimethalin 45.5% CS in bare soil (flower)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | | Bare soil (flower) | | | |
| Active substance/product | | Pendimethalin 45.5% CS | | | |
| Application rate (g/ha) | | 1 × 1600 g a.s./ha | | | |
| MAF | | 1 | | | |
| Test species | ER50  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | TER  criterion: TER ≥ 5 |
| Onion | 2300 | | 2.77% | 44.32 | 51.90 |
| Oat | 2300 | | 44.32 | 51.90 |

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

No risk to non-target plants is observed in any of the crops after the application of Pendimethalin 45.5% CS according to the GAP.

#### Higher-tier risk assessment

Not relevant.

#### Risk mitigation measures

No risk mitigation measures are needed.

### Overall conclusions

No risk to non-target plants located outside the treated area is expected in any of the crops after the application of PENTAGON.

**zRMS comments:**

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The deterministic risk based on the lowest value ER50 of 5036 g a.s./ha value and PERoff- field  for proposed uses of **PENTAGON**. The risk assessment for to non-target plants located outside the treated area is considered as acceptable after the application of **PENTAGON**.

**No risk mitigation measures are needed.**

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

No data on other non-target species is required

## Monitoring data (KCP 10.8)

Not relevant.

## Classification and Labelling

|  | PENTAGON |
| --- | --- |
| Common Name | PENTAGON |
| **Classification and proposed labelling** | |
| With regard to ecotoxicological endpoints (according to Reg. 1272/2008) | Hazard classes (s), categories:  **Aquatic acute 1; H400:** very toxic to aquatic life  **Aquatic Chronic 1; H410:** very toxic to aquatic life with long lasting effects  Code(s) for hazard pictogram(s):  **GHS 09**  Signal word:  **Warning**  EU specific statements:  EUH401  Precautionary statement:  P391  P501 |

1. Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP 10.1.1.2-01 | Romero, S. | 2018 | Magnitude of residue of Pendimethain in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial  Report No.: BPL17-010  BIOTEK Agriculture España  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.1.1.2-02 | Roehl, T. | 2017 | Residue study (decline) in wheat following one post emergence application with Pendimethlainl 33% EC in Germany 2017.  Report no. CT17-1-47  CropTrials GmbH  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.1.1.2-03 | Rubino, M. | 2018 | Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0  Report No 18.618095.0005  CHELAB S.R.L.  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.1.1.2-04 | Wágner, G. | 2020 | Determination of the residues of pendimethalin in/on wheat after one application of pendimethalin 33% EC in northern Europe- Hungary in 2019  Report No.: 034SRHU19R35  CPR Europe Kft.  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.1.1.2-05 | Rubino, M | 2020 | Determination of residual trials Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-289-LABCHI-REV.0  Report No.: 19.528632.0002  Chelab S.R.L.  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.2.1-01 | Murali, K. | 2020 | Rainbow trout (*Oncorhynchus mykiss*), acute toxicity test with Pendimethalin 455 g/l CS  Report No.: 7887/2020  Bioscience Research Foundation  GLP  Unpublished | Y | Sharda Cropchem Ltd. |
| KCP 10.2.1-02 | Rajeshwari, S. | 2021 | Study of *Daphnia magna* acute immobilisation with Pendimethalin 455 g/L CS  Report No.: 9010/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Ltd. |
| KCP 10.2.1-03 | Radha, S. | 2021 | Study of algal growth inhibition with Pendimethalin 455 g/L CS  Report No.: 9008/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Ltd. |
| KCP 10.2.1-04 | Radha, S. | 2021 | Study of *Lemna gibba* growth inhibition with Pendimethalin 455 g/l CS  Report No.: 9009/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Ltd. |
| KCP 10.3.1.1.1 | Viswanathan, K. | 2019 | Acute oral toxicity study of Pendimethalin 455 g/L CS in honey bee (*Apis mellifera*)  Report No. 18-212-G  Vanta Bioscience Limited  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.1.1.2 | Viswanathan, K. | 2019 | Acute contact toxicity study of Pendimethalin 455 g/L CS in honeybees (*Apis mellifera*)  Report No. 18-211-G  Vanta Bioscience Limited  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.1.2 | Glanas, A. | 2017 | Pendimethalin Technical Honeybees (*Apis mellifera*), chronic oral toxicity test  Report No.: B/107/17  Institute of Industrial Organic Chemistry Branch Pszczyna  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.1.3 | Kleebaum, K. | 2017 | Pendimethalin Technical – Repeated exposure of honey bee (*Apis mellifera* L.) larvae under laboratory conditions (*in vitro*)  Report No.: 17 48 BLC 0083  BioChem agrar  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.2.2-01 | Angayarkanni, V. | 2021 | A laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the rove beetle *Aleochara bilineata* (Gyllenhal).  Report No.: 8923/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.2.2-02 | Murali, K. | 2021 | An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on larvae of the green lacewing *Chrysoperla carnea* L. (Neuroptera: Chrysopidae).  Report No.: 8924/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.2.2-03 | Parma, P. | 2021 | An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the parasitic wasp, *Aphidius rhopalosiphi*, (Hymenoptera, Braconidae)  Report No.: EMI/4/43/2020  Ecomelius Institute Sp. Z o.o  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.3.2.2-04 | Angayarkanni, V. | 2022 | An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the predatory mite, *Typhlodromus pyri* (Scheuten).  Report No: 10895/2022  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.4.1.1-01 | Swoboda, T. | 2021 | Earthworm Reproduction Test (Eisenia andrei)  Report No.: EMI/4/40/2019  Ecomelius Institute Sp. z.o. o  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.4.2.1-01 | Dec, W. | 2021 | Collembolan (Folsomia candida) Reproduction Test  Report No.: EMI/4/17/2020  Ecomelius Institute Sp. z.o. o  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.4.2.1-02 | Angayarkanni, V. | 2021 | Effect of Pendimethalin 455 g/L CS on the Reproductive Output of the Predatory Soil Mite *Hypoaspis* (*Geolaelaps*) *aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil.  Report No.: 8925/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.5.1-01 | Dec, W. | 2021 | Soil Microorganisms: Nitrogen Transformation Test  Report No.: EMI/4/26/2019  Ecomelius Institute Sp. z o. o  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.6.2-01 | Radha, S. | 2021 | Effect of Pendimethalin 455 g/L CS on seedling emergence and seedling growth of terrestrial plants  Report No. 9419/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Limited |
| KCP 10.6.2-02 | Radha, S. | 2021 | Effect of Pendimethalin 455 g/L on vegetative vigour of terrestrial plants  Report No. 9420/2021  Bioscience Research Foundation  GLP  Unpublished | N | Sharda Cropchem Limited |

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

1. Detailed evaluation of the new studies
   1. KCP 10.1 Effects on birds and other terrestrial vertebrates
      1. KCP 10.1.1 Effects on birds
         1. KCP 10.1.1.1 Acute oral toxicity
         2. KCP 10.1.1.2 Higher tier data on birds

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Comments of zRMS: | | Residue Section. The study was valuated in Residue Section and was considered as an acceptable.  In Ecotox perspective the study can not be considered sufficiently acceptable to evaluate the decline of residue. The study was performed at crop growth stage BBCH 25-30 in **spring** cereals (wheat) in Poland, and do not cover the current GAP (BBCH 10-13) in winter cereals. The application was done on May.  It should be noted that if the crop itself is the proven food source treatment should be in line with the GAP (i.e. same crop, BBCH stage, number and spacing of applications, etc.). If the study is not performed according to the GAP, adequate support should be provided that these derivations had no impact on the DT50 estimation. | | |
| Reference: | | KCP 10.1.1.2-01 |
| Report | | Magnitude of residue of Pendimethalin in wheat Raw Agricultural Commodity after one application of Pendimethalin 33% EC under field conditions – 1 harvest trial and 1 decline trial and 1 refinement decline trial. S. Romero, 2018, Report No. BPL17-010. (Field phase) |
| Guideline(s): | | Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 |
| Deviations: | | No |
| GLP: | | Yes |

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

Three field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of wheat.

Each trial was comprised of one untreated control plot and one plot treated with Pendimethalin 33% EC (*Pendimethalin* 330 g/l).

One application was performed at crop growth stage BBCH 25-30 and at a dose rate between 4.51 and 4.74 l/ha of test item; corresponding to a total dose of active ingredient between 1497.6 and 1573.9 g/ha.

One trial was performed to gain grain specimens of wheat (raw agricultural commodities) at harvest.

The other two trials were conducted to study the decline curve of the active ingredient in wheat whole plants, grain and straw. In the decline trial specimens were generated at ±0 DAA, 30-50 DAA and at maturity (harvest at BBCH 89). In the refinement decline trial specimens were generated at ±0 DAA, 1DAA, 2 DAA, 3 DAA, 4 DAA, 5 DAA; 6 DAA, 7 DAA, 8 DAA, 9 DAA, 10 (+/-1) DAA, 12 (+/-1) DAA, 14 (+/-1) DAA and at maturity (harvest at BBCH 89).

**ANALYTICAL PHASE**

STUDY DESIGN AND METHODS

The analytical phase was conducted according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat grains by Liquid Chromatography” (applied for specimens of whole plants without roots and grain) and SOPa-289-LABCHI-Rev.0 “Analytical Procedure for the Determination of Pendimethalin (CAS: 40487-42-1), in wheat straw by Liquid Chromatography” applied for specimens of straw).

Residues of pendimethalin were extracted from grinded, homogenized wheat (whole plants and grain) with acetonitrile, acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and kept at about -20ºC for about 2 hours, following a further centrifugation to purify the supernatant. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The residues of pendimethalin of grinded, homogenized wheat straw were extracted with acetonitrile, glacial acetic acid and water. After vortexing, magnesium sulphate anhydrous and sodium acetate were added and vortexed again. The tube was centrifuged and the supernatant was purified. Then a part was transferred to a mixture of magnesium sulphate anhydrous and PSA resin. It was vortexed and centrifuged again. The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

The quantification as *pendimethalin* was performed by LC-MS (liquid chromatography with mass spectrometry detection).

For *pendimethalin* the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg.

| **Trial No./**  **Location/**  **EU zone/**  **Year** | **Commodity/ Variety** | **Date of**  **1.Sowing or planting**  **2.Flowering**  **3. Harvest** | **Application rate per treatment** | | | **Dates of treatment or no. of treatments and last date** | **Growth stage at last treatment or date** | **Portion analyzed** | **Residues (mg/kg)** | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Pendimethalin** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| BPL17-010-01/Poland/N-EU/2017 | Spring wheat/Arabella | 29/03/17  19-28/06/17  3-4/08/18 | 1574 | 306 | 510 | 18/05/17 | BBCH 25-30 | Grain | n.d. | 78 |  |
| BPL17-010-02/Poland/N-EU/2017 | Spring wheat/Harenda | 14/03/17  12-28/06/17  07/08/17 | 1510 | 294 | 510 | 08/05/17 | BBCH 25-30 | Whole plant  Whole plant  Grain  Straw | 6.23  0.13  <0.01  0.04 | 0  30  91  91 |  |
| BPL17-010-03/Poland/N-EU/2017 | Spring wheat/Rospuda | 30/03/17  19-26/06/17  07/08/17 | 1498 | 291 | 510 | 16/05/17 | BBCH 25-30 | Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 6.79  2.80  3.19  2.68  1.19  1.16  1.15  1.22  1.34  1.49  1.46  0.68  0.78  n.d.  0.04 | +0  1  2  3  4  5  6  7  8  9  10  13  14  83  83 |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Comments of zRMS: | | Residue Section. The study was valuated in Residue Section and was considered as an acceptable.  In Ecotox perspective the study can not be considered sufficiently acceptable to evaluate the decline of residue of a.s.-pendimethalin. The study was performed at crop growth stage BBCH 25-30 in spring cereals ( wheat) in Germany and do not cover the current GAP (10-13) in winter cereals. The application was done on May.  It should be noted that if the crop itself is the proven food source treatment should be in line with the GAP (i.e. same crop, BBCH stage, number and spacing of applications, etc.). If the study is not performed according to the GAP, adequate support should be provided that these derivations had no impact on the DT50 estimation. | | |
| Reference: | | KCP 10.1.1.2-02 |
| Report | | Residue study (Decline) in wheat following one post emergence application with Pendimethalin 33% EC in Germany 2017. T. Roehl (Field phase). Report No. CT17-1-47 |
| Guideline(s): | | OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)  - EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials  - The Principles of Good Laboratory Practice, ChemG 25.07.1994, § 19, Annex 1 (BGBL 21, I, 2001, p. 843-855)  - OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002  - The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002  - The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9  - Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992 |
| Deviations: | | No |
| GLP: | | Yes |

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: wheat

Crop parts(s) or processed commodity: whole plant, grain straw

STUDY DESIGN AND METHODS

The trial CT17-1-47DE1 was carried out in open field on the crop spring wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2017). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (8 subplots of 24 m² = 192 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (10 m).

The application was conducted with a knapsack sprayer with boom. The spraying equipment was cleaned with water before and after use. The output of the nozzles was checked for uniformity before start of application. The speed of walk was adapted to the output of the sprayer and test runs were performed before start of application. The application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant without roots were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 73 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

|  |  |
| --- | --- |
| Comments of zRMS: | Acceptable by residue expert. |

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| --- | --- |
| Reference: | KCP 10.1.1.2-03 |
| Report | Determination of Pendimethalin (CAS: 40487-42-1) in wheat by LC-MS according to SOPa-288-LABCHI-REV.0 and SOPa-2289-LABCHI-REV.0, M. Rubino, 2018, Report No 18.618095.0005(Analytical phase) |
| Guideline(s): | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC  Guideline 7029/VI/95 (rev. 5) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009  EU Guidance Document SANCO/3029/99 rev. 4  EU Guidance Document SANCO/825/00 rev. 8.1 |
| Deviations: | No |
| GLP: | Yes |

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-716452)

2. Test Commodity:

Crop: Wheat

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 18.618095.0005 was conducted to determine the residual level of Pendimethalin in wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about T<-18℃ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20℃ date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For whole plants and grain samples

About 5.00 g of sample grinded were introduced into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction mixture B were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1 min. The tube was centrifuged at 4750 rpm for 5 min and kept at about 20℃ for abour 2 hours. Then, the tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of suspernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

About 3.00 g of sample grinded were introduced into a 50 ml plastic tube. 12.5 ml of milliQ water and 15 ml of extraction mixture A were added to the sample. After vortexing for about 1 min, about 6 g (± 0.01 g) of magnesium sulphate anhydrous and about 1.5 g of sodium acetate were added to the sample and vortexed again for about 1min. The tube was centrifuged at 4750 rpm for 5 min and it was proceed to purification of the supernatant. 5 ml of supernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and crntrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spkied with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 101.3% with RSD = 9.0% for first mass transition and 90.3% with RSD = 11.0% for the second mass transition in whole plant.

Mean recovery was 103.0% with RSD = 4.0% for first mass transition and 101.4% with RSD = 6.0% for the second mass transition in grain.

Mean recovery was 80.6% with RSD = 13.0% for first mass transition and 92.7% with RSD = 14.0% for the second mass transition in straw.

| **Trial No./**  **Location/**  **EU zone/**  **Year** | **Commodity/ Variety** | **Date of**  **1.Sowing or planting**  **2.Flowering**  **3. Harvest** | **Application rate per treatment** | | | **Dates of treatment or no. of treatments and last date** | **Growth stage at last treatment or date** | **Portion analyzed** | **Residues (mg/kg)** | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Pendimethalin** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| CT17-1-47DE1/Germany/N-EU/2018 | Spring wheat/Dino | 25/03/2017  -  - | 1498.6 | 300 | 500 | 26/05/2017 | BBCH 30 | Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 5.81  3.69  3.42  1.39  1.19  1.21  0.31  0.34  0.21  0.03  0.19  0.07  0.12  n.d.  0.01 | 0  1  2  3  4  5  6  7  8  9  10  12  14  73  73 | 12 months  Analytical report:  18.618095.0005 |

|  |  |
| --- | --- |
| Comments of zRMS: | Acceptable for residue expert.  In Ecotox perspective the study can not be considered sufficiently acceptable to evaluate the decline of residue of a.s.- pendimethalin. The study was performed at crop growth stage BBCH 30 in winter cereals ( wheat) in Hungary and do not cover the current GAP (BBCH 10-13) in winter cereals. The application was done on April or May. It should be noted that if the crop itself is the proven food source treatment should be in line with the GAP (i.e. same crop, BBCH stage, number and spacing of applications, etc.). If the study is not performed according to the GAP, adequate support should be provided that these derivations had no impact on the DT50 estimation. |

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| --- | --- |
| 1. Reference: | KCP 10.1.1.2-04 |
| Report | DETERMINATION OF THE RESIDUES OF PENDIMETHALIN IN/ON WHEAT AFTER ONE APPLICATION OF PENDIMETHALIN 33% EC IN NORTHERN EUROPE - HUNGARY IN 2019. Gábor Wágner (Field phase). Report No. 034SRHU19R35 |
| Guideline(s): | Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament.  Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997.  OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)  European Community Guidelines SANCO 7525/VI/95 – Rev 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. |
| Deviations: | The temperature of the freezer (SYN-KDL-071) rose above -18.0ºC for more than 2 hours. The length of the event was 10 hours and 20 minutes. In this period the maximum temperature was -17.1ºC and the maximum of the average of the 24-hour cycles was -18-13ºC. The event happened because of the longer working time in the freezer that is acceptable. This had no impact, because the limit exceeding occurrence did not affect the quality of the samples and the maximum of the average of 24-hours was lower than -18ºC. |
| GLP: | Yes |

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-483228)

2. Test Commodity:

Crop: winter wheat

Crop parts(s) or processed commodity: whole plant, seed, straw

STUDY DESIGN AND METHODS

The trial 034SRHU19R35 was carried out in open field on the crop winter wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2019). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (18 m x 10 m = 180 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (≥10 m).

The application was conducted with an Air compressed backpack boom sprayer. Equipment calibration was performed on treatment dates, before each application. The target application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 71 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

|  |  |
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| Comments of zRMS: | Accepted by residue expert. |

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| --- | --- |
| Reference: | KCP 10.1.1.2-05 |
| Report | DETERMINATION OF RESIDUAL TRIALS PENDIMETHALIN (CAS: 40487-42-1) IN WHEAT BY LC-MS ACCORDING TO SOPA-288-LABCHI-REV.0 AND SOPA-289-LABCHI-REV.0, M. Rubino, 2020, Report No 19.528632.0002 (Analytical phase) |
| Guideline(s): | SOPa-288-LABCHI-Rev.0 "Analytical Procedure for the Determination of Pendimethalin (CAS : 40487-42-1), in wheat grains by Liquid Chromatography".  SOPa-289-LABCHI-Rev.0 "Analytical Procedure for the Determination of Pendimethalin (CAS : 40487-42-1), in straw grains by Liquid Chromatography".  OECD (1998). The OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CH EM(98)17.  Italian Legislative Decree (D.L. No. 50 dated March 2nd, 2007) as published in G.U. No. 86 of April 13th, 2007.  Annex II, Regulation EC 1107/2009 concerning the placing of Plant Protection Products on the market.  OECD guideline nº509, “Guidance document on crop field trials”, (2009).  SANCO/825/00 rev. 8.1 guideline, Guidance document on pesticide residue analytical methods.  SANCO/3029/99 rev. 4 guideline, Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414.  Study nº16.566423.0005 “Validation of the analytical procedure for Pendimethalin (CAS: 40487-42-1) in what grains by liquid chromatography”.  Study nº16.566423.0006 “Validation of the analytical procedure for Pendimethalin (CAS: 40487-42-1) in what straw by liquid chromatography”. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

MATERIAL AND METHODS

A. MATERIALS

Test material: Pendimethalin 33% EC (Batch No. SCL-483228)

2. Test Commodity:

Crop: Winter wheat

Crop parts(s) or processed commodity: grain, straw, whole plant

STUDY DESIGN AND METHODS

The analytical phase of the study 19.528632.0002 was conducted to determine the residual level of Pendimethalin in winter wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

Storage in laboratory: field samples were stored frozen at about T<-18℃ from reception time to extraction date. Before the analysis, the specimens were grinded and stored the extracts in a freezer about -20℃ date.

The determination of Pendimethalin in wheat by LC-MS.

SAMPLE EXTRACTION

For seed and whole plant samples

5.00 g (± 0.10 g) of ground sample were accurately weighted (weight accuracy ± 0.1 mg) into a 50 ml plastic tube, 7.5 ml of milliQ water and 10 ml of extraction phase A were added to the sample. After vortexing for about 1 min, a QuEChERS Extraction Packet-AOAC was added to the sample. After vortexing again for about 1 min, the tube was centrifuged at 4750 rpm for 5 min and kept at about -20ºC for about 2 hours. The tube then was centrifuged at 4750 rpm for 5 min the purification of the supernatant was carried out. 5 ml of suspernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample was recovered and transferred into an HPLC vial and injected.

For straw samples

3.00 g (± 0.10 g) of ground sample were accurately weighted (weight accuracy ± 0.1 mg) into a 50 ml plastic tube; 12.5 ml of milliQ water and 15 ml of extraction phase B were added to the sample. After vortexing for about 1 min, a QuEChERS Extraction Packet-AOAC was added to the sample. After vortexing again for about 1 min, the tube was centrifuged at 4750 rpm for 5 min and the purification of the supernatant was carried out. 5 ml of suspernatant were transferred into a 10 ml plastic tube, containing about 450 mg of magnesium sulphate anhydrous and 150 mg of PSA resin. It was vortexed for about 1 min and centrifuged at 4750 rpm for 5 min.

The supernatant of purified sample were recovered and transferred into an HPLC vial and injected.

LIMIT OF QUANTIFICATION AND LIMIT OF DETECTION

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.

ACCURACY

Accuracy evaluation was performed on sample aliquots spkied with Pendimethalin at LOQ (about 0.01 mg/kg) 3 replicate analyses were performed for each spiking level.

Mean recovery was 107% with RSD = 1% for first mass transition and 101% with RSD = 3% for the second mass transition in whole plant.

Mean recovery was 106% with RSD = 4% for first mass transition and 93% with RSD = 16% for the second mass transition in grain.

Mean recovery was 105% with RSD = 5% for first mass transition and 91% with RSD = 13% for the second mass transition in straw

| **Trial No./**  **Location/**  **EU zone/**  **Year** | **Commodity/ Variety** | **Date of**  **1.Sowing or planting**  **2.Flowering**  **3. Harvest** | **Application rate per treatment** | | | **Dates of treatment or no. of treatments and last date** | **Growth stage at last treatment or date** | **Portion analyzed** | **Residues (mg/kg)** | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./l** | **Pendimethalin** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| SRHU19-207-034HR/  Hungary/  NEU/  2019 | Winter Wheat/ Pitbull | 1) 18/10/2018  2) 20-30/05/2019  3) 04/07/2019 | 1635.399 | 300 | 5.451 | 24/04/2019 | BBCH 30 | Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Whole plant  Seed  Straw | 146.48  102.99  90.25  83.17  27.51  17.14  27.56  26.83  16.54  31.34  13.47  11.03  2.91  <0.01  0.052 | 0  1  2  3  4  5  6  7  8  9  10  12  14  71  71 | Analytical report: FR 19.528632.0002 |

* + 1. KCP 10.1.2 Effects on terrestrial vertebrates other than birds











Decay Times:

|  |  |  |
| --- | --- | --- |
| **Compartment** | **DT50 (days)** | **DT90 (days)** |
| Parent | 1.81 | 6.02 |

Graphical Summary:

Observations and Fitted Model: Residuals:



**Gabor, W. (2019) and Rubino, M (2020) (KCP 10.1.1.2-04 & 05)**

**Summary**

The trial 034SRHU19R35 was carried out in open field on the crop winter wheat. The study director assured before start of the trial, that no Pendimethalin containing products would be used on the trial site during the current season (2019). One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled for each trial. The plot size (18 m x 10 m = 180 m²) was chosen large enough to provide representative specimens for sampling.

Drift of spray solution during the application was avoided by choosing an adequate distance between the untreated and treated plot (≥10 m).

The application was conducted with an Air compressed backpack boom sprayer. Equipment calibration was performed on treatment dates, before each application. The target application rate of the test item Pendimethalin 33% EC was 5.0 L/ha. The water volume was 300 L/ha. The application was performed post emergence at crop stage BBCH 30.

The specimens from the untreated plot were always taken prior to the specimens of the treated plot. Ship and retain specimens were taken at each sampling date.

The specimens were taken from all subplots at each sampling date. Specimens of the raw agricultural commodity whole plant were taken from the untreated and treated plot at the day of the application and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 12 and 14 days after the application (DALA). Each of these specimen

consisted of ≥ 1.0 kg plant material. At the time of commercial harvest (crop stage BBCH 89, 71 DALA) specimens of the raw agricultural commodities grain (≥ 1.0 kg) and straw (≥ 0.5 kg) were collected from the untreated and treated plot by using a research size combine harvester.

The analytical phase of the study 19.528623.0002 was conducted to determine the residual level of Pendimethalin in winter wheat by LC-MS according to the in-house validated methods codified as SOPa-288-LABCHI-Rev.0 and SOPa-LABCHI-Rev.0 and as described in study No 16.566423.0005 and No 16.566423.0006 validated on the matrix wheat grains and wheat straw.

The LOQ of the method was defined as the lowest analyte concentration at which the methodology had been successfully validated. Thus, an LOQ of 0.01 mg/kg was confirmed Pendimethalin in wheat matrices.

The LOD was set at < 30 % of the LOQ (0.003 mg/kg for wheat). The chromatographic peaks at the LOD were more than three times the background noise.





**zRMS e-fate expert comment:**

The kinetic analysis of residues of pendimethalin in wheat (whole plants) was accepted.

**Agreed endpoints:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial** | **DT50**  **(d)** | **DT90**  **(d)** | **χ2**  **(%)** | **MODEL** |
| BPL17-010-03/Poland/N-EU/2017 | 2.79\* | 9.8\* | 31.3 | SFO |
| CT17-1-47DE1 | 1.81 | 6.02 | 16.7 | SFO |
| 034SRHU19R35 | 2.54 | 8.43 | 20.5 | SFO |

**\*Considered as not reliable**

**In conclusion:**

**The report was assessment in the report for PPP PENSHUI in 2022:**

***The DT50 value were not used for winter cereals/weeds in quantitative risk assessment for bird and mammals for the following reason:***

*In all of the referenced studies residues of pendimethalin were measured following post - emergence applications on cereals. However, the zRMS identified several shortcomings in the studies that are summarised in the following. For two study sites, applications were carried out in spring for spring cereals on april or May trials from Poland and Germany and BBCH from 25-30 and in spring for winter cereals from Hungary (BBCH 30), which reduces the data set for a refinement of the intended* ***PENTAGON*** *use in winter cereals/weeds.*

*In addition during evaluation of the dissipation kinetics of pendimethalin the trials from Poland were excluded from the kinetic analysis. Finally, only one from Germany and one from Hunagary were taken into account to estimate DT50 value in plants for a.s.*

*The minimum requirement in order to have a reliable refinement of the dissipation as defined by the EFSA (four sites per regulatory zone) is also not fulfilled.*

*Summarizing the above, the presented studies are not suitable to derive a DT50 for pendimethalin that is applicable for the intended uses of* ***PENTAGON*** *in the central zone for winter cereals post- emergence.*

*For winter cereals new decline studies is recommended with application in autumn to confirm the new DT50 for a.s.-pendimethalin.*

* + - 1. KCP 10.1.2.1 Acute oral toxicity to mammals
      2. KCP 10.1.2.2 Higher tier data on mammals
    1. KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)
  1. KCP 10.2 Effects on aquatic organisms
     1. KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

|  |  |
| --- | --- |
| Comments of zRMS: | Study was carried out according to appropriate OECD 203 and all validity criteria were met.  Deviation from the study: No deviation occurred from the study plan.  The validity criteria:    **The study is considered acceptable.**  **Agreed endpoints:** |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.2.1-01 |
| **Report:** | “Rainbow trout (*Oncorhynchus mykiss*), acute toxicity test with Pendimethalin 455 g/l CS”*.*  Murali K., 7887/2020, 2020  BIOSCENCE RESEARCH FOUNDATION |
| **Guideline(s):** | OECD No. 203 (2019) |
| **Deviations:** | No |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study):** | No |

**Summary**

The aim of the study was to assess the impact of Pendimethalin 455 g/L CS on rainbow trout (*Oncorhynchus mykiss*) to determine the concentration of the test item causing 50% mortality of rainbow trout (LC50­ value after 96 h of exposure) as well as the NOEC and LOEC values. The test was conducted in a static design for 96 h with seven concentrations of the test item plus the control. Each concentration was divided into one replicate with ten fish each. The fish were observed for mortality and intoxication symptoms after 2, 5, 24, 30, 48, 54, 72, 78 and 96 h of exposure.

**Material and methods**

Test item: Name: Pendimethalin 455 g/l CS

Batch number: SCL – 60400

Content: 456 g/L

Production date: 14th December, 2019

Expiry date: 13th December, 2021

Test organism: Rainbow trout (*Oncorhynchus mykiss*)

Supplier: Tharun aqua fish farm, Padappai-601301, Tamil Nadu, India.

Age: approximately 2 months

Test design: Test type: static

Exposure time: 96 hours

Number of replicates: 1 replicates per each concentration and the control

Number of fish: 10 fish in each aquarium

Nominal test item

concentration: 1.56, 3.13, 6.25, 12.5, 25, 50, 100 mg/L plus the control

Nominal concentrations

of Copper: 0.6, 1.2, 2.4, 4.8, 9.7, 19.3, 38.6 mg/L

Test conditions: Temperature: 12.0 – 12.33℃

pH: 7.1 – 7.4

Oxygen: 65 - 71 %

Lighting: 16 h light : 8 h dark – 659-899 lux

Endpoint values: LC50, LOEC and NOEC.

Statistical analysis: Probit analysis in the NCSS (Number Cruncher Statistical System).

Validity criteria: - the mortality in the control was 0% after 96 h (criterion: < 10%);

- dissolved oxygen concentrations were within the range of 65 – 71 % of air saturation value (criterion: > 60% of air saturation).

**Findings**

**Endpoint values for mortality of fish after 96h of exposure**

|  |  |  |
| --- | --- | --- |
| **Endpoint** | **Test item [mg/L] (nominal concentrations)** | **Active substance [mg/L] (nominal concentrations\*)** |
| **LC50** | **9.24** | **3.57** |
| **NOEC** | **1.56** | **0.6** |
| **LOEC** | **3.13** | **1.2** |

\* Calculated on the basis of of the Pendimethalin content int the test item declared by the Sponsor

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|  |  |
| --- | --- |
| Comments of zRMS: | Study was carried out according to appropriate OECD 202 and all validity criteria were met.  Deviation from the study: No deviation occurred from the study plan. No deviations occurred from the OECD Guideline No. 202.  **The validity criteria:**    **The study is considered acceptable.**  **Agreed endpoints:** |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.2.1-02 |
| **Report** | “Study of *Daphnia magna acute immobilization with Pendimethalin 455 g/L CS*”, Ms. S. Rajeshwari (2021), Report No. 9010/2021. Bioscience Research Foundation |
| **Guideline(s):** | OECD Guideline No. 202 (2004) |
| **Deviations:** | No |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study)** | Not relevant |

Materials and methods

The acute immobilization effect of the test item Pendimethalin 455 g/L CS was studied on *Daphnia magna* for 48 hours.

In definitive test, *Daphnia magna* less than 24 hours old were exposed to the nominal concentrations of 19.8, 29.8, 29.6, 44.4, 66.7 and 100 mg/L along with a negative control. Four replicates were maintained for both negative control and test concentrations. The number of daphnia immobilized was recorded at 24 and 48 hours exposure.

All the test concentrations along with the negative control were analysed for the test item concentration at the beginning and end of test. For analysis, single composite sample was drawn from prepared test concentrations. Validation of the analytical methods was done as per SANCO/3029/99. In fresh samples of the test item at exposure initiation, the determined concentrations of Pendimethalin 455 g/L CS were between 99.1 and 101.1 of the nominal concentration and between 102.2 and 100.8 at exposure termination, indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of ≤ 20%). Therefore, the concentrations of Pendimethalin 455 g/L CS were stable during 48h under test conditions.

Results

***Main test***

In the definitive test there was no immobility of daphnia in the negative control at 24 and 48 hour exposure. The daphnids in the control appeared normal throughout the study period.

Cumulative immobilization at the end of 48h was 0, 25, 45, 65 and 100% in 19.8, 29.6, 44.4, 66.7 and 100 mg/L test substance, respectively. Lethargy was observed in 29.6, 44.4 and 66.7 mg/L test substance. Surface trapping was observed in 29.6, 44.4 and 66.7 mg/L test substance.

**Table 1 - Immobilization of *Daphnia magna*, definitive test**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment**  **[mg/L]** | **Number of *Daphnia* immobilized**  **(5 Daphnia per replicate)** | | | | | | | | **% Immobilization** | |
| **24 h** | | | | **48 h** | | | |
| **Replicates** | | | | | | | |
| R1 | R2 | R3 | R4 | R1 | R2 | R3 | R4 | **24 h** | **48 h** |
| Negative control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 19.8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29.6 | 0 | 0 | 1 | 1 | 0 | 1 | 2 | 2 | 10 | 25 |
| 44.4 | 0 | 1 | 2 | 1 | 1 | 2 | 3 | 3 | 20 | 45 |
| 66.7 | 1 | 2 | 1 | 2 | 2 | 3 | 4 | 4 | 30 | 65 |
| 100 | 5 | 5 | 5 | 5 | - | - | - | - | 100 | 100 |

Validity criteria

The results are considered valid because the following criteria were satisfied:

* There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids.
* The dissolved oxygen concentration at the end of the test was more than ≥ 3 mg/L in negative control and other test vessels.

Conclusion

**Table 2 – Immobilization. Endpoint values**

|  |  |  |
| --- | --- | --- |
| **Endpoint** | **Value**  **[mg test item/L]** | **Pendimethalin**  **[mg a.s./L]** |
| **EC10** | **25.63**  (24.23 – 27.03) | **9.90**  (9.36 – 10.44) |
| **EC20** | **31.59**  (30.22 – 32.97) | **12.21**  (11.68 – 12.74) |
| **EC50** | **47.16**  (45.58 – 48.74) | **18.22**  (17.61 – 18.83) |
| **NOEC** | **29.6** | **11.44** |
| **LOEC** | **44.4** | **17.16** |

|  |  |
| --- | --- |
| Comments of zRMS: | Study was carried out according to appropriate OECD 201 and all validity criteria were met.  Deviation from the study: No deviation occurred from the study plan. No deviations occurred from the OECD Guideline No. 201.  **The validity criteria:**    **The study is considered acceptable.**  **Agreed endpoints:** |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.2.1-03 |
| **Report** | “Study of algal growt inhibition with Pendimethalin 455 g/L CS”, Dr. S. Radha, (2021), Report No. 9008/2021. Bioscience Research Foundation. |
| **Guideline(s):** | OECD Guideline No. 201 (2006) |
| **Deviations:** | No |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study)** | Not relevant |

Materials and methods

The effect of Pendimethalin 455 g/L CS was tested on the growth of freshwater unicellular green alga *Raphidocelis subcapitata* for 72 hours.

The algae were exposed to the test item at the test concentrations of 0.156, 0.313, 0.625, 1.250 and 2.500 mg/L along with a negative control. Six replicates were maintained for the negative control and three replicates for each of the test concentrations. The initial cell density of algal cells at the start of exposure was 0.9 x 104 cells/mL. The cell growth was measured at 24, 48 and 72 hours after the initiation of the test using a Bürker chamber.

Pendimethalin 455 g/L CS was stable during 72 h under test conditions. In fresh samples of the test item concentrations, the determined concentrations of the active ingredient were between 99.3 and 100.5% of the nominal concentration.

Results

***Definitive test***

At the end of the test (72 hours), the cell biomass in the test item solutions decreased with the increase in test concentration.

**Table 1 Growth rate and yield inhibition, definitive test**

|  |  |  |
| --- | --- | --- |
| **Nominal test item**  **concentration [mg/L]** | **% Inhibition after 72 h of exposure (growth rate)** | **% inhibition after 72 h of exposure (yield)** |
| Control | - | - |
| 0.156 | 4.71 | 18.52 |
| 0.313 | 9.62 | 33.94 |
| 0.625 | 32.65 | 76.12 |
| 1.250 | 51.07 | 89.96 |
| 2.50 | 70.58 | 96.41 |

Validity criteria

* The biomass in the control increased by a factor of 71.25 within 72-hour test period (criterion: at least a 16-fold growth)
* The coefficient of variation of the mean specific growth rate after 72-hour test period (exposure initiation – exposure termination) in the control culture was 3.10% (criterion: it must not exceed 7%)
* The mean coefficient of variation for the section-by-section growth rate in the control culture was 1953 (criterion: it must not exceed 35%).

Conclusion

The endpoint values determined for growth rate and yield at 72 hours are presented below based on nominal concentration.

Table 2 - Endpoint values for Growth rate and yield

|  |  |  |  |
| --- | --- | --- | --- |
| **Observations** | | **EC values (mg test item/L)** | **EC values (mg Pendimethalin/L)** |
| **72 hours** | **ErC50** | **1.233** (1.127 – 1.339) | **0.476**(0.436 – 0.517) |
| **ErC20** | **0.447** (0.404 – 0.490) | **0.173** (0.156 – 0.189) |
| **ErC10** | **0.263** (0.229 – 0.297) | **0.102** (0.088 – 0.115) |
| **LOECr** | **0.313** | **0.121** |
| **NOECr** | **0.156** | **0.060** |
| **EyC50** | **0.386** (0.360 – 0.411) | **0.149** (0.139 – 0.159) |
| **EyC20** | **0.175** (0.157 – 0.193) | **0.068** (0.061 – 0.074) |
| **EyC10** | **0.116** (0.114 – 0117) | **0.045** (0.044 – 0.045) |
| **LOECy** | **0.313** | **0.121** |
| **NOECy** | **0.156** | **0.060** |

Note: 1) ErC refers to growth rate, EyC refers to yield.

2) Range mentioned after EC value refers to 95% fiducial limits

|  |  |
| --- | --- |
| Comments of zRMS: | Study was carried out according to appropriate OECD 221 and all validity criteria were met.  Deviation from the study: No deviation occurred from the study plan. No deviations occurred from the OECD Guideline No. 221.  **The validity criteria:**    **The study is considered acceptable.**  **Agreed endpoints:** |

|  |  |
| --- | --- |
| Reference: | KCP 10.2.1-04 |
| Report | “Study of *Lemna gibba* growth inhibition with Pendimethalin 455 g/l CS”. Dr. S. Radha. 2021. Study code: 9009/2021. Bioscience Research Foundation |
| Guideline(s): | OECD Guideline No. 221 (2006) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication  (if vertebrate study) | No |

Materials and methods

|  |  |
| --- | --- |
| **Test item:** | Pendimethalin 455 g/l CS  Batch no.: SCL-80067  Active substance content: Pendimethalin 456 (g/L) |
| **Reference item :** | 3.5-dichlorophenol |
| **Test medium:** | 20X AAP medium |
| **Biological test system :** | *Lemna gibba* obtained from a standard laboratory culture at BRF  Colonies cultured for 8 days before exposure initiation |
| **Test doses:** | A control, 1.563, 3.125, 6.25, 12.5, 25, 50 and 100 mg test item/L. Equivalent to: 0.60, 1.21, 2.42, 4.83, 9.66, 19.32 and 38.64 mg Pendimethalin/L. There were 3 replicates of each test concentration and 6 replicates for the control. 3 colonies with 3 fronds each were introduced into each replicates. |
| **Test conditions:** | temperature: 22.1 – 24.6°C;  pH at the beginning of the test: 7.5 – 7.9;  pH at the end of the test: 7.3 – 7.6;  lighting: 16 h light and 8h dark;  light intensity: 7015 - 7553 lux |
| **Endpoints:** | EC10, EC20, EC50, NOEC, LOEC  LC10, LC20, LC50, NOEC, LOEC |

Results

No distinctive changes from the normal development of plants in the test item concentrations of 1.563, 3.125 and 6.25 mg/L and in the control group, whereas in the test item concentrations of 12.5, 25, 50 and 100 mg/L smaller fronds, spots of chlorosis and/or separated roots were observed during the 7-day experiment.

Samples of all the test item concentrations and the control collected at exposure initiation (day 0) and at exposure termination (day 7) were chemically determined. In fresh samples, the determined concentrations were between 99.3 and 101.5% of the nominal concentration. The results confirmed that the test item concentrations were prepared correctly. In spent samples, the determined concentrations were between 99 and 100.6% of the nominal concentrations. Therefore, the concentrations of Pendimethalin 455 g/L CS were stable during 7 days under test conditions.

Table 2 - Endpoint values – impact of the test item on Lemna gibba growth rate – main test

|  |  |  |
| --- | --- | --- |
| **Endpoint** | **Test item mg/L**  **(based on nominal concentrations)** | **Active substance mg/L**  **(based on nominal concentrations\*)** |
| **Growth rate – based on front number** | | |
| **ErC10** | **4.310**  (3.83 – 4.789) | **1.664**  (1.478 – 1.849) |
| **ErC20** | **7.207**  (6.571 – 7.842) | **2.782**  (2.536 – 3.027) |
| **ErC50** | **19.271**  (17.924 – 20.618) | **7.4**  (6.919 – 7.959) |
| **NOEC** | **3.125** | **1.21** |
| **LOEC** | **6.25** | **2.42** |
| **Growth rate – based on dry weight** | | |
| **EyC10** | **23.632**  (20.581 – 26.68) | **9.122**  (7.944 – 10.30) |
| **EyC20** | **47.013**  (41.46 – 52.57) | **18.147**  (16.00 – 20.29) |
| **EyC50** | **>100** | **>38.64** |
| **NOEC** | **6.25** | **2.42** |
| **LOEC** | **12.5** | **4.83** |

\*Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis

Table 3 - Endpoint values – impact of the test item on Lemna gibba yield – main test

|  |  |  |
| --- | --- | --- |
| **Endpoint** | **Test item mg/L**  **(based on nominal concentrations)** | **Active substance mg/L**  **(based on nominal concentrations\*)** |
| **Yield based on frond number** | | |
| **ErC10** | **2.184**  (1.928 – 2.440) | **0.843**  (0.744 – 0.942) |
| **ErC20** | **3.606**  (3.268 – 3.943) | **1.392**  (1.262 – 1.522) |
| **ErC50** | **9.407**  (8.765 – 10.048) | **3.631**  (3.383 – 3.878) |
| **NOEC** | **1.563** | **0.60** |
| **LOEC** | **3.125** | **1.21** |
| **Yield – based on dry weight** | | |
| **EyC10** | **11.409**  (10.048 – 12.769) | **4.404**  (3.879 – 4.929) |
| **EyC20** | **20.455**  (18.581 – 22.329) | **7.896**  (7.172 – 8.619) |
| **EyC50** | **62.501**  (56.014 – 68.988) | **24.125**  (21.622 – 26.629) |
| **NOEC** | **6.25** | **2.42** |
| **LOEC** | **12.5** | **4.83** |

\*Calculated on the basis of the content in the test item declared by the Sponsor in the Certificate of Analysis

**Validity Criteria**

The results are considered valid because the following criteria were satisfied

* The doubling time of frond number in the control was 2.1days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 10.1).

The average specific growth rate in the control between day 0 and day 7 was 0.321 d-1 (minimum requirement: higher than 0.275 d-1)

* + 1. KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms
    2. KCP 10.2.3 Further testing on aquatic organisms
  1. KCP 10.3 Effects on arthropods
     1. KCP 10.3.1 Effects on bees
        1. KCP 10.3.1.1 Acute toxicity to bees
           1. KCP 10.3.1.1.1 Acute oral toxicity to bees

|  |  |  |
| --- | --- | --- |
| Comments of zRMS: | Study was carried out according to appropriate OECD 213 and all validity criteria were met.  Deviation from the study: No deviation occurred from the study plan.  Study limitation: Confidence intervals were not established for toxicity endpoints.  **The validity criteria:**    **The study is considered acceptable.**  **Agreed endpoints:** | |
| Reference: | | | KCP 10.3.1.1.1 | |
| Report | | | “Acute oral toxicity study of Pendimethalin 455 g/L CS in Honey bee (*Apis mellifera* )”. K. Wiswanathan, 2019, Study code 18-212-G | |
| Guideline(s): | | | OECD Guideline for the Testing of Chemicals No. 213 (1998) | |
| Deviations: | | | No | |
| GLP: | | | Yes | |
| Acceptability: | | | Yes | |

Materials and methods

The acute oral toxicity study of Pendimethalin 455 g/L CS (batch number: SCL-60029) was conducted to determine the LD50 values for honeybees. Five doses of the test item were used. These included: 7.5, 15, 30, 60 and 120 µg/bee (7.40, 14.22, 29.50, 58.27 and 117.08 μg a.i /bee actual consumed dose) and a control (0.0 µg/bee). The range of doses was selected on the basis of the preliminary test results. Each group of 10 bees (3 replicates containing 10 bees each) was fed with 200 µL of a 50% sucrose solution, containing the test item at the doses enumerated above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.

The general condition of the test honeybees and the reliability of the test conducted on them were controlled using the recommended reference item - dimethoate.

After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

Results

**Acute oral toxicity on honeybees (*Apis mellifera L.*)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Dose** | **Nº of tested bees** | | **Mortality after 48 h** | | | | **LD50** |
| **Total** | | | |
| **[µg a.i./bee] b** | |  | | **[no.]** | | **[%]** | **[µg a.i./bee] b** | |
| 0.0 | 30 | | 0 | | 0.0 | |  |
| 7.5 | | 30 | | 0 | | 0.0 | >110.83 | |
| 15 | | 30 | | 0 | | 0.0 |
| 30 | | 30 | | 0 | | 0.0 |
| 60 | | 30 | | 0 | | 0.0 |
| 120 | | 30 | | 0 | | 0.0 |

Findings

* At the end of 48 hours observation, 13.3%, 60.0% and 96.7% cumulative mortality was observed in the tested doses of 0.06, 0.13 and 0.29 μg a.i /bee respectively (positive control).
* Since there no mortality observed in the limit test dose, the 48 hours acute oral LD50 of Pendimethalin 455 g/L CS is cannot be calculated and could be considered as greater than 110.83 μg a.i./bee (based on the actual consumed dose
* The range finding test showed no mortality and No bees exhibited abnormal behaviour in the control group and in all the tested nominal doses of 7.5, 15, 30, 60 and 120 μg a.i. /bee during 4, 24 and 48 hours test period after dosing.
* Based on the results of the limit test, the 48 hours acute oral LD50 of **Pendimethalin 455 g/L CS** is found to be **greater than 110.83 μg a.i /bee** (based on the actual consumed dose).

Validity criteria

The following validity criteria were met during the test:

* Mortality in the control should not exceed 10 %.
* The 24 hour oral LD50 of the positive control (Dimethoate) should meet the specified range: 0.10 to 0.35 μg a.i. /bee.

**Conclusion**

Based on the results of the limit test, the 48 hours acute oral LD50 of Pendimethalin 455 g/L CS found to be greater than 110.83 μg a.i./bee (based on the actual consumed dose).

* + - * 1. KCP 10.3.1.1.2 Acute contact toxicity to bees

|  |  |
| --- | --- |
| Comments of zRMS: | Study was carried out according to appropriate OECD 214 and all validity criteria were met.  Study limitation: Confidence intervals were not established for toxicity endpoints.  **The validity criteria:**    **The study is considered acceptable.**  **Agreed endpoints:** |

|  |  |
| --- | --- |
| Reference: | KCP 10.3.1.1.2 |
| Report | “Acute contact toxicity of Pendimethalin 455 g/L in Honeybees (*Apis mellifera*)”, K. Viswanathan, 2019, Study code 18-211-G |
| Guideline(s): | OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and methods

The acute contact toxicity study of Pendimethalin 455 g/L CS (batch No. SCL-60029) was conducted to determine the effects on honeybees. Five doses of the test item were used. These included: 6.25, 12.5, 25, 50 and 100 µg/honeybee. The range of doses was selected on the basis of the preliminary test results.

The test item was diluted in distilled water and applied to the dorsal part of thorax using a microapplicator. The volume was 1 µL/bee. During the entire experiment, the insects were caged in groups of 10 under controlled conditions of the temperature and the humidity.

The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.

After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24, and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

Results

**Acute contact toxicity on honeybees (*Apis mellifera* L.)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Dose** | **Nº of tested bees** | | **Mortality after 48 h** | | | | **LD50** |
| **Total** | | | |
| **[µg a.i./bee] b** | |  | | **[no.]** | | **[%]** | **[µg a.i./bee] b** | |
| 0.0 | 30 | | 0 | | 0.0 | |  |
| 6.25 | | 30 | | 0 | | 0.0 | >100 | |
| 12.5 | | 30 | | 0 | | 0.0 |
| 25 | | 30 | | 0 | | 0.0 |
| 50 | | 30 | | 0 | | 0.0 |
| 100 | | 30 | | 0 | | 0.0 |

**Findings**

* Mortality of the control group after 48 hours of exposure was 0%.
* The range finding test showed no mortality and No bees exhibited abnormal behaviour in the control groups and in all the tested nominal doses of 6.25, 12.5, 25, 50 and 100 μg a.i. /bee during 4, 24 and 48 hours test period after dosing.
* At the end of 24 hours observation, lethargic behaviour was exhibited in the tested dose of 0.06 μg a.i /bee whereas, rest of the bees in the tested dose of 0.13 μg a.i /bee appeared normal. At the end of 48 hours observation, lethargic behaviour was exhibited in the tested doses of 0.06 and 0.13 μg a.i /bee respectively

Validity criteria

The following validity criteria were met during the test:

* The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%).
* The 24 hour LD50 of the reference item (dimethoate) was 0.12 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

Conclusion

The median lethal dose LD50/48 h contact was found to be greater100 µg a.i./bee

* + - 1. KCP 10.3.1.2. Chronic toxicity to bees

|  |  |  |
| --- | --- | --- |
| Comments of zRMS: | Study was carried out according to proposal for a new OECD Guideline for Testing Chemicals (October 2016) and all validity criteria were met.  **The validity criteria:**    **The study is considered acceptable.**  **Agreed endpoints:** | |
| **Reference**  **Report** | | | KCP 10.3.1.2  Pendimethalin Technical: Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test”.  Glanas, A. 2017, B/107/17. Institute of Industrial Organic Chemistry Branch Pszczyna | |
| **Guideline(s):** | | | Proposal for a new OECD Guideline for Testing Chemicals (October 2016) | |
| **Deviations:** | | | No | |
| **GLP:** | | | Yes | |
| **Acceptability:** | | | Yes | |
| **Duplication  (if vertebrate study)** | | | No | |

Materials and methods

Test item:

Description: Pendimethalin Technical

Production batch: -

A.i. content: 98.09% (w/w)

Test system:

Species: *Apis mellifera*

Strain: carnica

Age: freshly emerged worker honeybees from the same queen-right colony

Average weight: -

Average length: -

Source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna

Acclimation period: 3 days

Diet: 50% solution of sucrose in water (w/v)

Experimental conditions:

Temperature: 31 – 33°C

Humidity: 60 – 69%

Hardness: -

pH: -

Light and photoperiod: 24h darkness (except during observations).

Loading: 3 replicates per dose, 10 bees per replicate

Test procedure: Each group of bees was fed with 2 mL of a 50% sucrose solution containing the reference item or the test item for 10 days.

Experimental period: 10d

**Test design and treatment**

Cages (8 x 10 x 6 cm) made of stainless steel with the front removable part made of glass and a hole on the upper wall of each cage. The hole was used to introduce the insects into the test cages. Then, it is capped with a feeder (5-mL syringe) containing a sucrose solution treated with the test item or a sucrose solution alone.

In total, 8 treatment groups were set up: 5 doses of the test item (5.00, 10.00, 20.00, 40.00 and 80.00 μg/bee/day), two untreated control groups and 1 dose of the reference item with 3 replicates per dose and 10 insects per replicate.

Food consumption (mg/bee/day) in each study group was determined by weighing the feeders with a sucrose solution and dividing the amount of food by the number of surviving bees in the previous observation time. The doses of the test item (μg/bee/day) consumed by the bees were calculated directly from treated 50% sucrose solution consumption, the concentrations of the test item, and the density of the solutions at each concentration.

Mortality results were analyzed using the log-probit method, in order to determine the LDD50, LC50, NOEDD and NOEC values. The statistical analysis of the data on mortality was conducted using the ToxRat Proffesional software.

**Results**

The results are summarized below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Concentration** | | **Consumed**  **concentration** | | **Number of tested bees**  **[no]** | **Mortality** | | | | | | **LC50** | **LDD50** |
| **[mg/kg]** | **[μg/bee/day]**  **[μg/30 mg/day]** | **[mg/kg]** | **[μg/bee/day]**  **[μg/30 mg/day] a** | **Number of**  **dead bees**  **[no.]** | | | **Total** | | |
| **replicates** | | |
| **I** | **II** | **III** | **No.** | **[%]** | **Corr. b [%]** | **[mg/kg]** | **[μg/bee/ day]** |
| **Pendimethalin Technical** | | | | | | | | | | | | |
| 0.0 (Control) | | | | 30 | 1 | 1 | 0 | 2 | 6.7 | - | 1533.1  (1276.85-1889.89) | 56.58  (48.11-66.76) |
| 0.0 (Control with acetone) | | | | 30 | 0 | 2 | 1 | 3 | 10.0 |
| 166.67 | 5.00 | 166.67 | 6.45 | 30 | 1 | 1 | 0 | 2 | 6.7 | (-3.7) \* |
| 333.33 | 10.00 | 333.33 | 11.71 | 30 | 1 | 0 | 0 | 1 | 3.3 | (-7.4) \* |
| 666.67 | 20.00 | 666.67 | 25.76 | 30 | 2 | 2 | 1 | 5 | 16.7 | 7.4 |
| 1333.34 | 40.00 | 1333.33 | 58.34 | 30 | 7 | 6 | 3 | 16 | 53.3\*\* | 48.2\*\* |
| 2666.68 | 80.00 | 2666.67 | 79.99 | 30 | 8 | 9 | 7 | 24 | 80.0\*\* | 77.8\*\* |
| NOEC | | | | | 666.7 [mg/kg] | | | | | | | |
| NOEDD | | | | | 25.8 [μg/bee/day] | | | | | | | |
| **Concentration** | | **Consumed**  **concentration** | | **Dimethoate** | | | | | | | | |
| **[mg/kg]** | **[μg/bee/day]**  **[μg/30 mg/day]** | **[mg/kg]** | **[μg/bee/day]**  **[μg/30 mg/day]** |
| 1.67 | 0.05 | 1.67 | 0.08 | 30 | 8 | 8 | 9 | 25 | 83.3 | 82.1 | not determined | |

a: ingested doses were calculated on the basis of the concentrations of the test item and average sucrose solution consumption

b: mortality corrected using Abbott’s formula [7]

\*: mortality in test item was higher from mortality of control

\*\*: statistically significant difference (Step-down Cochran-Armitage Test Procedure, p<0.05)

**Conclusion**

The validity criterion concerning mortality was met, because mortality in the control and in the control wit acetone was ≤ 15.0% (6.7 and 10.0 %) after 10 days of exposure [1].

The percentages of corrected mortality [7] of the honeybees exposed to the test item, Pendimethalin Technical at the concentrations of 166.67; 333.33; 666.67, 1333.33, 2666.67 mg/kg (6.45, 11.71, 25.76, 58.34 and 79.99 μg/bee/day) were (-3.7), (-7.4), 7.4, 48.2 and 77.8%, respectively. The negative mortality value indicate higher mortality in group treated with the test item than the control with acetone group. Mortality of the group treated with the test item at the doses 79.99 and 58.34 μg/bee/day (2666.67 and 1333.33 mg/kg), was statistically significantly different from the control group (Step-down Cochran- Armitage Test Procedure, p< 0.05).

On the basis of the obtained mortality results the LDD50 value, is 56.58 μg/bee/day. The LC50 is 1533.1 mg/kg, the NOEC is 666.7 mg/kg and NOEDD is 25.8 μg/bee/day were determined.

The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because corrected mortality was 82.1% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

Average consumption of a 50% sucrose solution in the control group was 34.37 mg/bee/day and in the control with acetone 34.31 mg/bee/day. Average consumption in the groups treated with the test item at the concentrations of 166.67; 333.33; 666.67, 1333.34, 2666.68 mg/kg (5.00, 10.00, 20.00, 40.00 and 80.00 μg/bee/day) were 38.67, 35.13, 38.65, 43.75, 30.00, respectively.

Average consumption of a 50% sucrose solution containing the reference item at the concentration of 0.05 μg/bee (1.67 mg/kg) was 45.35 mg/bee/day.

In all study groups average consumption of a 50% sucrose solution was 37.53 mg/bee/day. On the basis of average consumption of a 50% sucrose solution in the study groups, it may be concluded that each bee treated with the test item at the concentration of 5.0, 10.0, 20.0, 40.0 and 80.0 μg/30 mg/day of Pendimethalin Technical ingested 6.45, 11.71, 25.76, 58.34 and 79.99 μg of the test item/day. The ingested concentrations were 166.67; 333.33; 666.67, 1333.33, 2666.67 mg/kg, respectively.

Each insect from the group fed with a 50% sucrose solution containing the reference item at the concentration of 0.05 μg/30 mg of emulsion ingested 0.08 μg of dimethoate/day (1.67 mg/kg).

* + - 1. KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

|  |  |  |
| --- | --- | --- |
| Comments of zRMS: | Study was carried out according to OECD 239 and all validity criteria were met.  **The validity criteria:**  **The study is considered acceptable.**  **Agreed endpoints:**  ED50 (successful adult emergence up to D22) =5.8 μg a.i./larva, which is equivalent to an EC50 of 36.7 mg a.i./kg food.  The ED10 and ED20 (D22) =0.5 and 1.3 μg product/larva, respectively, which is equivalent to an EC10 and EC20 (D22) of 2.9 and 8.0 mg product/kg food, respectively.  NOED =0.64 μg a.i./larva and the corresponding NOEC =4.0 mg a.i./kg food. | |
| **Reference**  **Report** | | | KCP 10.3.1.3  Pendimethalin Technical - Repeated exposure of honey bee (*Apis mellifera* L.) larvae under laboratory conditions (*in vitro*).  Katharina Kleebaum, 2017, 17 48 BLC 0083. BioChem agrar | |
| **Guideline(s):** | | | OECD (2016), Guidance Document on Honey Bee Larval Toxicity Test following Repeated Exposure, Environment Monograph, Series on Testing and Assessment No. 239, OECD, Paris | |
| **Deviations:** | | | No | |
| **GLP:** | | | Yes | |
| **Acceptability:** | | | Yes | |
| **Duplication  (if vertebrate study)** | | | No | |

Materials and methods

Test item:

Description: Pendimethalin Technical

Production batch: SCL - 5983

A.i. content: 98.09% (w/w)

Test system:

Species: *Apis mellifera* *iberiensis Engel*

Strain: *Hymenoptera, Apoidea*

Age: one day old larvae

Average weight: -

Average length: -

Source: from three healthy and queen-right colonies; source: Beekeeper Joaquin Cordero, Paseo de Colón No. 19, 41370 Cazalla (Sevilla), Spain

Acclimation period: 3 days

Diet: 50% aqueous sugar solution and 50% royal jelly

Experimental conditions:

Temperature: 34.0 – 35.0°C

Humidity: Day 1 – Day 8: 90 - 100%

Day 8 – Day 15: 76 – 82%

Day 15 – Day 22: 52 – 59%

Hardness: -

pH: -

Light and photoperiod: 24h darkness (except during observations).

Loading: 3 replicates per dose, 10 bees per replicate

Test procedure: On 4 successive days (day 3 to day 6) the larvae were repeatedly exposed to Pendimethalin Technical diluted in the larval food.

Experimental period: 48h

**Test design and treatment**

Polystyrene grafting cells in 48-well cell culture plates. Durng 4 successive days the larvae were repeatedly exposed to Pendimethalin Technical diluted in the larval food (aqueous sugar solution mixed with royal jelly). After the applications no additional feedings of the larvae took place.

In total, 8 treatment groups were set up: 5 doses of the test item (63.0, 25.3, 10.1, 4.0 and 1.6 mg a.i./kg food), two untreated control groups and 1 dose of the reference item with 3 replicates per dose and 12 larvae per replicate.

Assessments of cumulated larval mortality were done on days 4, 5, 6, 7 and 8. Additionally, other observations such as small body size or large quantities of remaining food on day 8 were noted. Pupal mortality was assessed at day 15 and emergence of adults was evaluated at day 22.

Descriptive statistics; Step-down Cochran-Armitage Test (one-sided greater,

alpha = 0.05) were used for determination of NOED/NOEC. ED/EC10/20/50 values were determined using the Weibull analysis using linear max. likelihood regression.

**Results**

The results are summarised below.

**Toxicity of Pendimethalin Technical to larvae of *Apis mellifera* L.**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment**  **group** | **Test**  **solution**  **ID** | **Dose** | **Concentration** | **On day 8** | | | **On day 22** | | | | |
| **Larval mortality Day 3 – Day 8** | | **Mean OO** | **Pupal mortality**  **Day 8 – Day 22** | | **Total mortality**  **Day 3 – Day 22** | | **Adult**  **emergence**  **rate** |
| **[%]** | | **[%]** | **[%]** | | **[%]** | | **[%]** |
| [μg a.i./  larva] | [mg a.i./  kg food] | abs. | corr. |  | abs. | corr. | abs. | corr. | abs. |
| Control | AC | - | - | 2.8 | 0.0 | 0.0 | 8.6 | 0.0 | 11.1 | 0.0 | 88.9 |
| BC | - | - | 0.0 | - | 0.0 | 8.3 | 0.0 | 8.3 | 0.0 | 91.7 |
| Test item | AT | 10.0 | 63.0 | 2.8 | - | 0.0 | 62.9 | 59.5 | 63.9\* | 60.6 | 36.1 |
| BT | 4.0 | 25.3 | 2.8 | - | 0.0 | 45.7 | 40.8 | 472\* | 42.4 | 52.8 |
| CT | 1.6 | 10.1 | 2.8 | - | 0.0 | 37.1 | 31.4 | 38.9\* | 33.3 | 61.1 |
| DT | 0.64 | 4.0 | 0.0 | - | 0.0 | 16.7 | 9.1 | 16.7 | 9.1 | 83.3 |
| ET | 0.26 | 1.6 | 0.0 | - | 0.0 | 11.1 | 3.0 | 11.1 | 3.0 | 88.9 |
| Reference item | AR | 7.6 | 48.0 | 75.0 | 74.3 | 0.0 | 77.8 | 75.7 | 94.4 | 93.8 | 5.6 |
| **Treatment** | | **Endpoint: Successful adult emergence** | | | | | **Up to day 22** | | | | |
| Test item  doses | | ED50 [μg a.i./larva] 2 (95% CL) | | | | | 5.8 (3.9 – 8.7) | | | | |
| ED20 [μg a.i./larva] 2 (95% CL) | | | | | 1.3 (0.8 – 2.2) | | | | |
| ED10 [μg a.i./larva] 2 (95% CL) | | | | | 0.5 (0.2 – 1.1) | | | | |
| NOED [μg a.i./larva] 1 | | | | | 0.64 | | | | |
| Test item  concentrations | | EC50 [mg a.i./kg food] 2 (95% CL) | | | | | 36.7 (24.7 – 54.6) | | | | |
| EC20 [mg a.i./kg food] 2 (95% CL) | | | | | 8.0 (4.7 – 13.6) | | | | |
| EC10 [mg a.i./kg food] 2 (95% CL) | | | | | 2.9 (1.3 – 6.6) | | | | |
| NOEC [mg a.i./kg food] 1 | | | | | 4.0 | | | | |

Results are averages based on 3 replicates, containing 12 larvae each; see Appendix 4 for details

correct.: corrected mortality (according to SCHNEIDER-ORELLI 1947): reference item was corrected by AC and test item was corrected by BC; negative values are set to “0”; calculations are performed with non-rounded values; CL…confidence limit

\*Statistically significant difference in pairwise comparison between treatment and untreated control

(Step-down Cochran-Armitage Test; alpha=0.05; one sided greater)

OO: Other observations (e.g. remaining food)

1 Step-down Cochran-Armitage Test; alpha=0.05; one sided greater

2 Weibull analysis using linear max. likelihood regression

On D8, larval mortalities of 2.8 and 0.0% were observed in the both controls AC and BC, respectively. Pupal mortality (between D8 and D22) was 8.6% in the control AC and 8.3% in the solvent control BC. The control groups showed a total mortality of 11.1% (AC), and 8.3% (BC), respectively, at D22. In the test item groups larval mortalities at D8 ranged between 0.0 and 2.8%. Pupal mortalities ranged between 11.1 and 62.9% in the test item treatment groups. Total mortalities at D22 ranged between 11.1 and 63.9%. Mortality in the reference (AR) was above 50% across all replicates on D8, being 75.0%.

On D8, none of all remaining larvae treated with test item showed remaining food or other observations

such as a smaller body size.

In the final assessment at D22, adult emergence rates of 88.9% (AC) and 91.7% (BC) were determined for the honey bees in the control groups. In the test item groups the adult honey bees emerged at rates ranging between 36.1% and 88.9% following an application of 10.0, 4.0, 1.6, 0.64 and 0.26 μg a.i./larva, respectively, during the larval stages. On D22, larvae treated with 10.0, 4.0 or 1.6 μg a.i./larva showed a mortality, which was statistically significantly increased if compared to the solvent control.

The concentrations of active substances in the test item stock solutions A and E ranged between 94% and 107% of the respective nominal concentration. No test item was detected in the control specimen.

Because control mortality was ≤ 15% on D8, corrected cumulated mortality in the reference item dose of 7.6 μg a.i./larva was ≥ 50% on D8 and adult emergence in the control was ≥ 70% on D22, the study can be regarded as valid.

**Conclusion**

In a repeated exposure larval toxicity study with Pendimethalin Technical, the ED50 (successful adult emergence up to D22) was calculated to be 5.8 μg a.i./larva, which is equivalent to an EC50 of 36.7 mg a.i./kg food.

The ED10 and ED20 (D22) was determined to be 0.5 and 1.3 μg product/larva, respectively, which is equivalent to an EC10 and EC20 (D22) of 2.9 and 8.0 mg product/kg food, respectively.

The respective NOED was 0.64 μg a.i./larva and the corresponding NOEC was 4.0 mg a.i./kg food.

* + - 1. KCP 10.3.1.4 Sub-lethal effects
      2. KCP 10.3.1.5 Cage and tunnel tests
      3. KCP 10.3.1.6 Field tests with honeybees
  1. KCP 10.3.2 Effects on non-target arthropods other than bees
     + 1. KCP 10.3.2.1 Standard laboratory testing for non-target arthropods
       2. KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.    **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| Reference: | KCP 10.3.2.2-01 |
| Report | “A laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the rove beetle *Aleochara bilineata* (Gyllenhal)”. V. Angayarkanni, 2021, 8923/2021. Bioscience Research Foundation |
| Guideline(s): | ESCORT 1 (Barrett K.L. *et al.*, 1994)  ESCORT 2 (Candolfi M.P. *et al.*, 2000)  Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Grimm C. *et al.*, 2000) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication  (if vertebrate study) | No |

Materials and methods

Test item: Pendimethalin 455 g/L CS; Batch Number SCL-80067; active substance: Pendimethalin, 456 g/L

|  |  |
| --- | --- |
| Test species: | *Aleochara bilineata* (Gyll), Coleoptera: Staphylinidae from the BFR insectary. The adult bettles used in the study were 1 – 7 days old. |

Diet: *ad libitum*

Study design: Number of replicates: 4 per treatment

Number of bettles: 20 (10 female and 10 male) per replicate / 80 (40 female and 40 male) per treatment

Test duration: 77 days

The test item was sprayed onto the sand surface using a suitable spraying chamber. TAFGOR (Dimethoate 30% EC) was used as reference item whereas deionised water was used as control.

Application rates: Control, 5.9, 7.1, 8.5, 10.2 and 12.2 L test item/ha

Test conditions: Temperature: 19.5 – 20.5 ºC; humidity: 65 – 75%; lighting: 16 h light : 8 h dark; light intensity: 1500 – 1600 lux

Statistical analysis: Based upon the results, the LR50 and NOER for mortality and the ER50 and NOER for fecundity were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.

Endpoints: LR50, NOER

ER50, NOER

Results and Conclusions

The effects of Pendimethalin 455 g/L CS on mortality and fecundity of *Aleochara bilineata* in the extended laboratory test are summarized below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study group (application rate) (L/ha)** | **Mortality** | | **Fecundity** | |
| **Total (%)** | **Corrected# (%)** | **Offsprings produced (No)** | **Fecundity reduction (%)** |
| **Control** | | | | |
| **0.0** | 1.25 | - | 834.5 | - |
| **Pendimethalin 455 g/L CS** | | | | |
| **5.9** | 6.25 | 5.06 | 787.3 | 5.66 |
| **7.1** | 17.50 | 16.46+ | 699.3 | 16.21+ |
| **8.5** | 42.50 | 41.77+ | 474.0 | 43.20+ |
| **10.2** | 66.25 | 65.82+ | 342.3 | 58.99+ |
| **12.2** | 85.00 | 84.81+ | 188.0 | 77.47+ |
| **Reference item – TAFGOR (Dimethoate 30% EC)** | | | | |
| **5.0 mL/ha** | 95.00 | 94.94+ | 71.5 | 90.92+ |
| **Endpoints** | **LR50mortality** | **9.14 L/ha**  (4.17a kg a.i./ha) | **ER50fecundity** | **9.44 L/ha**  (4.30a kg a.i./ha) |
| **NOERmortality** | **5.9 L/ha**  (2.7a kg a.i./ha) | **NOERfecundity** | **5.9 L/ha**  (2.7a kg a.i./ha) |

#: Mortality corrected according to Abbott’s formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control

+: statistically significant difference between the control and the treatment group at *p* < 0.05

a: Pendimethalin

There were no statistically significant differences in mortality between groups treated with the test item at 5.9 L and the control group (one-way ANOVA, *p* < 0.05).

On the basis of the obtained mortality results, the **LR50** value is 9.14 L test item/ha, i.e. 4.17 kg pendimethalin/ha. The **NOERmortality** value is 5.9 L test item/L/ha, i.e. 2.7 kg Pendimethalin/ha.

For the reference item TAFGOR (Dimethoate 30% EC, w/w), the mortality % of beetles after 28 days of exposure at the rate of 5.0 mL/ha was 94.94%. The results showed that the test organisms were sensitive to dimethoate.

There were no statistically significant differences in fecundity between group treated with the test item at the rates of 5.9 L/ha and the control group (one-way ANOVA, *p* < 0.05).

On the basis of the obtained fecundity results, the **ER50** value is 9.44 L test item/L/ha, i.e. 4.30 kg Pendimethalin/ha. The NOERfecundity value is 5.9 L test item, i.e. 2.7 kg Pendimethalin/ha.

On the basis of the obtained results, it can be concluded that Pendimethalin 455 g/L CS had no adverse effects on mortality and fecundity of the beetles at the rates of 5.9 L/ha.

**Test validity criteria**

The following validity criteria were mete during the study:

* The mean number of beetles emerging from the fly pupae in the control was 834.5 (a criterion: >400).
* Reduction in reproduction of beetles in the reference group was 90.92 (a criterion: ≥50%).

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.    **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| Reference: | KCP 10.3.2.2-02 |
| Report | “An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on larvae of the green lacewing *Chrysoperla carnea* *L.* (Neuroptera: Chrysopidae).”. Mr. K. Murali, 2021, 8924/2021. Bioscience Research Foundation |
| Guideline(s): | ESCORT 1 (Barrett K.L. *et al.*, 1994)  ESCORT 2 (Candolfi M.P. *et al.*, 2001)  Guidelines developed by the IOBC/WPRS (Candolfi M. P. *et al.*, 2001) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication  (if vertebrate study) | No |

Materials and methods

Test item: Pendimethalin 455 g/L CS; Batch Number SCL-60067; active substance content: Pendimethalin, 456 (g/L)

|  |  |
| --- | --- |
| Test species: | *Chrysoperla carnea* (L.), Neuroptera, *Chrysopidae* from the BFR insectary. The larvae used in the study were 2 – 3 days old. |

Diet: Honeybee pollen

Study design: Number of replicates: 30 replicates for mortality, 10 replicates for reproduction

Number of larvae: 1/replicate

Test duration: until pupation

The test item was applied with a laboratory track sprayer on bean plants at seven application rates. TAFGOR (Dimethoate 30%) was used as reference item whereas deionised water was used as control. After treatment, the treated leaves were transferred to a reproduction unit.

Application rates: Control, 3.5, 5.6, 9.0, 14.4 and 23.0 L of the test item/ha

Test conditions: Temperature: 24.3 – 25.9 ºC; humidity: 65.9 – 79.4%; lighting: 16 h light : 8 h dark; light intensity: 1352 – 1651 lux

Statistical analysis: LR50 and NOER for mortality and ER50 and NOER for reproduction were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.

Endpoints: LR50, NOER

ER50, NOER

Results and Conclusions

The effects of Pendimethalin 455 g/L CS on mortality and fecundity of *Chrysoperla carnea* in the extended laboratory test are summarized below:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study group (application rate) (L/ha)** | **Mortality** | | **Reproduction** | | | | |
| **Total (%)** | **Corrected# (%)** | **Fecundity (No)** | **Fecundity reduction (%)** | **Fertility (%)** | | **Fertility reduction (%)** |
| **Control** | | | | | | | |
| **0.0** | 6.67 | - | 38.30 | - | 97.55 | | - |
| **Pendimethalin 455 g/L CS** | | | | | | | |
| **3.5** | 13.33 | 7.14 | 35.30 | 7.83+ | 97.55 | | 0.25 |
| **5.6** | 26.67 | 21.43 | 27.60 | 27.94+ | 96.25 | | 1.33 |
| **9.0** | 50.00 | 46.43+ | 20.35 | 46.87+ | 93.44 | | 4.21+ |
| **14.4** | 73.33 | 71.43+ | -\* | -\* | -\* | | -\* |
| **23.0** | 93.33 | 92.86+ | -\* | -\* | -\* | | -\* |
| **Endpoints** | **LR50mortality** | | **9.46 L/ha**  (4.31 kg a.i./ha) | **ER50fecundity** | | **9.24 L/ha**  (4.21 kg a.i./ha) | |
| **NOERmortality** | | **5.6 L/ha**  (2.6 kg a.i./ha) | **NOERfecundity** | | **<3.5 L/ha**  (<1.6 kg a.i./ha) | |
| **Reference item – TAFGOR (DIMETHOATE 30% EC)** | | | | | | | |
| **0.65** | 100 | 100 | - | | | | |

#: Mortality corrected according to Abbott’s formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control

+: statistically significant difference between the control and the treatment group at *p* < 0.05

\*: The reproduction was not determined due to the mortality higher than 50% in comparison with the control group

The validity criterion for mortality was met, because mortality of the control group after 10 days of exposure was 6.67% (criterion: ≤20%).

There were statistically significant differences in mortality between group treated with the test item at the rate of 9.0, 14.4 and 23.0 L/ha and the control group (one-way ANOVA, *p* < 0.05).

For the reference item Tafgor (Dimethoate 30% EC, w/w), the corrected mortality of *C. carnea* after exposure at the rate of 0.65 L/ha was 100%, hence the criterion (>50%) specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.

The validity criterion for fecundity was met, because the mean number of eggs per female per day in the control group was 37.85 (criterion: ≥15)

There were statistically significant difference in fecundity between group treated with the test item at rates of 3.5, 5.6 and 9.0 L/ha and the control group (one-way ANOVA, *p* < 0.05).

The validity criterion for fecundity was met, because the mean hatching rate in the control group was 97.55% (criterion: ≥70%).

There was statistically significant difference between group treated with the test item at the rate of 9.0 L/ha and the control group (one-way ANOVA, *p* < 0.05).

On the basis of the obtained results, it can be concluded that Pendimethalin 455 g/L CS had adverse effects on mortality and fecundity of *C. carnea* at rates of 9.0, 14.4 and 23.0 and at rates of 3.5, 5.6 and 9.0 L/ha, respectively.

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  The following validity criteria were met during the study:  – after 48 hours mortality of the control group was 0.0% (criterion: a maximum of 10.0%),  – after 48 hours mortality of the group treated with the reference item at the rate of 6 g/ha was 80.0% (criterion: > 50%)  – the mean number of mummies per female in the control group was 11.4 (criterion: a minimum of 5.0 mummies/female),  – all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no off-spring).  Deviations in the study:  1. An air temperature of place where test item was stored increased above required level (15 - 25°C). Between February 22and June30, 2021 the temperature reached a maximum value of 29.7°C.  2. According to study plan, study EMI/4/43/2020 should be completed in May/June 2021, but it was completed in October2021.  No other deviations occurred. Above mentioned deviations had no impact on the final results of the study.  **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.3.2.2-03 |
| **Report:** | “An extended laboratory test for evaluating the effects of Pendimethalin 455 g/L CS on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae)”. Pawel Parma, 2021. EMI/4/43/2020. Ecomelius Institute Sp. z o. o. |
| Guideline(s): | ESCORT 1 (Barrett K.L. et al., 1994), ESCORT 2 (Candolfi M.P. et al., 2001) ESCORT 3 (Alix A. et al., 2012) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010). |
| **Deviations:** | Yes. An air temperature of place where test item was stored increased above required level 15 - 25°C). Between February 22 and Ju ne 30, 2021 the temperature reached a maximum value of 29.7°C. The deviation had no impact on the final results of the study. |
| **GLP:** | Yes |
| **Acceptability:** |  |
| **Duplication  (if vertebrate study):** | No |

**SUMMARY**

The laboratory testinvolved the evaluation of the effects of the test item, Pendimethalin 455 g/L CS on mortality and fecundity of the parasitic wasp, *A. rhopalosiphi.* In the definitive test, five rates of the test item were used. These were 0.5, 1.0, 2.0, 4.0 and 8.0 L formulation/ha.

Adult wasps were exposed to the test item applied to barley seedlings as foliar substrate. Mortality assessments were made 2, 24 and 48 h after the introduction of the wasps to the test arenas.

Females which survived 48-hour exposure (without affected ones) to Pendimethalin 455 g/L CS were randomly subjected to fecundity assessment.

To allow the oviposition, 15 female wasps from each groups treated with the test item and the control group were individually introduced into the fecundity units containing the barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which the wasp pupae were developing) was recorded.

Mortality of the wasps after 48 hours of the exposure and the percentage of fecundity reduction (Pr) relative to the control group recorded 12 days after the oviposition were the endpoints.

To assess the susceptibility of the test system and the precision of the test procedure, dimethoate technical was used as a reference item. The rate of the reference item was 6 g dimethoate/ha. The control group was treated with ultra-pure water.

**Materials and methods:**

|  |  |
| --- | --- |
| Test item: | Pendimethalin 455 g/L CS  (3,4-dimethyl-2,6-dinitro-N-pentan-3-ylaniline)  Batch number: SCL-14177  manufacturing date: 27th October 2019  expiration date: 26th October 2021 |
| Reference substance: | Dimethoate technical was used to verify the precision of the test procedure and the sensitivity of the biological test system. |
| Biological test system: | the parasitic wasp, *Aphidius rhopalosiphi* (De-Stephani Perez, 1902); Hymenoptera: Braconidae. |
| Test design: | Rates of item test: 0.5, 1.0, 2.0, 4.0, and 8.0 L formulation/ha.  Mortality test duration: 48 h  5 item groups, 1 reference item group and 1 control group. 6 replicates of each group were used. There were 5 wasps in each replicate.  Fecundity test duration: 12 days after the oviposition  15 female wasps from each group treated and 15 females form the control were individually introduced into fecundity units containing barley plants infested with the aphid, *Rhopalosiphum padi*.  Source: commercial supplier: Katz Biotech AG  Age: adult females (24 – 48 hours after emerging from mummies) |
| Test conditions: | temperature: 20 – 21.2°C;  relative air humidity: 63.7 – 85.9 %  photoperiod: 16 hours light (mortality: 920 - 1063 lx; parasitisation: 883 - 1131 lx; fecundity: 7422 - 12705): 8 hours dark |
| Endpoints | Mortality of the wasps after 48 hours of exposure and the percentage of fecundity reduction (Pr) 12 days after the oviposition |
| Statistical analysis: | Shapiro-Wilk’s test, Kruskal – Wallis test and Williams Multiple Sequential t-test procedure. |

**RESULTS**

REPELLENT EFFECTS

The mean percentages of wasps settled on the plants were 56.0% in the control group, 56.0, 55.3, 53.3, 60.0, and 51,3% in the groups treated with the test item at the rates of 0.5, 1.0, 2.0, 4.0, and 8.0 L/ha, respectively, and 45.3% in the group treated with the reference item.

Repellent properties of the test item and the reference item were assessed. The results of Shapiro-Wilk’s test (p > 0.05) reject normal data distribution. Levene’s test (p > 0.05) confirmed variances homogeneity in the study groups. On the basis of the obtained results, it can be concluded that the test item at the rates of 0.5, 1.0, 2.0, 4.0, and 8.0 L/ha and the reference item at the rate of 6.0 g/ha had no repellent effects on the wasps (Kruskal – Wallis test, p > 0.05). At the significance level of 0.05, there were no statistically significant differences in the mean percentages of wasps settled on the plants at the rates of 0.5, 1.0, 2.0, 4.0, and 8.0 L/ha and the control groups (Kruskal – Wallis test, alpha = 0.05).

MORTALITY

In the main experiment, mortality of the control group after 48 hours of the exposure was 0.0%. After 48 hours of the exposure to the test item at the rates of 0.5, 1.0, 2.0, 4.0, and 8.0 L/ha, the percentages of mortality of *A. rhopalosiphi*, were 0.0, 0.0, 0.0, 0.0, and 0.0% respectively.

On the basis of the obtained mortality results, the LR50 and NOERmortality values could not be determined. It can only be concluded that the LR50 is higher than the maximum rate used in the experiment, i.e. > 8.0 L/ha and NOERmortality value is higher than or equal 8.0 L/ha.

Mortality of the wasps exposed to dimethoate technical at the rate of 6.0 g /ha was 80.0% after 48 hours hours. Therefore, the validity criterion specified in the Method description was met.

FECUNDITY

The fecundity assessment showed that the mean number of mummies per female in the control group was 11.4. As for the wasps treated with test item at the rates of 0.5, 1.0, 2.0, 4.0, and 8.0 L/ha, the numbers of mummies/female were 10.7, 8.3, 6.4, 6.4, and 2.5 respectively.´

Fecundity reduction (Pr) in the group treated with Pendimethalin 455 g/L CS at the rates of 0.5, 1.0, 2.0, 4.0 and 8.0 L/ha were 6.4, 27.5, 43.9, 43.9, and 77.8%, respectively. At the significance level of α 0. 05 there were statistically significant differences in fecundity between the wasps exposed to the test item at the rates of 0.5, 1.0, 2.0, 4.0, and 8.0 L/ha and the control group (Williams Multiple Sequential t-test procedure, │t│ > │t\*│).

On the basis of the obtained fecundity results results, the ER50 value is equal to 3.7 L/ha and NOERfecundity value is equal to 0.5 L/ha.

**Table 1: Mortality of *A. rhopalosiphi* after 48 h**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Rate [L/ha]** | **Tested wasps [no.]** | | **Mortality** | | | | | | | | | | | | | |
| **Dead wasp [no.]** | | | | | | | | | | **Total** | | | |
| **Replicates** | | | | | | | | | |
| **1** | | **2** | | **3** | **4** | **5** | | **6** | | **[no.]** | | **[%]** | |
| **Control [0.0]** | **30** | | 0 | | 0 | | 0 | 0 | 0 | | 0 | | **0** | | **0.0** | |
| **Pendimethalin 455 g/L CS** | | | | | | | | | | | | | | | | |
| **0.5** | **30** | | 0 | | 0 | | 0 | 0 | 0 | | 0 | | **0** | | **0.0** | |
| **1.0** | **30** | | 0 | | 0 | | 0 | 0 | 0 | | 0 | | **0** | | **0.0** | |
| **2.0** | **30** | | 0 | | 0 | | 0 | 0 | 0 | | 0 | | **0** | | **0.0** | |
| **4.0** | **30** | | 0 | | 0 | | 0 | 0 | 0 | | 0 | | **0** | | **0.0** | |
| **8.0** | **30** | | 0 | | 0 | | 0 | 0 | 0 | | 0 | | **0** | | **0.0** | |
| **LR50** | **> 8.0 L/ha** | | | | | | | | | | | | | | | |
| **NOERmortality** | **≥ 8.0 L/ha** | | | | | | | | | | | | | | | |
| **[g/ha]** | **Reference item** | | | | | | | | | | | | | | | |
| **6.0** | **30** | 5 | | 4 | | 2 | | 5 | | 4 | | 4 | | **24** | | **80.0** |

**Table 2: Fecundity of *A. rhopalosiphi***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Replicates** | **Mummies per female 12 days after oviposition [no.]** | | | | | |
| **Control** | **Pendimethalin 455 g/L CS** | | | | |
| **Application rates [L/ha]** | | | | |
| **0.0** | **0.5** | **1.0+** | **2.0+** | **4.0+** | **8.0+** |
| **I** | 15 | 9 | 9 | 5 | 8 | 1 |
| **II** | 8 | 18 | 6 | 11 | 7 | 3 |
| **III** | 17 | 8 | 10 | 4 | 10 | 2 |
| **IV** | 9 | 11 | 9 | 7 | 8 | 5 |
| **V** | 15 | 6 | 7 | 5 | 5 | 2 |
| **VI** | 11 | 8 | 8 | 6 | 4 | 3 |
| **VII** | 12 | 17 | 7 | 5 | 6 | 4 |
| **VIII** | 10 | 12 | 6 | 7 | 7 | 2 |
| **IX** | 11 | 12 | 8 | 8 | 5 | 4 |
| **X** | 6 | 6 | 14 | 5 | 4 | 0 |
| **XI** | 8 | 9 | 4 | 8 | 6 | 1 |
| **XII** | 11 | 14 | 7 | 8 | 7 | 2 |
| **XIII** | 12 | 10 | 11 | 9 | 6 | 0 |
| **XIV** | 15 | 12 | 10 | 4 | 8 | 4 |
| **XV** | 11 | 8 | 8 | 4 | 5 | 5 |
| Mean number mummies per female ± SD | **11.4 ± 3.1** | **10.7 ± 3.6** | **8.3 ± 2.4** | **6.4 ± 2.1** | **6.4 ± 1.7** | **2.5 ± 1.6** |
| Fecundity reduction relative to the control (Pr) [%] | **̶** | **6.4** | **27.5** | **43.9** | **43.9** | **77.8** |
| **ER50** | **3.7 L/ha** | | | | | |
| **NOERfecundity** | **0.5 L/ha** | | | | | |

+: statistically significant difference

**VALIDITY CRITERIA**

– after 48 hours mortality of the control group was 0.0% (criterion: a maximum of 10.0%),

– after 48 hours mortality of the group treated with the reference item at the rate of 6 g/ha was 80.0% (criterion: > 50%)

– the mean number of mummies per female in the control group was 11.4 (criterion: a minimum of 5.0 mummies/female),

– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  The following validity criteria were met during the study:    **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| Reference: | KCP 10.3.2.2-04 |
| Report | “An extended laboratory test for evaluating the effects of Pendimethalin 455g/L CS on the predatory mite, *Typhlodromus pyri* (Sch.)”. Angayarkanni, V., 2022. Bioscience Research Foundation. Study code: 10895/2022. |
| Guideline(s): | according to the ESCORT 1 (Barrett K.L. et al., 1994)  and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents  and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication  (if vertebrate study) | No |

Materials and methods

|  |  |
| --- | --- |
| Test item: | Pendimethalin 455 g/L CS  Batch number: SCL-96930 |
| Test organism: | the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: *Phytoseidae*)  – age: 24-hour-old protonymphs  – source: BRF Insectary |
| Experimental design: | 1 control, 5 treatments (6.25, 7.50, 9.00, 10.80 and 12.96 L/ha of the test item/ha) and 1 reference item  number of replicates: 3; number of mites in each replicate: 20  The study was conducted on bean leaf discs. |
| Test conditions: | temperature: 22.1 – 22.8 ºC  Relative air humidity: 65 - 75%  Photoperiod: 16 h light (5115 - 5450 lux): 8h dark |
| Endpoints: | – mite mortality after 7 days of the treatment  – LR50 and NOERmortality  – reproduction reduction (Pr) after 14 days of the treatment  – ER50 and NOERreproduction |
| Statistical analysis: | Based upon the results, the LR50 and NOER for mortality and the ER50 and NOER for fecundity was determined by using a Probit analysis in NCSS (Number Cruncher Statistical System and one-way ANOVA and Non-linear regression using Graphpad Prism 9.3.1). The means and standard deviations were calculated using Excel sheets. |

Results

Mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to Pendimethalin 455g/L CS at rates of 6.25, 7.50, 9.00, 10.80 and 12.96 L/ha, the percentages of *T. pyri* mortalities were 5.00, 23.33, 43.33, 71.67 and 93.33% respectively. There were statistically significant differences in mortality between group treated with the test ítem at rates 7.50, 9.00, 10.80 and 12.96 L/ha and the control group. (One-way ANOVA).

On the basis of the obtained mortality results, the LR50 value is 9.23 L Pendimethalin 455 g/L CS/ha, i.e., 4.22 Kg Pendimethalin/ha. The NOERmortality value is 6.25 L Pendimethalin 455g/L CS/ha, i.e., 2.86 Kg Pendimethalin/ha.

For the reference ítem ROGOR (Dimethoate 30% EC, w/w), the mortality of mites after 7 days of exposure at the rate of 12 mL/ha, was 81.67%, hence the criterion specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.

The mean reproduction rate (Rr) in the control group was 4.67 eggs/female after 14 days, whereas in the group treated with Pendimethalin 455g/L es at rates of 6.25, 7.50 and 9.00 L/ha was 4.50, 3.53 and 2.65 respectively. Reduction in reproduction (Pr) in the group treated with Pendimethalin 455g/L CS at rates of 6.25, 7.50 and 9.00 L/ha was 3.58, 24.30 and 43.23%. The reproduction rate at the rate of 10.80 and 12.96 L/ha was not determined dueto the mortality higher than 50% in comparison with the control group. There was statistically significant difference in reproduction rate (Rr) between the group treated with the Pendimethalin 455g/L CS at the rates of 7.50 and 9.00 L/ha and the control group (one-way ANOVA).

On the basis of the obtained reproduction results, the ER50 value is 9.24L Pendimethalin 455 g/L CS/ha, i.e., 4.23 Kg Pendimethalin/ha. The NOERreproduction value is 6.25 L Pendimethalin 455 g/L CS/ha, i.e., 2.86 Kg Pendimethalin/ha.

**Table 1. Eeffects of Pendimethalin 455g/L CS on mortality and reproduction of *Typhlodromus pyri* in a laboratory test.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study group (application rate)**  **(Test item**  **L/ha)** | **Parameter (endpoint)** | | | | |
| **Mortality after 7 days** | | **Reproduction** | | |
| **Total**  **(%)** | **LR50** | **Mean no. of**  **eggs/ female (Rr)** | **Reproduction**  **reduction Pr**  [%] | **ER50** |
| **L test item/ha**  **(Kg/ha)** | **L test item/ha**  **(Kg/ha)** |
| Control | O.O | - | 4.67 | - | - |
| **Pendimethalin 455g/L CS** | | | | | |
| 6.25 | 5.00 | 9.23 L/ha (4.22 Kg  Pendimethalin/ha) | 4.50 | 3.58 | 9.24 L/ha (4.23 Kg  Pendimethalin/ha) |
| 7.50 | 23.33+ | 3.53 | 24.30+ |
| 9.00 | 43.33+ | 2.65 | 43.23+ |
| 10.80 | 71.67+ | -\* | -\* |
| 12.96 | 93.33+ | -\* | -\* |
| **NOERmortality** | | 6.25 L/ha (2.86 Kg Pendimethalin/ha) | **NOERrcproduction** | | 6.25 L/ha (2.86 Kg  Pendimethalin/ha) |
| **TAFGOR** | **Mortality after 7 days** | | | | |
| 12.0 mL/ha | **81.67%** | | | | |

+: statistically insignificant differences at *p< 0.05*

\* : the reproduction was not determined due to the mortality higher than 50% in comparison with the control group

**Validity criteria**

The following validity criteria were met during the study:

* Mortality ofthe control group was 0.0% on day 7 of exposure (criterion: a maximum of

20%)

* Mortality of the mites exposed to the reference item at the rate of 12.0 mL/ha was 81.67% on day 7 of exposure (criterion: from 50 to 100%)
* The mean number of eggs per female in the control group was 4.47 (required: 2: 4 eggs per female).

**Conclusions**

On the basis of the obtained results, it can be concluded that Pendimethalin 455g/L CS had no ad verse effects on mortality and reproduction of the predatory mite, *T. pyri* at 6.25 L/ha.

* 1. KCP 10.4 Effects on non-target soil meso- and macrofauna
     1. KCP 10.4.1 Earthworms
        1. KCP 10.4.1.1 Earthworms - sub-lethal effects

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  The following validity criteria were met during the test:   * Mortality of adult worms over initial days od the test was 1.25% (criterion: it have not to exceed 10%). * The lowest number of offspring produced in replicate was 30 (criterion: a minimum of 30 offspring are produced in each replicate containing 10 adults). * The highest value of the coefficient of variation (CV) of offspring number was 16.9 (criterion: the CV of offspring number does not exceed 30%).   Deviations: Study Plan concerning a study completion date occurred. Twelve times during the test temperatures below the range specified in the guideline were recorded. Retention times during analytical verification of pendimethalin content in samples collected on Day 56 of study were changed due to capillary exchange in UHPLC (higher void volume). Retention times were in range 2.2 – 2.4 min. Additional abiotic control was prepared in the same way and incubated under the same conditions as the other abiotic controls made for R1, R4, R8 treatments. This abiotic control was used for sampling for analytical verification of nominal concentration of tested material on Day 0 and on Day 56. According to Study Plan lost soil moisture is replaced by adding deionized water to the soil surface by hand-held sprayer. An automatic pipette was used to make up the water loss. This deviations did not affected the study results.  **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.4.1.1-01 |
| **Report:** | “Earthworm Reproduction Test (*Eisenia andrei*)”.  Swoboda T., Study Code.: EMI/4/40/2019, 2021 Ecomelius Institute |
| **Guideline(s):** | OECD Guideline No. 222 (2016) |
| **Deviations:** | Yes  Study Plan concerning a study completion date occurred. Twelve times during the test temperatures below the range specified in the guideline were recorded. Retention times during analytical verification of pendimethalin content in samples collected on Day 56 of study were changed due to capillary exchange in UHPLC (higher void volume). Retention times were in range 2.2 – 2.4 min. Additional abiotic control was prepared in the same way and incubated under the same conditions as the other abiotic controls made for R1, R4, R8 treatments. This abiotic control was used for sampling for analytical verification of nominal concentration of tested material on Day 0 and on Day 56. According to Study Plan lost soil moisture is replaced by adding deionized water to the soil surface by hand-held sprayer. An automatic pipette was used to make up the water loss. This deviations did not affected the study results. |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study):** | No |

**Summary**

The effect on Pendimethalin 455 CS, to the reproduction of the earthworm (*Eisenia andrei*) was studied in the artificial soil substrate for 56 days. The adults earthworms were exposed to the tested item for the first 28 days of the test and were removed from the test vessels on day 28 to be examined for signs of toxicity and mortality. The soil and cocoons were returned to the test vessels for an additional 28 days to determine the numbers of juveniles produced in each replicate by the end of the test on day 56. Each treatment was divided into four replicates and control was divided into eight replicates. Earthworms were exposed to nominal concentrations of 16, 29, 53, 95, 171, 309, 556 and 1000 mg test item/kg soil dry weight. Test item concentrations in soil were not verified. Observations of burrowing behaviour were conducted at the initiation. Mortality, behavioural and morphological changes were assessed after 28 days of exposure. The number of juveniles were determined at test end on day 56.

**Material and methods**

**Test item:** Pendimethalin 455 CS

Batch number: SCL- 14177

Content: 455.0 g/L

Production date: 27th October, 2019

Expiry date: 26th October, 2021

**Test system:** Species: *Eisenia andrei*

Stage: Adult worms

Source: Wurmwelten, Inch. Jasper Rimpau

**Test substrate:** Artificial soil

**Feeding:** Alfalfa

**Test design:** Test duration: 56 days

Number of treatments: 9 (8 treatments, 1 control)

Number of replicates: 4 for treatment, 8 for control

Number of organisms/replicate: 10

**Test concentrations:** 16, 29, 53, 95, 171, 309, 556 and 1000 mg dry weight of the artificial soil

**Test conditions:** temperature: 18.0 - 20.2°C;

pH at the beginning of the experiment: 6.05 – 6.17;

pH at the end of the experiment: 6.16 – 6.39;

soil moisture content at the beginning of the experiment: 16.44 – 16.85 %

soil moisture content at the end of the experiment: 16.72 – 17.67 %

photoperiod: 16h light: 8 h dark

light intensity: 487.2 – 573.9 lux

**Statistical analysis:** EC50, EC20, EC10 and LC50 values were calculated with the probit analysis using linear max. likehood regressions. NOEC and LOEC values using the Shapiro-Wilk’s Test on Normal Distribution, the Levene’s Test on Variance Homogeneity (with Residuals), and the Williams Multiple Sequential t-test Procedure.

EC50, EC20, EC10, LC50, NOEC and LOEC values were calculated using ToxRatPro statistical computer software.

**Validity criteria:** The following validity criteria were met during the test:

* Mortality of adult worms over initial days od the test was 1.25% (criterion: it have not to exceed 10%).
* The lowest number of offspring produced in replicate was 30 (criterion: a minimum of 30 offspring are produced in each replicate containing 10 adults).
* The highest value of the coefficient of variation (CV) of offspring number was 16.9 (criterion: the CV of offspring number does not exceed 30%)

**Findings:**

**Earthworms mortality, changes in behavior and morphology – 28 days of the test**

|  |  |  |  |
| --- | --- | --- | --- |
| **Concentration (mg/kg dry soil)** | **Total mortality** | | **Changes in beaviour and morphology** |
| **Number** | **%** |
| Control | 1 | 1.25 | 10 nc x 8 |
| 16 | 0 | 0 | 10 nc x 4 |
| 29 | 0 | 0 | 10 nc x 4 |
| 53 | 0 | 0 | 10 nc x 4 |
| 95 | 0 | 0 | 10 nc x 4 |
| 171 | 0 | 0 | 10 nc x 4 |
| 309 | 0 | 0 | 10 nc x 4 |
| 556 | 17+ | 42.5 | 18 nc; 5r; 1 bd |
| 1000 | 35+ | 87.5 | 5 r; 2 bd |

nc – no changes in behavior and morphology were observed; r – weak response to stimulation; bd – visible body damage; + - statistically significant

**Earthworms reproduction and morphological observations after 8 weeks of the experiment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Concentration (mg/kg dry soil)** | **Mean ± SD** | **Coefficient of variation (%)** | **Morphological observations** |
| Control | 46.1 ± 7.77 | 16.9 | nc |
| 16 | 44.0 ± 7.44 | 16.9 | nc |
| 29 | 49.8 ± 9.00 | 18.1 | nc |
| 53 | 40.8 ± 10.01 | 24.6 | nc |
| 95 | 38.5 ± 5.32 | 13.8 | nc |
| 171 | 31.5 ± 5.20 | 16.5 | nc |
| 309 | 29.3 ± 4.27 | 14.6 | nc |
| 556 | 22.8 ± 6.55 | 28.8 | nc |
| 1000 | 10.0 ± 4.16 | 41.6 | nc |

nc – no changes

Endpoint values determined for earthworm reproduction after 8 weeks and for mortality after 4 weeks – Test item

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value [mg test item/kg dry weight of artificial soil]** | **Value**  **[mg active substance/kg dry soil]** |
| **EC10** | 58.94 (26.45 – 93.19) | 22.73 (10.20 – 35.93) |
| **EC20** | 123.02 (73.08 – 169.69) | 47.44 (28.18 – 65.43) |
| **EC50** | 432.81 (338.68 – 579.60) | 166.89 (130.59 – 223.49) |
| **NOEC(offspring number)** | 95.00 | 36.63 |
| **LOEC(offspring number)** | 170.00 | 65.94 |
| **LC10** | 401.38 (324.04 – 460.10) | 154.77 (124.95 – 177.41) |
| **LC20** | 469.04 (397.25 – 526.82) | 180.86 (153.18 – 203.14) |
| **LC50** | 631.91 (566.47 – 706.75) | 243.66 (218.43 – 272.52) |
| **NOEC(survival)** | 309.00 | 119.15 |
| **LOEC(survival)** | 556.00 | 214.39 |

* + - 1. KCP 10.4.1.2 Earthworms - field studies
    1. KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  The study is considered valid. All validity criteria were met.  • mean adult mortality: 12.5% (criterion: ≤ 20%),  • the mean number of juveniles per vessel at the end of the test: 250.1  (criterion: ≥ 100 juveniles at the end of the test),  • the coefficient of variation calculated for the number of juveniles: 18.0% (criterion: ≤ 30%).  **Agreed endpoints:**   |  |  |  | | --- | --- | --- | | **Parameter** | **Test item**  **(mg/kg d.w. soil)** | **Active substannce**  **(mg/kg d.w. soil)** | | **Mortality** | | | | **LC10** | 305.03  (194.80 – 427.62) | 117.62  (75.11 – 164.89) | | **LC20** | 582.62  (415.65 – 919.50) | 224.65  (160.27 – 354.55) | | **LC50** | > 1000.0 | >385.59 | | **NOEC** | 308.64 | 119.01 | | **LOEC** | 555.56 | 214.22 | | **Reproduction** | | | | **EC10** | 225.12  (139.26 – 286.13) | 86.80  (53.70 – 110.33) | | **EC20** | 290.31  (205.65 – 350.10) | 111.94  (79.30 – 135.00) | | **EC50** | 472.24  (401.49 – 556.09) | 182.09  (154.81 – 214.42) | | **NOEC** | 171.47 | 66.12 | | **LOEC** | 308.64 | 119.01 | |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.4.2-01 |
| **Report:** | “Collembolan (*Folsomia candida*) Reproduction Test”.  Dec W., Study Code.: EMI/4/17/2020, 2021 Ecomelius Institute |
| **Guideline(s):** | OECD Guideline No. 232 (2016) |
| **Deviations:** | Yes - An editorial mistake was found in point 5.3.5 (page 12) of the Study Plan. The test item in the form of aqueous suspension was mixed with a suitable amount of the artificial soil, not in the form of aqueous emulsion. Deviation from the Study Plan and SOP/P/62: retention time of pendimethalin at validation was 2.25 ± 0.1 instead of 2.1 ± 0.1. Deviation from the Study Plan and SOP/A/4 concerning short term (<1 h) increased air temperature of place where the test item was stored occurred. Deviation from the Study Plan, OECD No. 232, and SOP/B/12 concerning decreased <18ºC (17.2 – 17.9ºC ) air temperature of test room occurred. The increase in temperature in total lasted about 2 days (mainly at night). The validity criteria were met, therefore deviations did not affect the results of the study. Contrary to what had been planned, the study was finalized in March 2021, not in January 2021. An editorial mistake was found in point 11 (page 17) of the Study Plan. Should be: [5] ISO-Guideline No. 10390: 1997. ‘Soil Quality - determination of pH’ [6] ISO-Guideline No. 11465: 1999 ‘Soil Quality - determination of dry matter and water content on a mass basis - gravimetric method’ instead of: [5] ISO-Guideline No. 10390: 1994. “Soil Quality - determination of pH”, Geneve [6] ISO-Guideline No. 11465: 1993 “Soil Quality - determination of dry matter and water content on a mass basis - gravimetric method” Above deviations did not affect the results of the study. |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study):** | No |

**Summary**

The aims of the study were to assess the impact of Pendimethalin 455 g/L CS on reproduction of the collembolans, *Folsomia candida* and to determine the EC10, EC20, EC50, and NOEC. Moreover, the LC10, LC20, LC50 were calculated (i.e. the concentration of the test item causing 10 or 20% mortality of adults in comparison to the control). Eight concentrations of the test item were used. These were 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, and 1000.00 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with ultrapure water alone. The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

**Material and methods**

**Test item:** Pendimethalin 455 g/L CS

Batch number: SCL- 14177

Content: Pendimethalin – 455.0 g/L

Production date: 27th October, 2019

Expiry date: 26th October, 2021

**Test system:** Species: The collembolan, *Folsomia candida*

Stage: 9-12 days old

Source: laboratory culture from Ecomelius Institute

**Artificial soil:** Artificial soil: 5% sphagnum peat, 20% kaolin clay, and 75% quartz sand

**Test design:** Test duration: 28 days

Number of treatments: 10 (8 treatments, 1 control, 1 abiotic control)

Number of replicates: 4 for treatment, 8 for control, 2 for abiotic control

Number of organisms/replicate: 10

**Test concentrations:** 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56, and 1000.00 mg/kg dry artificial soil

**Test conditions:** temperature: 17.2 – 22.0°C;

pH at the beginning of the test: 5.53 – 5.84;

pH at the end of the test: 5.51 – 5.57;

soil moisture content at the beginning of the test: 16.94 – 17.51% (49.53 – 51.20% of the maximum water holding capacity);

soil moisture content at the end of the test: 16.76 – 17.25% (49.02 – 50.44% of the maximum water holding capacity);

lighting: 16 h light and 8h dark;

light intensity at the beginning of the experiment: 492.1 – 541.8 lux

light intensity after two weeks of the experiment: 481.7 – 545.1 lux

light intensity at the end of the experiment: 472.1 – 536.1 lux

**Statistical analysis:** EC10, EC20, and EC50 – a probit analysis

LC10, LC20, LC50 - a probit analysis

NOEC (number of juveniles):

- Shapiro-Wilk’s Test on Normal Distribution,

- Bartlett’s Test Procedure on Variance Homogeneity,

- Williams Multiple Sequential t-test Procedure, NOEC (survival):

- Qualitative trend Analysis by Contrast (Monotonicity of Concentration/Response) - Chi2 2x2 Table Test with Bonferroni Correction

**Validity criteria:** The results are considered valid because the following criteria were satisfied in the controls:

• mean adult mortality: 12.5% (criterion: ≤ 20%),

• the mean number of juveniles per vessel at the end of the test: 250.1 (criterion: ≥ 100 juveniles at the end of the test),

• the coefficient of variation calculated for the number of juveniles: 18.0% (criterion: ≤ 30%).

**Findings:**

**Mortality of adult collembolans (*Folsomia candida*) – 28 days of the test**

|  |  |  |
| --- | --- | --- |
| **Concentration (mg/kg dry soil)** | **Total mortality** | |
| **Number** | **%** |
| Control | 10 | 12.5 |
| 16.33 | 5 | 12.5 |
| 29.40 | 5 | 12.5 |
| 52.92 | 6 | 15.0 |
| 95.26 | 6 | 15.0 |
| 171.47 | 6 | 15.0 |
| 308.64 | 3 | 7.5 |
| 555.56 | 15+ | 37.5 |
| 1000.0 | 16+ | 40.0 |

+ - statistically significant difference between the control and the treatment group (Chi2 2x2 Table Test with Bonferroni Correction, significance level = 0.05, one-sided greater)

**Number of juvenile collembolans (*Folsomia candida*) after 28 days of the experiment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Concentration (mg/kg dry soil)** | **Mean ± SD** | **Reduction (%)** | **CV\* (%)** |
| Control | 250.125 ± 44.994 | - | 18.0 |
| 16.33 | 242.750 ± 47.233 | 2.9 | 19.5 |
| 29.40 | 242.750 ± 36.719 | 2.9 | 15.1 |
| 52.92 | 228.500 ± 54.945 | 8.6 | 24.0 |
| 95.26 | 233.750 ± 37.880 | 6.5 | 16.2 |
| 171.47 | 232.750 ± 28.076 | 6.9 | 12.1 |
| 308.64 | 186.500+ ± 34.962 | 25.4 | 18.7 |
| 555.56 | 115.750+ ± 24.851 | 53.7 | 21.5 |
| 1000.0 | 0.000+ ± 0.000 | 100.0 | - |

\*CV – coefficient of variation

+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, one-sided smaller)

‘-‘ not determined

The impact of the test item on the survival and reproduction of adult collembolans.

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Test item**  **(mg/kg d.w. soil)** | **Active substannce**  **(mg/kg d.w. soil)** |
| **Mortality** | | |
| **LC10** | 305.03  (194.80 – 427.62) | 117.62  (75.11 – 164.89) |
| **LC20** | 582.62  (415.65 – 919.50) | 224.65  (160.27 – 354.55) |
| **LC50** | > 1000.0 | >385.59 |
| **NOEC** | 308.64 | 119.01 |
| **LOEC** | 555.56 | 214.22 |
| **Reproduction** | | |
| **EC10** | 225.12  (139.26 – 286.13) | 86.80  (53.70 – 110.33) |
| **EC20** | 290.31  (205.65 – 350.10) | 111.94  (79.30 – 135.00) |
| **EC50** | 472.24  (401.49 – 556.09) | 182.09  (154.81 – 214.42) |
| **NOEC** | 171.47 | 66.12 |
| **LOEC** | 308.64 | 119.01 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.   * Mean adult mortality: 0.00% (criterion: ≤20%). * The mean number of juveniles per replicate at the end of the test: 129.50 (criterion: ≥50 juveniles at the end of the test). * The coefficient of variation for the number of juveniles: 1.24 (criterion: ≤30%)   **Agreed endpoints:**   |  |  |  | | --- | --- | --- | | **Endpoints** | **[mg t.i./kg sdw]** | **[mg Pendimethalin/kg sdw]** | | **NOEC mortality** | >1000 | >386.44 | | **LOEC mortality** | >1000 | >386.44 | | **LC10** | >1000  (n.d) | >386.44  (n.d) | | **LC20** | >1000  (n.d) | >386.44  (n.d) | | **LC50** | >1000  (n.d) | >386.44  (n.d) | | **NOEC reproductive output** | >1000 | >386.44 | | **LOEC reproductive output** | >1000 | >386.44 | | **EC10** | >1000  (n.d) | >386.44  (n.d) | | **EC20** | >1000  (n.d) | >386.44  (n.d) | | **EC50** | >1000  (n.d) | >386.44  (n.d) |   n.d. – not determined |

|  |  |
| --- | --- |
| Reference: | KCP 10.4.2-02 |
| Report | “Effect of Pendimethalin 455 g/L CS on the Reproductive Output of the Predatory Soil Mite *Hypoaspis* *(Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in Artificial Soil”. Dr. V. Angayarkanni. 2021. Study code: 8925/2021. Bioscience Research Foundation |
| Guideline(s): | OECD Guideline No. 226 (2016) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication  (if vertebrate study) | No |

Materials and methods

|  |  |
| --- | --- |
| **Test item:** | Pendimethalin 455 g/L CS  batch no.: SCL-80067  active substance content: Pendimethalin, 456 (g/L) |
| **Artificial soil** | 5% sphagnum peat (a particle size of 2 ± 1 mm); 20% kaolin clay; 75% air-dried industrial sand (predominantly fine sand with more than 50 % of the particles between 50 and 200 microns) |
| **Biological test system :** | *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari, Laelapidae), from in-house culture, adult mites (33 days after starting of the egg-laying for synchronisation). |
| **Test design:** | Adult females were exposed to the test substance in artificial soil. After 14 days, the surviving individuals were extracted from the test units. The number of juveniles per test unit and additionally the number of surviving adult females were determined. The reproductive output and the mortality in each test item group were compared to that of the control group. A Dose-response test with 10 different test substance concentrations and 4 replicates each as well as a water control (without test substance) with eight replicates; 10 adult females were exposed per replicate. |
| **Test doses:** | 0 (control), 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000.00 mg test substance/kg soil dry weight. Equivalent to 0, 1.95, 3.51, 6.31, 11.36, 20.45, 36.81, 66.26, 119.27, 214.69 and 386.44 mg Pendimethalin/kg soil dry weight. |
| **Test conditions:** | Temperature during exposure: 20.5 °C to 21.5 °C  pH at the beginning of the test: 5.85 to 6.10  pH at the end of the test: 5.92 to 6.08  Soil moisture content at the beginning of the test: 20.10 % to 21.30 % (corresponding to 51.47 – 52.40 % of the WHCmax)  Soil moisture content at the end of the test: 19.32 % to 20.73 % (corresponding to 49.42 – 50.44 % of the WHCmax)  Lighting: 16 h light and 8 h dark (long day conditions); light intensity: 595 lux to 650 lux |
| **Endpoints:** | LOEC and NOEC for mortality and reproductive output; EC10, 20, 50 for reproductive output and LC10, 20, 50 for mortality output where possible. |

Results and discussions

Mortality after 14 days of experiment at the concentrations of the test item ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, mortality was between 0.00 and 7.5%. As for the control group, it was 0.00%.

No behavioural abnormalities or any pathological symptoms of the test organisms could be observed in the control group and in any of the test substance groups.

After the application of the test item at the concentration ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 129.25 and 125.25 per replicate. As for the control group, the number of juveniles was equal to 129.50per replicate.

The toxic reference item (a.i. dimethoate) was conducted between 03.06.2020 and 26.06.2020. The EC50 for reproductive output was determined to be 4.02 mg/kg soil dry weight. This is within the target range of 3.0 to 7.0 mg dimethoate/kg soil dry weight given by the OECD guideline 226 (2016) and hence acceptable sensitivity of the test system was assured.

**Mortality and reproductive output of *H. aculeifer* after exposure to artificial soil treated with test item**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Treatment**  **group** | **Test substance**  **concentration**  [mg t.s./kg sdw] | **Mean**  **Mortality**  **[%]** | **Mean nº of**  **juveniles per replicate** | **Coefficient of**  **Variation**  **[%]** | **Reduction in**  **reproductive output compared to control [%]** |
| Control | 0 | 0.0 | 129.50 ± 1.6 | 1.24 | - |
| Pendimethalin 455 g/L CS | 5.04 | 0.0 | 129.25 ± 2.50 | 1.93 | 0.19 |
| 9.07 | 0.0 | 129.25 ± 2.22 | 1.72 | 0.19 |
| 16.33 | 0.0 | 129.00 ± 1.63 | 1.27 | 0.39 |
| 29.40 | 0.0 | 128.75 ± 2.06 | 1.60 | 0.58 |
| 52.92 | 2.5 ± 5 | 128.50 ± 3.11 | 2.42 | 0.77 |
| 95.26 | 2.5 ± 5 | 128.25 ± 2.50 | 1.95 | 0.97 |
| 171.47 | 2.5 ± 5 | 128.00 ± 2.16 | 1.69 | 1.16 |
| 308.64 | 5.0 ± 5.8 | 126.25 ± 1.71 | 1.35 | 2.51 |
| 555.56 | 5.0 ± 5.8 | 126.00 ± 1.41 | 1.12 | 2.70 |
| 1000 | 7.5 ± 5.0 | 125.25 ± 1.26 | 1.00 | 3.28 |
| **Endpoints** | | **[mg t.i./kg sdw]** | | **[mg Pendimethalin/kg sdw]** | |
| NOEC mortality | | **>1000** | | **>386.44** | |
| LOEC mortality | | **>1000** | | **>386.44** | |
| LC10 | | **>1000**  (n.d) | | **>386.44**  (n.d) | |
| LC20 | | **>1000**  (n.d) | | **>386.44**  (n.d) | |
| LC50 | | **>1000**  (n.d) | | **>386.44**  (n.d) | |
| NOEC reproductive output | | **>1000** | | **>386.44** | |
| LOEC reproductive output | | **>1000** | | **>386.44** | |
| EC10 | | **>1000**  (n.d) | | **>386.44**  (n.d) | |
| EC20 | | **>1000**  (n.d) | | **>386.44**  (n.d) | |
| EC50 | | **>1000**  (n.d) | | **>386.44**  (n.d) | |

n.d. – not determined

Conclusion

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.

**Test validity criteria**

The results are considered valid because the following criteria were satisfied in the control:

* Mean adult mortality: 0.00% (criterion: ≤20%).
* The mean number of juveniles per replicate at the end of the test: 129.50 (criterion: ≥50 juveniles at the end of the test).

The coefficient of variation for the number of juveniles: 1.24 (criterion: ≤30%).

* + - 1. KCP 10.4.2.1 Species level testing
      2. KCP 10.4.2.2 Higher tier testing
  1. KCP 10.5 Effects on soil nitrogen transformation
     1. KCP 10.5.1 Soil Microorganisms: Nitrogen Transformation Test

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  **Agreed endpoints:**  On the basis of the results, it can be concluded that Pendimethalin 455 g/L CS at the concentration corresponding to the PEC and upper PEC, 27.53 and 137.67 mg test item/kg dry weight soil, respectively (10.62 and 53.08 mg Pendimethalin kg/dry weight soil, respectively) can be perceived as having no long-term influence on nitrogen transformations in soil. |

|  |  |
| --- | --- |
| Reference | KCP 10.5.1 |
| Report | “Soil Microorganisms: Nitrogen Transformation Test”. Weronika Dec, PhD Eng., 2021. STUDY CODE: EMI/4/26/2019. Ecomelius Institute sp. z.o.o. |
| Guideline(s) | OECD Guidelines for Testing of Chemicals. Test No. 216 (OECD, 2000) |
| Deviations | No |
| GLP | Yes |
| Acceptability | Yes |
| Duplication  (if vertebrate study) | No |

**Material and methods**

|  |  |
| --- | --- |
| Test material | Pendimethalin 455 g/L CS, batch number SCL-14177 |
| Soil | Agricultural soil (Type 5M). The soil was from a place where there was no organic fertilization and pesticides use at the sampling site in neither sampling year. |
| Test design | Three portions of soil (3 x 1800 g. dry weight), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 600 g). The soil was amended with a suitable organic substrate, i.e. powdered Lucerne-grass meal (C/N range is 15.85, Nitrogen in dry material % is 2.66) at dose of 5 g/kg dry weight of soil. Test duration: 28 days. |
| Concentrations of the test material | Control; 27.53 mg of test item/kg dry weight soil (10.62 mg Pendimethalin/kg of dry weight of soil) and 137.67 mg of test item/kg of dry weight soil (53.08 mg Pendimethalin/kg of dry weight of soil) |
| Test conditions | Temperature: 19.2 – 20.4°C, soil moisture: 49.02 – 54.1% MWHC, pH in Milli-Q water: 6.46 |
| Endpoints | The concentration of nitrate ions [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation and percent deviation from the control in nitrate formation. |
| Statistical analysis | The statistical tests were performed with the use of ToxRat Professional (version 3.3.0)   * Shapiro-Wilk’s Test on Normal Distribution * Levene’s Test on Variance Homogeneity * STUDENT-t test for Homogeneous Variances |

**Study design**

The aim of the study was to detect long-term adverse effects of Pendimethalin 455 g/L CS on the processes of nitrogen transformation in aerobic surface soils.

Agricultural soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm. The concentrations of the test item were 27.53 (PEC) and 137.67 (5xPEC) mg of test item/kg of dry weight soil, equivalent to 10.62 and 53.08 mg Pendimethalin/kg of dry weight soil. The treated and the control soils were divided into three replicates. On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrates.

The method involves a measurement of the nitrate ion concentration in a soil extract obtained by using

0.1 M KCl. The absorbance of the solution was measured at 500 nm.

The nitrate formation rate in each treated group was compared with that in the control and the percent deviation of the treated from the control was calculated.

**Results**

Deviations from the control based on nitrogen between the control and the group treated with test item at booth concentrations. i.e. PEC: 27.53 mg test Item/kg dry soil and upper PEC: 137.67 mg the test item/kg dry soil in nitrate concentration after 0, 7, 14, and 28 days of incubation.

There were no statistically significant differences between the control and the group with test item at the concentration of 27.53 and 137.67 mg test item/kg dry weight soil in nitrate formation rates at time intervals: 0-7, 0-14, 0-28.

The percent deviation from the control calculated on the basis of the nitrate formation rate at the concentration of 27.53 and 137.67 mg test item/kg dry weight soil did not exceed 25% on 28 day of analysis. Hence it can be evaluated as having no long-term influence on nitrogen formation in soil at the concentrations corresponding to the PEC and upper PEC, 27.53 and 137.67 mg test item/kg dry weight soil, respectively (10.62 and 53.08 mg of pendimethalin/kg dry weight soil, respectively)

**Table 1: Nitrate content in soil - deviations from the control [%]:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Day** | **Sample details** | **Nitrate ion concentration (mg/kg dws)** | **Coefficient of variation [%]** |
| 0 | Control | 71.26 ± 3.42 | 4.8 |
| PEC | 69.19 ± 0.07 | 4.0 |
| Upper PEC | 58.19+ ± 8.22 | 14.1 |
| 7 | Control | 94.78 ± 5.75 | 6.1 |
| PEC | 115.06+ ± 11.72 | 10.2 |
| Upper PEC | 100.63 ± 8.49 | 8.4 |
| 14 | Control | 166.46 ± 5.30 | 3.2 |
| PEC | 220.31+ ± 19.39 | 8.8 |
| Upper PEC | 125.83+ ± 3.69 | 2.9 |
| 28 | Control | 283.54 ± 9.8 | 3.6 |
| PEC | 313.41 ± 23.06 | 7.4 |
| Upper PEC | 300.35 ± 43.36 | 14.4 |

+: statistically significant differences in nitrate concentrations between the control soil and the soil treated with the test item (STUDENT-t test for homogeneous variances, two-sided)

Control: Milli-Q water

PEC: 27.53 mg of test item/kg of dry weight soil

Upper PEC: 137.67 mg of test item/kg of dry weight soil

**Conclusions**

On the basis of the results, it can be concluded that Pendimethalin 455 g/L CS at the concentration corresponding to the PEC and upper PEC, 27.53 and 137.67 mg test item/kg dry weight soil, respectively (10.62 and 53.08 mg Pendimethalin Kg/dry weight soil, respectively) can be perceived as having no long-term influence on nitrogen transformations in soil.

**Test material: Pendimethalin 40% SC (Batch SWEPL – 7489)**

* + 1. KCP 10.5.2 Soil Microorganisms: Carbon Transformation Test
  1. KCP 10.6 Effects on terrestrial non-target higher plants
     1. KCP 10.6.1 Summary of screening data
     2. KCP 10.6.2 Testing on non-target plants

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  The seedling emergence in the control (validity criterion: at least 70%) was as follows:  - 100% – Soybean,  - 95.2% – Oilseed rape,  - 100% – Onion,  - 100% – Oats,  - 100% – Lettuce,  - 100% – Sugar beet,  - the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%)  - the control seedlings did not exhibit any visible phytotoxic symptoms  - environmental conditions for all plants belonging to the same species were identical.  **Agreed endpoints:**  **Pendimethalin 455 g/L CS: the ER10, ER25, ER50, NOER values.**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Endpoint value** | | **Soybean (*Glycine max*)** | | **Oilseed rape (*Brassica napus*)** | **Onion (*Allium cepa*)** | **Oats**  **(*Avena sativa)*** | **Lettuce**  **(*Lactuca sativa*)** | **Sugar beet (*Beta vulgaris*)** | | **Plant number at the end of the experiment** | | | | | | | | | | **ER10** | kg/haa | 1.307 | | 1.468 | 1.371 | 1.371 | 1.487 | 1.886 | | kg/hab | 0.6 | | 0.7 | 0.6 | 0.6 | 0.7 | 0.9 | | **ER25** | kg/haa | 2.813 | | 3.108 | 2.758 | 2.758 | 3.197 | 3.902 | | kg/hab | 1.3 | | 1.4 | 1.3 | 1.3 | 1.5 | 1.8 | | **ER50** | kg/haa | 6.589 | | 7.152 | 5.993 | 5.993 | 7.482 | 8.752 | | kg/hab | 3.0 | | 3.3 | 2.7 | 2.7 | 3.4 | 4.0 | | **NOER** | kg/haa | 2.25 | | 2.25 | 2.25 | 2.25 | 2.25 | 2.25 | | kg/hab | 0.5 | | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | | **Shoot length (plants without roots)** | | | | | | | | | | **ER10** | kg/haa | 1.259 | 1.296 | | 1.165 | 1.130 | 1.288 | 1.551 | | kg/hab | 0.6 | 0.6 | | 0.5 | 0.5 | 0.6 | 0.7 | | **ER25** | kg/haa | 2.761 | 2.828 | | 2.542 | 2.510 | 3.019 | 3.380 | | kg/hab | 1.3 | 1.3 | | 1.2 | 1.1 | 1.4 | 1.5 | | **ER50** | kg/haa | 6.611 | 6.726 | | 6.052 | 6.096 | 7.783 | 8.031 | | kg/hab | 3.0 | 3.1 | | 2.8 | 2.8 | 3.5 | 3.7 | | **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 | | kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 | | **Plant dry weight (plants without roots)** | | | | | | | | | | **ER10** | kg/haa | 1.312 | 1.534 | | 1.081 | 1.237 | 1.352 | 1.747 | | kg/hab | 0.6 | 0.7 | | 0.5 | 0.6 | 0.6 | 0.8 | | **ER25** | kg/haa | 2.618 | 3.352 | | 2.256 | 2.474 | 2.926 | 3.430 | | kg/hab | 1.2 | 1.5 | | 1.0 | 1.1 | 1.3 | 1.6 | | **ER50** | kg/haa | 5.639 | 7.985 | | 5.112 | 5.342 | 6.896 | 7.260 | | kg/hab | 2.6 | 3.6 | | 2.3 | 2.4 | 3.1 | 3.3 | | **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 | | kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 |   a: value for the test item, i.e. Pendimethalin 455 g/l CS expressed as kg/ha  b: value for active substance, i.e. Pendimethalin expressed as kg/ha  The visual phytotoxic effects are covered by the lowest of the presented endpoints for each species. The additional risk assessment required. |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.6.2-01 |
| **Report:** | “Effect of Pendimethalin 455 g/L CS on Seedling Emergence and Seedling Growth of Terrestrial Plants”.  S. Radha, 9419/2021, 2021. Bioscience Research Foundation |
| **Guideline(s):** | OECD No. 208 (2006) |
| **Deviations:** | No |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study):** | No |

**Summary**

The study, aimed at evaluating the effect of Pendimethalin 455 g/L CS on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. For each species, five application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots (3 seeds/pot, i.e. 21 seeds/application rate (7 pots/application rate) for oilseed rape and lettuce, 2 seeds/pot i.e. 20 seeds/application rate (10 pots/application rate) for soybean and sugar beet and 5 seeds/pot i.e. 20 seeds/application rate (4 pots/application rate) for onion and oats). The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence on every day and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER.

**Material and methods**

Test item: Name: Pendimethalin 455 g/L CS

Batch number: SCL - 80067

Manufacturing date: 18th May 2020

Expiry date: 17th May 2022

Test species: Soybean (*Glycine max*), Oilseed rape (*Brassica napus*), Onion (*Allium cepa*), Oats (*Avena sativa*), Lettuce (*Lactuca sativa*), Sugar beet (*Beta vulgaris*)

Test design: Number of rates: 5 application rates + control

Number of replicates: 4, 7, 10 per application  
Number of seeds: 20, 21 per application

Test termination: 14 days after the emergence of 50% of the control seedlings

Application rates: Control (test soil without test item), 1.125, 2.25, 4.5, 9 and 18 kg/ha Pendimethalin 455 g/L CS

Soil: sandy loam soil soil containing 1.2% organic carbon, the soil was sieved it to 2 mm particle size

Endpoints: ER10, ER25, ER50, NOER

Test conditions: Temperature: 20°C – 23.1°C

Humidity: 58.1 – 64.2

Photoperiod: 16 hours light / 8 hours darkness

Light intensity: 326–400 µE/m2/s

Carbon dioxide concentration: 328 – 341ppm

Statistical analysis: Probit analysis in the NCSS and one-way ANOVA using GraphPad Prism 8.0

Validity criteria: - the seedling emergence in the control (validity criterion: at least 70%) was as follows:

- 100% – Soybean,

- 95.2% – Oilseed rape,

- 100% – Onion,

- 100% – Oats,

- 100% – Lettuce,

- 100% – Sugar beet,

- the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%)

- the control seedlings did not exhibit any visible phytotoxic symptoms

- environmental conditions for all plants belonging to the same species were identical

**Findings**

**Compared effect to the control (%)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Appl. Rate (kg/ha)** | **Soybean** | | | **Oilseed rape** | | | **Onion** | | |
| **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** |
| **Ctrl** | - | - | - | - | - | - | - | - | - |
| **1.125** | 5.0 | 4.6 | 3.4 | 5.0 | 3.9 | 2.1 | 5.0 | 5.1 | 6.2 |
| **2.25** | 23.8 | 24.4 | 25.3 | 15.0 | 21.6 | 18.6 | 20.0 | 27.3 | 29.2 |
| **4.5** | 38.1 | 42.4 | 48.6 | 45.0 | 47.5 | 38.7 | 45.0 | 45.0 | 50.8 |
| **9** | 61.9 | 57.4 | 61.4 | 55.0 | 54.6 | 56.1 | 65.0 | 58.8 | 65.7 |
| **18** | 76.2 | 76.5 | 83.8 | 75.0 | 75.8 | 68.4 | 80.0 | 79.3 | 83.4 |
| **Appl. Rate (kg/ha)** | **Oats** | | | **Lettuce** | | | **Sugar beet** | | |
| **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** |
| **Ctrl** | - | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| **1.125** | 5.0 | 4.1 | 5.1 | 4.8 | 4.7 | 3.7 | 5.0 | 2.8 | 2.0 |
| **2.25** | 20.0 | 29.9 | 25.8 | 14.3 | 22.5 | 23.2 | 10.0 | 17.9 | 14.2 |
| **4.5** | 45.0 | 43.6 | 48.5 | 42.9 | 39.4 | 41.4 | 30.0 | 39.3 | 41.9 |
| **9** | 65.0 | 60.6 | 65.4 | 57.1 | 51.3 | 55.2 | 55.0 | 51.8 | 56.2 |
| **18** | 80.0 | 77.1 | 84.4 | 71.4 | 71.3 | 76.4 | 70.0 | 71.0 | 76.4 |

**Phytotoxicity and plant damage**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Appl. Rate (kg/ha)** | **Soybean** | | **Oilseed rape** | | **Onion** | |
| **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** |
| **Ctrl** | 0.00 | N | 0.00 | N | 0.00 | N |
| **1.125** | 0.00 | N | 0.00 | N | 0.00 | N |
| **2.25** | 2.5 | N,C | 0.00 | N | 0.71 | N,C |
| **4.5** | 9 | N,C,Ld | 5.71 | N,C | 7.5 | N,C,Ld |
| **9** | 14.38 | C,Ld,Sd | 7.86 | N,C,Ld | 17.5 | C,Ld |
| **18** | 27.5 | C,Ld,Sd,W | 18 | C,Ld,Sd,Ne | 28.33 | C,Ld,Sd,W |
| **Appl. Rate (kg/ha)** | **Oats** | | **Lettuce** | | **Sugar beet** | |
| **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** |
| **Ctrl** | 0.00 | N | 0.00 | N | 0.00 | N |
| **1.125** | 0.00 | N | 0.00 | N | 0.00 | N |
| **2.25** | 3.75 | N,C | 1.43 | N,C | 1.5 | N,C |
| **4.5** | 10 | C,Ld | 4.29 | N,C,Ld | 9.5 | N,C |
| **9** | 20 | C,Ld,Sd | 11.43 | C,Ld | 14.38 | C,Ld,Sd |
| **18** | 31.67 | C,Ld,Sd,W | 26.67 | C,Ld,Sd,Ne | 19.17 | C,Ld,Sd,Ne |

N: normal; C: chlorosis; Ld: leaf deformation; Sd: stem deformation; Ne: necrosis; W: wilting

**Pendimethalin 455 g/L CS: the ER10, ER25, ER50, NOER values.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Endpoint value** | | **Soybean (*Glycine max*)** | | **Oilseed rape (*Brassica napus*)** | **Onion (*Allium cepa*)** | **Oats**  **(*Avena sativa)*** | **Lettuce**  **(*Lactuca sativa*)** | **Sugar beet (*Beta vulgaris*)** |
| **Plant number at the end of the experiment** | | | | | | | | |
| **ER10** | kg/haa | 1.307 | | 1.468 | 1.371 | 1.371 | 1.487 | 1.886 |
| kg/hab | 0.6 | | 0.7 | 0.6 | 0.6 | 0.7 | 0.9 |
| **ER25** | kg/haa | 2.813 | | 3.108 | 2.758 | 2.758 | 3.197 | 3.902 |
| kg/hab | 1.3 | | 1.4 | 1.3 | 1.3 | 1.5 | 1.8 |
| **ER50** | kg/haa | 6.589 | | 7.152 | 5.993 | 5.993 | 7.482 | 8.752 |
| kg/hab | 3.0 | | 3.3 | 2.7 | 2.7 | 3.4 | 4.0 |
| **NOER** | kg/haa | 2.25 | | 2.25 | 2.25 | 2.25 | 2.25 | 2.25 |
| kg/hab | 0.5 | | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| **Shoot length (plants without roots)** | | | | | | | | |
| **ER10** | kg/haa | 1.259 | 1.296 | | 1.165 | 1.130 | 1.288 | 1.551 |
| kg/hab | 0.6 | 0.6 | | 0.5 | 0.5 | 0.6 | 0.7 |
| **ER25** | kg/haa | 2.761 | 2.828 | | 2.542 | 2.510 | 3.019 | 3.380 |
| kg/hab | 1.3 | 1.3 | | 1.2 | 1.1 | 1.4 | 1.5 |
| **ER50** | kg/haa | 6.611 | 6.726 | | 6.052 | 6.096 | 7.783 | 8.031 |
| kg/hab | 3.0 | 3.1 | | 2.8 | 2.8 | 3.5 | 3.7 |
| **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 |
| kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 |
| **Plant dry weight (plants without roots)** | | | | | | | | |
| **ER10** | kg/haa | 1.312 | 1.534 | | 1.081 | 1.237 | 1.352 | 1.747 |
| kg/hab | 0.6 | 0.7 | | 0.5 | 0.6 | 0.6 | 0.8 |
| **ER25** | kg/haa | 2.618 | 3.352 | | 2.256 | 2.474 | 2.926 | 3.430 |
| kg/hab | 1.2 | 1.5 | | 1.0 | 1.1 | 1.3 | 1.6 |
| **ER50** | kg/haa | 5.639 | 7.985 | | 5.112 | 5.342 | 6.896 | 7.260 |
| kg/hab | 2.6 | 3.6 | | 2.3 | 2.4 | 3.1 | 3.3 |
| **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 |
| kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 |

a: value for the test item, i.e. Pendimethalin 455 g/l CS expressed as Kg/ha

b: value for active substance, i.e. Pendimethalin expressed as Kg/ha

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | The study is considered valid. All validity criteria were met.  **Agreed endpoins:**  **Pendimethalin 455 g/L CS: the ER10, ER25, ER50, NOER values.**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Endpoint value** | | **Soybean (*Glycine max*)** | | **Oilseed rape**  **(*Brassica napus*)** | **Onion (*Allium cepa*)** | **Oats (*Avena sativa*)** | **Lettuce (*Lactuca sativa*)** | **Sugar beet (*Beta vulgaris*)** | | **Plant number** | | | | | | | | | | **ER10** | kg/haa | 1.733 | 1.231 | | 1.308 | 0.989 | 1.734 | 1.595 | | kg/hab | 0.8 | 0.6 | | 0.6 | 0.5 | 0.8 | 0.7 | | **ER25** | kg/haa | 3.576 | 2.860 | | 2.819 | 2.203 | 3.559 | 3.554 | | kg/hab | 1.6 | 1.3 | | 1.3 | 1.0 | 1.6 | 1.6 | | **ER50** | kg/haa | 7.996 | 7.295 | | 6.613 | 5.362 | 7.915 | 8.658 | | kg/hab | 3.6 | 3.3 | | 3.0 | 2.4 | 3.6 | 3.9 | | **NOER** | kg/haa | 2.25 | 2.25 | | 2.25 | 1.125 | 2.25 | 2.5 | | kg/hab | 1.0 | 1.0 | | 1.0 | 0.5 | 1.0 | 1.1 | | **Shoot length (plants without roots)** | | | | | | | | | | **ER10** | kg/haa | 1.315 | 1.509 | | 1.192 | 1.197 | 1.610 | 1.757 | | kg/hab | 0.6 | 0.7 | | 0.5 | 0.5 | 0.7 | 0.8 | | **ER25** | kg/haa | 2.757 | 3.075 | | 2.493 | 2.402 | 3.261 | 3.467 | | kg/hab | 1.3 | 1.4 | | 1.1 | 1.1 | 1.5 | 1.6 | | **ER50** | kg/haa | 6.272 | 6.781 | | 5.660 | 5.208 | 7.143 | 7.377 | | kg/hab | 2.9 | 3.1 | | 2.6 | 2.4 | 3.3 | 3.4 | | **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 | | kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 | | **Plant dry weight (plants without roots)** | | | | | | | | | | **ER10** | kg/haa | 1.357 | 1.466 | | 1.124 | 1.161 | 1.508 | 1.639 | | kg/hab | 0.6 | 0.7 | | 0.5 | 0.5 | 0.7 | 0.7 | | **ER25** | kg/haa | 2.919 | 3.202 | | 2.317 | 2.326 | 3.202 | 3.434 | | kg/hab | 1.3 | 1.5 | | 1.1 | 1.1 | 1.5 | 1.6 | | **ER50** | kg/haa | 6.835 | 7.631 | | 5.176 | 5.036 | 7.394 | 7.810 | | kg/hab | 3.1 | 3.5 | | 2.4 | 2.3 | 3.4 | 3.6 | | **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 | | kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 |   a: value for the test item, i.e. Pendimethalin 455 g/L CS expressed as kg/ha  b: value for active substance, i.e. Pendimethalin expressed as kg/ha  The visual phytotoxic effects are covered by the lowest of the presented endpoints for each species. The additional risk assessment required. |

|  |  |
| --- | --- |
| **Reference:** | KCP 10.6.2-02 |
| **Report:** | “Effect of Pendimethalin 455 g/l CS on vegetative vigour of terrestrial plants”.  S. Radha, 9420/2021, 2021. Bioscience Research Foundation |
| **Guideline(s):** | OECD No. 227 (2006) |
| **Deviations:** | No |
| **GLP:** | Yes |
| **Acceptability:** | Yes |
| **Duplication  (if vertebrate study):** | No |

**Summary**

The study, aimed at evaluating the effect of Pendimethalin 455 g/L CS on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the plant leaf surface. For each species, five application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots (3 seeds/pot, i.e. 21 seeds/application rate (7 pots/application rate) for oilseed rape and lettuce, 2 seeds/pot i.e. 20 seeds/application rate (10 pots/application rate) for soybean and sugar beet and 5 seeds/pot i.e. 20 seeds/application rate (4 pots/application rate) for onion and oats). The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application) and mortality. The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER.

**Material and methods**

Test item: Name: Pendimethalin 455 g/L CS

Batch number: SCL - 80067

Manufacturing date: 18th May 2020

Expiry date: 17th May 2022

Test species: Soybean (*Glycine max*), Oilseed rape (*Brassica napus*), Onion (*Allium cepa*), Oats (*Avena sativa*), Lettuce (*Lactuca sativa*), Sugar beet (*Beta vulgaris*)

Test design: Number of rates: 5 application rates + control

Number of replicates: 4, 7, 10 per application  
Number of seeds: 20, 21 per application

Test termination: 21 days after the spraying

Application rates: Control (test soil without test item), 1.125, 2.25, 4.5, 9 and 18 kg/ha Pendimethalin 455 g/L CS

Soil: sandy loam soil soil containing 1.2% organic carbon, the soil was sieved it to 2 mm particle size

Endpoints: ER10, ER25, ER50, NOER

Test conditions: Temperature: 20.5°C – 22.6°C

Humidity: 54.5 – 65.6

Photoperiod: 16 hours light / 8 hours darkness

Light intensity: 328–400 µE/m2/s

Carbon dioxide concentration: 332–350 ppm

Statistical analysis: Probit analysis in the NCSS and one-way ANOVA using GraphPad Prism 8.0

Validity criteria: - the seedling emergence in the control (validity criterion: at least 70%) was as follows:

- 100% – Soybean,

- 100% – Oilseed rape,

- 100% – Onion,

- 100% – Oats,

- 100% – Lettuce,

- 100% – Sugar beet,

- the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%)

- the control seedlings did not exhibit any visible phytotoxic symptoms

- environmental conditions for all plants belonging to the same species were identical

**Findings**

**Compared effect to the control (%)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Appl. Rate (kg/ha)** | **Soybean** | | | **Oilseed rape** | | | **Onion** | | |
| **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** |
| **Ctrl** | - | - | - | - | - | - | - | - | - |
| **1.125** | 5.0 | 4.6 | 3.8 | 9.5 | 3.2 | 1.5 | 5.0 | 4.6 | 4.0 |
| **2.25** | 15.0 | 22.9 | 22.1 | 19.0 | 19.8 | 21.5 | 20.0 | 25.4 | 27.9 |
| **4.5** | 30.0 | 43.2 | 42.0 | 38.1 | 39.9 | 41.5 | 45.0 | 48.5 | 54.4 |
| **9** | 55.0 | 61.1 | 57.5 | 52.4 | 60.2 | 53.0 | 60.0 | 65.8 | 67.3 |
| **18** | 75.0 | 78.5 | 75.5 | 76.2 | 77.0 | 71.5 | 75.0 | 78.9 | 80.8 |
| **Appl. Rate (kg/ha)** | **Oats** | | | **Lettuce** | | | **Sugar beet** | | |
| **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** | **Plant nº** | **Shoot lenght** | **Plant weight** |
| **Ctrl** | - | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| **1.125** | 10.0 | 3.9 | 3.4 | 4.8 | 3.0 | 4.5 | 5.0 | 1.6 | 1.8 |
| **2.25** | 25.0 | 25.9 | 28.5 | 14.3 | 17.7 | 19.0 | 15.0 | 16.2 | 19.0 |
| **4.5** | 50.0 | 53.6 | 54.6 | 33.3 | 38.3 | 36.0 | 35.0 | 37.1 | 36.4 |
| **9** | 65.0 | 68.1 | 68.4 | 52.4 | 58.4 | 56.2 | 50.0 | 59.2 | 54.5 |
| **18** | 80.0 | 81.8 | 82.7 | 76.2 | 76.1 | 75.1 | 70.0 | 74.8 | 72.6 |

**Phytotoxicity and plant damage**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Appl. Rate (kg/ha)** | **Soybean** | | **Oilseed rape** | | **Onion** | |
| **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** |
| **Ctrl** | 0.0 | N | 0.0 | N | 0.0 | N |
| **1.125** | 0.0 | N | 0.0 | N | 0.0 | N |
| **2.25** | 0.0 | N | 0.0 | N | 6.25 | N,C |
| **4.5** | 8.0 | N,C | 8.57 | N,C,Ld | 16.25 | C,Ld,Sd |
| **9** | 12.78 | N,C,Ld | 15.71 | C,Ld,Sd | 22.5 | C,Ld,Sd |
| **18** | 27.0 | C,Ld,Sd,W | 26.0 | C,Ld,Sd,Ne | 28.75 | C,Ld,Sd,W |
| **Appl. Rate (kg/ha)** | **Oats** | | **Lettuce** | | **Sugar beet** | |
| **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** | **Mean effect (%)** | **Symptoms** |
| **Ctrl** | 0.0 | N | 0.0 | N | 0.0 | N |
| **1.125** | 0.0 | N | 0.0 | N | 0.0 | N |
| **2.25** | 6.25 | N,C | 2.14 | N,C | 0.0 | N |
| **4.5** | 17.5 | C,Ld | 8.57 | N,C | 8 | N,C,Ld |
| **9** | 23.75 | C,Ld | 15 | C,Ld,Sd | 16.88 | N,C,Ld |
| **18** | 30.0 | C,Ld,Sd,Ne | 27.0 | C,Ld,Sd,Ne | 23.0 | C,Ld,Sd,Ne |

N: normal; C: chlorosis; Ld: leaf deformation; Sd: stem deformation; Ne: necrosis; W: wilting

**Pendimethalin 455 g/L CS: the ER10, ER25, ER50, NOER values.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Endpoint value** | | **Soybean (*Glycine max*)** | | **Oilseed rape**  **(*Brassica napus*)** | **Onion (*Allium cepa*)** | **Oats (*Avena sativa*)** | **Lettuce (*Lactuca sativa*)** | **Sugar beet (*Beta vulgaris*)** |
| **Plant number** | | | | | | | | |
| **ER10** | kg/haa | 1.733 | 1.231 | | 1.308 | 0.989 | 1.734 | 1.595 |
| kg/hab | 0.8 | 0.6 | | 0.6 | 0.5 | 0.8 | 0.7 |
| **ER25** | kg/haa | 3.576 | 2.860 | | 2.819 | 2.203 | 3.559 | 3.554 |
| kg/hab | 1.6 | 1.3 | | 1.3 | 1.0 | 1.6 | 1.6 |
| **ER50** | kg/haa | 7.996 | 7.295 | | 6.613 | 5.362 | 7.915 | 8.658 |
| kg/hab | 3.6 | 3.3 | | 3.0 | 2.4 | 3.6 | 3.9 |
| **NOER** | kg/haa | 2.25 | 2.25 | | 2.25 | 1.125 | 2.25 | 2.5 |
| kg/hab | 1.0 | 1.0 | | 1.0 | 0.5 | 1.0 | 1.1 |
| **Shoot length (plants without roots)** | | | | | | | | |
| **ER10** | kg/haa | 1.315 | 1.509 | | 1.192 | 1.197 | 1.610 | 1.757 |
| kg/hab | 0.6 | 0.7 | | 0.5 | 0.5 | 0.7 | 0.8 |
| **ER25** | kg/haa | 2.757 | 3.075 | | 2.493 | 2.402 | 3.261 | 3.467 |
| kg/hab | 1.3 | 1.4 | | 1.1 | 1.1 | 1.5 | 1.6 |
| **ER50** | kg/haa | 6.272 | 6.781 | | 5.660 | 5.208 | 7.143 | 7.377 |
| kg/hab | 2.9 | 3.1 | | 2.6 | 2.4 | 3.3 | 3.4 |
| **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 |
| kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 |
| **Plant dry weight (plants without roots)** | | | | | | | | |
| **ER10** | kg/haa | 1.357 | 1.466 | | 1.124 | 1.161 | 1.508 | 1.639 |
| kg/hab | 0.6 | 0.7 | | 0.5 | 0.5 | 0.7 | 0.7 |
| **ER25** | kg/haa | 2.919 | 3.202 | | 2.317 | 2.326 | 3.202 | 3.434 |
| kg/hab | 1.3 | 1.5 | | 1.1 | 1.1 | 1.5 | 1.6 |
| **ER50** | kg/haa | 6.835 | 7.631 | | 5.176 | 5.036 | 7.394 | 7.810 |
| kg/hab | 3.1 | 3.5 | | 2.4 | 2.3 | 3.4 | 3.6 |
| **NOER** | kg/haa | 1.125 | 1.125 | | 1.125 | 1.125 | 1.125 | 1.125 |
| kg/hab | 0.5 | 0.5 | | 0.5 | 0.5 | 0.5 | 0.5 |

a: value for the test item, i.e. Pendimethalin 455 g/L CS expressed as kg/ha

b: value for active substance, i.e. Pendimethalin expressed as kg/ha

* + 1. KCP 10.6.3 Extended laboratory studies on non-target plants
  1. KCP 10.7 Effects on other terrestrial organisms (flora and fauna)
  2. KCP 10.8 Monitoring data

1. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. [↑](#footnote-ref-1)
2. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. [↑](#footnote-ref-2)
3. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. [↑](#footnote-ref-3)
4. Prosser P, 2010. Consolidation of bird and mammal PT data for use in risk assessment. UK Food and Environment Research Agency, London UK. [↑](#footnote-ref-4)
5. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009. Version 2.1, December 2021. <https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/cooperation-in-the-north-zone/> [↑](#footnote-ref-5)