FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 2619 A

Product name(s): KONARK

Chemical active substances:

Flufenacet, 60 g/L
Pendimethalin, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: May 2023

Version history

When	What
January 2022	Applicant Update
December 2022	Applicant update
January 2023	zRMS version for comments
May 2023	zRMS revision after commenting phase – final version of the RR

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9 Ecotoxicology (KCP 10)

9.1 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: develop-mental 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 arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	**Winter wheat**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							
2	CEU	**Winter wheat**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							
3	CEU	**Winter barley**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
4	CEU	**Winter barley**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							
5	CEU	**Winter rye**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							
6	CEU	**Winter rye**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							
7	CEU	**Triticale**	F	Broadleaved and grass weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							
8	CEU	**Triticale**	F	Broadleaved and grass weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages							

* 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

zRMS comments:

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

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), No acute risk was observed for birds after exposure to Flufenacet and Pendimethalin. However, long-term risk was observed and further refinement was needed. After the refinement DT50 and ftwa for Flufenacet and after refinement of the endpoint for Pendimethalin, the values were above the trigger showing an acceptable long-term risk for birds.

No risk from drinking water is expected and the risk for earthworm-eating birds was considered acceptable for Flufenacet, however unacceptable risk was detected for Pendimethalin. After refinement, no unacceptable risk was detected. No risk for birds of secondary poisoning via fish is expected.

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

- **Birds**

No acute risk was observed for birds after exposure to Flufenacet and Pendimethalin. However, long-term risk was observed and further refinement was needed. After the refinement DT50 and ftwa for Flufenacet and after refinement of the endpoint for Pendimethalin, the values were above the trigger showing an acceptable long-term risk for birds.

No risk from drinking water is expected and the risk for earthworm-eating birds was considered acceptable for Flufenacet, however unacceptable risk was detected for Pendimethalin. After refinement, no unacceptable risk was detected. No risk for birds of secondary poisoning via fish is expected.

- **Mammals**

No acute and long-term risk were observed for mammals after exposure to Flufenacet.
Regarding Pendimethalin, acute risk was not observed, however, long-term risk was observed and further refinement was needed. After the refinement the value was above the trigger showing an acceptable long-term risk for mammals.

However, use refinement long-term risk assement for pendimethalin for post-emergence applications of Konark in winter cereals should be decided at national level.

No risk from drinking water is expected and the risk for earthworm-eating mammals was considered acceptable for Flufenacet, however unnacceptable risk was detected for Pendimethalin. After refine-ment, no unacceptable risk was detected. No risk for mammals of secondary poisoning via fish is expected.

9.1.1.3 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.*

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

Regarding **Flufenacet,** for the intended use in spring cereals, calculated PEC/RAC ratios indicated an

acceptable risk for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton as characterised by a NOEC of 0.012 mg a.s./L in connection with an assessment factor of 3 for microcosms) all FOCUS Steps 3 scenarios. Therefore, a further refinement is not needed. For the intended use in winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton as characterised by a NOEC of 0.012 mg a.s./L in connection with an assessment factor of 3 for microcosms) in several FOCUS Steps 3 scenarios (D1 ditch, D2 ditch, D2 stream, D6 ditch and R3 stream). Therefore, PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, an unacceptable risk was identified for D1 ditch, D2 ditch, D2 stream and D6 ditch scenarios for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton). These scenarios are not relevant under CEU conditions. Regarding R scenarios, the risk was acceptable according to the following risk mitigation measures:

- R1 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.
- R3 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.

Concerning Flufenacet metabolites, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish and algae as characterised by an LC_{50}/EC_{50} for *Oncorhynchus mykiss* and *Pseudokirchneriella subcapitata* of 9100 µg/L and 83800 µg/L in connection with an assessment factor of 100 and 10, respectively) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment was necessary.

Regarding **Pendimethalin**, For the intended uses on winter and spring cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for algae as characterised by an EC_{50} for *P. subcapitata* of 9.3 µg/L in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, PEC/RAC ratios were <1 when the following risk mitigation options are considered:

Winter cereals

- D1 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D4 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D5 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D6 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- R1 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are consid-

ered.

- R3 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 20 m no spray buffer zone together with 20 m vegetated filter strip are considered.
- R3 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.

Spring cereals

- D1 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D4 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D5 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- R1 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.
- R4 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are consid

WINTER CEREALS

For the intended use in <u>winter cereals (pre emergence use)</u>, the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D4 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D4 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D5 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 10 m no spray vegetated buffer zone together with 75% of nozzles reduction

or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered.

- R3 stream: 15 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered
- R3 stream: 15 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered

For the intended use in <u>winter cereals (post-emergence use)</u>, the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D4 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D4 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D5 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 pond: 10 m no spray vegetated buffer zone or 5 m no spray vegetated buffer zone together with 50% of nozzles reduction are considered.
- R1 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 15 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.
- R3 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 20 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.
- R3 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 15 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.

The mitigation measures should be considered by member states that comply with their national requirements.

Concerning Pendimethalin metabolites, for metabolite M455H001 calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary. For metabolites M455H033, M455H032 and M455H029, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 3 scenarios. Therefore, no further assessment is necessary.

Regarding **KONARK**, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC_{50} for *Oncorhynchus mykiss* of 483.3

µg/L in connection with an assessment factor of 100) following the next mitigation measures: 10 m no spray buffer zone or 5m no spray buffer zone with the use of 50% NR.
Acceptable risk was obtained due to combined exposure.

Conclusions

Winter cereals– Spe3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 75% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies.*
Spring cereals– Spe3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies.*

zRMS comments:

The final risk mitigation measures should be considered at MSs level.
It is noted that mitigation measures might be envisaged by other member states that comply with their national requirements. Furthermore, member states might check if the scenarios for which an unacceptable risk was indicated are relevant according to their national requirements.

9.1.1.5 Effects on bees (KCP 10.3.1)

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

However, no risk assessment for larvae can be proposed as the toxicity study for larvae is considered not sufficient by zRMS to address the possible effects of the formulation on larval development.
The EFSA bee GD (2013) is not implemented and currently is undergoing a revision. Therefore, no risk assessment are included.
According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant should provide the chronic test on bees and chronic test for larvae for formulated product.

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

zRMS comments:

The HQ values based on the acute oral/contact LD_{50} are below the trigger of 50 for both active substances (pendimethalin and flufenacet) and the formulation for oral and acute toxicity showing an acceptable risk to bees after the application of Konark.

No risk assessment for larvae can be proposed as the toxicity study for larvae is considered not sufficient by zRMS to address the possible effects of the formulation on larval development.
The EFSA bee GD (2013) is not implemented and currently is undergoing a revision. Therefore, no risk assessment are included.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant should provide the chronic test on bees and chronic test for larvae for formulated product.

Toxicity endpoints for chronic effects of on larvae and worker honeybees with the mixed formulation

KONARK are not available. Therefore, the specific requirements of the Regulation (EU) 284/2013 with regard to effects on bee brood development and possible chronic effects on adults are not fulfilled. Chronic toxicity data are available for each of the two active substances. However, according to the Regulation testing is required for plant protection products which contain more than one active substance.
There is currently no EU accepted guidance which can be used to provide a complete chronic risk assessment

9.1.1.7 Effects on arthropods other than bees (KCP 10.3.2)

The results of the risk assessment show no risk ~~in field and~~ off-field for *T.Pyri* and *Aphidius rhopalosiphi* when exposed to KONARK according to the proposed GAP.
The risk to non-target arthropods from the use of the product cannot be resolved as an unacceptable risk on standard species and *Coccinella septempunctata* in the in-field area was identified**.**
Additional toxicity data (aged-residue studies) are necessary for formulation Konark.

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

Studies on the toxicity to earthworms and other non-target soil organisms show that Flufenacet and Pendimethalin hazard toxicity exposure ratios are clearly over the cut-off value. An application of KONARK in respect of the GAP does not present an unacceptable long-term risk for earthworms and other soil macrofauna.

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

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

zRMS comments:

Konark has no significant effect on soil micro-organisms at 141.35 mg a.s./kg dry soil.
Based on it, can be concluded that Konark under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

The calculated TER values are below the Annex VI trigger of 5 for seedling emergence and vegetative vigour when a distance of 1 m is considered. Therefore, no potential risk to non-target plants located outside the treated area after application of KONARK according to the GAP table is expected when risk mitigation measures are considered.

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles*.

zRMS comments:

The final risk mitigation measures should be decided at MSs level.

9.1.1.11 The calculated TER values are below the Annex VI trigger of 5 for seedling emergence and vegetative vigour when a distance of 1 m is considered. Therefore, no potential risk to non-target plants located outside the treated area after application of KONARK according to the GAP table is expected when risk mitigation measures are considered.

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles*.

zRMS comment:

The risk assessment is based on the "Guidance Document Terrestrial Ecotoxicology", (SAN-CO/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.
SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles.*

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zRMS comment:

Risk assessment in base phytotoxicity effect:
ER_{50} values for phytotoxicity based on visual effect, estimated by RMS *(where it could be determined):*

Vegetative vigour test:
Sunflower ER_{50} > 1333.33 mL/ha
Perennial ryegrass ER_{50} > 444.44 ml/ha

Seedling emergence test:
Perennial ryegrass ER_{50} > 444.44 ml/ha
Oats ER_{50} > 444.44 ml/ha

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 1m to non-agricultural land OR*

Intended use		Cereals			
Product		KONARK			
Application rate (mL f.p./ha)		1 x 4000			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	110.80	55.40	27.70	11.08
5	0.57	22.80	11.40	5.70	2.28
Toxicity value		**TER**			
ER_{50} = 444.44g/ha		**criterion: TER ≥ 5**			
1/3		**4.0**	8.0	16.1	46.5
5		19.5	39.0	78.0	194.9

the use of 50% drift reducing nozzles.

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

Not relevant.

9.1.2 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 KONARK grouped according to crop group

Grouping according to crop group			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Bare soil	Winter wheat, winter barley, winter rye and triticale	1 x 4.0 L f.p./ha (equivalent to 240 g Flufenacet/ha + 1200 g Pendimethalin/ha)	Birds and mammals
Cereals	Winter wheat, winter barley, winter rye and triticale	1 x 4.0 L f.p./ha (equivalent to 240 g Flufenacet/ha + 1200 g Pendimethalin/ha)	Birds and mammals

9.1.3 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 KONARK is indicated in the table.

Table 9.1-3 Metabolites of Flufenacet

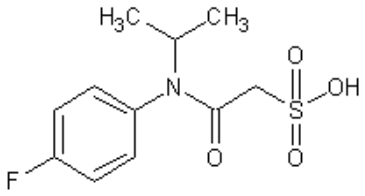
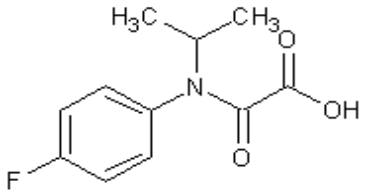
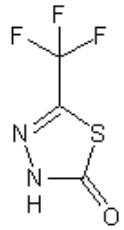
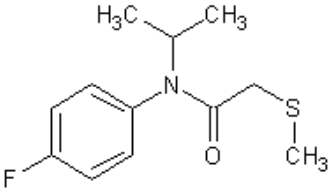
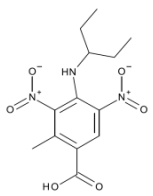
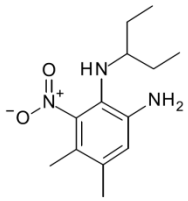
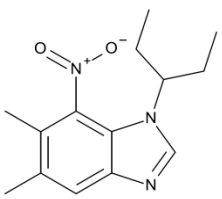
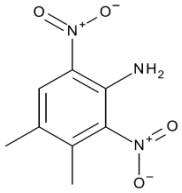
Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
FOE sulfonic acid (M2)	275.30		Soil: 26.3%	Yes
FOE oxalate (M1)	225.22		Soil: 15.6%	Yes
Thiadone (M9)	170.11		Water: 82% Sediment: <10%	Yes
FOE Methylsulfide (M5)	241.33		Water: 8% Sediment: 3.4%	Yes

Table 9.1-4 Metabolites of Pendimethalin

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
M455H001	311.1		Soil: 6.9 % Water/sediment: 0.00001 %	Yes
P48 (M455H033)	251.3		Soil: 25.9 % Water/sediment: 12.1%	Yes
P36 (M455H029; M12)	261.3		Soil: 0.00001% Water/sediment: 23.4%	Yes

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
2,6-dinitro-3,4-dimethylaniline (aqueous photolysis metabolite)	211.2		Soil: 0.00001% Water/sediment: 14.2 %	Yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

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

Effects on birds of KONARK were not evaluated as part of the EU assessment of Flufenacet and Pendimethalin. 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
Bobwhite quail	Flufenacet	Acute	LD_{50} = **1608 mg/kg bw**	Review Report 7469/VI/98-Final
Mallard duck	Flufenacet	Dietary	LC_{50} > 4970 ppm	Review Report 7469/VI/98-Final
Mallard duck	Flufenacet	Reproductive toxicity	NOEC = 88 ppm (88 mg/kg feed) = **9.87 mg/kg bw/d***	Review Report 7469/VI/98-Final
Anas platyrhynchos	Pendimethalin	Acute	LD_{50} = **1421 mg/kg bw/d**	EFSA Journal 2016;14(3):4420
Anas platyrhynchos	Pendimethalin	Short-term	LC_{50} > 4640 ppm	EFSA Journal 2016;14(3):4420
Colinus virginianus	Pendimethalin	Short-term	LC_{50} > 4187 ppm	EFSA Journal 2016;14(3):4420
Anas platyrhynchos	Pendimethalin	Long-term	NOEC = 141 ppm NOEL = **17.5 mg/kg bw/d**	EFSA Journal 2016;14(3):4420
Colinus virginianus	Pendimethalin	Long-term	NOEC = 1410 ppm NOEL = 141 mg/kg bw/d	EFSA Journal 2016;14(3):4420

*in the Review Report, the NOEL was expressed in ppm. The conversion to daily dose to 9.87 mg/kg bw/d was agreed by RMS France in zonal assessment.

9.2.1.1 Justification for new endpoints

Not relevant. EU agreed endpoints are used.

9.2.2 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).

9.2.2.1 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 KONARK in bare soil (cereals in pre-emergence)

Intended use	**Bare soil (cereals in pre-emergence)**				
Active substance/product	Flufenacet				
Application rate (g/ha)	1 x 240				
Acute toxicity (mg/kg bw)	1608				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH < 10	Small granivorous bird “finch” Small seeds 100% weed seeds	24.7	1.0	5.93	271.3
Bare soil BBCH < 10	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	10.9	1.0	2.62	614.7
Bare soil BBCH < 10	Small omnivorous birds “lark” combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	17.4	1.0	4.18	385.1
Reprod. toxicity (mg/kg bw/d)	9.87				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soil BBCH < 10	Small granivorous bird “finch” Small seeds 100% weed seeds	11.4	1.0 × 0.53	1.45	6.8
Bare soil BBCH < 10	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	5.9	1.0 × 0.53	0.75	13.2
Bare soil BBCH < 10	Small omnivorous birds “lark” combination (ground invertebrates without	8.2	1.0 × 0.53	1.04	9.5

	interception) 50% seeds, 50% ground arthropods				
Intended use	**Bare soil (cereals in pre-emergence)**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1200				
Acute toxicity (mg/kg bw)	1421				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH < 10	Small granivorous bird "finch" Small seeds 100% weed seeds	24.7	1.0	29.64	47.9
Bare soil BBCH < 10	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	10.9	1.0	13.08	108.6
Bare soil BBCH < 10	Small omnivorous birds "lark" combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	17.4	1.0	20.88	68.1
Reprod. toxicity (mg/kg bw/d)	17.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soil BBCH < 10	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	1.0 × 0.53	7.25	**2.4**
Bare soil BBCH < 10	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9	1.0 × 0.53	3.75	**4.7**
Bare soil BBCH < 10	Small omnivorous birds "lark" combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	8.2	1.0 × 0.53	5.22	**3.4**

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 KONARK in cereals

Intended use	**Cereals**				
Active substance/product	Flufenacet				
Application rate (g/ha)	1 x 240				
Acute toxicity (mg/kg bw)	1608				
TER criterion	10				
Crop scenario	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90}**	**TER_a**

Growth stage				**(mg/kg bw/d)**	
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" 100% cereal shoots	30.5	1.0	7.32	219.7
Cereals BBCH 10 – 29	Small omnivorous bird “lark”	24.0	1.0	5.76	279.2
Reprod. toxicity (mg/kg bw/d)	9.87				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" 100% cereal shoots	16.2	1.0 × 0.53	2.06	**4.8**
Cereals BBCH 10 – 29	Small omnivorous bird “lark”	10.9	1.0 × 0.53	1.39	7.1
Intended use	**Cereals**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1200				
Acute toxicity (mg/kg bw)	1421				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" 100% cereal shoots	30.5	1.0	36.60	38.8
Cereals BBCH 10 – 29	Small omnivorous bird “lark”	24.0	1.0	28.80	49.3
Reprod. toxicity (mg/kg bw/d)	17.5				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" 100% cereal shoots	16.2	1.0 × 0.53	10.30	**1.7**
Cereals BBCH 10 – 29	Small omnivorous bird “lark”	10.9	1.0 × 0.53	6.93	**2.5**

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.

Risk Assessment for combined exposure

According to the EFSA Journal (2009)[1], the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD_{50} for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. For the calculation, the following equation was used:

$$LD_{50}(\text{mix}) = \left(\sum_{i} \frac{X(\text{a.s.}_i)}{LD_{50}(\text{a.s.}_i)} \right)^{-1}$$

With:

$X(\text{a.s.}_i)$ = fraction of each a.s. in the mixture

$LD_{50}(\text{a.s.}_i)$ = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation KONARK addressed in this dossier is 6 % Flufenacet and 30 % Pendimethalin, making up a total of 360 g a.s./L product. According to GAP, the maximum application rate is 2.5 L product/ha, therefore, application rate of 1440 g a.s./ha was considered in the assessment.

Table 9.2-4 shows the calculation of the predicted LD_{50} (mix) of Flufenacet and Pendimethalin when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

Table 9.2-4:: Avian LD_{50} (mix) for Flufenacet and Pendimethalin when combined as KONARK (step 1 in EFSA GD 2009, Appendix B)

	Flufenacet	Pendimethalin
Content in the formulation KONARK	6%	30%
Fraction in the a.s. mixture	0.1667	0.8333
LD_{50} of a.s. [mg/kg bw]	1608	1421
Fraction / LD_{50}	0.00010	0.00059
Sum	0.00069009	
1/ sum = predicted LD_{50} (mix)	1449.09 mg mix/kg bw	

It is obvious from the comparison of the (low) acute oral toxicity of the active substances, and their relative proportions of the formulated product KONARK.

[1]European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.2-5: Avian "tox per fraction" for the KONARK (step 1 in EFSA GD 2009, Appendix B)

	Flufenacet	Pendimethalin	"mix"
Content in the formulation KONARK	6%	30%	36%
Fraction in mixture	0.1667	0.8333	1.0
LD_{50} (mg/kg bw)	1608	1421	1449.09
Tox per fraction	9648.00	1705.20	1449.09
Contribution to predicted toxicity	15.02 %	84.98 %	

Flufenacet contributes to 15.02 % to mixture toxicity, while the Pendimethalin have an impact on the predicted risk of 84.98 %, therefore, surrogate LD_{50} was used in the acute risk assessment.

Table 9.2-6: Screening risk assessment of the acute risk for birds due to the use of KONARK in bare soil (pre-emergence)

Intended use	**Bare soil (pre-emergence)**				
Active substance/product	KONARK				
Application rate (g/ha)	1 x 1440				
LD_{50} (mix) (mg/kg bw)	1449.09				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil	Indicator species for screening	25.3	1.0	36.43	39.8

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 9.2-7: Screening risk assessment of the acute risk for birds due to the use of KONARK in cereals

Intended use	**Cereals**				
Active substance/product	KONARK				
Application rate (g/ha)	1 x 1440				
LD_{50} (mix) (mg/kg bw)	1449.09				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" 100% cereal shoots	30.5	1.0	43.92	33.0
Cereals BBCH 10 – 29	Small omnivorous bird "lark"	24.0	1.0	34.56	41.9

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 results, no unacceptable acute risk is obtained in all intended uses acording to the proposed GAP.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TERmix value can only be used for illustrating purposes. Hence, in the case of an unacceptable TERmix, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

zRMS comments:

We agree with the acute combined risk assessment provided by the applicant.

zRMS agrees with the applicant that "according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect.

9.2.2.2 Higher-tier risk assessment

After Tier I risk assessment, unacceptable risk is detected for Flufenacet in cereals for large herbivorous bird "goose" and for Pendimethalin in bare soil (cereals pre-emergence) for small granivorous bird "finch" and in cereals post-emergence for large herbivorous bird "goose" and small omnivorous bird "lark". Therefore a refinement is needed and proposed below by the Applicant.

Flufenacet

DT50

In the Tier I risk assessment, for the dissipation and degradation of residues from plant material a default DT_{50} value of 10 days was assumed. The Applicant wishes to refer to report Toll, P. A. (1995) from the DAR of Flufenacet, *Volume 3 Annex B.8, Ecotoxicology*. This report consists of residue trials on avian forage and the availability of forage plants in corn field. The representative formulation FOE 5043 WG 60 is applied at 200-600 g a.s./ha. The samples of weeds were collected on days 0, 1, 3, 7 and 14 for residue analysis. The results obtained are presented in the table below:

Plot	Application rate (g a.s./ha)	Residues (mg/kg)	Time (days)	DT_{50} (days)
1	200	4.5 5.3 3.3 0.1 0.5	0 1 3 7 14	4.42
2	200	5.3 4.6 4.0 0.2 0.5	0 1 3 7 14	4.11
3	600	18.4 20.2 3.9 0.2 0.8	0 1 3 7 14	2.79

Plot	Application rate (g a.s./ha)	Residues (mg/kg)	Time (days)	DT_{50} (days)
4	600	13.0 12.8 1.5 2.0 1.0	0 1 3 7 14	3.78
Mean				**3.78**
Geo mean				3.72

Based on residue data in corn fields the initial foliar residues of flufenacet will decline a mean half-life of 3.78 days

TWA

In the Tier I assessment, a default TWA = 0.53 was used (estimates time-weighted exposure over 21 days, assuming a default DT_{50} of 10 days). However, the estimated decline of the residues of Flufenacet on corn fields is lower than the default value of 10 days. Considering a value of DT_{50} of 3.78 d, the TWA factor was re-calculated considering the formula of the EFSA/2009/1438, and the resulting TWA was 0.25. This value was used for the refinement.

Table 9.2-8: Higher-tier assessment of the long-term risk for birds due to the use of KONARK in cereals – refined parameters (*) are further described and justified in the text

Intended use **Active substance/product** **Application rate (g/ha)**	Cereals Flufenacet 1 × 240						
Reprod. toxicity (mg/kg bw/d) **TER criterion**	9.87 5						
Focal species	**Food category, % in diet**	**FIR/bw**	**RUD_m × DF** (mg/kg food)	**MAF_m × TWA***	**PT**	**DDD_m** (mg/kg bw/d)	**TER_{lt}**
Pink-foot goose (*Anser brachyrhynchus*)	100% cereal shoots	0.30	54.2 × 1.0	1.0 × 0.25[1]	1.0	0.98	10.1

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.
[1]Refinement of ftwa based on Toll, P. A. (1995) from Monograph of flufenacet.

zRMS comments:

The proposed refinement of the f_{TWA} is based on a DT_{50} app. of 3 days (3.78 d) that was derived from a residue study evaluated during the authorization of flufenacet (EU DAR, Volume 3, Annex B.8).
The respective study (Toll, 1995) was conducted in winter wheat fields in Stilwell, Kansas, US. Based on the provided information it cannot be retraced if the prevailing conditions during the study were representative for the conditions in the central zone of the EU. Hence, even though the study was conducted on the relevant crop (i.e. cereals), it cannot be excluded that a study conducted within the central zone of the EU would lead to higher residue levels. However, the determined results give indication that the DT_{50} for flufenacet in cereals is lower than the default DT_{50} of 10 days applied for the first-tier assessment. Taking into account the small margin between the TER calculated for the large herbivorous goose at first-tier (TER = 4.8) and the relevant trigger for the reproductive risk (i.e. 5); the information provided

by the respective study would still be evaluated as sufficient to conclude an acceptable risk for birds after use of Konark in cereals.
In zRMS's opinion the DT_{50} of 3d value in plants for a.s.- flufenacet cannot be used quantitatively but can be considered as part of a weight-of-evidence approach. Therefore, we do not apply this value in the risk assessment.

In conclusion:

The risk for birds is considered as acceptable.

Pendimethalin

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 $BMDL_5$ 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.

Table 9.2-9: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of KONARK in bare soil (cereals in pre-emergence) – refined parameters (*) are further described and justified in the text

Intended use	**Bare soil (cereals in pre-emergence)**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1200				
Reprod. toxicity (mg/kg bw/d)	61.5*				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soil BBCH < 10	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	1.0 × 0.53	7.25	8.5
Bare soil BBCH < 10	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9	1.0 × 0.53	3.75	16.4
Bare soil BBCH < 10	Small omnivorous birds "lark" combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	8.2	1.0 × 0.53	5.22	11.8

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.

Table 9.2-10: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of KONARK in cereals – refined parameters (*) are further described and justified in the text

Intended use	**Cereals**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1200				
Reprod. toxicity (mg/kg bw/d)	61.5*				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" 100% cereal shoots	16.2	1.0 × 0.53	10.30	6.0
Cereals BBCH 10 – 29	Small omnivorous bird “lark”	10.9	1.0 × 0.53	6.93	8.9

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.

zRMS comments:

*Considering the BMD approach, it is stated by the zRMS that the refined reproductive endpoint (61.5 mg/kg bw/day) was already applied in the refined long-term risk assessment for birds during EU evaluation of a.s. pendimethalin.

9.2.2.3 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 KONARK is not 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 202, Flufenacet (Review report flufenacet, 7469/VI/98-Final, 3 July 2003) belongs to the group of less sorptive substances.

Effective application rate (g/ha) =	240		

Acute toxicity (mg/kg bw)	=	1608	quotient	=	0.15
Reprod. toxicity (mg/kg bw/d)	=	9.87	quotient	=	24.32

With a K(f)oc of 13792 (EFSA Journal 2016;14(3):4420), Pendiethalin belongs to the group of more sorptive substances.

Effective application rate (g/ha)	=	1200			
Acute toxicity (mg/kg bw)	=	1421	quotient	=	0.84
Reprod. toxicity (mg/kg bw/d)	=	17.5	quotient	=	68.57

zRMS comments:

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical values of 3000 and 500 for flufenacet and pendimethalin, respectively, a quantitative risk assessment (calculation of TER values) is not required.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Flufenacet amounts to 3.2 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} 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.

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

Parameter	Flufenacet	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.280	PEC_{soil} twa 21 d of flufenacet (please refer to sec 8, Table 8.7-3)
log P_{ow} / P_{ow}	3.2 / 1584.89	Log Pow = 3.2 (Review report flufenacet, 7469/VI/98-Final, 3 July 2003). The Pow = 1584.89 was calculated from the log Pow value
Koc	202	Mean (n = 7) (Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
foc	0.02	Default
BCF_{worm}	4.92	$BCF_{worm/soil} = (C_{worm,ww}/C_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$

Parameter	Flufenacet	comments
PEC_{worm}	1.38	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	1.45	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	9.87	(Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
TER_{lt}	6.8	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

zRMS comments:

We agree with the risk assessment provided risk for earthworm-eating birds due to exposure to Flufenacet via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals.

Table 9.2-12: Assessment of the risk for earthworm-eating birds due to exposure to Pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in winter cereals

Parameter	Pendimethalin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	1.539	PEC_{soil} twa 21 d of pendimethalin (please refer to sec 8, Table 8.7-3)
log P_{ow} / P_{ow}	5.2	EFSA Journal 2016;14(3):4420. The Pow = 158489.32 was calculated from the log Pow value
Koc	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default
BCF_{worm}	6.90	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	10.62	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	11.15	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	17.5	EFSA Journal 2016;14(3):4420
TER_{lt}	**1.6**	Risk (TERlt<5)

TER values shown in bold fall below the relevant trigger.

Since the TER is below the trigger, further assessment with refined $BMDL_5$ value of 61.5 mg/kg bw/d was conducted

Table 9.2-13: Assessment of the risk for earthworm-eating birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in ornamentals

Parameter	Pendimethalin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	1.539	PEC_{soil} twa 21 d of pendimethalin (please refer to sec 8, Table 8.7-3)
log P_{ow} / P_{ow}	5.2	EFSA Journal 2016;14(3):4420. The Pow = 158489.32 was calculated from the log Pow value
Koc	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default

Parameter	Pendimethalin	comments
BCF_{worm}	6.90	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	10.62	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	11.15	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	61.5	EFSA Journal 2016;14(3):4420
TER_{lt}	5.5	Risk (TERlt<5)

TER values shown in bold fall below the relevant trigger.

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 PECs $_{accum.}$

Parameter	Pendimethalin	Comments
$PEC_{soil\ accumulation,}$ (mg/kg soil)	1.739	$PEC_{soil\ accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)
log P_{OW}; P_{OW}	5.4*; 251188	-
K_{OC}	13792	Arithmetic mean (n = 9)
f_{OC}	0.02	Default
BAF_{Worm}	2.44	Refined BAF; worst-case approach
PEC_{Worm}	1.739 x 2.44 = 4.24	$PEC_{worm} = PEC_{soil} \times BAF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	4.24 x 1.05 = 4.45	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	61.5	Refined endpoint: BMDL5
TER_{LT}	14.044	TER_{LT} = 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.

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

Parameter	Flufenacet	comments
PEC_{sw} (mg/L)	0.02519	21 – d PECsw $_{TWA}$ flufenacet step 2 – winter cereals for NEU (please refer to sec 8, table 8.9-4)
BCF_{fish}	71.4	(Review report flufenacet, 7469/VI/98-Final, 3 July

Parameter	Flufenacet	comments
		2003).
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	1.80	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.29	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	9.87	(Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
TER_{lt}	34.5	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

zRMS comment:

We agree with the risk assessment provided risk for fish-eating birds due to exposure to Flufenacet via bioaccumulation in fish (secondary poisoning) is considered as acceptable for intended use of Konark.

Table 9.2-15: Assessment of the risk for fish-eating birds due to exposure to Pendimethalin via bioaccumulation in fish (secondary poisoning) for the intended use in winter cereals

Parameter	Pendimethalin	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00940	21 – d PECsw $_{TWA}$ pendimethalin ~~flufenacet~~ step 2 – winter cereals for NEU (please refer to sec 8, table 8.9-14)
BCF_{fish}	931	EFSA Journal 2016;14(3):4420 (most reliable endpoint)

BMF	CT_{50}=5.1 days, 1.34 d ; 2.5 – 4.4 d CT_{90}: 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*, BMF_{KGL}= 0.1054 *Oncorhynchus mykiss* BMF_{KGL}= 0.0402 BMF_{KGL}= 0.0423 Outdoor mesocosms *Leuciscus idus melanotus* mean $BCF_{actual\ conc}$ = 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
PEC_{fish}	8.75	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	1.39	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	17.5	EFSA Journal 2016;14(3):4420
TER_{lt}	12.6	Risk (TERlt<5)

TER values shown in bold fall below the relevant trigger.

zRMS comment:

zRMS verified the risk for earthworm-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**
PEC_{SW} (mg/L)	0.01173	FOCUS Step 2, winter cereals, Max PEC_{SW}
BCF_{Fish}	931 / 3300*	Lowest and highest available BCF values
PEC_{Fish}	10.92/ 38.70	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	1.73 / 6.15	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	61.5	Refined endpoint: BMDL5
TER_{LT}	5.63/ 10	TER_{LT} = 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 birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable.

9.2.2.5 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"*

zRMS comments:
please see above.

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

Not relevant.

9.2.4 Overall conclusions

No acute risk was observed for birds after exposure to Flufenacet and Pendimethalin. However, long-term risk was observed and further refinement was needed. After the refinement DT50 and ftwa for Flufenacet and after refinement of the endpoint for Pendimethalin, the values were above the trigger showing an acceptable long-term risk for birds.

No risk from drinking water is expected and the risk for earthworm-eating birds was considered acceptable for Flufenacet, however unacceptable risk was detected for Pendimethalin. After refinement, no unacceptable risk was detected. No risk for birds of secondary poisoning via fish is expected.

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

9.3.1 Toxicity data

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

Effects on mammals of KONARK were not evaluated as part of the EU assessment of Flufenacet and Pendimethalin. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

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
Rat	Flufenacet	Acute	**LD_{50}: 589 mg/kg bw**	Review Report (7469/VI/98-Final – 03/07/2003)
Rat, rabbit	Flufenacet	Reproduction	**NOEL = 37.4 mg/kg bw**	DAR
Mouse	Pendimethalin	Acute	LD_{50} (male) = 3399 mg/kg bw LD_{50} (female) = 2899 mg/kg bw LD_{50} (combined) = 3189 mg/kg bw	EFSA Journal 2016;14(3):4420
Rat	Pendimethalin	Acute	LD_{50} (male) > 5000 mg/kg bw/d LD_{50} (female) > 5000 mg/kg bw/d LD_{50} (combined) > 5000 mg/kg bw/d	EFSA Journal 2016;14(3):4420
Rat	Pendimethalin	Acute	LD_{50} (male) = 4665 mg/kg bw/d LD_{50} (female) = 5000 mg/kg bw/d LD_{50} (combined) = 4830 mg/kg bw/d	EFSA Journal 2016;14(3):4420
	Pendimethalin	Acute	Overall geomean LD_{50} = **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	$NOAEL_{developmental}$ = 500 mg/kg bw/d	EFSA Journal 2016;14(3):4420
Rabbit	Pendimethalin	Long-term Developmental	$NOAEL_{developmental}$ = 30 mg/kg bw/d	EFSA Journal 2016;14(3):4420

9.3.1.1 Justification for new endpoints

Not relevant. EU agreed endpoints are used.

9.3.2 Risk assessment for spray applications

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

9.3.2.1 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 KONARK in bare soil (cereals in pre-emergence)

Intended use	**Bare soil (cereals in pre-emergence)**				
Active substance/product	Flufenacet				
Application rate (g/ha)	1 x 240				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH <10	Small omnivorous mammal "mouse" combination (ground invertebrate without interception) 50% weed seeds, 50% ground arthropods	14.3	1.0	3.43	171.6
Reprod. toxicity (mg/kg bw/d)	37.4				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soil BBCH <10	Small omnivorous mammal "mouse" combination (ground invertebrate without interception) 50% weed seeds, 50% ground arthropods	5.7	1.0 × 0.53	0.73	51.6
Intended use	**Bare soil (cereals in pre-emergence)**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x ~~750~~ 1200				
Acute toxicity (mg/kg bw)	3927				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH <10	Small omnivorous mammal "mouse" combination (ground invertebrate without interception) 50% weed seeds, 50% ground arthropods	14.3	1.0	17.16	228.8
Reprod. toxicity (mg/kg bw/d)	30				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Bare soil BBCH <10	Small omnivorous mammal "mouse" combination (ground invertebrate without interception) 50% weed seeds, 50% ground arthropods	5.7	1.0 × 0.53	3.63	8.3

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 KONARK in cereals

Intended use	**Cereals**				
Active substance/product	Flufenacet				
Application rate (g/ha)	1 x 240				
Acute toxicity (mg/kg bw)	589				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH 10-19	Small insectivorous mammal "shrew" 100% ground arthropods	7.6	1.0	1.82	322.9
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" 100% ground arthropods	5.4	1.0	1.30	454.5
Cereals Early (shoots)	Large herbivorous mammal "lagomorph" 100% cereal shoots	42.1	1.0	10.10	58.3
Cereals BBCH 10-29	Small omnivorous mammal "mouse" 25% weeds, 50% weed seeds, 25% ground arthropods	17.2	1.0	4.13	142.7
Reprod. toxicity (mg/kg bw/d)	37.4				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH 10-19	Small insectivorous mammal "shrew" 100% ground arthropods	4.2	1.0 × 0.53	0.53	70.0
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" 100% ground arthropods	1.9	1.0 × 0.53	0.24	154.8
Cereals Early (shoots)	Large herbivorous mammal "lagomorph" 100% cereal shoots	22.3	1.0 × 0.53	2.84	13.2
Cereals BBCH 10-29	Small omnivorous mammal "mouse" 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.0 × 0.53	0.99	37.7

Intended use	**Cereals**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1200				
Acute toxicity (mg/kg bw)	3927				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH 10-19	Small insectivorous mammal "shrew" 100% ground arthropods	7.6	1.0	9.12	430.6
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" 100% ground arthropods	5.4	1.0	6.48	606.0
Cereals Early (shoots)	Large herbivorous mammal "lagomorph" 100% cereal shoots	42.1	1.0	50.52	77.7
Cereals BBCH 10-29	Small omnivorous mammal "mouse" 25% weeds, 50% weed seeds, 25% ground arthropods	17.2	1.0	20.64	190.3
Reprod. toxicity (mg/kg bw/d)	30				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH 10-19	Small insectivorous mammal "shrew" 100% ground arthropods	4.2	1.0 × 0.53	2.67	11.2
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" 100% ground arthropods	1.9	1.0 × 0.53	1.21	24.8
Cereals Early (shoots)	Large herbivorous mammal "lagomorph" 100% cereal shoots	22.3	1.0 × 0.53	14.18	**2.1**
Cereals BBCH 10-29	Small omnivorous mammal "mouse" 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.0 × 0.53	4.96	6.0

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.

Risk Assessment for combined exposure

According to the EFSA Journal (2009)[2], the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD_{50} for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. For the calculation, the following equation was used:

[2]European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Acute risks from combined exposure

The active substance content of the formulation KONARK addressed in this dossier is 6 % Flufenacet and 30 % Pendimethalin, making up a total of 360 g a.s./L product. According to GAP, the maximum application rate is 2.5 L product/ha, therefore, application rate of 1440 g a.s./ha was considered in the assessment.

Table 9.3-4 shows the calculation of the predicted LD_{50} (mix) of Flufenacet and Pendimethalin when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

Table 9.3-4:: Mammalian LD_{50} (mix) for Flufenacet and Pendimethalin when combined as KONARK (step 1 in EFSA GD 2009, Appendix B)

	Flufenacet	Pendimethalin
Content in the formulation KONARK	6%	30%
Fraction in the a.s. mixture	0.1667	0.8333
LD_{50} of a.s. [mg/kg bw]	589	3927
Fraction / LD_{50}	0.00028	0.00021
Sum	0.00050	
1/ sum = predicted LD_{50} (mix)	2019.50 mg mix/kg bw	

It is obvious from the comparison of the (low) acute oral toxicity of the active substances, and their relative proportions of the formulated product KONARK.

Table 9.3-5: Mammalian "tox per fraction" for the KONARK (step 1 in EFSA GD 2009, Appendix B)

	Flufenacet	Pendimethalin	"mix"
Content in the formulation KONARK	6%	30%	36%
Fraction in mixture	0.1667	0.8333	1.0
LD_{50} (mg/kg bw)	589	3927	2019.50
Tox per fraction	3534.00	4712.40	2019.50
Contribution to predicted toxicity	57.14 %	42.86 %	

Flufenacet contributes to 57.14 % to mixture toxicity, while the Pendimethalin have an impact on the predicted risk of 42.86 %, therefore, surrogate LD_{50} was used in the acute risk assessment.

Table 9.3-6: Screening risk assessment of the acute risk for mammals due to the use of KONARK in bare soil (pre-emergence)

Intended use	**Bare soil (pre-emergence)**				
Active substance/product	KONARK				
Application rate (g/ha)	1 x 1440				
LD_{50} (mix) (mg/kg bw)	2019.50				
TER criterion	10				
Crop scenario	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90}**	**TER_a**

Growth stage				**(mg/kg bw/d)**	
Bare soil	Indicator species for screening	14.4	1.0	20.74	97.4

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 9.3-7: Screening risk assessment of the acute risk for mammals due to the use of KONARK in cereals

Intended use	**Cereals**				
Active substance/product	KONARK				
Application rate (g/ha)	1 x 1440				
LD_{50} (mix) (mg/kg bw)	2019.50				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH 10-19	Small insectivorous mammal "shrew" 100% ground arthropods	7.6	1.0	10.94	184.5
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew" 100% ground arthropods	5.4	1.0	7.78	259.7
Cereals Early (shoots)	Large herbivorous mammal “lagomorph” 100% cereal shoots	42.1	1.0	60.62	33.3
Cereals BBCH 10-29	Small omnivorous mammal “mouse” 25% weeds, 50% weed seeds, 25% ground arthropods	17.2	1.0	24.77	81.5

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 results, no unacceptable acute risk is obtained in all intended uses acording to the proposed GAP.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TERmix value can only be used for illustrating purposes. Hence, in the case of an unacceptable TERmix, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

9.3.2.2 Higher-tier risk assessment

After Tier I risk assessment, unacceptable long-term risk is detected for Pendimethalin in cereals for large herbivorous mammal "lagomorph". Therefore a refinement is needed and proposed below by the Applicant.

Refinement of toxicity endpoint
Seeking for the options of the higher tier reproductive risk assessment to mammals, SHARDA has inspected available resources. Considering the publicly available conclusions of the national evaluation of the product Stomp, conducted by the Dutch Competent Authority, CTGB, for the purpose of authorizating Stomp in the Netherlands3, it became evident that the long-term EU-agreed endpoint of 500 ppm (=30 mg/kg bw/d) is apparently not ecotoxicologically relevant and, as such, use of this endpoint leads to too conservative and overestimating assessment.

Citing the comments made by the Dutch Authority:

Summaries of the reproduction studies are available in the DAR. The endpoint given in the LoE comes from the two-generation study toxicity/reproduction study in rat. Information from the DAR:

"For two generations the animals were fed AC 92,553 (92.6 % content) in the diet at concentrations 0, 500, 2500, and 5000 ppm, which correspond to 30, 150, 296 mg/kg bw/day for males (M) and 39, 195, 388 mg/kg bw/day for females (F). There were no significant mortalities either in the P1 and F1 generation related to treatment. Discoloured yellow urine was observed in all treated animals. Yellow fur staining was also observed, mainly in the F1 generation animals in the 296(M)-388(F) mg/kg bw/day dose level (fed 5000 ppm), and to a lesser degree in those of the 150(M)-195(F) mg/kg bw/day dose level (fed 2500 ppm).

Lower body weight gain was statistically significant in the animals fed 5000 ppm [296(M)-388(F) mg/kg bw/day], and to a lesser degree in those of 2500 ppm group [150(M)-195(F) mg/kg bw/day]. Food reduction consumption was also related to dose level, being more remarkable in the 5000 ppm group than in the 2500 ppm dose level. There were no significant adverse effect at any dose level on vaginal smear pattern, time- course of mating, performance of mating (males and females), fecundity and fertility in either generation, neither on gestation duration, or outcome of pregnancy; there was only a slight decrease of the number of pups in the group administered 5000 ppm in both litters of both generations, as compared to the control.

Conclusions:

There was parental toxicity at 296(M)-388(F) mg/kg bw/day dose level and, to a lesser degree, at 150(M)-195(F) mg/kg bw/day when AC 92,553 was administered over two successive generations.
Parental toxicity manifested as a lower body weight, lower body weight gain during lactation and lower food consumption. There was no other treatment related effect than skin and or urine discoloration at necropsy, as far as histopathological abnormalities, clinical condition and abnormalities of the pups are concerned. Fertility, fecundity, gestation, pregnancies and other reproductive characteristics were unaltered by treatment as compared to controls. Based on all these findings, NOAEL is set 30(M)-39(F) mg/kg bw/day as there was no association of adverse effect on offspring and parental toxicity at this level and below."

Germany has, in a recent national evaluation of pendimethalin in 2005, considered a higher endpoint relevant, with the following argumentation.

"2-generation study with rats: dosing with 0, 500, 2500 and 5000 ppm. In the first generation, lower body weight, lower body-weight gain during lactation and lower food consumption were recorded at 5000 pppm (296 (m)-388 (f) mg/kg bw/d) and to a lesser extent also at 2500 ppm (150 (m) - 195 (f) mg/kg bw/d). Except from colour changes of urine and skin, no effects regarding the offspring, fertility, fecundity

or pregnancy or regarding other adverse effects on reproduction were seen. It may be thus assumed that even a dose of 2500 ppm (150(m) -195 (f) mg/kg KG/d) does not adversely affect population development. In the context of the refined risk assessment, thus the NOAEL = 195 mg/kg KG/d is used."

Two other reproduction studies with mammals are available in the DAR, a teratology study with rats and one with rabbits. In both studies, no effects were seen at the highest tested dose (around 40 mg as/kg bw/d).

Note that several other MS have for national authorisation used a different endpoint than the one given in the Final LoEP (information from personal correspondence with risk assessors). Germany used a NOAEL of 195 mg/kg bw/d (2500 ppm, females), and France agreed to a NOAEL of 296 mg/kg bw/d (5000 ppm, males). All these endpoints are derived from the same study.

Therefore, to refined **NOAEL of 150 mg/kg bw/d** was used in the higher tier risk assessment.

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

Intended use	**Cereals**				
Active substance/product	Pendimethalin				
Application rate (g/ha)	1 x 1440				
Reprod. toxicity (mg/kg bw/d)	150*				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals Early (shoots)	Large herbivorous mammal "lagomorph" 100% cereal shoots	22.3	1.0 × 0.53	17.02	8.8

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:

In z RMS's opinion the agreed endpoints at EU level should be not change during zonal authorisation of ppp according to recommendation given in EFSA technical document on Ecotoxicology, 2015.
Therefore, the NOEAL of 30 mg a.s./kg is still valid and was used in the risk assessment.
Further refinement is needed for winter cereals.
Considering the EU agreed refinement of f_{TWA} (DT_{50} for wheat = 2.73; Jene, 2014), it is stated in the EFSA conclusion on pendimethalin that the available residue decline studies can be applied for winter cereals (north and south Europe) and winter cereals (south Europe only). Furthermore, it is stated that '*as dissipation was measured for residues on plants surface and not for residues within plant tissues, such refinement was not considered suitable for pre-emergence applications*'. As Konark is intended for a use in central Europe and for a growth stage of cereals including pre-emergence (BBCH 00-25), the refinement is only applicable for post-emergence applications (BBCH 10-29) in winter cereals.

However, for the intended use of Konark in winter cereals (BBCH 00-25) the raffinement is not applicable.

Higher tier assessment of the long-term/reproductive risk to mammals due to the post-emergence use of Konark in winter cereals – pendimethalin.

Intended use	Winter cereals
Active substance/product	Pendimethalin
Application rate (g/ha)	1 x 1200
Reprod. toxicity **(mg/kg bw/d)**	NOEL = 30
TER criterion	5

Crop scenario Growth stage	**Indicator species**	**SV**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{LT}**
Cereals Early (shoots)	Large herbivorous mammal "lagomorph"	22.3	1 x 0.20 = 0.20	5.35	5.61
Cereals BBCH 10-29	Small onmnivorous mammal "mouse"	7.8	1 x 0.2 = 0.2	1.87	16.03

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

Based on the higher tier assessment for pendimethalin, the TER_{LT} values are above the relevant trigger of 5, indicating an acceptable long-term risk for mammals following post-emergence application of Konark in **winter cereals**.

However, for post-emergence applications of Konark in **winter cereals**, the risk for mammals remains unacceptable (see Tier 1 assessment).

Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Konark in winter cereals.

Intended use		winter cereals
Active substance/product		Pendimethalin
Application rate (g/ha)		1 × 1200
Reprod. toxicity (mg/kg bw/d)		30
TER criterion		5

Focal species	**Food category, % in diet**	**SV**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**PT**	**TER_{LT}**	**TER_{LT}**
Rabbit (*Oryctolagus cuniculus*)	Cereals shoots, 100 %	22.3	1 x 0.53	11.74	0.69	**2.55**	> 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.
*PT According to Prosser, 2010, 90% th percentile, consumer only for winter cereals

Further risk assessment for post-emergence applications of Konark in winter cereals should be considered at national level.

9.3.2.3 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 202, Flufenacet (Review report flufenacet, 7469/VI/98-Final, 3 July 2003) belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	240		
Acute toxicity (mg/kg bw)	=	589	quotient	= 0.41
Reprod. toxicity (mg/kg bw/d)	=	37.4	quotient	= 6.42

With a K(f)oc of 13792 (EFSA Journal 2016;14(3):4420), Pendimethalin belongs to the group of more sorptive substances.

Effective application rate (g/ha)	=	1200		
Acute toxicity (mg/kg bw)	=	3927	quotient	= 0.31
Reprod. toxicity (mg/kg bw/d)	=	30	quotient	= 40.00

zRMS comment:

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical values of 3000 and 500 for flufenacet and pendimethalin, respectively, a quantitative risk assessment (calculation of TER values) is not required.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Flufenacet amounts to 3.2 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} 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 measured/predicted concentrations in soil/porewater / is based on experimental data.

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

Parameter	Flufenacet	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.280	PEC_{soil} twa 21 d of flufenacet (please refer to sec 8, Table 8.7-3)
log P_{ow} / P_{ow}	3.2 / 1584.89	Log Pow = 3.2 (Review report flufenacet, 7469/VI/98-Final, 3 July 2003). The Pow = 1584.89 was calculated from the log Pow value
Koc	202	Mean (n = 7) (Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
foc	0.02	Default
BCF_{worm}	4.92	$BCF_{worm/soil} = (C_{worm,ww}/C_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	1.38	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	1.45	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	37.4	(Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
TER_{lt}	21.2	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

zRMS comments:

We agree with the risk assessment provided risk for earthworm-eating mammals due to exposure to Flufenacet via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals.

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 winter cereals

Parameter	Pendimethalin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	1.539	PEC_{soil} twa 21 d of pendimethalin (please refer to sec 8, Table 8.7-3)
log P_{ow} / P_{ow}	5.2	EFSA Journal 2016;14(3):4420. The Pow = 158489.32 was calculated from the log Pow value
Koc	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default
BCF_{worm}	6.90	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	10.62	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	13.59	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	30	EFSA Journal 2016;14(3):4420
TER_{lt}	**2.2**	No 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 9.3-11: Higher-tier risk assessment for earthworm-eating mammals due to exposure to Pendimethalin via bioaccumulation in earthworms (secondary poisoning) for the intended use in ~~ornamentals~~ cereals

Parameter	Pendimethalin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	1.539	PEC_{soil} twa 21 d of pendimethalin (please refer to sec 8, Table 8.7-3)
log P_{ow} / P_{ow}	5.2	EFSA Journal 2016;14(3):4420. The Pow = 158489.32 was calculated from the log Pow value
Koc	13792	EFSA Journal 2016;14(3):4420
foc	0.02	Default
BCF_{worm}	0.81	Study from RAR of bioaccumulation on earthworms (Garret, 2000)
PEC_{worm}	1.25	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	1.60	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	30	EFSA Journal 2016;14(3):4420
TER_{lt}	18.8	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 KONARK 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 $PECs_{accum}$..

Parameter	Pendimethalin	Comments
$PEC_{soil\ accumulation,}$ (mg/kg soil)	1.739	$PEC_{soil\ accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)
log P_{OW}; P_{OW}	5.4*; 251188	-
K_{OC}	13792	Arithmetic mean (n = 9)
f_{OC}	0.02	Default
BAF_{Worm}	2.44	Refined BAF; worst-case approach
PEC_{Worm}	1.739 x 2.44 = 4.24	$PEC_{worm} = PEC_{soil} \times BAF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	4.24 x 1.28 = 5.42	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	30	Refined endpoint: BMDL5
TER_{LT}	5.53	TER_{LT} = 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 9.3-12: Assessment of the risk for fish-eating mammals due to exposure to Flufenacet via bioaccumulation in fish (secondary poisoning) for the intended use in winter cereals

Parameter	Flufenacet	comments
PEC_{sw} (mg/L)	0.02519	21 – d PECsw $_{TWA}$ flufenacet step 2 – winter cereals for NEU (please refer to sec 8, table 8.9-4)
BCF_{fish}	71.4	(Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	1.80	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.26	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	37.4	(Review report flufenacet, 7469/VI/98-Final, 3 July 2003).
TER_{lt}	146.4	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

zRMS comments:

We agree with the risk assessment provided risk for earthworm-eating mammals due to exposure to Flufenacet via bioaccumulation in fish (secondary poisoning) for the intended use in cereals.

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

Parameter	Pendimethalin	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00940	21 – d PECsw $_{TWA}$ flufenacet step 2 – winter cereals for NEU (please refer to sec 8, table 8.9-14)
BCF_{fish}	931	EFSA Journal 2016;14(3):4420 (most reliable endpoint)
BMF	CT_{50}=5.1 days, 1.34 d ; 2.5 – 4.4 d CT_{90}: 87% depuration in 14 d; -; 96-97% clearance within 21 d (CT90 8.3-15 d) Two outdoor mesocosm	biomagnification factor (relevant for BCF ≥ 2000) EFSA Journal 2016;14(3):4420

	studies with a.s. pedimethalin targeted at bioconcentration are available: *Lepomis macrochirus*, BMF_{KGL}= 0.1054 *Oncorhynchus mykiss* BMF_{KGL}= 0.0402 BMF_{KGL}= 0.0423 Outdoor mesocosms *Leuciscus idus melanotus* mean $BCF_{actual\ conc}$ = 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	
PEC_{fish}	8.75	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	1.24	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	30	EFSA Journal 2016;14(3):4420
TER_{lt}	24.1	No risk, TER > 5

TER values shown in bold fall below the relevant trigger.

zRMS comment:

zRMS verified the risk for earthworm-eating mammals 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**
PEC_{SW} (mg/L)	0.01173	FOCUS Step 2, winter cereals, Max PEC_{SW}
BCF_{Fish}	931 / 3300*	Lowest and highest available BCF values
PEC_{Fish}	10.92/ 38.70	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	1.55 / 5.49	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	30	Refined endpoint: BMDL5
TER_{LT}	19.35/5.46	TER_{LT} = 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 birds due to exposure to pendimethalin via bioaccumulation in earthworms (secondary poisoning) is considered as acceptable.

9.3.2.5 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".*

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

Not relevant.

9.3.4 Overall conclusions

No acute and long-term risk were observed for mammals after exposure to Flufenacet. Regarding Pendimethalin, acute risk was not observed, however, long-term risk was observed and further refinement was needed. After the refinement of the endpoint, the value was above the trigger showing an acceptable long-term risk for mammals.
For pendimethalin an unacceptable long-term risk (lagomorph) was concluded based on the Tier 1 assessment.
No risk from drinking water is expected and the risk for earthworm-eating mammals was considered acceptable for Flufenacet, however unnacceptable risk was detected for Pendimethalin. After refinement, no unacceptable risk was detected. No risk for mammals of secondary poisoning via fish is expected.

zRMS comments:

For the intended post-emergence use of Konark in winter cereals (BBCH 10-29) a refined DT_{50} for pendimethalin was applied in the higher-tier risk assessment. According to that, an acceptable long-term risk for mammals following post-emergence application of Konark in winter cereals could be demonstrated. However, for post-emergence applications of Konark in winter cereals, the risk for mammals remains unacceptable.

Considering the long-term risk assessment for the toxicity of active substances present in Konark an unacceptable risk for lagomorph (Cereals Early (shots); applicable for winter and winter cereals) and for the small **omnivorous mammal mouse** (Cereals, BBCH 10-29; applicable only for winter cereals) was concluded.

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

No available data for Flufenacet.

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.*

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

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

Effects on aquatic organisms of KONARK were not evaluated as part of the EU assessment of Flufenacet and 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 – Flufenacet and its relevant metabolites

Species	Substance	Exposure System	Results	Reference
Lepomis macrochirus	Flufenacet	96 h, ss	**LC_{50} = 2.13 mg a.s./L $_{mm}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Oncorhynchus mykiss	Flufenacet-sulfonic acid	96 h, ss	**LC_{50} > 86.7 mg/L $_{nom}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Oncorhynchus mykiss	Thiadone	96 h, s	**LC_{50} = 9.1 mg/L $_{mm}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Oncorhynchus mykiss	Flufenacet	97 d, f	**NOEC = 0.2 mg a.s./L $_{nom}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Daphnia magna	Flufenacet	48 h, s	**EC_{50} = 30.9 mg a.s./L $_{nom}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Daphnia magna	Flufenacet-sulfonic acid	48 h, s	**EC_{50} >87.3 mg/L**	Review Report (7469/VI/98-Final – 03/07/2003)
Daphnia magna	Thiadone	48 h, s	**EC_{50} = 31.7 mg/L $_{mm}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Daphnia magna	Flufenacet	21 d, ss	**NOEC = 3.26 mg a.s./L $_{nom}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Pseudokirchneriella subcapitata	Flufenacet	120 h, s	E_bC_{50} = 0.00204 mg a.s./L $_{nom}$ **E_rC_{50} = 0.0045 mg a.s./L $_{nom*}$**	Review Report (7469/VI/98-Final – 03/07/2003)
Scenedesmus subspicatus	Flufenacet-sulfonic acid	72 h, s	**E_rC_{50} > 86.7 mg/L $_{nom}$**	Review Report (7469/VI/98-Final – 03/07/2003)

Species	Substance	Exposure System	Results	Reference
Pseudokirchneriella subcapitata	Thiadone	72 h, s	**E_bC_{50} = 4.1 mg/L** $_{mm}$	Review Report (7469/VI/98-Final – 03/07/2003)
Pseudokirchneriella subcapitata	Flufenacet-methylsulfide	72 h, s	**E_rC_{50} = 83.8 mg/L** $_{nom}$	Review Report (7469/VI/98-Final – 03/07/2003)
Lemna gibba	Flufenacet	14 d, s	**EC_{50} = 0.00243 mg a.s./L** $_{nom}$	Review Report (7469/VI/98-Final – 03/07/2003)
Lemna gibba	Flufenacet-sulfonic acid	14 d, s	**EC_{50} > 86.7 mg/L** $_{nom}$	Review Report (7469/VI/98-Final – 03/07/2003)
Higher-tier studies (micro- or mesocosm studies)				
~~Flufenacet (61.5%, macrophyte, duckweed and periphyton) – NOEC = 0.012 mg a.s./L~~				

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

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms regarding Pendimethalin and its relevant metabolites

Species	Substance	Exposure System	Results	Reference
Fish				
Oncorhynchus mykiss	Pendimethalin	Acute 96 hr (static, with and without sediment)	Without sediment: LC_{50} = **0.196** mg a.s./L $_{mm}$ LC_{50} = 0.283 mg a.s./L $_{mm}$	EFSA Journal 2016;14(3):4420
Pimephales promelas	Pendimethalin	Acute 96 hr (flow-through)	LC_{50} > 0.240 mg a.s./L $_{mm}$	EFSA Journal 2016;14(3):4420
Oncorhynchus mykiss	BAS 455 48 H	Acute 96 hr (static)	LC_{50} = 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)	LC_{50} = 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)	LC_{50} = 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)	LC_{50} = 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

Species	Substance	Exposure System	Results	Reference
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	EC_{50} = **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: EC_{50}> 1.0 mg a.s./L (nom) / 0.701 (mm) With sediment : EC_{50}> 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	EC_{50} > 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)	EC_{50} = 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	EC_{50} = 0.613 mg/L(mm)	EFSA Journal 2016;14(3):4420
Daphnia magna	M455H001 (P44)	48 h, s	EC_{50} = 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				

Species	Substance	Exposure System	Results	Reference
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)	E_bC_{50} = 0.0041 mg a.s./L (mm) **E_rC_{50} = 0.0093 mg a.s./L (mm)** E_yC_{50} = 0.0038 mg a.s./L (mm)	EFSA Journal 2016;14(3):4420
	Pendimethalin	72 h (static)	E_rC_{50} >0.055 mg a.s./L (mm) E_yC_{50} = 0.0043 mg a.s./L (mm)	EFSA Journal 2016;14(3):4420
	Pendimethalin	72 h (static)	E_rC_{50} = 0.0243 mg a.s./L (mm) E_yC_{50} = 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)	E_yC_{50} > 0.174 (mm)	EFSA Journal 2016;14(3):4420
Pseudokirchneriella subcapitata	BAS 455 48 H	72 h (static)	E_rC_{50} = 1.13 mg prep./L (0.438 mg a.s./L (mm)) E_yC_{50} = 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)	E_rC_{50} = 0.120 mg prep./L (0.0429 mg a.s./L (mm)) E_yC_{50} = 0.0256 mg prep./L (0.00915 mg a.s./L (mm))	EFSA Journal 2016;14(3):4420
	M455H033 (P48)	72 h (static)	E_rC_{50} > 1.45 mg/L(mm) E_yC_{50} = 0.498 mg/L(mm)	EFSA Journal 2016;14(3):4420
	M455H001 (P44)	72 h (static)	E_rC_{50} > 2.5 mg/L(nom) E_yC_{50} > 2.5 mg/L(nom)	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
	M455H032	72 h (static)	E_rC_{50} = 1.48 mg/L$_{(nom)}$ E_bC_{50} = 0.90 mg/L$_{(nom)}$	EFSA Journal 2016;14(3):4420
Higher plant				
Lemna gibba	Pendimethalin	14 d, s	Frond number E_rC_{50} = 0.022 mg a.s./L ($_{mm}$) E_yC_{50} = 0.0084 mg a.s./L $_{mm}$)	EFSA Journal 2016;14(3):4420
Lemna gibba	Pendimethalin	7 d, s	Frond number E_rC_{50} = 0.0156 mg a.s./L (im)/ **0.012 mg a.s./L ($_{mm}$)** E_yC_{50} = 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 E_rC_{50} = 7.55 mg a.s./L (nom) E_yC_{50} = 1.74 mg a.s./L ($_{nom}$) Dry weight E_rC_{50} >39.2 mg a.s./L (nom) E_yC_{50} = 23.2 mg a.s./L ($_{nom}$)	EFSA Journal 2016;14(3):4420
Lemna gibba	AG-P4-400-SC	7 d, ss	Frond number E_rC_{50} = 0.0366 mg a.s./L ($_{nom}$) E_yC_{50} = 0.0122 mg a.s./L ($_{nom}$) Dry weight E_rC_{50} >0.263 mg a.s./L ($_{nom}$) E_yC_{50} = 0.0366 mg a.s./L ($_{nom}$)	EFSA Journal 2016;14(3):4420
Further testing on aquatic organisms				

Species	Substance	Exposure System	Results	Reference
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.				
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 parameters (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

Species	Substance	Exposure System	Results	Reference
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 parameters	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.				

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

*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 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – KONARK

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	KONARK	96 h, ss	**LC_{50} = 0.4833 mg/L** $_{nom}$	KCP 10.2.1-01 xxx W/192/17

Species	Substance	Exposure System	Results	Reference
Daphnia magna	KONARK	48 h, ss	**EC_{50} = 0.95 mg/L $_{nom}$**	KCP 10.2.1-02 xxx W/194/17
Pseudokirchneriella subcapitata	KONARK	72 h, s	**E_rC_{50} = 0.1230 mg/L $_{nom}$** E_yC_{50} = 0.0324 mg/L $_{nom}$	KCP 10.2.1-03 xxx W/193/17
Lemna gibba	KONARK	7 d, ss	Frond number **E_rC_{50} = 0.6532 mg/L $_{nom}$** E_yC_{50} = 0.1596 mg/L $_{nom}$ Dry weight E_rC_{50} = 8.1935 mg/L $_{nom}$ E_yC_{50} = 0.3735 mg/L $_{nom}$	KCP 10.2.1-04 xxx W/195/17
Higher-tier studies (micro- or mesocosm studies)				

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

9.5.1.1 Justification for new endpoints

The used endpoints are the EU agreed ones. Additionally new studies were conducted with the formulation KONARK and the risk assessment was also done considering these new endpoints.

9.5.2 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 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

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

KONARK FORMULATION

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for KONARK for most sensitive groups of aquatic organism for the use of KONARK in winter cereals

Group		~~Fish acute~~	Invertebrate acute	Algae	*Lemna*

Group			~~**Fish acute**~~	**Invertebrate acute**	**Algae**	***Lemna***
Test species			~~***Oncorhynchus mykiss***~~	***Daphnia magna***	~~***Pseudokirchneriella subcapitata***~~	***Lemna gibba***
Endpoint			~~LC_{50}~~	EC_{50}	~~E_rC_{50}~~	EC_{50}
(µg/L)			~~483.3~~	950	~~123~~	653.2
AF			~~100~~	100	~~10~~	10
RAC (µg a.s./L)			~~4.833~~	9.50	~~12.3~~	65.32
Distance (m)	**Nozzles (%)**	**PEC $_{gl-max}$ (µg/L)**				
5 m	None	6.886	~~**1.425**~~	0.725	~~0.560~~	0.105
5 m	50%	3.443	~~0.712~~	0.362	~~0.280~~	0.053
10m	None	3.652	~~0.756~~	0.384	~~0.297~~	0.056

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 use in cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC_{50} for *Oncorhynchus mykiss* of 483.3 µg/L in connection with an assessment factor of 100) following the next mitigation measures:~~

~~— Distance of 10 m or 5m with the use of 50% NR.~~

~~The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.~~

ZRMS comment:

Risk assessment for formulation Konark was not accepted due the fact unacceptables the studies for *Oncorhynchus mykiss* and *Pseudokirchneriella subcapitata.*
Risk assessment performed for aquatic organisms on the base active substances cover risk for formulation.

FLUFENACET

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

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Flufenacet for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic plants**	**Higher-tier information**
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***	**Macrophyte, duckweed and periphyton**
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	EC_{50}	NOEC
(µg/L)		2130	200	30900	3260	2.1	2.43	12
AF		100	10	100	10	10	10	3
RAC (µg/L)		21.3	20	309	326	0.21	0.243	4
FOCUS Scenario	**PEC_{gl-max} (µg/L)**							
Step 1								
	66.21	**3.108**	**3.311**	0.214	0.203	**315.286**	**272.469**	**16.553**
Step 2								
S-Europe	23.43	**1.100**	**1.172**	0.076	0.072	**111.571**	**96.420**	**5.858**
N-Europe	28.84	**1.354**	**1.442**	0.093	0.088	**137.333**	**118.683**	**7.210**
Step 3								
D1/ditch	10.17	0.477	0.509	0.033	0.031	**48.429**	**41.852**	**2.543**
D1/stream	6.476	0.304	0.324	0.021	0.020	**30.838**	**26.650**	**1.619**
D2/ditch	20.54	0.964	**1.027**	0.066	0.063	**97.810**	**84.527**	**5.135**
D2/stream	13.12	0.616	0.656	0.042	0.040	**62.476**	**53.992**	**3.280**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Higher-tier information
D3/ditch	1.517	0.071	0.076	0.005	0.005	**7.224**	**6.243**	0.379
D4/pond	0.806	0.038	0.040	0.003	0.002	**3.838**	**3.317**	0.202
D4/stream	1.316	0.062	0.066	0.004	0.004	**6.267**	**5.416**	0.329
D5/pond	1.326	0.062	0.066	0.004	0.004	**6.314**	**5.457**	0.332
D5/stream	1.688	0.079	0.084	0.005	0.005	**8.038**	**6.947**	0.422
D6/ditch	6.399	0.300	0.320	0.021	0.020	**30.471**	**26.333**	**1.600**
R1/pond	0.115	0.005	0.006	0.000	0.000	0.548	0.473	0.029
R1/stream	6.516	0.306	0.326	0.021	0.020	**31.029**	**26.815**	**1.629**
R3/stream	9.128	0.429	0.456	0.030	0.028	**43.467**	**37.564**	**2.282**
R4/stream	2.104	0.099	0.105	0.007	0.006	**10.019**	**8.658**	0.526

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 Flufenacet for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Higher-tier information
Test species		***Lepomis macrochirus***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***	**Macrophyte, duckweed and periphyton**
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	EC_{50}	NOEC
(µg/L)		2130	200	30900	3260	2.1	2.43	12
AF		100	10	100	10	10	10	3
RAC (µg/L)		21.3	20	309	326	0.21	0.243	4
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							
Step 1								
	66.21	**3.108**	**3.311**	0.214	0.203	**315.286**	**272.469**	**16.553**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic plants	Higher-tier information
Step 2								
S-Europe	23.43	**1.100**	**1.172**	0.076	0.072	**111.571**	**96.420**	**5.858**
N-Europe	12.61							
Step 3								
D1/ditch	1.642	0.077	0.082	0.005	0.005	**7.819**	**6.757**	0.411
D1/stream	1.343	0.063	0.067	0.004	0.004	**6.395**	**5.527**	0.336
D3/ditch	1.520	0.071	0.076	0.005	0.005	**7.238**	**6.255**	0.380
D4/pond	0.053	0.002	0.003	0.000	0.000	0.252	0.218	0.013
D4/stream	1.161	0.055	0.058	0.004	0.004	**5.529**	**4.778**	0.290
D5/pond	0.055	0.003	0.003	0.000	0.000	0.262	0.226	0.014
D5/stream	1.207	0.057	0.060	0.004	0.004	**5.748**	**4.967**	0.302
R1/pond	0.132	0.006	0.007	0.000	0.000	0.629	0.543	0.033
R1/stream	1.946	0.091	0.097	0.006	0.006	**9.267**	**8.008**	0.487
R4/stream	1.001	0.047	0.050	0.003	0.003	**4.767**	**4.119**	0.250

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 use in winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton as characterised by a NOEC of 0.012 mg a.s./L in connection with an assessment factor of 3 for microcosms) in several FOCUS Steps 3 scenarios (D1 ditch, D2 ditch, D2 stream, D6 ditch and R3 stream). Therefore, PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. For the intended use in spring cereals, calculated PEC/RAC ratios indicated an acceptable risk for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton as characterised by a NOEC of 0.012 mg a.s./L in connection with an assessment factor of 3 for microcosms) all FOCUS Steps 3 scenarios.

Table 9.5-7: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Flufenacet based on FOCUS Step 4 calculations and toxicity data for macrophyte, duckweed and periphyton (microcosm) with mitigation of spray drift and run-off for the use of KONARK in winter cereals pre-emergence

Intended use		Winter cereals			
Active substance		Flufenacet			
Application rate (g/ha)		1 x 240			
Nozzle reduction	Vegetative strip (m)	None	10	15*	20
	No spray buffer (m)	5	10	15	20
90%	D1 ditch	10.16	-	-	-
	D1 stream	6.476	-	-	-
	D2 ditch	20.54	-	-	-
	D2 stream	13.12	-	-	-
	D6 ditch	6.398	-	-	-
None	R1 stream	-	2.920	-	-
90%		6.514	-	-	-
None	R3 stream	-	4.167	3.199	2.186
90%		9.128	-	-	-
RAC 4 (µg/L)	**PEC/RAC ratio**				
90%	D1 ditch	**2.540**	-	-	-
	D1 stream	**1.619**	-	-	-
	D2 ditch	**5.135**	-	-	-
	D2 stream	**3.280**	-	-	-
	D6 ditch	**1.600**	-	-	-
None	R1 stream	-	0.730	-	-
90%		**1.629**	-	-	-
None	R3 stream	-	**1.042**	0.800	0.547
90%		**2.282**	-	-	-

*0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the

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

For the intended use in winter cereals, an unacceptable risk was identified for D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch scenarios for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton). These scenarios are not relevant under CEU conditions.
Regarding R scenarios, the risk was acceptable according to the following risk mitigation measures:

- R1 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.
- R3 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.

zRMS comments:

Flufenacet

The zRMS notes that the EU agreed endpoint derived from the aquatic indoor microcosm study (NOEC = 12 µg/L) can be applied to refine the toxicity of both, algae and macrophytes. Due to several shortcomings of the respective microcosm study (e.g. low number of species tested, missing of the most sensitive species indicated in Tier 1 studies (i.e. *Pseudokirchneriella subcapitata*), limited representativeness for freshwater communities), the proposed AF may be considered protective, resulting in a RAC of 4 µg/L.
It is further noted that the determination of an AF is - for the most part - based on expert judgement, which might offer the opportunity for deviations between member states. However, the above-mentioned shortcomings of the respective microcosm study indicate that lowering the AF might lead to an underestimation of potential effects.
Based on RAC =4 µg/L for the intended use in winter cereals, an unacceptable risk was identified for D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch scenarios for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton) was noted. However, these scenarios are not relevant under CEU conditions.
Regarding R scenarios, the risk was acceptable according to the following risk mitigation measures:

- R1 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.
- R3 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip are considered

Final decision of risk mitigation measures should be decided at MSs level.

<u>Metabolites Flufenacet</u>

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Thiadone (M9) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Selenastrum capricornutum***
Endpoint		LC_{50}	EC_{50}	E_bC_{50}
(µg/L)		9100	31700	4100
AF		100	100	10
RAC (µg/L)		91	317	410
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				

Group		Fish acute	Inverteb. acute	Algae
	35.34	0.388	0.111	0.086
Step 2				
S-Europe	12.58	0.138	0.040	0.031
N-Europe	15.48	0.170	0.049	0.038

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 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Thiadone (M9) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		Fish acute	Inverteb. acute	Algae
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Selenastrum capricornutum***
Endpoint		LC_{50}	EC_{50}	E_bC_{50}
(µg/L)		9100	31700	4100
AF		100	100	10
RAC (µg/L)		91	317	410
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	35.34	0.388	0.111	0.086
Step 2				
S-Europe	12.58	0.138	0.040	0.031
N-Europe	15.48	0.074	0.021	0.016

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 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Flufenacet methytlsulfide (M5) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		Algae
Test species		***Pseudokirchneriella subcapitata***
Endpoint		E_rC_{50}
(µg/L)		83800
AF		10
RAC (µg/L)		8380
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
	6.21	< 0.001

Group		**Algae**
Step 2		
S-Europe	2.21	< 0.001
N-Europe	2.72	< 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 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Flufenacet methytlsulfide (M5) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		**Algae**
Test species		***Pseudokirchneriella subcapitata***
Endpoint		E_rC_{50}
(µg/L)		83800
AF		10
RAC (µg/L)		8380
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1		
	6.21	< 0.001
Step 2		
S-Europe	2.21	< 0.001
N-Europe	1.19	< 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

For the intended uses on winter and spring cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish and algae as characterised by an LC_{50}/EC_{50} for *Oncorhynchus mykiss* and *Pseudokirchneriella subcapitata* of 9100 µg/L and 83800 µg/L in connection with an assessment factor of 100 and 10, respectively) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary.

zRMS comments:

We agree with the risk assessment provided for flufenacet metabolites.

PENDIMETHALIN

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		**Fish acute**	**Fish pro-longed**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Higher plant**	**Higher-tier information**		**Sed. dweller prolonged**
Test species		***O. mykiss***	***P.promelas***	***Danio rerio***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna gibba***	pelagic and bentic species, phytoplankton and peryphyton, macrophytes.		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	NOEC geomean	EC_{50}	NOEC	E_rC_{50}	NOEC	ErC_{50}	NOEC		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12	0.23		227300
AF		100	10	10	100	10	10	10	10	1		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2	0.23		22730
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										**PEC $_{gl-max}$ (µg/kg)**	
Step 1												
	32.95	**16.811**	**52.302**	**10.297**	**22.415**	**22.724**	**35.430**	**4.018**	**27.458**	**143.261**	2850	0.125
Step 2												
S-Europe	11.04	**5.633**	**17.524**	**3.450**	**7.510**	**7.614**	**11.871**	**1.346**	**9.200**	**48.000**	1190	0.052
N-Europe	11.73	**5.985**	**18.619**	**3.666**	**7.980**	**8.090**	**12.613**	**1.430**	**9.775**	**51.000**	1470	0.001
Step 3												
D1/ditch	7.601	**3.878**	**12.065**	**2.375**	**5.171**	**5.242**	**8.173**	0.927	**6.334**	**33.048**	15.70	0.001
D1/stream	6.732	**3.435**	**10.686**	**2.104**	**4.580**	**4.643**	**7.239**	0.821	**5.610**	**29.270**	3.891	<0.001
D2/ditch	7.705	**3.931**	**12.230**	**2.408**	**5.241**	**5.314**	**8.285**	0.940	**6.421**	**33.500**	13.18	0.001
D2/stream	6.855	**3.497**	**10.881**	**2.142**	**4.663**	**4.728**	**7.371**	0.836	**5.713**	**29.804**	11.61	0.001

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dweller prolonged
D3/ditch	7.585	**3.870**	**12.040**	**2.370**	**5.160**	**5.231**	**8.156**	0.925	**6.321**	**32.978**	4.012	<0.001
D4/pond	0.263	0.134	0.417	0.082	0.179	0.181	0.283	0.032	0.219	**1.143**	1.210	<0.001
D4/stream	6.579	**3.357**	**10.443**	**2.056**	**4.476**	**4.537**	**7.074**	0.802	**5.483**	**28.604**	1.375	<0.001
D5/pond	0.263	0.134	0.417	0.082	0.179	0.181	0.283	0.032	0.219	**1.143**	1.530	<0.001
D5/stream	7.097	**3.621**	**11.265**	**2.218**	**4.828**	**4.894**	**7.631**	0.865	**5.914**	**30.857**	1.947	<0.001
D6/ditch	7.671	**3.914**	**12.176**	**2.397**	**5.218**	**5.290**	**8.248**	0.935	**6.393**	**33.352**	15.83	0.001
R1/pond	0.267	0.136	0.424	0.083	0.182	0.184	0.287	0.033	0.223	**1.161**	3.223	<0.001
R1/stream	5.001	**2.552**	**7.938**	**1.563**	**3.402**	**3.449**	**5.377**	0.610	**4.168**	**21.743**	10.36	<0.001
R3/stream	6.943	**3.542**	**11.021**	**2.170**	**4.723**	**4.788**	**7.466**	0.847	**5.786**	**30.187**	408.3	0.018
R4/stream	5.032	**2.567**	**7.987**	**1.573**	**3.423**	**3.470**	**5.411**	0.614	**4.193**	**21.878**	3.823	<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 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		**Fish acute**	**Fish pro-longed**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Higher plant**	**Higher-tier information**		**Sed. dweller pro-longed**
Test species		***O. mykiss***	***P.promelas***	***Danio rerio***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna gibba***	pelagic and bentic species, phytoplankton and peryphyton, macrophytes.		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	NOEC geomean	EC_{50}	NOEC	E_rC_{50}	NOEC	ErC_{50}	NOEC		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12	0.23		227300

Group		**Fish acute**	**Fish pro-longed**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Higher plant**	**Higher-tier information**		**Sed. dwell-er pro-longed**
AF		100	10	10	100	10	10	10	10	1		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2	0.23		22730
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**										**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 1												
	32.95	**16.811**	**52.302**	**10.297**	**22.415**	**22.724**	**35.430**	**4.018**	**27.458**	**143.261**	2850	0.125
Step 2												
S-Europe	11.04	**5.633**	**17.524**	**3.450**	**7.510**	**7.614**	**11.871**	**1.346**	**9.200**	**48.000**	1190	0.052
N-Europe										**48.000**	628.56	0.028
Step 3												
D1/ditch	7.669	**3.913**	**12.173**	**2.397**	**5.217**	**5.289**	**8.246**	0.935	**6.391**	**33.343**	14.69	0.001
D1/stream	6.398	**3.264**	**10.156**	**1.999**	**4.352**	**4.412**	**6.880**	0.780	**5.332**	**27.817**	0.678	<0.001
D3/ditch	7.599	**3.877**	**12.062**	**2.375**	**5.169**	**5.241**	**8.171**	0.927	**6.333**	**33.039**	4.620	<0.001
D4/pond	0.262	0.134	0.416	0.082	0.178	0.181	0.282	0.032	0.218	**1.139**	1.542	<0.001
D4/stream	5.805	**2.962**	**9.214**	**1.814**	**3.949**	**4.003**	**6.242**	0.708	**4.838**	**25.239**	0.207	<0.001
D5/pond	0.263	0.134	0.417	0.082	0.179	0.181	0.283	0.032	0.219	**1.143**	1.449	<0.001
D5/stream	6.028	**3.076**	**9.568**	**1.884**	**4.101**	**4.157**	**6.482**	0.735	**5.023**	**26.209**	0.166	<0.001
R1/pond	0.273	0.139	0.433	0.085	0.186	0.188	0.294	0.033	0.228	**1.187**	2.936	<0.001
R1/stream	5.010	**2.556**	**7.952**	**1.566**	**3.408**	**3.455**	**5.387**	0.611	**4.175**	**21.783**	5.976	<0.001
R4/stream	5.005	**2.554**	**7.944**	**1.564**	**3.405**	**3.452**	**5.382**	0.610	**4.171**	**21.761**	5.401	<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 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Step 3 calculations for the use of KONARK in winter cereals post-emergence BBCH 11

Group		**Fish acute**	**Fish prolonged**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Higher plant**	**Higher-tier information**		**Sed. dweller prolonged**
Test species		***O. mykiss***	***P.promelas***	***Danio rerio***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna gibba***	pelagic and bentic species, phytoplankton and peryphyton, macrophytes.		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	NOEC geomean	EC_{50}	NOEC	E_rC_{50}	NOEC	ErC_{50}	NOEC		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12	0.23		227300
AF		100	10	10	100	10	10	10	10	1		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2	0.23		22730
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**										**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 3												
D1/ditch	7.601	**3.878**	**12.065**	**2.375**	**5.171**	**5.242**	**8.173**	**3.878**	**6.334**	**33.048**	19.780	0.0009
D1/stream	6.647	**3.391**	**10.551**	**2.077**	**4.522**	**4.584**	**7.147**	**3.391**	**5.539**	**28.900**	4.021	0.0002
D2/ditch	7.557	**3.856**	**11.995**	**2.362**	**5.141**	**5.212**	**8.126**	**3.856**	**6.298**	**32.857**	12.380	0.0005
D2/stream	3.132	**1.598**	**4.971**	0.979	**2.131**	**2.160**	**3.368**	**1.598**	**2.610**	**13.617**	0.426	0.0000
D3/ditch	7.487	**3.820**	**11.884**	**2.340**	**5.093**	**5.163**	**8.051**	**3.820**	**6.239**	**32.552**	3.847	0.0002
D4/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.132	0.216	**1.126**	1.333	0.0001
D4/stream	6.496	**3.314**	**10.311**	**2.030**	**4.419**	**4.480**	**6.985**	**3.314**	**5.413**	**28.243**	1.375	0.0001
D5/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.132	0.216	**1.126**	1.530	0.0001

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dweller pro-longed
D5/stream	7.008	**3.576**	**11.124**	**2.190**	**4.767**	**4.833**	**7.535**	**3.576**	**5.840**	**30.470**	1.947	0.0001
D6/ditch	7.575	**3.865**	**12.024**	**2.367**	**5.153**	**5.224**	**8.145**	**3.865**	**6.313**	**32.935**	15.830	0.0007
R1/pond	0.263	0.134	0.417	0.082	0.179	0.181	0.283	0.134	0.219	**1.143**	3.216	0.0001
R1/stream	4.937	**2.519**	**7.837**	**1.543**	**3.359**	**3.405**	**5.309**	**2.519**	**4.114**	**21.465**	10.300	0.0005
R3/stream	6.928	**3.535**	**10.997**	**2.165**	**4.713**	**4.778**	**7.449**	**3.535**	**5.773**	**30.122**	3.460	0.0002
R4/stream	4.897	**2.498**	**7.773**	**1.530**	**3.331**	**3.377**	**5.266**	**2.498**	**4.081**	**21.291**	4.867	0.0002

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 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Step 3 calculations for the use of KONARK in spring cereals post-emergence BBCH 11

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dweller pro-longed
Test species		***O. mykiss***	***P.promelas***	***Danio rerio***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna gibba***	pelagic and bentic species, phytoplankton and peryphyton, macrophytes.		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	NOEC geomean	EC_{50}	NOEC	E_rC_{50}	NOEC	ErC_{50}	NOEC		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12	0.23		227300
AF		100	10	10	100	10	10	10	10	1		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2	0.23		22730

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dwell-er pro-longed
FOCUS Scenario	PEC $_{gl\text{-}max}$ (µg/L)										PEC $_{gl\text{-}max}$ (µg/kg)	
Step 3												
D1/ditch	7.550	**3.852**	**11.984**	**2.359**	**5.136**	**5.207**	**8.118**	**0.921**	**6.292**	**32.826**	9.722	0.00043
D1/stream	6.045	**3.084**	**9.595**	**1.889**	**4.112**	**4.169**	**6.500**	0.737	**5.038**	**26.283**	0.343	0.00002
D3/ditch	7.504	**3.829**	**11.911**	**2.345**	**5.105**	**5.175**	**8.069**	0.915	**6.253**	**32.626**	4.620	0.00020
D4/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.032	0.216	**1.126**	1.368	0.00006
D4/stream	5.949	**3.035**	**9.443**	**1.859**	**4.047**	**4.103**	**6.397**	0.725	**4.958**	**25.865**	0.290	0.00001
D5/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.032	0.216	1.126	1.444	0.00006
D5/stream	5.966	3.044	9.470	1.864	4.059	4.114	6.415	0.728	4.972	25.939	0.169	0.00001
R1/pond	0.268	**0.137**	0.425	0.084	0.182	0.185	0.288	0.033	0.223	**1.165**	**2.643**	0.00012
R1/stream	4.946	**2.523**	**7.851**	**1.546**	**3.365**	**3.411**	**5.318**	0.603	**4.122**	**21.504**	**5.286**	0.00023
R4/stream	4.941	**2.521**	**7.843**	**1.544**	**3.361**	**3.408**	**5.313**	0.603	**4.118**	**21.483**	**5.386**	0.00024

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 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Step 3 calculations for the use of KONARK in winter cereals post-emergence BBCH 21

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dwell-er pro-longed

Group		**Fish acute**	**Fish pro-longed**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Higher plant**	**Higher-tier information**		**Sed. dwell-er pro-longed**
Test species		***O. mykiss***	***P.promelas***	***Danio rerio***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna gibba***	pelagic and bentic species, phytoplankton and peryphyton, macrophytes.		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	NOEC geomean	EC_{50}	NOEC	E_rC_{50}	NOEC	ErC_{50}	NOEC		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12	0.23		227300
AF		100	10	10	100	10	10	10	10	1		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2	0.23		22730
FOCUS Scenario	**PEC gl-max (µg/L)**										**PEC gl-max (µg/kg)**	
Step 3												
D1/ditch	7.535	**3.844**	**11.960**	**2.355**	**5.126**	**5.197**	**8.102**	0.919	**6.279**	**32.761**	7.782	0.0003
D1/stream	5.859	**2.989**	**9.300**	**1.831**	**3.986**	**4.041**	**6.300**	0.715	**4.883**	**25.474**	0.249	0.00001
D2/ditch	7.567	**3.861**	**12.011**	**2.365**	**5.148**	**5.219**	**8.137**	0.923	**6.306**	**32.900**	13.970	0.0006
D2/stream	6.260	**3.194**	**9.937**	**1.956**	**4.259**	**4.317**	**6.731**	0.763	**5.217**	**27.217**	0.595	0.00003
D3/ditch	7.502	**3.828**	**11.908**	**2.344**	**5.103**	**5.174**	**8.067**	0.915	**6.252**	**32.617**	4.535	0.0002
D4/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.032	0.216	**1.126**	1.657	0.0001
D4/stream	5.549	**2.831**	**8.808**	**1.734**	**3.775**	**3.827**	**5.967**	0.677	**4.624**	**24.126**	0.164	0.00001
D5/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.032	0.216	**1.126**	1.448	0.0001
D5/stream	5.932	**3.027**	**9.416**	**1.854**	**4.035**	**4.091**	**6.378**	0.723	**4.943**	**25.791**	0.162	0.00001

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dweller pro-longed
D6/ditch	7.376	**3.763**	**11.708**	**2.305**	**5.018**	**5.087**	**7.931**	0.900	**6.147**	**32.070**	1.719	0.0001
R1/pond	0.260	0.133	0.413	0.081	0.177	0.179	0.280	0.032	0.217	**1.130**	1.569	0.0001
R1/stream	4.946	**2.523**	**7.851**	**1.546**	**3.365**	**3.411**	**5.318**	0.603	**4.122**	**21.504**	4.676	0.0002
R3/stream	6.948	**3.545**	**11.029**	**2.171**	**4.727**	**4.792**	**7.471**	0.847	**5.790**	**30.209**	3.284	0.0001
R4/stream	4.968	**2.535**	**7.886**	**1.553**	**3.380**	**3.426**	**5.342**	0.606	**4.140**	**21.600**	3.735	0.0002

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 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pendimethalin for each organism group based on FOCUS Step 3 calculations for the use of KONARK in spring cereals post-emergence BBCH 21

Group		Fish acute	Fish pro-longed	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plant	Higher-tier information		Sed. dweller pro-longed
Test species		***O. mykiss***	***P.promelas***	***Danio rerio***	***Daphnia magna***	***Daphnia magna***	***P. subcapitata***	***Chironomus riparius***	***Lemna gibba***	pelagic and bentic species, phytoplankton and peryphyton, macrophytes.		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	NOEC geomean	EC_{50}	NOEC	E_rC_{50}	NOEC	ErC_{50}	NOEC		NOEC
(µg/L)		196	6.3	32	147	14.5	9.3	82	12	0.23		227300
AF		100	10	10	100	10	10	10	10	1		10
RAC (µg/L)		1.96	0.63	3.2	1.47	1.45	0.93	8.2	1.2	0.23		22730

Group		**Fish acute**	**Fish pro-longed**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Higher plant**	**Higher-tier information**		**Sed. dwell-er pro-longed**
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**										**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 3												
D1/ditch	7.601	**3.878**	**12.065**	**2.375**	**5.171**	**5.242**	**8.173**	**0.927**	**6.334**	**33.048**	15.360	0.0007
D1/stream	6.647	**3.391**	**10.551**	**2.077**	**4.522**	**4.584**	**7.147**	0.811	**5.539**	**28.900**	3.877	0.0002
D3/ditch	7.509	**3.831**	**11.919**	**2.347**	**5.108**	**5.179**	**8.074**	0.916	**6.258**	**32.648**	4.940	0.0002
D4/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.032	0.216	**1.126**	1.134	0.00005
D4/stream	6.143	**3.134**	**9.751**	**1.920**	**4.179**	**4.237**	**6.605**	0.749	**5.119**	**26.709**	0.427	0.00002
D5/pond	0.259	0.132	0.411	0.081	0.176	0.179	0.278	0.032	0.216	**1.126**	1.444	0.0001
D5/stream	5.966	**3.044**	**9.470**	**1.864**	**4.059**	**4.114**	**6.415**	0.728	**4.972**	**25.939**	0.169	0.00001
R1/pond	0.268	0.137	0.425	0.084	0.182	0.185	0.288	0.033	0.223	**1.165**	2.605	0.0001
R1/stream	4.946	**2.523**	**7.851**	**1.546**	**3.365**	**3.411**	**5.318**	0.603	**4.122**	**21.504**	5.440	0.0002
R4/stream	4.941	**2.521**	**7.843**	**1.544**	**3.361**	**3.408**	**5.313**	0.603	**4.118**	**21.483**	5.159	0.0002

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 on winter and spring cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for algae as characterised by an NOEC for higher tier study of 0.23 ~~EC_{50} for P. subcapitata of 9.3~~ µg/L in connection with an assessment factor of 1~~0~~) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

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 algae with mitigation of spray drift and run-off for the use of KONARK in winter cereals pre-emergence

Intended use		Winter cereals							
Active sub-stance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.0	1.112	0.764	–	–	–	–	–
50%		1.0	0.599	–	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	D1 stream	2.4	1.307	0.893	–	–	–	–	–
50%		1.2	0.654	–	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	D2 ditch	2.0	1.116	0.767	–	–	–	–	–
50%		1.0	0.603	–	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	D2 stream	2.5	1.330	0.909	–	–	–	–	–
50%		1.2	0.666	–	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	D3 ditch	2.0	1.091	0.745	–	–	–	–	–
50%		1.0	0.545	–	–	–	–	–	–
75%		0.5	–	–	–	–	–	–	–
None	D4 stream	2.4	1.277	0.873	–	–	–	–	–
50%		1.2	0.647	–	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	D5 stream	2.5	1.378	0.941	0.716	–	–	–	–
50%		1.3	0.693	0.475	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	D6 ditch	2.0	1.115	0.766	–	–	–	–	–
50%		1.0		–	–	–	–	–	–
75%		0.6	–	–	–	–	–	–	–
None	R1 stream	1.8	1.366	1.366	–	1.864	1.000	0.686	0.522
50%		1.3	1.366	–	–	0.956	0.617	–	–
75%		1.3	–	–	–	0.886	–	–	–
None	R3 stream	2.5	1.380	1.324	–	2.574	1.380	0.946	0.720

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50%		1.3	1.324	-	-	1.319	0.715	0.492	-
75%		1.3	-	-	-	0.854	-	-	-
None	R4 stream	1.8	1.672	1.672	-	1.866	1.004	0.689	0.524
50%		1.6	1.672	-	-	1.086	0.755	-	-
75%		1.6	-	-	-	1.086	-	-	-
RAC (µg/L)		**PEC/RAC ratio**							
0.93 (*P. subcapitata*)									
None	D1 ditch	**2.2**	**1.196**	0.822	-	-	-	-	-
50%		**1.1**	0.644	-	-	-	-	-	-
75%		0.6	-	-	-	-	-	-	-
None	D1 stream	**2.6**	**1.405**	0.960	-	-	-	-	-
50%		**1.3**	0.703	-	-	-	-	-	-
75%		0.6	-	-	-	-	-	-	-
None	D2 ditch	**2.2**	**1.200**	0.825	-	-	-	-	-
50%		**1.1**	0.648	-	-	-	-	-	-
75%		0.6	-	-	-	-	-	-	-
None	D2 stream	**2.6**	**1.430**	0.977	-	-	-	-	-
50%		**1.3**	0.716	-	-	-	-	-	-
75%		0.6	-	-	-	-	-	-	-
None	D3 ditch	**2.2**	**1.173**	0.801	-	-	-	-	-
50%		**1.1**	0.586	-	-	-	-	-	-
75%		0.5	-	-	-	-	-	-	-
None	D4 stream	**2.5**	**1.373**	0.939	-	-	-	-	-
50%		**1.2**	0.696	-	-	-	-	-	-
75%		0.6	-	-	-	-	-	-	-
None	D5 stream	**2.7**	**1.482**	**1.012**	0.770	-	-	-	-
50%		**1.3**	0.745	0.511	-	-	-	-	-
75%		0.7	-	-	-	-	-	-	-
None	D6 ditch	**2.2**	**1.199**	0.824	-	-	-	-	-
50%		**1.1**	-	-	-	-	-	-	-
75%		0.6	-	-	-	-	-	-	-
None	R1 stream	**2.0**	**1.469**	**1.469**	-	2.004	1.075	0.739	0.563

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50%		**1.4**	**1.469**	-	-	**1.028**	0.663	-	-
75%		**1.4**	-	-	-	0.953	-	-	-
None	R3 stream	**2.7**	**1.484**	**1.424**	-	**2.768**	**1.484**	1.017	0.754
50%		**1.4**	**1.424**	-	-	**1.418**	0.769	0.529	-
75%		**1.4**	-	-	-	0.918	-	-	-
None	R4 stream	**2.0**	**1.798**	**1.798**	-	**2.006**	**1.080**	0.741	0.563
50%		**1.7**	**1.798**	-	-	**1.168**	0.812	-	-
75%		**1.7**	-	-	-	**1.168**	-	-	-

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.087	1.112	0.764	0.573	-	-	-	-
50%		1.072	0.599	0.412	0.312	-	-	-	-
75%		0.607	0.354	0.252	0.191	-	-	-	-
90%		0.346	0.228	0.166	-	-	-	-	-
None	D1 stream	2.462	1.307	0.893	0.669	-	-	-	-
50%		1.233	0.654	0.441	0.335	-	-	-	-
75%		0.618	0.324	0.224	0.170	-	-	-	-
90%		0.288	0.188	-	-	-	-	-	-
None	D2 ditch	2.089	1.116	0.767	0.575	-	-	-	-
50%		1.076	0.603	0.415	0.314	-	-	-	-
75%		0.611	0.358	0.255	0.219	-	-	-	-
90%		0.350	0.230	0.219	-	-	-	-	-
None	D2 stream	2.507	1.330	0.909	0.682	-	-	-	-
50%		1.255	0.666	0.449	0.342	-	-	-	-
75%		0.629	0.329	0.225	0.171	-	-	-	-
90%		0.250	0.142	-	-	-	-	-	-
None	D3 ditch	2.056	1.091	0.745	0.559	-	-	-	-
50%		1.028	0.545	0.370	0.281	-	-	-	-
75%		0.533	0.298	0.209	0.158	-	-	-	-
90%		0.271	0.175	-	-	-	-	-	-
None	D4 pond	0.238	0.172	-	-	-	-	-	-
50%		0.134	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.407	1.277	0.873	0.655	-	-	-	-
50%		1.205	0.647	0.439	0.334	-	-	-	-
75%		0.626	0.340	0.235	0.197	-	-	-	-
90%		0.282	0.197	0.197	-	-	-	-	-
None	D5 pond	0.242	0.175	-	-	-	-	-	-
50%		0.137	-	-	-	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.596	1.378	0.941	0.706	-	-	-	-
50%		1.300	0.693	0.475	0.356	-	-	-	-
75%		0.667	0.362	0.250	0.190	-	-	-	-
90%		0.306	0.184	0.131	-	-	-	-	-
None	D6 ditch	2.080	1.115	0.766	0.575	-	-	-	-
50%		1.075	0.597	0.417	0.322	-	-	-	-
75%		0.613	0.362	0.322	0.322	-	-	-	-
90%		0.353	0.322	0.322	-	-	-	-	-
None	R1 pond	0.263	0.253	0.248	0.244	0.246	0.178	-	-
50%		0.248	0.242	0.239	0.237	0.158	-	-	-
75%		0.240	0.237	0.235	-	-	-	-	-
90%		0.236	0.234	0.232	-	-	-	-	-
None	R1 stream	1.864	1.366	1.366	-	1.864	1.000	0.686	0.522
50%		1.366	1.366	-	-	0.956	0.617	0.467	0.318
75%		1.366	-	-	-	0.886	0.609	0.467	0.318
90%		-	-	-	-	0.874	0.609	-	-
None	R3 stream	2.574	1.380	1.324	-	2.574	1.380	0.946	0.720
50%		1.324	1.324	-	-	1.319	0.715	~~0.492~~ 0.485	0.369
75%		1.324	-	-	-	0.854	0.596	0.458	0.313
90%		-	-	-	-	0.854	0.596	0.458	0.313
None	R4 stream	1.866	1.672	1.672	-	1.866	1.004	0.689	0.524
50%		1.672	1.672	-	-	1.086	0.755	0.570	0.389
75%		1.672	-	-	-	1.086	0.744	0.570	0.389
90%		-	-	-	-	1.071	0.744	-	-
RAC (µg/L) 0.23 (H*igher tier*)		**PEC/RAC ratio**							
None	D1 ditch	**9.074**	**4.835**	**3.322**	**2.491**	-	-	-	-
50%		**4.661**	**2.604**	**1.791**	**1.357**	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		**2.639**	**1.539**	**1.096**	0.830	-	-	-	-
90%		**1.504**	0.991	0.722	-	-	-	-	-
None	D1 stream	**10.704**	**5.683**	**3.883**	**2.909**	-	-	-	-
50%		**5.361**	**2.843**	**1.917**	**1.457**	-	-	-	-
75%		**2.687**	**1.409**	0.974	0.739	-	-	-	-
90%		**1.252**	0.817	-	-	-	-	-	-
None	D2 ditch	**9.083**	**4.852**	**3.335**	**2.500**	-	-	-	-
50%		**4.678**	**2.622**	**1.804**	**1.365**	-	-	-	-
75%		**2.657**	**1.557**	**1.109**	0.952	-	-	-	-
90%		**1.522**	**1.000**	0.952	-	-	-	-	-
None	D2 stream	**10.900**	**5.783**	**3.952**	**2.965**	-	-	-	-
50%		**5.457**	**2.896**	**1.952**	**1.487**	-	-	-	-
75%		**2.735**	**1.430**	0.978	0.743	-	-	-	-
90%		**1.087**	0.617	-	-	-	-	-	-
None	D3 ditch	**8.939**	**4.743**	**3.239**	**2.430**	-	-	-	-
50%		**4.470**	**2.370**	**1.609**	**1.222**	-	-	-	-
75%		**2.317**	**1.296**	0.909	0.687	-	-	-	-
90%		**1.178**	0.761	-	-	-	-	-	-
None	D4 pond	**1.035**	0.748	-	-	-	-	-	-
50%		0.583	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	**10.465**	**5.552**	**3.796**	**2.848**	-	-	-	-
50%		**5.239**	**2.813**	**1.909**	**1.452**	-	-	-	-
75%		**2.722**	**1.478**	**1.022**	0.857	-	-	-	-
90%		**1.226**	0.857	0.857	-	-	-	-	-
None	D5 pond	**1.052**	0.761	-	-	-	-	-	-
50%		0.596	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	**11.287**	**5.991**	**4.091**	**3.070**	-	-	-	-
50%		**5.652**	**3.013**	**2.065**	**1.548**	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		**2.900**	**1.574**	**1.087**	0.826	-	-	-	-
90%		**1.330**	0.800	0.570	-	-	-	-	-
None	D6 ditch	**9.043**	**4.848**	**3.330**	**2.500**	-	-	-	-
50%		**4.674**	**2.596**	**1.813**	**1.400**	-	-	-	-
75%		**2.665**	**1.574**	**1.400**	**1.400**	-	-	-	-
90%		**1.535**	**1.400**	**1.400**	-	-	-	-	-
None	R1 pond	**1.143**	**1.100**	**1.078**	**1.061**	**1.070**	0.774	-	-
50%		**1.078**	**1.052**	**1.039**	**1.030**	0.687	-	-	-
75%		**1.043**	**1.030**	**1.022**	-	-	-	-	-
90%		**1.026**	**1.017**	**1.009**	-	-	-	-	-
None	R1 stream	**8.104**	**5.939**	**5.939**	-	**8.104**	**4.348**	**2.983**	**2.270**
50%		**5.939**	**5.939**	-	-	**4.157**	**2.683**	**2.030**	**1.383**
75%		**5.939**	-	-	-	**3.852**	**2.648**	**2.030**	**1.383**
90%		-	-	-	-	**3.800**	**2.648**	-	-
None	R3 stream	**11.191**	**6.000**	**5.757**	-	**11.191**	**6.000**	**4.113**	**3.130**
50%		**5.757**	**5.757**	-	-	**5.735**	**3.109**	**2.109**	**1.604**
75%		**5.757**	-	-	-	**3.713**	**2.591**	**1.991**	**1.361**
90%		-	-	-	-	**3.713**	**2.591**	**1.991**	**1.361**
None	R4 stream	**8.113**	**7.270**	**7.270**	-	**8.113**	**4.365**	**2.996**	**2.278**
50%		**7.270**	**7.270**	-	-	**4.722**	**3.283**	**2.478**	**1.691**
75%		**7.270**	-	-	-	**4.722**	**3.235**	**2.478**	**1.691**
90%		-	-	-	-	**4.657**	**3.235**	-	-

*0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
**0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Table 9.5-19: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pendimethalin based on VFSMOD STEP 4 calculations and toxicity data for algae with mitigation of spray drift and run-off for the use of KONARK in winter cereals pre-emergence

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.268
75 %		0.278	0.193	0.147
90 %		0.139	-	-
50 %	R3 stream	-	-	-
75 %		0.470	0.377	0.297
90 %		0.471	0.377	0.297
50 %	R4 stream	-	-	0.271
75 %		0.280	0.195	0.148
90 %		0.149	-	-
RAC (µg/L) 0.23 (*Higher tier*)		**PEC/RAC ratio**		
50 %	R1 stream	-	-	1.165
75 %		**1.209**	0.839	0.639
90 %		0.604	-	-
50 %	R3 stream	-	-	-
75 %		**2.043**	**1.639**	**1.291**
90 %		**2.048**	**1.639**	**1.291**
50 %	R4 stream	-	-	**1.178**
75 %		**1.217**	0.848	0.643
90 %		0.648	-	-

For the intended use in winter cereals (pre emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D4 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray

buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.

- D5 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D6 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- R1 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.
- R3 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 20 m no spray buffer zone together with 20 m vegetated filter strip are considered.
- R3 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.
- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D4 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D4 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D5 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 10 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered.
- R3 stream: 15 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered
- R3 stream: 15 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered

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 algae with mitigation of spray drift and run-off for the use of KONARK in winter cereals in post-emergence (BBCH 11)

Intended use	Spring cereals
Active substance	Pendimethalin

Application rate (g/ha)		1 x 1200						
Nozzle reduction	Vegetative strip (m)	None			5*	10	15	20
	No spray buffer (m)	5	10	15	5	10	15	20
None	D1 ditch	2.07	1.112	0.764	-	-	-	-
50%		1.07	0.602	-	-	-	-	-
75%		0.61	-	-	-	-	-	-
None	D1 stream	2.36	1.263	0.865	-	-	-	-
50%		1.20	0.650	-	-	-	-	-
75%		0.62	-	-	-	-	-	-
None	D3 ditch	2.06	1.093	0.746	-	-	-	-
50%		1.03	0.549	-	-	-	-	-
75%		0.54	-	-	-	-	-	-
None	D4 stream	2.14	1.143	0.782	-	-	-	-
50%		1.08	0.580	-	-	-	-	-
75%		0.55	-	-	-	-	-	-
None	D5 stream	2.22	1.183	0.809	-	-	-	-
50%		1.12	0.599	-	-	-	-	-
75%		0.57	-	-	-	-	-	-
None	R1 stream	1.86	1.288	1.288	1.864	0.848	-	-
50%		1.28	1.288	-	0.955	-	-	-
75%		1.28	-	-	0.840	-	-	-
None	R4 stream	1.86	1.569	1.569	1.863	0.999	0.695	0.534
50%		1.56	1.569	-	1.024	0.714	-	-
75%		1.56	-	-		-	-	-
RAC (µg/L) 0.93 (*P. sub-*		**PEC/RAC ratio**						
None	D1 ditch	**2.23**	**1.196**	0.822	-	-	-	-
50%		**1.15**	0.647	-	-	-	-	-
75%		0.65	-	-	-	-	-	-
None	D1 stream	**2.53**	**1.358**	0.930	-	-	-	-
50%		**1.29**	0.699	-	-	-	-	-
75%		0.67	-	-	-	-	-	-
None	D3 ditch	**2.21**	**1.175**	0.802	-	-	-	-
50%		**1.10**	0.590	-	-	-	-	-
75%		0.58	-	-	-	-	-	-
None	D4 stream	**2.30**	**1.229**	0.841	-	-	-	-
50%		**1.16**	0.624	-	-	-	-	-

Intended use	Spring cereals							
Active substance	Pendimethalin							
Application rate (g/ha)	1 x 1200							
Nozzle reduction	Vegetative strip (m)	None			5*	10	15*	20
	No spray buffer (m)	5	10	15	5	10	15	20
75%		0.59	-	-	-	-	-	-
None	D5 stream	**2.38**	**1.272**	0.870	-	-	-	-
50%		**1.20**	0.644	-	-	-	-	-
75%		0.61	-	-	-	-	-	-
None	R1 stream	**2.00**	**1.385**	**1.385**	**2.004**	0.912	-	-
50%		**1.38**	**1.385**	-	**1.027**	-	-	-
75%		**1.38**	-	-	0.903	-	-	-
None	R4 stream	**2.00**	**1.687**	**1.687**	**2.003**	**1.074**	0.532	0.509
50%		**1.68**	**1.687**	-	**1.101**	0.768	-	-
75%		**1.68**	-	-	-	-	-	-

*0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegeta tive simulation, according to the Austrian Environmental Agency AGES.
**0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use	Winter cereals							
Active substance	Pendimethalin							
Application rate (g/ha)	1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.059	1.110	0.763	0.580	-	-	-	-
50%		1.077	0.608	0.424	0.321	-	-	-	-
75%		0.615	0.372	0.265	0.201	-	-	-	-
90%		0.363	0.239	0.174	-	-	-	-	-
None	D1 stream	2.430	1.289	0.880	0.669	-	-	-	-
50%		1.216	0.645	0.441	0.335	-	-	-	-
75%		0.609	0.331	0.231	0.176	-	-	-	-
90%		0.299	0.196	0.143	-	-	-	-	-

Intended use	Winter cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D2 ditch	2.047	1.085	0.741	0.564	-	-	-	-
50%		1.038	0.574	0.400	0.303	-	-	-	-
75%		0.581	0.345	0.244	0.195	-	-	-	-
90%		0.336	0.226	0.195	-	-	-	-	-
None	D2 stream	2.273	1.213	0.830	0.632	-	-	-	-
50%		1.154	0.620	0.425	0.323	-	-	-	-
75%		0.594	0.323	0.222	0.169	-	-	-	-
90%		0.259	0.148	-	-	-	-	-	-
None	D3 ditch	2.028	1.075	0.734	0.559	-	-	-	-
50%		1.014	0.537	0.368	0.280	-	-	-	-
75%		0.524	0.297	0.207	0.157	-	-	-	-
90%		0.267	0.172	-	-	-	-	-	-
None	D4 pond	0.238	0.172	-	-	-	-	-	-
50%		0.134	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.375	1.260	0.861	0.655	-	-	-	-
50%		1.189	0.368	0.439	0.334	-	-	-	-
75%		0.617	0.340	0.235	0.182	-	-	-	-
90%		0.282	0.182	0.182	-	-	-	-	-
None	D5 pond	0.242	0.175	-	-	-	-	-	-
50%		0.137	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.562	1.359	0.928	0.706	-	-	-	-
50%		1.282	0.683	0.468	0.356	-	-	-	-
75%		0.658	0.362	0.250	0.190	-	-	-	-
90%		0.306	0.184	0.131	-	-	-	-	-
None	D6 ditch	2.052	1.100	0.756	0.575	-	-	-	-
50%		1.060	0.597	0.417	0.326	-	-	-	-
75%		0.605	0.362	0.326	0.326	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		0.353	0.326	0.326	-	-	-	-	-
None	R1 pond	0.262	0.252	0.247	0.244	0.246	0.178	-	-
50%		0.247	0.242	0.239	0.237	0.157	-	-	-
75%		0.240	0.236	0.234	0.233	-	-	-	-
90%		0.235	0.233	0.232	0.231	-	-	-	-
None	R1 stream	1.839	1.343	1.343	-	1.839	0.986	0.676	0.514
50%		1.343	1.343	-	-	0.943	0.607	0.466	0.318
75%		1.343	-	-	-	0.872	0.607	0.466	0.318
90%		-	-	-	-	0.872	-	-	-
None	R3 stream	2.553	1.370	1.179	1.179	2.553	1.370	0.939	0.714
50%		1.312	1.179	1.179	-	1.311	0.712	0.490	0.373
75%		1.179	1.179	-	-	0.762	0.530	0.406	0.277
90%		1.179	-	-	-	0.762	0.530	0.406	0.277
None	R4 stream	1.825	1.740	1.740	-	1.825	0.979	0.671	0.510
50%		1.740	1.740	-	-	1.130	0.785	0.601	0.410
75%		1.740	-	-	-	1.130	0.785	0.601	0.410
90%		-	-	-	-	-	-	-	-
RAC (µg/L) 0.23 (H*igher tier*)		**PEC/RAC ratio**							
None	D1 ditch	**8.952**	**4.826**	**3.317**	**2.522**	-	-	-	-
50%		**4.683**	**2.643**	**1.843**	**1.396**	-	-	-	-
75%		**2.674**	**1.617**	**1.152**	0.874	-	-	-	-
90%		**1.578**	**1.039**	0.757	-	-	-	-	-
None	D1 stream	**10.565**	**5.604**	**3.826**	**2.909**	-	-	-	-
50%		**5.287**	**2.804**	**1.917**	**1.457**	-	-	-	-
75%		**2.648**	**1.439**	**1.004**	0.765	-	-	-	-
90%		**1.300**	0.852	0.622	-	-	-	-	-
None	D2 ditch	**8.900**	**4.717**	**3.222**	**2.452**	-	-	-	-
50%		**4.513**	**2.496**	**1.739**	**1.317**	-	-	-	-
75%		**2.526**	**1.500**	**1.061**	0.848	-	-	-	-
90%		**1.461**	0.983	0.848	-	-	-	-	-

Intended use	Winter cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D2 stream	**9.883**	**5.274**	**3.609**	**2.748**	-	-	-	-
50%		**5.017**	**2.696**	**1.848**	**1.404**	-	-	-	-
75%		**2.583**	**1.404**	0.965	0.735	-	-	-	-
90%		**1.126**	0.643	-	-	-	-	-	-
None	D3 ditch	**8.817**	**4.674**	**3.191**	**2.430**	-	-	-	-
50%		**4.409**	**2.335**	**1.600**	**1.217**	-	-	-	-
75%		**2.278**	**1.291**	0.900	0.683	-	-	-	-
90%		**1.161**	0.748	-	-	-	-	-	-
None	D4 pond	**1.035**	0.748	-	-	-	-	-	-
50%		0.583	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	**10.326**	**5.478**	**3.743**	**2.848**	-	-	-	-
50%		**5.170**	**1.600**	**1.909**	**1.452**	-	-	-	-
75%		**2.683**	**1.478**	**1.022**	0.791	-	-	-	-
90%		**1.226**	0.791	0.791	-	-	-	-	-
None	D5 pond	**1.052**	0.761	-	-	-	-	-	-
50%		0.596	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	**11.139**	**5.909**	**4.035**	**3.070**	-	-	-	-
50%		**5.574**	**2.970**	**2.035**	**1.548**	-	-	-	-
75%		**2.861**	**1.574**	**1.087**	0.826	-	-	-	-
90%		**1.330**	0.800	0.570	-	-	-	-	-
None	D6 ditch	**8.922**	**4.783**	**3.287**	**2.500**	-	-	-	-
50%		**4.609**	**2.596**	**1.813**	**1.417**	-	-	-	-
75%		**2.630**	**1.574**	**1.417**	**1.417**	-	-	-	-
90%		**1.535**	**1.417**	**1.417**	-	-	-	-	-
None	R1 pond	**1.139**	**1.096**	**1.074**	**1.061**	**1.070**	0.774	-	-
50%		**1.074**	**1.052**	**1.039**	**1.030**	0.683	-	-	-
75%		**1.043**	**1.026**	**1.017**	**1.013**	-	-	-	-
90%		**1.022**	**1.013**	**1.009**	**1.004**	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	R1 stream	**7.996**	**5.839**	**5.839**	-	**7.996**	**4.287**	**2.939**	**2.235**
50%		**5.839**	**5.839**	-	-	**4.100**	**2.639**	**2.026**	**1.383**
75%		**5.839**	-	-	-	**3.791**	**2.639**	**2.026**	**1.383**
90%		-	-	-	-	**3.791**	-	-	-
None	R3 stream	**11.100**	**5.957**	**5.126**	**5.126**	**11.100**	**5.957**	**4.083**	**3.104**
50%		**5.704**	**5.126**	**5.126**	-	**5.700**	**3.096**	**2.130**	**1.622**
75%		**5.126**	**5.126**	-	-	**3.313**	**2.304**	**1.765**	**1.204**
90%		**5.126**	-	-	-	**3.313**	**2.304**	**1.765**	**1.204**
None	R4 stream	**7.935**	**7.565**	**7.565**	-	**7.935**	**4.257**	**2.917**	**2.217**
50%		**7.565**	**7.565**	-	-	**4.913**	**3.413**	**2.613**	**1.783**
75%		**7.565**	-	-	-	**4.913**	**3.413**	**2.613**	**1.783**
90%		-	-	-	-	-	-	-	-

*0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
**0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Table 9.5-21: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pendimethalin based on VFSMOD STEP 4 calculations and toxicity data for algae with mitigation of spray drift and run-off for the use of KONARK in winter cereals pre-emergence post-emergence (BBCH 11)

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.268
75 %		0.278	0.193	0.147
90 %		0.139	-	-
50 %	R3 stream	-	-	-
75 %		0.470	0.377	0.297

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
90 %		0.471	0.377	0.297
50 %	R4 stream	-	-	0.271
75 %		0.280	0.195	0.148
90 %		0.149	-	-
RAC (µg/L) 0.23 (*Higher tier*)		**PEC/RAC ratio**		
50 %	R1 stream	-	-	**1.165**
75 %		**1.209**	0.839	0.639
90 %		0.604	-	-
50 %	R3 stream	-	-	-
75 %		**2.043**	**1.639**	**1.291**
90 %		**2.048**	**1.639**	**1.291**
50 %	R4 stream	-	-	**1.178**
75 %		**1.217**	0.848	0.643
90 %		0.648	-	-

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 algae with mitigation of spray drift and run-off for the use of KONARK in winter cereals in post-emergence (BBCH 21)

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.041	1.082	0.739	0.562	-	-	-	-
50%		1.027	0.564	0.390	0.296	-	-	-	-
75%		0.566	0.336	0.238	0.180	-	-	-	-
90%		0.315	0.208	0.150	-	-	-	-	-
None	D1 stream	2.166	1.155	0.790	0.601	-	-	-	-
50%		1.096	0.588	0.403	0.306	-	-	-	-
75%		0.561	0.304	0.209	0.159	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		0.241	0.134	-	-	-	-	-	-
None	D2 ditch	2.050	1.089	0.748	0.569	-	-	-	-
50%		1.050	0.585	0.408	0.309	-	-	-	-
75%		0.592	0.351	0.250	0.189	-	-	-	-
90%		0.343	0.226	0.165	-	-	-	-	-
None	D2 stream	2.314	1.233	0.844	0.642	-	-	-	-
50%		1.175	0.634	0.436	0.332	-	-	-	-
75%		0.611	0.335	0.232	0.176	-	-	-	-
90%		0.273	0.156	0.109	-	-	-	-	-
None	D3 ditch	2.032	1.077	0.736	0.560	-	-	-	-
50%		1.016	0.540	0.373	0.284	-	-	-	-
75%		0.531	0.302	0.213	0.161	-	-	-	-
90%		0.281	0.182	-	-	-	-	-	-
None	D4 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.045	1.088	0.744	0.566	-	-	-	-
50%		1.031	0.551	0.377	0.287	-	-	-	-
75%		0.525	0.283	0.194	0.147	-	-	-	-
90%		0.221	0.121	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.184	1.162	0.795	0.604	-	-	-	-
50%		1.101	0.588	0.403	0.306	-	-	-	-
75%		0.559	0.301	0.206	0.157	-	-	-	-
90%		0.234	0.129	-	-	-	-	-	-
None	D6 ditch	1.998	1.059	0.723	0.550	-	-	-	-
50%		0.999	0.529	0.362	0.298	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		0.499	0.298	0.298	0.298	-	-	-	-
90%		0.298	0.298	0.298	-	-	-	-	-
None	R1 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.839	0.986	0.830	-	1.839	0.986	0.676	0.514
50%		0.942	0.830	-	-	0.942	0.513	0.354	0.269
75%		0.830	0.830	-	-	0.541	0.377	0.289	0.197
90%		0.830	-	-	-	0.541	0.377	0.289	-
None	R3 stream	2.552	1.366	0.936	0.918	2.552	1.365	0.936	0.712
50%		1.305	0.918	0.918	-	1.305	0.707	0.486	0.370
75%		0.918	0.918	-	-	0.686	0.412	0.316	0.215
90%		0.918	-	-	-	0.594	0.412	0.316	-
None	R4 stream	1.841	1.639	1.639	-	1.841	0.990	0.679	0.516
50%		1.639	1.639	-	-	1.064	0.740	0.567	0.386
75%		1.639	-	-	-	1.064	0.740	0.567	0.386
90%		-	-	-	-	-	-	-	-
RAC (µg/L) 0.23 (H*igher tier*)		**PEC/RAC ratio**							
None	D1 ditch	**8,874**	**4,704**	**3,213**	**2,443**	-	-	-	-
50%		**4,465**	**2,452**	**1,696**	**1,287**	-	-	-	-
75%		**2,461**	**1,461**	**1,035**	0,783	-	-	-	-
90%		**1,370**	0,904	0,652	-	-	-	-	-
None	D1 stream	**9,417**	**5,022**	**3,435**	**2,613**	-	-	-	-
50%		**4,765**	**2,557**	**1,752**	**1,330**	-	-	-	-
75%		**2,439**	**1,322**	0,909	0,691	-	-	-	-
90%		**1,048**	0,583	-	-	-	-	-	-
None	D2 ditch	**8,913**	**4,735**	**3,252**	**2,474**	-	-	-	-
50%		**4,565**	**2,543**	**1,774**	**1,343**	-	-	-	-
75%		**2,574**	**1,526**	**1,087**	0,822	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		**1,491**	0,983	0,717	-	-	-	-	-
None	D2 stream	**10,061**	**5,361**	**3,670**	**2,791**	-	-	-	-
50%		**5,109**	**2,757**	**1,896**	**1,443**	-	-	-	-
75%		**2,657**	**1,457**	**1,009**	0,765	-	-	-	-
90%		**1,187**	0,678	0,474	-	-	-	-	-
None	D3 ditch	**8,835**	**4,683**	**3,200**	**2,435**	-	-	-	-
50%		**4,417**	**2,348**	**1,622**	**1,235**	-	-	-	-
75%		**2,309**	**1,313**	0,926	0,700	-	-	-	-
90%		**1,222**	0,791	-	-	-	-	-	-
None	D4 pond	**1,057**	0,765	-	-	-	-	-	-
50%		0,600	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	**8,891**	**4,730**	**3,235**	**2,461**	-	-	-	-
50%		**4,483**	**2,396**	**1,639**	**1,248**	-	-	-	-
75%		**2,283**	**1,230**	0,843	0,639	-	-	-	-
90%		0,961	0,526	-	-	-	-	-	-
None	D5 pond	**1,043**	0,757	-	-	-	-	-	-
50%		0,591	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	**9,496**	**5,052**	**3,457**	**2,626**	-	-	-	-
50%		**4,787**	**2,557**	**1,752**	**1,330**	-	-	-	-
75%		**2,430**	**1,309**	0,896	0,683	-	-	-	-
90%		**1,017**	0,561	-	-	-	-	-	-
None	D6 ditch	**8,687**	**4,604**	**3,143**	**2,391**	-	-	-	-
50%		**4,343**	**2,300**	**1,574**	**1,296**	-	-	-	-
75%		**2,170**	**1,296**	**1,296**	**1,296**	-	-	-	-
90%		**1,296**	**1,296**	**1,296**	-	-	-	-	-
None	R1 pond	**1,057**	0,765	-	-	-	-	-	-
50%		0,600	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-

Intended use		Winter cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		-	-	-	-	-	-	-	-
None	R1 stream	**7,996**	**4,287**	**3,609**	-	**7,996**	**4,287**	**2,939**	**2,235**
50%		**4,096**	**3,609**	-	-	**4,096**	**2,230**	**1,539**	**1,170**
75%		**3,609**	**3,609**	-	-	**2,352**	**1,639**	**1,257**	0,857
90%		**3,609**	-	-	-	**2,352**	**1,639**	**1,257**	-
None	R3 stream	**11,096**	**5,939**	**4,070**	**3,991**	**11,096**	**5,935**	**4,070**	**3,096**
50%		**5,674**	**3,991**	**3,991**	-	**5,674**	**3,074**	**2,113**	**1,609**
75%		**3,991**	**3,991**	-	-	**2,983**	**1,791**	**1,374**	0,935
90%		**3,991**	-	-	-	**2,583**	**1,791**	**1,374**	-
None	R4 stream	**8,004**	**7,126**	**7,126**	-	**8,004**	**4,304**	**2,952**	**2,243**
50%		**7,126**	**7,126**	-	-	**4,626**	**3,217**	**2,465**	**1,678**
75%		**7,126**	-	-	-	**4,626**	**3,217**	**2,465**	**1,678**
90%		-	-	-	-	-	-	-	-

*0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
**0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.
PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

Table 9.5-23: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pendimethalin based on VFSMOD STEP 4 calculations and toxicity data for algae with mitigation of spray drift and run-off for the use of KONARK in winter cereals post-emergence (BBCH 21)

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.269
75 %		0.279	0.194	0.148
90 %		0.140	-	-
50 %	R3 stream	-	-	0.370

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
75 %		0.384	0.267	0.203
90 %		0.194	-	-
50 %	R4 stream	-	-	0.271
75 %		0.281	0.195	0.148
90 %		0.145	-	-
RAC (µg/L) 0.23 (*Higher tier*)		**PEC/RAC ratio**		
50 %	R1 stream	-	-	**1,170**
75 %		**1,213**	0,843	0,643
90 %		0,609	-	-
50 %	R3 stream	-	-	**1,609**
75 %		**1,670**	**1,161**	0,883
90 %		0,843	-	-
50 %	R4 stream	-	-	**1,178**
75 %		**1,222**	0,848	0,643
90 %		0,630	-	-

For the intended use in winter cereals (post-emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D4 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D4 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered

- D5 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 pond: 10 m no spray vegetated buffer zone or 5 m no spray vegetated buffer zone together with 50% of nozzles reduction are considered.
- R1 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 15 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.
- R3 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 20 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.
- R3 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 15 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.

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 algae with mitigation of spray drift and run-off for the use of KONARK in spring cereals pre-emergence

Intended use	Spring cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

PEC$_{sw}$ (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.079	1.112	0.764	0.573	-	-	-	-
50%		1.072	0.602	0.414	0.314	-	-	-	-
75%		0.610	0.359	0.256	0.194	-	-	-	-
90%		0.351	0.231	0.168	-	-	-	-	-
None	D1 stream	2.360	1.263	0.865	0.649	-	-	-	-
50%		1.204	0.650	0.440	0.335	-	-	-	-
75%		0.626	0.338	0.233	0.177	-	-	-	-
90%		0.274	0.156	0.109	-				
None	D3 ditch	2.060	1.093	0.746	0.560	-	-	-	-
50%		1.030	0.549	0.374	0.284	-	-	-	-
75%		0.540	0.303	0.214	0.162	-	-	-	-
90%		0.283	0.183	-	-	-	-	-	-
None	D4 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.144	1.143	0.782	0.586	-	-	-	-
50%		1.084	0.580	0.392	0.298	-	-	-	-

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		0.554	0.295	0.203	0.154	-	-	-	-
90%		0.232	0.143	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.221	1.183	0.809	0.607	-	-	-	-
50%		1.120	0.599	0.404	0.307	-	-	-	-
75%		0.570	0.302	0.207	0.158	-	-	-	-
90%		0.236	0.129	-	-	-	-	-	-
None	R1 pond	0.251	0.200	-	-	-	-	-	-
50%		0.200	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.864	1.288	1.288	-	1.864	0.848	0.676	0.514
50%		1.288	1.288	-	-	0.955	0.577	0.442	0.302
75%		1.288	-	-	-	0.840	0.577	0.442	0.302
90%		-	-	-	-	0.828	-	-	-
None	R4 stream	1.863	1.569	1.569	-	1.863	0.999	0.685	0.521
50%		1.569	1.569	-	-	1.024	0.714	0.540	0.369
75%		1.569	-	-	-	1.010	0.704	0.540	0.369
90%		-	-	-	-	1.010	0.704	-	-
RAC (µg/L) 0.23 (Higher tier)		PEC/RAC ratio							
None	D1 ditch	**9.039**	**4.835**	**3.322**	**2.491**	-	-	-	-
50%		**4.661**	**2.617**	**1.800**	**1.365**	-	-	-	-
75%		**2.652**	**1.561**	**1.113**	0.843	-	-	-	-
90%		**1.526**	**1.004**	0.730	-	-	-	-	-
None	D1 stream	**10.261**	**5.491**	**3.761**	**2.822**	-	-	-	-
50%		**5.235**	**2.826**	**1.913**	**1.457**	-	-	-	-

Intended use	Spring cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		**2.722**	**1.470**	**1.013**	0.770	-	-	-	-
90%		**1.191**	0.678	0.474	-	-	-	-	-
None	D3 ditch	**8.957**	**4.752**	**3.243**	**2.435**	-	-	-	-
50%		**4.478**	**2.387**	**1.626**	**1.235**	-	-	-	-
75%		**2.348**	**1.317**	0.930	0.704	-	-	-	-
90%		**1.230**	0.796	-	-	-	-	-	-
None	D4 pond	**1.057**	0.765	-	-	-	-	-	-
50%		0.600	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	**9.322**	**4.970**	**3.400**	**2.548**	-	-	-	-
50%		**4.713**	**2.522**	**1.704**	**1.296**	-	-	-	-
75%		**2.409**	**1.283**	0.883	0.670	-	-	-	-
90%		**1.009**	0.622	-	-	-	-	-	-
None	D5 pond	**1.043**	0.757	-	-	-	-	-	-
50%		0.591	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	**9.657**	**5.143**	**3.517**	**2.639**	-	-	-	-
50%		**4.870**	**2.604**	**1.757**	**1.335**	-	-	-	-
75%		**2.478**	**1.313**	0.900	0.687	-	-	-	-
90%		**1.026**	0.561	-	-	-	-	-	-
None	R1 pond	**1.091**	0.870	-	-	-	-	-	-
50%		0.870	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	**8.104**	**5.600**	**5.600**	-	**8.104**	**3.687**	**2.939**	**2.235**
50%		**5.600**	**5.600**	-	-	**4.152**	**2.509**	**1.922**	**1.313**
75%		**5.600**	-	-	-	**3.652**	**2.509**	**1.922**	**1.313**
90%		-	-	-	-	**3.600**	-	-	-

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	R4 stream	**8.100**	**6.822**	**6.822**	-	**8.100**	**4.343**	**2.978**	**2.265**
50%		**6.822**	**6.822**	-	-	**4.452**	**3.104**	**2.348**	**1.604**
75%		**6.822**	-	-	-	**4.391**	**3.061**	**2.348**	**1.604**
90%		-	-	-	-	**4.391**	**3.061**	-	-

Table 9.5-25: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pendimethalin based on VFSMOD STEP 4 calculations and toxicity data for algae with mitigation of spray drift and run-off for the use of KONARK in spring cereals pre-emergence

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.473
75 %		0.473	0.473	-
90 %		0.473	-	-
50 %	R4 stream	0.511	0.352	0.268
75 %		0.279	0.194	0.147
90 %		0.268	-	-
RAC (µg/L) 0.23 (H*igher tier*)		**PEC/RAC ratio**		
50 %	R1 stream	-	-	**2.057**
75 %		**2.057**	**2.057**	-
90 %		**2.057**	-	-
50 %	R4 stream	**2.222**	**1.530**	**1.165**
75 %		**1.213**	0.843	0.639
90 %		**1.165**	-	-

For the intended use in spring cereals (pre emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D4 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.
- R4 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.

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 algae with mitigation of spray drift and run-off for the use of KONARK in spring cereals post-emergence (BBCH 11)

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.045	1.084	0.740	0.563	-	-	-	-
50%		1.029	0.565	0.392	0.297	-	-	-	-
75%		0.568	0.337	0.239	0.180	-	-	-	-
90%		0.319	0.211	0.154	-	-	-	-	-
None	D1 stream	2.240	1.195	0.818	0.622	-	-	-	-
50%		1.136	0.610	0.418	0.318	-	-	-	-
75%		0.584	0.317	0.219	0.166	-	-	-	-
90%		0.253	0.142	-	-	-	-	-	-
None	D3 ditch	2.033	1.078	0.736	0.560	-	-	-	-
50%		1.016	0.541	0.374	0.284	-	-	-	-
75%		0.532	0.303	0.214	0.162	-	-	-	-
90%		0.283	0.183	-	-	-	-	-	-

Intended use	Spring cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D4 pond	0.243	0.176	-	-	-	-	-	-
50%		0.138	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.202	1.175	0.804	0.611	-	-	-	-
50%		1.116	0.599	0.411	0.312	-	-	-	-
75%		0.573	0.311	0.214	0.163	-	-	-	-
90%		0.247	0.138	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.197	1.169	0.799	0.608	-	-	-	-
50%		1.108	0.592	0.405	0.308	-	-	-	-
75%		0.563	0.303	0.208	0.158	-	-	-	-
90%		0.236	0.130	-	-	-	-	-	-
None	R1 pond	0.250	0.184	-	-	-	-	-	-
50%		0.180	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.839	1.132	1.132	-	1.839	0.986	0.676	0.514
50%		1.132	1.132	-	-	0.942	0.514	0.394	0.269
75%		1.132	-	-	-	0.738	0.514	0.394	0.269
90%		-	-	-	-	0.738	-	-	-
None	R4 stream	1.838	1.544	1.544	-	1.838	0.986	0.676	0.514
50%		1.544	1.544	-	-	1.007	0.702	0.539	0.368
75%		1.544	-	-	-	1.007	0.702	0.539	0.368
90%		-	-	-	-	-		-	-

RAC (µg/L)
0.23 (Higher tier) PEC/RAC ratio

Intended use	Spring cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	**8.891**	**4.713**	**3.217**	**2.448**	-	-	-	-
50%		**4.474**	**2.457**	**1.704**	**1.291**	-	-	-	-
75%		**2.470**	**1.465**	**1.039**	0.783	-	-	-	-
90%		**1.387**	0.917	0.670	-	-	-	-	-
None	D1 stream	**9.739**	**5.196**	**3.557**	**2.704**	-	-	-	-
50%		**4.939**	**2.652**	**1.817**	**1.383**	-	-	-	-
75%		**2.539**	**1.378**	0.952	0.722	-	-	-	-
90%		**1.100**	0.617	-	-	-	-	-	-
None	D3 ditch	**8.839**	**4.687**	**3.200**	**2.435**	-	-	-	-
50%		**4.417**	**2.352**	**1.626**	**1.235**	-	-	-	-
75%		**2.313**	**1.317**	0.930	0.704	-	-	-	-
90%		**1.230**	0.796	-	-	-	-	-	-
None	D4 pond	**1.057**	0.765	-	-	-	-	-	-
50%		0.600	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	**9.574**	**5.109**	**3.496**	**2.657**	-	-	-	-
50%		**4.852**	**2.604**	**1.787**	**1.357**	-	-	-	-
75%		**2.491**	**1.352**	0.930	0.709	-	-	-	-
90%		**1.074**	0.600	-	-	-	-	-	-
None	D5 pond	**1.043**	0.757	-	-	-	-	-	-
50%		0.591	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	**9.552**	**5.083**	**3.474**	**2.643**	-	-	-	-
50%		**4.817**	**2.574**	**1.761**	**1.339**	-	-	-	-
75%		**2.448**	**1.317**	0.904	0.687	-	-	-	-
90%		**1.026**	0.565	-	-	-	-	-	-
None	R1 pond	**1.087**	0.800	-	-	-	-	-	-
50%		0.783	-	-	-	-	-	-	-

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	**7.996**	**4.922**	**4.922**	-	**7.996**	**4.287**	**2.939**	**2.235**
50%		**4.922**	**4.922**	-	-	**4.096**	**2.235**	**1.713**	**1.170**
75%		**4.922**	-	-	-	**3.209**	**2.235**	**1.713**	**1.170**
90%		-	-	-	-	**3.209**	-	-	-
None	R4 stream	**7.991**	**6.713**	**6.713**	-	**7.991**	**4.287**	**2.939**	**2.235**
50%		**6.713**	**6.713**	-	-	**4.378**	**3.052**	**2.343**	**1.600**
75%		**6.713**	-	-	-	**4.378**	**3.052**	**2.343**	**1.600**
90%		-	-	-	-	-	-	-	-

Table 9.5-27: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pendimethalin based on VFSMOD STEP 4 calculations and toxicity data for algae with mitigation of spray drift and run-off for the use of KONARK in spring cereals post-emergence (BBCH 11)

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.473
75 %		0.473	0.473	-
90 %		0.473	-	-
50 %	R4 stream	0.511	0.352	0.268
75 %		0.279	0.194	0.147
90 %		0.268	-	-
RAC (µg/L) 0.23 (*Higher tier*)		**PEC/RAC ratio**		
50 %	R1 stream	-	-	**2.057**

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
75 %	R4 stream	**2.057**	**2.057**	-
90 %		**2.057**	-	-
50 %		**2.222**	**1.530**	**1.165**
75 %		**1.213**	0.843	0.639
90 %		**1.165**	-	-

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 algae with mitigation of spray drift and run-off for the use of KONARK in spring cereals post-emergence (BBCH 21)

Intended use	Spring cereals
Active substance	Pendimethalin
Application rate (g/ha)	1 x 1200

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	2.059	1.095	0.753	0.572	-	-	-	-
50%		1.056	0.589	0.411	0.311	-	-	-	-
75%		0.596	0.353	0.251	0.190	-	-	-	-
90%		0.344	0.227	0.165	-	-	-	-	-
None	D1 stream	2.430	1.289	0.880	0.669	-	-	-	-
50%		1.216	0.645	0.441	0.335	-	-	-	-
75%		0.609	0.324	0.224	0.170	-	-	-	-
90%		0.287	0.187	-	-	-	-	-	-
None	D3 ditch	2.034	1.078	0.736	0.560	-	-	-	-
50%		1.017	0.544	0.376	0.286	-	-	-	-
75%		0.535	0.307	0.217	0.164	-	-	-	-
90%		0.287	0.186	-	-	-	-	-	-
None	D4 pond	0.239	0.173	-	-	-	-	-	-
50%		0.135	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		-	-	-	-	-	-	-	-
None	D4 stream	2.277	1.215	0.831	0.632	-	-	-	-
50%		1.155	0.620	0.425	0.324	-	-	-	-
75%		0.594	0.323	0.222	0.169	-	-	-	-
90%		0.260	0.148	-	-	-	-	-	-
None	D5 pond	0.240	0.174	-	-	-	-	-	-
50%		0.136	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	2.197	1.169	0.799	0.608	-	-	-	-
50%		1.108	0.592	0.405	0.308	-	-	-	-
75%		0.563	0.303	0.208	0.158	-	-	-	-
90%		0.236	0.130	-	-	-	-	-	-
None	R1 pond	0.250	0.183	-	-	-	-	-	-
50%		0.177	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	1.839	1.118	1.118	-	1.839	0.986	0.676	0.514
50%		1.118	1.118	-	-	0.942	0.513	0.389	0.269
75%		1.118	-	-	-	0.729	0.507	0.389	0.266
90%		-	-	-	-	0.729	0.507	-	-
None	R4 stream	1.838	1.470	1.470	-	1.838	0.986	0.676	0.514
50%		1.470	1.470	-	-	0.959	0.668	0.513	0.350
75%		1.470	-	-	-	0.959	0.668	0.513	0.350
90%		-	-	-	-	-	-	-	-
RAC (µg/L) 0.23 (Higher tier)		PEC/RAC ratio							
None	D1 ditch	**8.952**	**4.761**	**3.274**	**2.487**	-	-	-	-
50%		**4.591**	**2.561**	**1.787**	**1.352**	-	-	-	-
75%		**2.591**	**1.535**	**1.091**	0.826	-	-	-	-

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90%		**1.496**	0.987	0.717	-	-	-	-	-
None	D1 stream	**10.565**	**5.604**	**3.826**	**2.909**	-	-	-	-
50%		**5.287**	**2.804**	**1.917**	**1.457**	-	-	-	-
75%		**2.648**	**1.409**	0.974	0.739	-	-	-	-
90%		**1.248**	0.813	-	-	-	-	-	-
None	D3 ditch	**8.843**	**4.687**	**3.200**	**2.435**	-	-	-	-
50%		**4.422**	**2.365**	**1.635**	**1.243**	-	-	-	-
75%		**2.326**	**1.335**	0.943	0.713	-	-	-	-
90%		**1.248**	0.809	-	-	-	-	-	-
None	D4 pond	**1.039**	0.752	-	-	-	-	-	-
50%		0.587	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D4 stream	**9.900**	**5.283**	**3.613**	**2.748**	-	-	-	-
50%		**5.022**	**2.696**	**1.848**	**1.409**	-	-	-	-
75%		**2.583**	**1.404**	0.965	0.735	-	-	-	-
90%		**1.130**	0.643	-	-	-	-	-	-
None	D5 pond	**1.043**	0.757	-	-	-	-	-	-
50%		0.591	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	D5 stream	**9.552**	**5.083**	**3.474**	**2.643**	-	-	-	-
50%		**4.817**	**2.574**	**1.761**	**1.339**	-	-	-	-
75%		**2.448**	**1.317**	0.904	0.687	-	-	-	-
90%		**1.026**	0.565	-	-	-	-	-	-
None	R1 pond	**1.087**	0.796	-	-	-	-	-	-
50%		0.770	-	-	-	-	-	-	-
75%		-	-	-	-	-	-	-	-
90%		-	-	-	-	-	-	-	-
None	R1 stream	**7.996**	**4.861**	**4.861**	-	**7.996**	**4.287**	**2.939**	**2.235**

Intended use		Spring cereals							
Active substance		Pendimethalin							
Application rate (g/ha)		1 x 1200							
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Pendimethalin**							
Nozzle Reduction	Vegetative strip (m)	None				5*	10	15*	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50%		**4.861**	**4.861**	-	-	**4.096**	**2.230**	**1.691**	**1.170**
75%		**4.861**	-	-	-	**3.170**	**2.204**	**1.691**	**1.157**
90%		-	-	-	-	**3.170**	**2.204**	-	-
None	R4 stream	**7.991**	**6.391**	**6.391**	-	**7.991**	**4.287**	**2.939**	**2.235**
50%		**6.391**	**6.391**	-	-	**4.170**	**2.904**	**2.230**	**1.522**
75%		**6.391**	-	-	-	**4.170**	**2.904**	**2.230**	**1.522**
90%		-	-	-	-	-	-	-	-

Table 9.5-29: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pendimethalin based on VFSMOD STEP 4 calculations and toxicity data for algae with mitigation of spray drift and run-off for the use of KONARK in spring cereals post-emergence (BBCH 21)

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
50 %	R1 stream	-	-	0.419
75 %		0.419	0.419	0.419
90 %		0.419	-	-
50 %	R4 stream	-	-	0.268
75 %		0.279	0.194	0.147
90 %		0.203	-	-
RAC (µg/L) 0.23 (H*igher tier*)		**PEC/RAC ratio**		
50 %	R1 stream	-	-	**1.822**
75 %		**1.822**	**1.822**	**1.822**
90 %		**1.822**	-	-
50 %	R4 stream	-	-	**1.165**

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Pendimethalin**		
Nozzle reduction	Vegetative strip (m)	10	15	20
	No spray buffer (m)	10	15	20
75 %		**1.213**	0.843	0.639
90 %		0.883	-	-

For the intended use in spring cereals (post-emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D4 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.
- R4 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.

~~- D1 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.~~
~~- D1 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.~~
~~- D3 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.~~
~~- D4 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.~~
~~- D5 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.~~
~~- R1 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.~~
~~- R4 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.~~

Metabolites Pendimethalin

Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	**-**
Endpoint		LC_{50}	EC_{50}	E_rC_{50}
(µg/L)		8280	7730	> 2500
AF		100	100	10
RAC (µg/L)		82.8	77.3	> 250
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	23.54	0.284	0.305	0.094
Step 2				
S-Europe	8.78	0.106	0.114	0.035
N-Europe	10.98	0.133	0.142	0.044

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 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H001 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	**-**
Endpoint		LC_{50}	EC_{50}	E_rC_{50}
(µg/L)		8280	7730	> 2500
AF		100	100	10
RAC (µg/L)		82.8	77.3	> 250
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	23.54	0.284	0.305	0.094
Step 2				
S-Europe	8.78	0.106	0.114	0.035
N-Europe	4.39	0.053	0.057	0.018

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 9.5-32: 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 KONARK in winter cereals pre-emergence

Group		**Inverteb. acute**	**Algae**
Test species		***Daphnia magna***	**-**
Endpoint		EC_{50}	E_rC_{50}
(µg/L)		613	>1450
AF		100	10
RAC (µg/L)		6.13	>145
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			
	27.15	**4.429**	0.187
Step 2			
S-Europe	6.83	**1.114**	0.047
N-Europe	8.46	**1.380**	0.058
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	0.008	0.001	<0.001
D5/pond	0.001	<0.001	<0.001
D5/stream	0.002	<0.001	<0.001
D6/ditch	0.018	0.003	<0.001
R1/pond	0.005	0.001	<0.001
R1/stream	0.023	0.004	<0.001
R3/stream	0.018	0.003	<0.001
R4/stream	0.032	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 9.5-33: 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 KONARK in spring cereals pre-emergence

Group		**Inverteb. acute**	**Algae**
Test species		***Daphnia magna***	**-**
Endpoint		EC_{50}	E_rC_{50}
(µg/L)		613	>1450
AF		100	10

Group		**Inverteb. acute**	**Algae**
RAC (µg/L)		6.13	>145
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**		
Step 1			
	27.15	**4.429**	0.187
Step 2			
S-Europe	6.83	**1.114**	0.047
N-Europe	3.56	0.581	0.025
Step 3			
D1/ditch	0.005	0.001	<0.001
D1/stream	<0.001	<0.001	<0.001
D3/ditch	<0.001	<0.001	<0.001
D4/pond	0.001	<0.001	<0.001
D4/stream	0.006	0.001	<0.001
D5/pond	0.001	<0.001	<0.001
D5/stream	0.001	<0.001	<0.001
R1/pond	0.009	0.001	<0.001
R1/stream	0.027	0.004	<0.001
R4/stream	0.031	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 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		LC_{50}	EC_{50}	E_rC_{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				
	43.82	**223.571**	**298.095**	**471.183**
Step 2				
S-Europe	17.57	**89.643**	**119.524**	**188.925**
N-Europe	21.77	**111.071**	**148.095**	**234.086**
Step 3				
D1/ditch	0.001	0.005	0.007	0.011

Group		**Fish acute**	**Inverteb. acute**	**Algae**
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 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H032 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		LC_{50}	EC_{50}	E_rC_{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 $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	43.82	**223.571**	**298.095**	**471.183**
Step 2				
S-Europe	17.57	**89.643**	**119.524**	**188.925**
N-Europe	9.17	**46.786**	**62.381**	**98.602**
Step 3				
D1/ditch	<0.001	0.005	0.007	0.011
D1/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

Group		Fish acute	Inverteb. acute	Algae
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
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 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in winter cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		LC_{50}	EC_{50}	E_rC_{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 $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	8.46	**43.163**	**57.551**	**90.968**
Step 2				
S-Europe	2.58	**13.163**	**17.551**	**27.742**
N-Europe	3.18	**16.224**	**21.633**	**34.194**
Step 3				
D1/ditch	0.011	0.056	0.075	0.118
D1/stream	<0.001	0.005	0.007	0.011
D2/ditch	0.002	0.010	0.014	0.022
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	0.003	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 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for M455H029 (P36) for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of KONARK in spring cereals pre-emergence

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Pseudokirchneriella subcapitata***
Endpoint		LC_{50}	EC_{50}	E_rC_{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 $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	8.46	**43.163**	**57.551**	**90.968**
Step 2				
S-Europe	2.58	**13.163**	**17.551**	**27.742**
N-Europe	2.40	**12.245**	**16.327**	**25.806**
Step 3				
D1/ditch	0.002	0.010	0.014	0.022
D1/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
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

M455H001:
For the intended uses winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrates as characterised by an EC_{50} for *Daphnia magna* of 7730 µg/L in connection with an assessment factor of 100) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary.

M455H033 (P48):
For the intended uses winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrates as characterised by an EC_{50} for *Daphnia magna* of 613 µg/L in connection with an assessment factor of 100) in all FOCUS Steps 3 scenarios. Therefore, no further assessment is necessary.

M455H032:
For the intended uses on winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for algae as characterised by an E_rC_{50} for *Pseudokirchneriella subcapitata* of 0.93 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios. Therefore, no further assessment is necessary.

M455H029 (P36):
For the intended uses on winter cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for algae as characterised by an E_rC_{50} for *Pseudokirchneriella subcapitata* of 0.93 in connection with an assessment factor of 10) in all FOCUS Steps 3 scenarios. Therefore, no further assessment is necessary.

Risk assessment for the combinations of a.s. in the formulation

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the active substance present in the formulation. In addition, as demonstrated in the short-term studies here above there are no indications for interactions of the active substances (no synergisms or additional toxicity occurs due to the co-formulants) given that the formulation does not cause an (unexpected) increased toxicity compared to the active substances. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute/short-term assessment. The long-term risk was assessed considering data for the active substances in the formulation and no chronic combined risk assessment has been performed.

According to the new EFSA Scientific Opinion (EFSA, 2013) measured and calculated mixture toxicity should be compared to determine synergistic, additive or antagonistic effects of the formulation. In the following the concentration addition (CA) model is used as proposed by EFSA.

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity ($LC_{50}/EC_{50\ mix\text{-}CA}$) by the measured mixture toxicity ($LC_{50}/EC_{50\ KONARK}$). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, *i.e.* if the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement.

Active susbtance / species	**Test system**	**Endpoint (mg a.s./L)**
Flufenacet		
Lepomis macrochirus	LC_{50} 96h	2.13
Daphnia magna	EC_{50} 48h	30.9
P. subcapitata	ErC50 72h	0.004
Microcosmos (Macrophyte, duckweed	NOEC	0.012

and periphyton)		
Pendimethalin		
Oncorhynchus mykiss	LC_{50} 96h	0.196
Daphnia magna	EC_{50} 48h	0.147
P. subcapitata	E_rC_{50} 72h	0.0093–0.00023
Lemna gibba	E_rC_{50}	0.0012

The calculated MDR values are between 0.2 and 5 for all organisms except to macrophytes (see Table 9.5-24), indicating that the formulation does not cause an (unexpected) increased toxicity compared to the active substances for fish, aquatic invertebrates and algae. No synergisms or additional toxicity occurs due to the co-formulants for these species. However, antagonistic (less than additive) mixture toxicity is indicated if the MDR is <0.2 in case of macrophytes.

Table 9.5-38: Summary of results obtained in the studies with the formulated product KONARK and comparison of calculated and measured mixture toxicity

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]			
		Measured toxicity of KONARK (LC_{50} KONARK or EC_{50} KONARK) (mg/L)	Measured toxicity of KONARK (converted to be a.i. based) (LC_{50} KONARK or EC_{50} KONARK) (mg a.s./L)	Calculated mixture toxicity[a] LC_{50} mix-CA or EC_{50} mix-CA	Model deviation ratio (MDR = EC_{50} mix-CA / EC_{50} KONARK)
O. mykiss	LC_{50}, acute, 96 h	0.4833	0.176	0.231	1.312
D. magna	EC_{50}, acute, 48 h	0.95	0.346	0.176	0.51-09
P. subcapitata	E_rC_{50}, 72 h	0.123	0.045	0.010-0.0003	0.22-0.006
Macrophytes	E_rC_{50}, 14 d	0.6532	0.238	0.001	0.01-0.006

a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Flufenacet (60 g/L) and Pendimethalin (300 g/L) within the formulation.

The calculated factors fall outside 0.8-1.2 for fish and aquatic invertebrates (see Table 9.5-25), indicating that the mixture composition in the formulation study giving the measured mixture toxicity is not similar to the mixture composition at the PEC_{mix} for these organisms.

Table 9.5-39: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in KONARK) LC_{50} mix-CA or EC_{50} mix-CA	Calculated mixture toxicity (a.s. in PEC_{mix})[b] LC_{50} mix-CA or EC_{50} mix-CA at higher exposure tier	Factors (EC_{50} mix-CA (a.s. in KONARK)/EC_{50} mix-CA (a.s. in PEC_{mix})) at higher exposure tier
O. mykiss	LC_{50}, acute, 96 h	0.231	0.618	0.594-0.597
D. magna	EC_{50}, acute, 48 h	0.176	0.585	0.548 0.551
P. subcapitata	E_rC_{50}, static, 72 h	0.010-0.0003	0.011	0.911 0.579
Macrophytes	E_rC_{50}, 14 d	0.001	0.004	*0.599* 0.601

[a] The mixture toxicity of the formulation was re-calculated based on the nominal contents of Flufenacet (60 g/L) and Pendimethalin (300 g/L) within the formulation.

[b] The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Flufenacet 0.002186 mg/L at Step 4 for R3 winter cereals with 20 m no-spray buffer zone + 20 m vegetative strip) and Pendimethalin

(0.000720 mg/L at Step 4 for R3 winter cereals with 20 m no-spray buffer zone + 20 m vegetative strip). D1, D2 and D6 scenarios have not been considered because these scenarios are not relevant for CEU (please, refer to the risk assessment for actives).

With regard to the mixture risk assessment EFSA further states that if the toxicity of the mixture is largely explained by the toxicity of a single active substance, a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single 'driver'. Regarding KONARK, Pendimethalin is clearly driving the acute risk for fish, daphnia and macrophytes, the studies performed with the formulated product reflect the toxicity of one particular active substance, as the formulation toxicity – endpoint recalculated to each active substance concentrations – comes above 90 % from the toxicity per fraction of a single a.s. (TUi).

Regarding algae, no active substance is clearly driving the chronic risk. The study performed with the formulated product do not reflect the toxicity of one particular active substance, as the formulation toxicity – endpoint recalculated to each active substance concentrations – does not come for 90 % (of more) from the toxicity per fraction of a single a.s. (TUi) (see Table 9.5-26).

Table 9.5-40: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC_{50} / EC_{50} [mg/L]		
		Calculated mixture toxicity (a.s. in FLUPEN) $LC_{50\ mix\text{-}CA}$ or $EC_{50\ mix\text{-}CA}$	**Calculated toxicity per fraction of FLUPEN (based on each a.s.) $(1/TU_i)$[a]**	**Deviation from mixture toxicity (1-$EC_{x\ mix\text{-}CA}$ x $(1/EC_{x\ mix\text{-}CA} - TU_i)$) [%]**
O. mykiss	LC_{50}, acute, 96 h	0.231	Flufenacet: 12.780 Pendimethalin: 0.235	Flufenacet: 1.8% **Pendimethalin: 98.19%**
D. magna	EC_{50}, acute, 48 h	0.176	Flufenacet: 185.400 Pendimethalin: 0.176	Flufenacet: 0.1% **Pendimethalin: 99.90%**
P. subcapitata	E_rC_{50}, static, 72 h	~~0.010~~-0.0003	Flufenacet: ~~0.072~~24 Pendimethalin: ~~0.011~~ 0.0003	Flufenacet: ~~13.4%~~-1.1% **Pendimethalin:** ~~86.6%~~-**98.9%**
Macrophytes	E_rC_{50}, 14 d	0.001	Flufenacet: 0.072 Pendimethalin: 0.00144	Flufenacet: 2.0% **Pendimethalin: 98.0%**

[a] TUi is defined as the concentration of the i^{th} a.s. at the $EC_{50\ KONARK}$ (re-caculated to the sum of a.s.) divided by the respective single-substance toxicity ($EC_{50\ a.s.}$). This is calculated based on the nominal contents of Flufenacet (60 g/L) and Pendimethalin (300 g/L) within the formulation.

Table 9.5-41: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in winter cereals pre-emergence (worst case) for algae

The refinement is conducted by taking into account FOCUS PECsw values for Flufenacet and Pendimethalin (Step 4) (see Table 9.5-20). No unacceptable risk to all organisms are expected from the exposure to the combined active substances following proposed uses of the product.

Exposure	Higher exposure tier (refinement)	
	Flufenacet	Pendimethalin
PECsw [mg a.s./L]	~~0.002186~~ 0.003199	~~0.000720~~ 0.000473
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	~~0.002906~~ 0.003672	
Aquatic organisms	Algae	
Exposure	Higher (refinement)	
ETRmix = PECmix/ECx KONARK	~~0.065~~ 0.082	
Trigger	0.10	

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented below:

Fish and aquatic invertebrates

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment*.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxKONARK) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (ECxKONARK) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxKONARK) by means of the model deviation ratio (MDR = ECxmix-CA/ECxKONARK).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-24	Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxKONARK) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECxKONARK with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECxmix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is <0.8 or >1.2	Please refer to table 9.5-25	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PPP), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation (≥ 90 %) comes from a single a.s. (TUi)?	Deviation from mixture toxicity = 1-ECx mix-CA x (1/ECx mix-CA-TUi) [%] >=90% for Pendimethalin	Please refer to table 9.5-26	Go to 6
8	Conduct a RA based on single-substance toxicity data (ECx a.s.) for the identified 'driver' of mixture toxicity, with the exposure-toxicity ratio (ETRa.s.) being defined as the PECa.s. divided by the measured ECx a.s. and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	**Covered by active substance assessment**		

Algae and Lemna

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for algae.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxKONARK) and a.s. (ECxa.s.):	Please refer to tables 9.5-1, 9.5-2 and 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (ECxKONARK) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxKONARK) by means of the model deviation ratio (MDR = ECxmix-CA/ECxKONARK).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-24	Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxKONARK) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECxKONARK with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECxmix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is 0.8-1.2	Please refer to table 9.5-25	Go to 4 9
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETRmix) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR_{mix} < trigger	Please refer to table 9.5-27	**Low risk**

~~*Macrophytes*~~

~~Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for macrophytes.~~

~~Step~~	~~EFSA AGD provisions~~	~~Option~~	~~Justification~~	~~Outcome~~
~~1~~	~~Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?~~	~~For both formulation (ECxKONARK) and a.s. (ECxa.s.):~~	~~Please refer to tables 9.5-1, 9.5-2 and 9.5-3~~	~~Go to 2~~
~~2~~	~~Check the plausibility of the measured formulation toxicity (ECxKONARK) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxKONARK) by means of the model deviation ratio (MDR = ECxmix-CA/ECxKONARK).~~	~~MDR <0.2 (Antagonistic (less than additive) mixture toxicity)~~	~~Please refer to table 9.5-17~~	~~Go to 9~~

9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible	Some explanations could explain the apparent antagonism between measured mixture toxicity data regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation: The use of endpoints with different nature for finally risk assessment for macrophytes (NOEC from mesocosms study on different macrophyte, duckweed and periphyton species for Flufenacet,and values of E_rC_{50} from chronic studies for Pendimethalin and KONARK on *Lemna gibba*). The difference in the duration of the studies in *Lemna gibba*, it was 14 d in case of Flufenacet and 7 d in case of the formulated KONARK.	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxKONARK) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECxKONARK with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECxmix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is <0.8 or >1.2	Please refer to table 9.5-25	Go to 5
5	Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity (ECx PPP), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation (≥ 90 %) comes from a single a.s. (TUi)?	Deviation from mixture toxicity = 1-ECx mix-CA x (1/ECx mix-CA-TUi) [%] >=90% for Pendimethalin	Please refer to table 9.5-19	Go to 6

8	Conduct a RA based on single substance toxicity data (ECx a.s.) for the identified 'driver' of mixture toxicity, with the exposure-toxicity ratio (ETRa.s.) being defined as the PECa.s. divided by the measured ECx a.s. and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	**Covered by active substance assessment** –

9.5.3 Overall conclusions

Regarding **Flufenacet,** for the intended use in spring cereals, calculated PEC/RAC ratios indicated an acceptable risk for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton as characterised by a NOEC of 0.012 mg a.s./L in connection with an assessment factor of 3 for microcosms) all FOCUS Steps 3 scenarios. Therefore, a further refinement is not needed. For the intended use in winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton as characterised by a NOEC of 0.012 mg a.s./L in connection with an assessment factor of 3 for microcosms) in several FOCUS Steps 3 scenarios (D1 ditch, D2 ditch, D2 stream, D6 ditch and R3 stream). Therefore, PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, an unacceptable risk was identified for D1 ditch, D2 ditch, D2 stream and D6 ditch scenarios for the most sensitive group of aquatic organisms (risk for Macrophyte, duckweed and periphyton). These scenarios are not relevant under CEU conditions. Regarding R scenarios, the risk was acceptable according to the following risk mitigation measures:

- R1 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.
- R3 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.

Concerning Flufenacet metabolites, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish and algae as characterised by an LC_{50}/EC_{50} for *Oncorhynchus mykiss* and *Pseudokirchneriella subcapitata* of 9100 µg/L and 83800 µg/L in connection with an assessment factor of 100 and 10, respectively) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment was necessary.

Regarding **Pendimethalin**, For the intended uses on winter and spring cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (higher tier NOEC = 0.23 µg/L risk for algae as characterised by an EC_{50} for *P. subcapitata* of 9.3 µg/L in connection with an assessment factor of 1) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, PEC/RAC ratios were <1 when the following risk mitigation options are considered:

Winter cereals

- D1 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray

buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.

- D2 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D4 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D5 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D6 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- R1 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.
- R3 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 20 m no spray buffer zone together with 20 m vegetated filter strip are considered.
- R3 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.

Spring cereals

- D1 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered. However, this scenario is not relevant under CEU conditions.
- D4 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- D5 stream: 5 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 50% of nozzles reduction or 15 m no spray buffer zone are considered.
- R1 stream: 5 m no spray buffer zone together with 5 m vegetated filter strip and 75% of nozzles reduction or 10 m no spray buffer zone together with 10 m vegetated filter strip are considered.
- R4 stream: 10 m no spray buffer zone together with 10 m vegetated filter strip and 50% of nozzles reduction or 15 m no spray buffer zone together with 15 m vegetated filter strip are considered.

For the intended use in winter cereals (pre emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray

buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D4 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D4 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D5 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 10 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are consid-ered.
- R3 stream: 15 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered
- R3 stream: 15 m no spray vegetated buffer zone together with 75% of nozzles reduction or 10 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered

For the intended use in winter cereals (post-emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 15 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D2 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D4 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D4 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 pond: 5 m no spray buffer zone together with 50% of nozzles reduction 10 m no spray buffer zone are considered
- D5 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 pond: 10 m no spray vegetated buffer zone or 5 m no spray vegetated buffer zone to-gether with 50% of nozzles reduction are considered.
- R1 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 15 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.

- R3 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 20 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.
- R3 stream: 10 m no spray vegetated buffer zone together with 90% of nozzles reduction or 15 m no spray vegetated buffer zone together with 75% of nozzles reduction are considered.

For the intended use in spring cereals (pre emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D4 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.
- R4 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.

For the intended use in spring cereals (post-emergence use), the risk was acceptable according to the following risk mitigation measures:

- D1 ditch: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D1 stream: 20 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction. However, this scenario is not relevant under CEU conditions.
- D3 ditch: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered. However, this scenario is not relevant under CEU conditions.
- D4 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- D5 stream: 15 m no spray buffer zone together with 75% of nozzles reduction or 10 m no spray buffer zone together with 90% of nozzles reduction are considered.
- R1 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.
- R4 stream: 15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.

Concerning Pendimethalin metabolites, for metabolite M455H001 calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary. For metabolites M455H033, M455H032 and M455H029, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 3 scenarios. Therefore, no further assessment is necessary.

Regarding **KONARK**, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC_{50} for *Oncorhynchus mykiss* of 483.3 µg/L in connection with an assessment factor of 100) following the next mitigation measures: 10 m no spray buffer zone or 5m no spray buffer zone with the use of 50% NR.

Acceptable risk was obtained due to combined exposure.

zRMS comments:

We agree with risk assessment for aquatic organisms.
Regarding pendimethalin, For the intended uses on winter and winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (higher tier NOEC = 0.23 µg/L risk for algae as characterised by an EC_{50} for *P. subcapitata* of 9.3 µg/L in connection with an assessment factor of 1) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, PEC/RAC ratios were <1 when risk mitigation options are considered.

For metabolites M455H033, M455H032 and M455H029, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 3 scenarios.

The final risk mitigation measures should be considered at MSs level.
It is noted that mitigation measures might be envisaged by other member states that comply with their national requirements. Furthermore, member states might check if the scenarios for which an unacceptable risk was indicated are relevant according to their national requirements.

Conclusions

~~***Winter cereals – Spe3:*** *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies with 75% of nozzles reduction OR an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 20 m to surface water bodies.~~

~~***Spring cereals – Spe3:*** *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies with 50% of nozzles reduction OR an unsprayed vegetated buffer zone of 15 m to surface water bodies.~~

Winter cereals (*pre-emergence****) – Spe3:*** *To protect aquatic organisms respect an 20 m no spray vegetated buffer zone together with 75% of nozzles reduction or 15 m no spray vegetated buffer zone together with 90% of nozzles reduction are considered*

Winter cereals *(post-emergence)* ***– Spe3:*** *To protect aquatic organisms respect an winter cereals in post-emergence*
20 m no spray vegetated buffer zone together with 90% of nozzles reduction

Spring cereals (*pre-emergence****) – Spe3:*** *To protect aquatic organisms respect an spring cereals pre-emergence*
15 m no spray buffer zone together with 15 m vegetated filter strip and 75% of nozzles reduction are considered.

Spring cereals *(post-emergence)* ***– Spe3:*** *To protect aquatic organisms respect an spring cereals in post-emergence*

15 m no spray buffer zone together with 75% of nozzles reduction

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Flufenacet, Pendimethalin and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of KONARK were not evaluated as part of the EU assessment of Flufenacet and 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	Flufenacet	Oral	**LD_{50} > 170 µg/bee**	SANCO 7469/VI/98-Final
Apis mellifera	Flufenacet	Contact	**LD_{50} > 194 µg/bee**	SANCO 7469/VI/98-Final
Apis mellifera	Pendimethalin	Acute oral	**LD_{50} > 101.2 µg a.s./bee**	EFSA Journal 2016;14(3):4420
Apis mellifera	Pendimethalin	Acute contact	**LD_{50} > 100 µg a.s./bee**	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation BAS 455 48 H	Acute oral	LD_{50} > 120 µg a.s./bee	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation BAS 455 48 H	Acute contact	LD_{50} > 100 µg a.s./bee	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation BAS 455 48 H	Chronic 10d	LDD_{50} > 96.5 µg a.s./bee/day	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation BAS 455 48 H	72 h	$NOED_{larvae}$ > 105.6 µg a.s./larvae	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation AG-P4-400-SC	Acute oral	LD_{50} > 198.5 µg a.s./bee	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation AG-P4-400-SC	Acute contact	LD_{50} > 200 µg a.s./bee	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation AG-P4-400-SC	Chronic 10d	LDD_{50} > 88.2 µg a.s./bee/day	EFSA Journal 2016;14(3):4420
Apis mellifera	Formulation AG-P4-400-SC	72 h	$NOED_{larvae}$ > 100 µg a.s./larvae	EFSA Journal 2016;14(3):4420
Apis mellifera	KONARK	Oral	**LD_{50} > 400 µg f.p./bee**	KCP 10.3.1.1.1 Parma, P. 2018 B/27/17

Species	Substance	Exposure System	Results	Reference
Apis mellifera	KONARK	Contact	**LD_{50} > 400 µg f.p./bee**	KCP 10.3.1.1.2 Parma, P. 2018 B/28/17
Apis mellifera	Flufenacet	Chronic, 10 d	LDD_{50} >23.44 µg a.s./bee/day NOEDD = **23.44 µg a.s./bee/day**	KCP 10.3.1.2-01 Ansaloni, T., 2018, TRC16-116BA
Apis mellifera	Pendimethalin	Chronic, 10d	LDD_{50} = **56.58 µg a.s./bee/day** NOEDD = 25.8 µg a.s./bee/day	KCP 10.3.1.2-02 Glanas, A. 2017 B/107/17
Apis mellifera	Flufenacet	Larval, repeated exposure, 22 d	NOED = **48.00 µg as/larva**	KCP10.3.1.3-01 Marín, M., 2019, S17-08182
Apis mellifera	Pendimethalin	Honeybee larvae study, 22d	NOED larvae > > **0.64 µg a.s.µg/larva**	KCP 10.3.1.3-02 Keebaum, K. 2017 17 48 BLC 0083
Higher-tier studies (tunnel test, field studies)				
None				

9.6.1.1 Justification for new endpoints

The EU agreed endpoints were used and the endpoints from studies with the formulation KONARK are used for the assessment of the formulation.

9.6.2 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).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of KONARK in winter cereals

Intended use	Wintr cereals		
Active substance	Flufenacet		
Application rate (g a.s./ha)	1 x 240		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g a.s./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>170	150	<1.41
Contact toxicity	>194		<1.24
Intended use	Wintr cereals		

Active substance	Pendimethalin		
Application rate (g a.s./ha)	1 x 1200		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g a.s./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>101.2	750	<11.86
Contact toxicity	>100		<12.00
Product	KONARK		
Application rate (g f.p./ha)	1 × 4.0 L f.p./ha (equivalent to 3954.4* g f.p./ha)		
Test design	**LD_{50} (lab.) (µg f.p./bee)**	**Single application rate (g f.p./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>400	3954.4	<9.89
Contact toxicity	>400		<9.89

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
*Based on a density for formulation of 0.9886 g/mL

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

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

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

zRMS comments:

The HQ values based on the acute oral/contact LD_{50} are below the trigger of 50 for both active substances (pendimethalin and flufenacet) and the formulation for oral and acute toxicity showing an acceptable risk to bees after the application of Konark.

No risk assessment for larvae can be proposed as the toxicity study for larvae is considered not sufficient by zRMS to address the possible effects of the formulation on larval development.
The EFSA bee GD (2013) is not implemented and currently is undergoing a revision. Therefore, no risk assessment are included.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant should provide the chronic test on bees and chronic test for larvae for formulated product.

Toxicity endpoints for chronic effects of on larvae and worker honeybees with the mixed formulation KONARK are not available. Therefore, the specific requirements of the Regulation (EU) 284/2013 with

regard to effects on bee brood development and possible chronic effects on adults are not fulfilled. Chronic toxicity data are available for each of the two active substances. However, according to the Regulation testing is required for plant protection products which contain more than one active substance.
There is currently no EU accepted guidance which can be used to provide a complete chronic risk assessment

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

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

Effects on non-target arthropods of KONARK were not evaluated as part of the EU assessment of Flufenacet and 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 regarding Flufenacet

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi (adults)	FOE 5043 WG 60	Laboratory, semi-field test glass plates (2D)	Mortality, parasitism and fecondity: > 30 % at 0.6 kg a.s./ha	SANCO 7469/VI/98-Final
Aphidius rhopalosiphi (adults)	FOE 5043 WG 60	Extended laboratory test barley plants (3D)	Fecundity: < 30 % at 0.6 kg a.s./ha	SANCO 7469/VI/98-Final
Typhlodromus pyri (protonymphs)	WG 62.5 (60% Flufenacet and 2.6% metosulam)	Laboratory test Glass plates (2D)	Mortality, reproduction: 100% at 0.6 kg a.s./ha No effect (5% drift)	SANCO 7469/VI/98-Final
Poecilus cupreus (adults)	FOE 5043 WG 60	Laboratory test Quartz sand (2D)	Mortality, behaviour, feeding activity: No effect at 0.6 kg a.s./ha	SANCO 7469/VI/98-Final
Aleochara bilineata (adults)	FOE 5043 WG 60	Laboratory test	Mortality, behaviour, feeding activity: No effect at 0.6 kg a.s./ha	SANCO 7469/VI/98-Final
Coccinella septempunctata (larvae)	FOE 5043 WG 60	Laboratory test Glass plates (2D)	Reproduction: No effect at 0.6 kg a.s./ha	SANCO 7469/VI/98-Final

Table 9.7-2: Endpoints and effect values relevant for the risk assessment for non-target arthropods regarding Pendimethalin

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. LR_{50} = 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. LR_{50} >4.0 kg a.s./ha (> 8791 mL formulation /ha)	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
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 LR_{50} and ER_{50} > 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 LR_{50} and ER_{50} > 4.0 kg a.s./ha (> 8791 mL formulation /ha	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
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 LR_{50} and ER_{50} > 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 LR_{50} and ER_{50} > 1.983 kg a.s./ha (> 5000 mL formulation /ha	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
Pardosa spec.	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 parasitization 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 LR_{50}> 2.4 kg a.s./ha (> 6 L Stomp 400 SC/ha)	EFSA Journal 2016;14(3):4420

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 parameter 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.

Table 9.7-3: Endpoints and effect values relevant for the risk assessment for non-target arthropods regarding KONARK formulation

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	KONARK	Extended study on rosa leaves	~~LR_{50} > 20.0 L f.p./ha~~ ~~ER_{50} > 20 L f.p./ha~~ LR_{50} > 2.5 L f.p./ha ER50 =0.92 Lf.p.//ha	~~KCP 10.3.2.2-01 Parma, P. 2018 B/30/17~~ Monika Stalmach, 2018 B/163/16
Aphidius rhopalosiphi (adults)	KONARK	Extended study on barley seedlings	~~LR_{50} > 20.0 L f.p.~~ ~~LR_{50} > 20.0 L f.p./ha~~ ~~ER_{50} = 8.9 L f.p./ha~~ LR50 > 4.2 L/ha ER_{50} = 2.14 L f.p./ha	~~KCP 10.3.2.2-02 Parma, P. 2018 B/29/17~~ Monika Stalmach, 2018 B/162/16
Poecilus cupreus	KONARK	Extended study on natural standard soil	LR_{50} = 4.27 L f.p./ha ER_{50} = 4.11 L f.p./ha	KCP 10.3.2.2-03 Angayarkanni, V. 2021. 8903/2021
Coccinella septempunctata	KONARK	Extended study on rose leaves	LR_{50} = 4.05 L f.p./ha ER_{50} >> 3.2 L f.p./ha ER50 repr. 0.512 L/ha	KCP 10.3.2.2-04 Fulczyk A., 2022, B-45-22
Field or semi-field tests				

9.7.1.1 Justification for new endpoints

As KONARK is not the representative formulation, endpoints of the new generated studies are used for the assessment.

9.7.2 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.

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-4: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of KONARK in winter cereals

Intended use	Winter cereals
Product	KONARK
Application rate (L f.p./ha)	1 × 4.0
MAF	1.0

Test species Higher-tier	**Rate with ≤ 50 % effect* (L f.p./ha)**	**$PER_{in-field}$ (L f.p./ha)**	**$PER_{in-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	0.92	4.0	**no**
Aphidius rhopalosiphi	2.14		**no**
Poecilus cupreus	4.14		yes
Coccinella septempunctata	0.512	4.0	**no**

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 LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

zRMS comment: The risk to non-target arthropods from the use of the product cannot be resolved as an unacceptable risk on standard species and *Coccinella septempunctata* in the in-field area was identified.

Additional toxicity data (aged-residue studies) are necessary for formulation Konark.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of KONARK in winter cereals

Intended use	Winter cereals
Product	KONARK
Application rate (L f.p./ha)	1 × 4.0
MAF	1.0

Test species Higher-tier	**Rate with ≤ 50 % effect* (L f.p./ha)**	**Drift rate**	**$PER_{off-field}$ (L f.p./ha)**	**CF**	**corr. $PER_{off-field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	0.92	0.0277	0.01	5	yes
Aphidius rhopalosiphi	2.14	0.0277	0.11	5	yes
Poecilus cupreus	4.11	0.0277	0.11	5	yes
Coccinella septempunctata	>0.512	0.0277	0.11	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.

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

zRMS comments:

The risk assessment presented in table 9.7-5 was accepted by the zRMS. It should be noted that when endpoints derived from 3dimensional study are considered, no vegetation distribution factor should be included in off-field exposure calculations.
Moreover, according to ESCORT 2 guidance document for Tier II studies correction factor of 5 may be applied~~.~~.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The results of the risk assessment show no risk ~~in-field and~~ off-field for *T.Pyri* and *Aphidius rhopalosiphi* when exposed to KONARK according to the proposed GAP.

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

9.8.1 Toxicity data

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

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of KONARK were not evaluated as part of the EU assessment of Flufenacet and 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	Flufenacet	Acute, 14 d	LC_{50} = 219 mg/kg soil $LC_{50, corr}$ = 109.5 mg/kg soil*	Review Report (7469/VI/98-Final – 03/07/2003)
Eisenia fetida	Flufenacet-sulfonic acid Na salt	Acute, 14 d	LC_{50} > 1000 mg/kg soil $LC_{50, corr}$ > 500 mg/kg soil*	Review Report (7469/VI/98-Final – 03/07/2003)
Eisenia fetida	Flufenacet oxalate	Acute, 14 d	LC_{50} > 1000 mg/kg soil $LC_{50, corr}$ > 500 mg/kg soil*	Review Report (7469/VI/98-Final – 03/07/2003)
Eisenia fetida	Flufenacet	Chronic, 56 d	NOEC > 4 mg/kg soil **$NOEC_{corr}$ > 2 mg/kg soil***	Review Report (7469/VI/98-Final – 03/07/2003)
~~*Eisenia fetida*~~	~~FLUFENACET 50% SC~~	~~Chronic, 56 d Soil with 5% peat~~	~~NOEC = 9 mg a.s./kg soil~~ ~~**$NOEC_{corr}$ = 4.5 mg a.s./kg soil***~~	~~KCP 10.4.1.1-01 Gierbuszewska, A. 2014 G/22/14~~
~~*Folsomia candida*~~	~~FLUFENACET 50% SC~~	~~Chronic, 56 d Soil with 5% peat~~	~~NOEC = 28 mg a.s./kg soil~~ ~~**$NOEC_{corr}$ = 14 mg a.s./kg soil***~~	~~KCP 10.4.2.1-01 Arendarczyk, A. 2015 G/28/15~~
Field studies				
None				
Litter bag test				
None				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

Table 9.8-2: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) regarding Pendimethalin

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 **$NOEC_{corr}$ = 16.73 mg a.s./kg dw soil** EC_{10} = 49 mg a.s./kg d.w.soil dw EC_{10corr} = 24.5 mg a.s./kg d.w.soil dw **EC_{10corr} = 12 mg/kg soil dw**	EFSA Journal 2016;14(3):4420
Eisenia fetida	M455H001	Chronic, Mixed through soil 5% peat	NOEC= 32 mg a.s./kg soil dw $NOEC_{corr}$= 16 mg a.s./kg soil dw EC_{10}= 24 mg a.s./kg d.w.soil dw **EC_{10corr} = 12 mg/kg soil dw**	EFSA Journal 2016;14(3):4420
Eisenia fetida	M455H033	Chronic, Mixed through soil 10% peat	NOEC= 25 mg a.s./kg soil dw $NOEC_{corr}$= 12.5 mg a.s./kg soil dw EC_{10}= 14.9 mg a.s./kg d.w.soil dw **EC_{10corr} = 7.5 mg/kg soil dw**	EFSA Journal 2016;14(3):4420
~~*Eisenia fetida*~~	~~Pendimethalin 40% SC~~	~~Chronic, 56 d Soil 5% peat~~	~~NOEC= 168.2 mg a.s./kg soil dw **$NOEC_{corr}$ = 84.1 mg a.s./kg soil dw**~~	~~KCP 10.4.1.1-02 Servajean, E. 2018 17-99-135-ES~~
Eisenia fetida	KONARK	Chronic, 56 d Soil 5% peat	NOEC = 18.0 mg f.p./kg dw soil NOEC = 1.019 mg flufenacet /kg dw soil NOEC = 5.094 mg pendimethalin/kg dw soil **5.544 mg/kg dw soil**	KCP 10.4.1.1-03
Folsomia candida	BAS455 48 H	Chronic, Mixed through soil 5% peat	NOEC=193 mg a.s./kg soil dw $NOEC_{corr}$ =96.5 mg a.s./kg soil dw EC_{10}= 561 mg a.s./kg d.w.soil dw EC_{10corr} = 280.5 mg a.s./kg soil dw	EFSA Journal 2016;14(3):4420

Species	Substance	Exposure System	Results	Reference
Folsomia candida	AG-P4-400-SC	Chronic, Mixed through soil 5% peat	NOEC= 78.22 mg a.s./kg soil dw **$NOEC_{corr}$ = 39.1 mg a.s./kg soil dw**	EFSA Journal 2016;14(3):4420
~~*Folsomia candida*~~	~~Pendimethalin 40% SC~~	~~Chronic, 28 d Soil 5% peat~~	~~NOEC= 37.5 mg a.s./kg soil dw **$NOEC_{corr}$ = 18.8 mg a.s./kg soil dw**~~	~~KCP 10.4.2.1-02 Servajean, E. 2018 17-99-128-ES~~
Folsomia candida	KONARK	Chronic, 28 d Soil 5% peat	NOEC = 18 mg f.p./kg dw soil NOEC = 1.02 mg flufenacet /kg dw soil NOEC = 5.09 mg pendimethalin/kg dw soil	KCP 10.4.1.1-03
Hypoaspis aculeifer	BAS455 48 H	Chronic, Mixed through soil 5% peat	NOEC= 385 mg a.s./kg soil dw EC_{10}= 257 mg a.s./kg d.w.soil dw **EC_{10corr} = 128.5 mg a.s./kg 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 **$NOEC_{corr}$= 190.75 mg a.s./kg soil dw**	EFSA Journal 2016;14(3):4420

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.

One earthworm, collembola and acari study with Pendimethalin 33% EC (KCP 10.4.1.2):
After autumn application of Pendimethalin 33% EC at 1386 g a.s./ha, 1980 g a.s./ha and 3960 g a.s./ha, no significant effect on populations of earthworms, *collembola* and *acari*, was observed compared with a control treatment over a 12 month experimental period.

Konark formulation was tested under field conditions (KCP 10.4.2.2-1)
It can be concluded that Flufenacet 6% + Pendimethalin 30% EC tested at an application rate of 4.5 L/ha (corresponding to 0.27 kg flufenacet/ha + 1.35 kg pendimethalin/ha) had no adverse effects on single species, ecological groups (represented by dominant endogeic and anecic earthworm species), morphological classes (represented by dominant epilobous and tanylobous earthworm species) and total earthworm abundance and biomass about one year after application. No statistically significant reductions in total earthworm abundance and biomasscould be observed for the tested application rate of 4.5 L test item/ha about 1, 5 and 12 months after application.

The decision to use field trials should be made at national level.

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

The EU agreed endpoints for Flufenacet and Pendimethalin are used for the assessments regarding the active substance. In addition, chronic studies on earthworms and collembolan with formulations Flufenacet 50% SC and Pendimethalin 40% SC are provided. The Applicant wishes to note that both formulations contents more amount of each a.s. than KONARK (500 g Flufenacet/L and 400 g Pendimethalin/L respect to 60g Flufenacet/L and 300 g Pendimethalin/L for KONARK). Moreover, the endpoints from these formulations are expressed in terms of mg a.s./kg dw soil, which means that only the toxicity of each a.s is considered.

9.8.2 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).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is to be considered for FOE sulfonic (M2), Pendimethalin and M455H001 and does not need to be considered for Flufenacet and metabolite M455H033.

Table 9.8-3: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) regarding KONARK

Species	Substance	Exposure System	Results	Reference
Eisenia andrei	KONARK (Flufenacet 6% + Pendimethalin 30% EC)	56d, chronic Mixed through soil 5% peat	NOEC = 18 mg/kg dw soil	KCP 10.4.1.1 Gierbuszewska, A., 2020 G/68/17
Folsomia candida	KONARK (Flufenacet 6% + Pendimethalin 30% EC)	28d, chronic. Mixed through soil 5% peat	NOEC = 18 mg/kg dw soil	KCP 10.4.2.1-01 Gierbuszewska, A., 2020 G/69/17
Hypoaspis aculeifer	KONARK (Flufenacet 6% + Pendimethalin 30% EC)	14d, chronic. Mixed through soil 5% peat	NOEC = 95.26 mg/kg dw soil	KCP 10.4.2.1-02 Angayarkanni, V., 2022 10416/2022

Table 9.8-4: 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 KONARK in winter cereals

Intended use	Winter cereals

Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Flufenacet	> 2	0.320	>6.3
Pendimethalin	16.7	1.739	9.6
M455H001	12	0.126	95.2
M455H033	7.45	0.370	20.1
FLUFENACET 50% SC[1]	4.5	0.320	14.1
Pendimethalin 40%SC[2]	84.1	1.739	48.4
KONARK	18	3.954	**4.55**
KONARK Flufenacet	1.019	0.320	3.18
KONARK Pendimethalin	5.094	1.739	2.93
Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
FLUFENACET 50% SC[1] (*Folsomia candida*)	14	0.320	43.8
Pendimethalin (*Folsomia candida*)	39.1	1.739	22.5
Pendimethalin 40%SC[2] (*Folsomia candida*)	18.8	1.739	10.8
KONARK	18	3.954	**4.55**
KONARK Flufenacet	1.02	0.320	3.19
KONARK Pendimethalin	5.09	1.739	2.93
Pendimethalin (*Hypoaspis aculeifer*)	128.5	1.739	73.9
KONARK (Hypoaspis aculeifer)	95.26	3.954	24.09

TER values shown in bold fall below the relevant trigger.
[1]Risk assessment based on an endpoint expressed as mg Flufenacetd/kg dw from Flufenacet 50%SC study.
[2]Risk assessment based on an endpoint expressed as mg Pendimethalin/kg dw from Pendimethalin 40%SC study.

zRMS comments:

The long-term risks to earthworms and soil meso - and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}.
The relevant predicted environmental concentrations in soil (PEC_{soil}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate).
For earthworms the risk provided for the active substances and their substances, indicated acceptable risk.
The applicant included endpoints from earthworms, Folsomia and Hypoapsis studies conducted with solo formulations containing flufenacet and Pendimethalin. Both formulations contents more amount of each a.s. than KONARK (500 g Flufenacet/L and 400 g Pendimethalin/L respect to 60g Flufenacet/L and 300 g Pendimethalin/L for KONARK).
However, it should be noted that for a.s. pendimethalin one field study for earthworm, collembola and acari study with Pendimethalin 33% EC was evaluated at EU level.
After autumn application of Pendimethalin 33% EC at 1386 g a.s./ha, 1980 g a.s./ha and 3960 g a.s./ha, no significant effect on populations of earthworms, collembola and acari, was observed compared with a control treatment over a 12-month experimental period.
Therefore, the risk from formulation Konark containing the a.s.- pendimethalin seems be as acceptable in the rate of 1200 g a.s./ha.

Konark formulation was tested under field conditions (KCP 10.4.2.2-1)
It can be concluded that Flufenacet 6% + Pendimethalin 30% EC tested at an application rate of 4.5 L/ha (corresponding to 0.27 kg flufenacet/ha + 1.35 kg pendimethalin/ha) had no adverse effects on single species, ecological groups (represented by dominant endogeic and anecic earthworm species), morphological classes (represented by dominant epilobous and tanylobous earthworm species) and total earthworm abundance and biomass about one year after application.

Therefore, the risk from formulation Konark is acceptable.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

Studies on the toxicity to earthworms and other non-target soil organisms show that Flufenacet and Pendimethalin hazard toxicity exposure ratios are clearly over the cut-off value. An application of KONARK in respect of the GAP does not present an unacceptable long-term risk for earthworms and other soil macrofauna.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

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

Effects on soil microorganisms of KONARK were not evaluated as part of the EU assessment of Flufenacet and 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 deviates from the results of the EU review process. Justifications are provided below.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Flufenacet	28 d, silty sand and loamy silt soil	Nitrate formation rate < 25 % effect at 0.8 and **4 mg/kg d.w.soil**	Review Report (7469/VI/98-Final – 03/07/2003)
C-mineralisation	Flufenacet	28 d, silty sand and loamy silt soil	CO_2 formation rate < 25 % effect at 0.8 and 4 mg/kg d.w.soil	Review Report (7469/VI/98-Final – 03/07/2003)
N-mineralisation	BAS 455 48 H	28 d	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	28 d	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	28 d	Effect on N-transormation rate +17% at 0.5 mg /kg soil dw, and +11% at **5.0 mg/kg soil dw**	EFSA Journal 2016;14(3):4420
N-mineralisation	M455H033	28 d	Effect on N-transormation rate +5% at 0.5 mg /kg soil dw, and +2% at **5.0 mg/kg soil dw**	EFSA Journal 2016;14(3):4420
N-mineralisation	KONARK	56 d	Effect on N-transormation rate +7.9% at 28.27 mg /kg soil dw, and -22.7% at **141.35 mg/kg soil dw**	KCP 10.5.1 Gierbuszewska, A. 2020 G/67/17

9.9.1.1 Justification for new endpoints

As KONARK is not the representative formulation, endpoints of the new generated studies are used for the assessment.

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

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

Intended use			
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Flufenacet	4 (at 28 d)	0.320	Yes
Pendimethalin	11 (at 28 d)	1.739	Yes
M455H001	5 (at 28 d)	0.126	Yes
M455H033	5 (at 28 d)	0.370	Yes
KONARK	141.35 (at 56 d)	5.273	Yes

9.9.3 Overall conclusions

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

zRMS comments:

Konark has no significant effect on soil micro-organisms at 141.35 mg a.s./kg dry soil.
Based on it, can be concluded that Konark under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

9.10.1 Toxicity data

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

Effects on non-target terrestrial plants of KONARK were not evaluated as part of the EU assessment of Flufenacet and Pendimethalin. 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 deviates from the results of the EU review

process. Justifications are provided below.

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	Seedling emergence	ER_{50} emergence = 543 g/ha	EFSA Journal 2016;14(3):4420
Tomato	AG-P4-400-SC	Seedling emergence	ER_{50} emergence = 402 g/ha	EFSA Journal 2016;14(3):4420
[1)]*Helianthus annuus* [d] [2)]*Brassica oleracea var. capitata* [d] [3)]*Pisum sativum* [d] [4)]*Daucus carota* [d] [5)]*Lolium perenne* [m] [6)]*Avena sativa* [m]	KONARK	14 d Seedling emergence	[1)] ER_{50} > 4000 mL f.p./ha [2)] ER_{50} = 3063.21 mL f.p. /ha [3)] ER_{50} > 4000 mL f.p./ha [4)] ER_{50} > 4000 mL f.p./ha **[5)] ER_{50} = 545.46 mL f.p./ha** [6)] ER_{50} = 1750.87 mL f.p./ha	KCP 10.6.2-01 Gierbuszewska, A. 2020 G/71/17
[1)]*Helianthus annuus* [d] [2)]*Brassica oleracea var. capitata* [d] [3)]*Pisum sativum* [d] [4)]*Daucus carota* [d] [5)]*Lolium perenne* [m] [6)]*Avena sativa* [m]	KONARK	21 d Vegetative vigour	[1)] ER_{50} > 4000 mL f.p./ha [2)] ER_{50} > 4000 mL f.p./ha [3)] ER_{50} > 4000 mL f.p./ha [4)] ER_{50} > 4000 mL f.p./ha **[5)] ER_{50} = 515.16 mL f.p./ha** [6)] ER_{50} > 4000 mL f.p./ha	KCP 10.6.2-02 Gierbuszewska, A. 2020 G/72/17

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

As KONARK is not the representative formulation, endpoints of the new generated studies are used for the assessment.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 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 KONARK in cereals

Intended use	Cereals			
Product	KONARK			
Application rate (mL f.p./ha)	1 x 4000			
MAF	1			
Test species	**ER_{50} (mL f.p./ha**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL f.p./ha)**	**TER criterion: TER ≥ 5**
Lolium perenne	545.46 (seedling emergence)	2.77	110.80	**4.9**
	515.16 (vegetative vigour)	2.77	110.80	**4.6**

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

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of KONARK in cereals considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Cereals			
Product		KONARK			
Application rate (mL f.p./ha)		1 x 4000			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (g/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (g/ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (g/ha)**
1	2.77	110.80	55.40	27.70	11.08
5	0.57	22.80	11.40	5.70	2.28
Toxicity value		**TER**			
ER_{50} = 515.16 g/ha		**criterion: TER ≥ 5**			

1/3	**4.6**	9.3	18.6	46.5
5	22.6	45.2	90.4	225.9

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

9.10.3 Overall conclusions

The calculated TER values are below the Annex VI trigger of 5 for seedling emergence and vegetative vigour when a distance of 1 m is considered. Therefore, no potential risk to non-target plants located outside the treated area after application of KONARK according to the GAP table is expected when risk mitigation measures are considered.

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles*.

zRMS comment:

The risk assessment is based on the "Guidance Document 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.
SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land OR the use of 50% drift reducing nozzles.*

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zRMS comment:

Risk assessment in base phytotoxicity effect:
ER_{50} values for phytotoxicity based on visual effect, estimated by RMS *(where it could be determined):*

Vegetative vigour test:
Sunflower ER_{50} > 1333.33 mL/ha
Perennial ryegrass ER_{50} > 444.44 ml/ha

Seedling emergence test:
Perennial ryegrass ER_{50} > 444.44 ml/ha
Oats ER_{50} > 444.44 ml/ha

Intended use		Cereals			
Product		KONARK			
Application rate (mL f.p./ha)		1 x 4000			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1	2.77	110.80	55.40	27.70	11.08
5	0.57	22.80	11.40	5.70	2.28
Toxicity value		**TER**			
ER_{50} = 444.44g/ha		**criterion: TER ≥ 5**			
1/3		**4.0**	8.0	16.1	46.5
5		19.5	39.0	78.0	194.9

SPe 3: *To protect non-target plants respect an unsprayed buffer zone of 1m to non-agricultural land OR the use of 50% drift reducing nozzles.*

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

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	KONARK
Common Name	Flufenacet 6% + Pendimethalin 30% EC
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** Precautionary statement: **P273, P391 and P501**

Appendix 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 10.2.1-01	xxx	2019	Flufenacet 6% + Pendimethaline 30% EC Rainbow trout, Acute toxicity test Report No: W/192/17 xxx GLP Unpublished	Y	Sharda Cropchem Limited
KCP 10.2.1-02	Konfederak, E.	2019	Flufenacet 6% + Pendimethaline 30% EC *Daphnia magna*, Acute immobilisation test Report No: W/194/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	Konfederak, E.	2019	Flufenacet 6% + Pendimethaline 30% EC *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) Growth inhibition test Report No: W/193/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-04	Konfederak, E.	2019	Flufenacet 6% + Pendimethaline 30% EC *Lemna gibba* CPCC 310, Growth inhibition test Report No: W/195/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited

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 10.3.1.1.1	Kulec-Płoszczyca, E.	2017	Flufenacet 6% + Pendimethalin 30% SCHoneybees (*Apis mellifera* L.), Acute Oral Toxicity Test Report No: B/160/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Kulec-Płoszczyca, E.	2017	Flufenacet 6% + Pendimethalin 30% SC Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Report No: B/161/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2-01	Ansaloni, T.	2018	Chronic toxicity of Flufenacet technical on honeybees (*Apis mellifera* L.) Company Report No TRC16-116BA Trialcamp S.L.U. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2-02	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 10.3.1.3-01	Marín, M.	2019	Flufenacet Technical – Honey Bee Larval (*Apis mellifera* L.) Toxicity Test following Repeated Exposure under laboratory conditions Company Report No S17-08182 Trialcamp S.L.U. GLP Unpublished	N	Sharda Cropchem Limited

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 10.3.1.3-02	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	Stalmach, M.	2018	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the predatory mite, *Typhlodromus pyri* (Sch.) Report No: B/163/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-02	Stalmach, M.	2018	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani – Perez) Report No: B/162/16 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.2-03	Angayarkanni, V.	2021	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the carabid beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae). Report No: 8903/2021 Bioscience research foundation GLP Unpublished	N	Sharda Cropchem Limited

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 10.3.2.2-04	Fulczyk, A.	2022	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the ladybird beetle, Coccinella septempunctata L. B-45-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished		
KCP 10.4.1.1-01	Gierbuszewska A.	2014	Flufenacet 50% SC Earthworm Reproduction Test (*Eisenia fetida*) Institute of industrial organic chemistry Branch Pszczyna, G/22/14 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1-02	Servajean, E.	2018	Earthworm reproduction test with Pendimethalin 40% SC Report No.: 17-99-135-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1-03	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethalin 30% EC Earthworm Reproduction Test (Eisenia andrei) Report No: G/68/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Arendarczyk A.	2015	Flufenacet 50% SC Collembolan (*Folsomia candida*) Reproduction Test Institute of industrial organic chemistry Branch Pszczyna, G/28/15 GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-02	Servajean, E.	2018	Collembolan reproduction test in soil with Pendimethalin 40% SC Report No.: 17-99-128-ES Phytosafe s.a.r.l. GLP Unpublished	N	Sharda Cropchem Limited

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 10.4.1.1-03	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethalin 30% EC Collembolan (Folsomia candida) Reproduction Test Report No: G/69/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.2-1	Schulz, L.	2022	Effects of Flufenacet 6% + Pendimethalin 30% EC on earthworms under field conditions 21 48 FEW 0002 BioChem agrar GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.5.1	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethaline 30% EC Soil Microorganisms: Nitrogen Transformation Test Report No: G/67/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-01	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethaline 30% EC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test Report No: G/71/17 Institute of industrial organic chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	Gierbuszewska, A.	2020	Flufenacet 6% + Pendimethaline 30% EC Terrestial Plant Test: Vegetative Vigour Test Report No: G/72/17 Institute of industrial organic chemistry Branch Pszczyna 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

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

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Comments of zRMS:	The study is considered valid. All validity criteria were met. **Agreed endpoints:** • **<u>The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:</u>** The LC_{50}/96 h value is 0.4833 mg/L (with 95% confidence limit: 0.3165 – 0.7993). The LOEC/96 h value is 0.25 mg/L. The NOEC/96 h value is 0.125 mg/L. • <u>The endpoint values determined on the basis of the nominal concentrations of flufenacet and mortality of fish:</u> The LC_{50}/96 h value is 0.02736 mg/L (with 95% confidence limit: 0.01792 – 0.04524). The LOEC/96 h value is 0.01415 mg/L. The NOEC/96 h value is 0.00708 mg/L. • <u>The endpoint values determined on the basis of the nominal concentrations of pendimethalin and mortality of fish:</u> The LC_{50}/96 h value is 0.13679 mg/L (with 95% confidence limit: 0.08959 – 0.22620). The LOEC/96 h value is 0.07076 mg/L.

	The NOEC/96 h value is 0.03538 mg/L.

Reference: KCP 10.2.1 - 01

Report "Flufenacet 6% + Pendimethalin 30% EC: Rainbow Trout, Acute Toxicity Test". xxx Report No. W/192/17. xxx

Guideline(s): Yes, OECD Guideline No. 203 (1992)

Deviations: In section 5.4.5 of the study plan, a typing error concerning the rounding of the concentration occurred. In the Study plan, the written value was 0.031 mg/L whereas it should be 0.0313 mg/L. This yping error did not have any impact on the results generated during the study. Moreover, the study
plan stated that the Study Completion Date was January 2019. However, due to a delay in compilation of the report, the Study Completion Date is postponed till February 2019. This deviation did not impact the generated results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Yes

Materials and methods

Test item:

Description:	Flufenacet 6% + Pendimethalin 30% EC
Production batch:	SCL - 78154
A.i. content:	flufenacet 60 g/l, pendimethalin 300 g/l

Test system:

Species:	Rainbow trout (*Oncorhynchus mykiss*)
Strain:	-
Age:	Approximately 5.5 months
Average weight:	1.08 g ± 0.14 g
Average length:	5.00 cm ± 0.48 cm
Source:	The Culture of Salmonidae Fish in Zawoja', Poland.
Acclimation period:	7 days
Diet:	-

Experimental conditions:

Temperature:	14.1 – 15.2°C
Dissolved O_2:	92 – 100%
Hardness:	39.5 mg $CaCo_3$/L
pH:	7.04 – 7.58
Light and photoperiod:	16h light and 8h dark.
Loading:	-
Test procedure:	Semi-static with renewal of test solution at 24 h interval

Experimental period:96h

Test design and treatment

Semi-static with renewal of test solution at 24 h interval (96 hours, one replicate of seven fish for each test item concentration and the control).
According to a range finding test, the following nominal test item concentrations were used: 1.0, 0.5, 0.25, 0.125, 0.063 and 0.0313mg/L plus a negative control. The fish were observed for mortality and intoxication symptoms after 3, 6, 24, 48, 72 and 96 h of exposure.
The concentrations of flufenacet and pendimethalin were chemically analyzed with a validated gas chromatographic method with TSD detection. All samples of fresh test item concentrations and the control at exposure initiation and at renewals and all samples of spent test item concentrations and
control at each renewal and at exposure termination were chemically analyzed.

The concentration of flufenacet was below LoQ in the test item concentration of 0.125 mg/L. The concentration of flufenacet was below LoD in the test item concentrations of 0.063 and 0.0313 mg/L.
In the fresh samples, the determined concentrations of flufenacet were in the range of 99.0 – 104.7% of the nominal concentration.
In the spent samples, the determined concentrations of flufenacet were in the range of 98.7 – 101.1% of the nominal concentration.
In fresh samples, the determined concentration of pendimethalin were in the range of 98.6 – 104.3% of nominal concentration.
spent samples, the determined concentration of pendimethalin were in the range of 88.6 – 93.1% of nominal concentration.
Therefore, the concentrations of flufenacet and pendimethalin were stable during 24 h under test conditions.
The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of flufenacet and nominal concentrations of pendimethalin.
Probit method calculations and analysis by Student-t test for Homogenenous Variances with Bonferroni-Holm Adjustment.

Results
For the range finding test, in the test item concentrations of 0.01 and 0.001 mg/L and the control neither mortality of fish nor symptoms of intoxication were observed during exposure (i.e. after 3, 6, 24, 48, 72 and 96 h of exposure).
In the test item concentration of 0.1 mg/L one fish was dead and nontypical swimming for one fish after 24 h of exposure was observed. After 48 and 72 h of exposure one fish was dead. After 96 h of exposure two fish were dead.
In the test item concentration of 1.0 mg/L loss of balance, nontypical swimming for one fish and respiratory problems for all fish were observed 6 h of exposure. After 24 h of exposure three fish were dead, loss of balance, nontypical swimming for one fish and respiratory problems for two fish were observed. After 48 h of exposure three fish were dead, loss of balance, nontypical swimming and respiratory problems for two fish were observed. After 72 h of exposure four fish were dead, loss of balance, nontypical swimming and respiratory problems for one fish were observed. After 96 h of exposure all fish were dead. The

On the definitive test, In the control and in the test item concentrations of 0.0313, 0.063 and 0.125 mg/L neither mortality of fish nor symptoms of intoxication were observed during exposure (i.e. after 3, 6, 24, 48, 72 and 96 h of exposure).
In the test item concentration of 0.25 mg/L, nontypical swimming for one fish was observed after 3 and 6 h of exposure. After 24 h of exposure, one fish was dead. After 48, 72 and 96 h of exposure, one fish was dead, nontypical swimming and respiratory problems for three fish were observed.
In the test item concentration of 0.5 mg/L, nontypical swimming for two fish and respiratory problems for seven fish, was observed after 3 and 6 h of exposure. After 24 h of exposure, nontypical swimming for three fish and respiratory problems for seven fish were observed. After 48 h of exposure, two fish were dead, loss of balance for two fish, nontypical swimming and respiratory problems for five fish were observed. After 72 h of exposure four fish were dead, nontypical swimming and respiratory problems for three fish were observed. After 96 h of exposure four fish were dead, loss of balance for two fish, nontypical swimming and respiratory problems for three fish were observed.
In the test item concentration of 1.0 mg/L, respiratory problems for all fish were observed after 3, 6 and 24 h of exposure. After 48 h of exposure, one fish was dead, respiratory problems for six fish were observed. After 72 and 96 h of exposure, six fish were dead, respiratory problems for one fish was observed.

- <u>The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:</u>
  The LC_{50}/96 h value is 0.4833 mg/L (with 95% confidence limit: 0.3165 – 0.7993).
  The LOEC/96 h value is 0.25 mg/L.
  The NOEC/96 h value is 0.125 mg/L.
- <u>The endpoint values determined on the basis of the nominal concentrations of flufenacet and mortality of fish:</u>
  The LC_{50}/96 h value is 0.02736 mg/L (with 95% confidence limit: 0.01792 – 0.04524).
  The LOEC/96 h value is 0.01415 mg/L.
  The NOEC/96 h value is 0.00708 mg/L.

- The endpoint values determined on the basis of the nominal concentrations of pendimethalin and mortality of fish:
  The LC_{50}/96 h value is 0.13679 mg/L (with 95% confidence limit: 0.08959 – 0.22620).
  The LOEC/96 h value is 0.07076 mg/L.
  The NOEC/96 h value is 0.03538 mg/L.

Conclusion
The 96 h NOEC of Flufenacet 6% + Pendimethalin 30% EC is 0.125 mg/L.
The LC_{50} value of Flufenacet 6% + Pendimethalin 30% EC at 96 h was 0.4833 mg/L with fiducial limits of 0.3165 to 0.7993 mg/L.

Comments of zRMS:	The study is considered valid. All validity criteria were met. • 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. The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration was 99.6 to 105.4 % at the start of test and 95.8 to 101.7 % at the end of the test (48 hour), indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of ≤ 20%). The endpoint values were determined based on nominal concentrations **Agreed endpoints:** The endpoint values determined based on nominal test item concentrations: The EC_{50}/48 h is 0.95 mg/L (95% confidence interval: 0.78 – 1.15). The LOEC/48 h value is 0.63 mg/L. The NOEC/48 h value is 0.31 mg/L. The endpoint values determined based on nominal concentrations of flufenacet: The EC_{50}/48 h is 0.0536 mg/L (95% confidence interval: 0.0443 – 0.0649). The LOEC/48 h value is 0.0357 mg/L. The NOEC/48 h value is 0.0175 mg/L. The endpoint values determined based on nominal concentrations of pendimethalin: The EC_{50}/48 h is 0.2680 mg/L (95% confidence interval: 0.2213 – 0.3243). The LOEC/48 h value is 0.1783 mg/L. The NOEC/48 h value is 0.0877 mg/L.

Reference:	KCP 10.2.1-02
Report	"Flufenacet 6% + Pendimethalin 30% EC: *Daphnia magna*, Acute Immobilization Test", xxx
Guideline(s):	OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

Immobilization of young *Daphnia magna* (< 24 hours old) exposed to Flufenacet 6% + Pendimethalin 30% EC (batch No. SCL – 78154) was investigated during a 48-hour test in semi-static design with a renewal after 24h of exposure. Five test item concentrations: 10, 5, 2.5, 1.25, 0.63 and 0.31 mg/L plus the control were used according to a range finding test. Four replicates of each test item concentration and the control with five *Daphnia magna* per replicate were used. The *Daphnia magna* were observed for immobilization after 24 and 48 hours of 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. The concentrations of flufenacet and pendimethalin were determined using a validated gas chromatographic method with TDS detection. The criteria for acceptance of analysis results of test concentration were 80 to 120 % of claimed concentration with ≤ 20% RSD of analysed concentration.
The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration was 99.6 to 105.4 % at the start of test and 95.8 to 101.7 % at the end of the test (48 hour), indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of ≤ 20%).
The endpoint values were determined based on nominal concentrations.

Results

Preliminary test
In the preliminary test four test item concentrations of 0.001, 0.01, 0.1, 1 and 10 mg/L plus the control were used for 48 hours in semi-static system.
No immobility of the daphnia was observed in the negative control and test concentration of 0.001, 0.01 and 0.1 mg/L at 24 and 48 hours of exposure. The percent immobilization of daphnia was 0 and 45 at 24-hour; 55 and 100% at 48-hour at the tested concentrations of 1 and 10 mg/L, respectively.

Definitive test
In the definitive test *Daphnia magna* was exposed to the test item concentrations 10, 5, 2.5, 1.25, 0.63 and 0.31 mg/L plus the control for 48 hours in a static system. The results are summarized in the table below.

Table 10.2.1-02-01 Immobilization of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilized *Daphnia magna*								Total of immobilized *Daphnia magna* [%]	
		24 h				48 h					
		Replicates									
		R1	R2	R3	R4	R1	R2	R3	R4	**24 h**	**48 h**
Control	20	0	0	0	0	0	0	0	0	0	0
0.31	20	0	0	0	0	0	0	0	0	0	0
0.63	20	0	0	0	1	2	1	0	1	5	20
1.25	20	1	0	1	0	2	5	4	3	10	70
2.5	20	1	1	1	1	5	5	5	5	20	100
5	20	1	3	2	2	5	5	5	5	40	100
10	20	2	3	4	2	5	5	5	5	55	100

Validity criteria

In the definitive test the validity criteria were met according to OECD Guideline No. 202 (2004):

- 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

The endpoint values determined based on nominal test item concentrations:
The EC_{50}/48 h is 0.95 mg/L (95% confidence interval: 0.78 – 1.15).
The LOEC/48 h value is 0.63 mg/L.
The NOEC/48 h value is 0.31 mg/L.

The endpoint values determined based on nominal concentrations of flufenacet:
The EC_{50}/48 h is 0.0536 mg/L (95% confidence interval: 0.0443 – 0.0649).
The LOEC/48 h value is 0.0357 mg/L.
The NOEC/48 h value is 0.0175 mg/L.

The endpoint values determined based on nominal concentrations of pendimethalin:

The EC_{50}/48 h is 0.2680 mg/L (95% confidence interval: 0.2213 – 0.3243).
The LOEC/48 h value is 0.1783 mg/L.
The NOEC/48 h value is 0.0877 mg/L.

Comments of zRMS:	The study is not considered valid. All validity criteria were met. The test will not be used in the risk assessment due to the nominal concentrations of pendimethalin in the range of 36.9 - 39.7% and the impossibility of calculating the concentration measured for the entire scope of the test. The endpoint values determined on the basis of the nominal test item concentrations: The concentration causing a 50% inhibition of the growth rate of Raphidocelis subcapitata (formerly Pseudokirchneriella subcapitata), i.e. the ErC_{50}/72 h value is 0.1230 mg/L (95% confidence interval: 0.1167 – 0.1296). The concentration causing a 50% inhibition of yield of Raphidocelis subcapitata (formerly Pseudokirchneriella subcapitata), i.e. the EyC_{50}/72 h value is 0.0324 mg/L (95% confidence interval: 0.0298 – 0.0350). ErC_{50} = 0.1021 mg formulation/L (based on the geometric mean measured test item concentrations) NOErC = 0.0099 µg formulation/L (based on the geometric mean measured test item concentrations) The LOEC/72 h value for growth rate and yield is 0.037 mg/L. The NOEC/72 h value for growth rate and yield is 0.012 mg/L. **The study will not used in risk assessment due to nominal concentrations of pendimethalin in the range of 36.9 – 39.7%.**

Reference:	KCP 10.2.1-03
Report	"Flufenacet 6% + Pendimethaline 30% EC Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata) Growth inhibition test", xxx
Guideline(s):	OECD Guideline No. 201 (2006)
Deviations:	The study plan stated that the highest concentration should be prepared from the weighed amount, whereas the highest test item concentration was prepared by dilution the stock test item concentration. This mistake did not have any impact on the results generated during the study. Moreover, the study plan stated that the Study Completion Date was January 2019. However, due to a delay in compilation of the report, the Study Completion Date is postponed till February 2019. This deviation did not impact the generated results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The growth of the green algae *Pseudokirchneriella subcapitata* SAG 61.81 (formerly Pseudokirchneriella subcapitata) exposed to the test item Flufenacet 6% + Pendimethalin 30% EC, (batch No. SCL-78154) was investigated during a 72-hour test. The test was performed in conical flasks of 250 mL capacity covered with cotton plugs. Each of them contained 100 mL of a given test item concentration and the control. The initial density of the algae was 1 x 10^4 cells/mL. A range finding test was carried out using 0.0001, 0.001, 0.01, 0.1 and 1 mg/L and the test item exhibited 0.0, 0.2, 10.5, 67.4 and 81.9% growth rate inhibition (%). According to it, the following test item concentrations were used on the definitive test: 1.0, 0.33, 0.11, 0.037, 0.012 and 0.0041mg/L plus the control. Three replicates were used for each test item concentration, whereas six replicates were used for control.

The concentrations of flufenacet and pendimethalin were determined using a validated gas chromatographic method with TSD. Samples of each test item concentration and the control collected at exposure initiation, after 24, 48 and 72 h of exposure were chemically analysed.
The analysed concentration of flufenacet was below LoQ in the test item concentration of 0.11 mg/L. The analysed concentration of flufenacet was below LoD in the test item concentrations of 0.037, 0.012, 0.0041 mg/L. In the test item concentration of 0.012 mg/L, the analysed concentration of pendimethalin was below LoQ at exposure initiation, and after 24 and 48 h of exposure and was below LoD at exposure termination. In the test item concentration of 0.0041 mg/L, the analysed concentration of pendimethalin was below LoD during each analyses.
In the test item concentrations 0.33 and 1.0 mg/L, the determined concentrations of flufenacet were 100.2% of the nominal concentration. In the test item concentrations in the range of 0.037 – 1.0 mg/L, the determined concentrations of pendimethalin were in the range of 97.6 – 100.4% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly.
After 24 h of exposure, in the test item concentrations of 0.33 and 1.0 mg/L, the determined concentrations of flufenacet were 101.1% and 99.6% of the nominal concentration, respectively. In the test item concentrations in the range of 0.037 – 1.0 mg/L, the determined concentrations of
pendimethalin were in the range of 87.4 – 91.8% of the nominal concentration.
After 48 h of exposure, in the test item concentrations of 0.33 and 1.0 mg/L, the determined concentrations of flufenacet were 97.3 and 99.3% of the nominal concentration, respectively. In the test item concentrations in the range of 0.037 – 1.0 mg/L, the determined concentrations of pendimethalin were in the range of 65.0 – 66.8% of the nominal concentration.
At exposure termination, in the test item concentrations of 0.33 and 1.0 mg/L, the determined concentrations of flufenacet were 100.4% and 99.1% of the nominal concentration, respectively. In the test item concentrations in the range of 0.11 – 1.0 mg/L, the determined concentrations of
pendimethalin were in the range of 36.9 – 39.7% of the nominal concentration.
Since the concentration of pendimethalin was below 80% of the nominal concentration, it can be concluded that the concentration of pendimethalin was not stable under test conditions.
The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of flufenacet and pendimethalin and geometric means of determined concentrations of pendimethalin.
The endpoint values were determined on the basis of the nominal test item concentrations.

Results

Preliminary test
The preliminary test was performed using the test item concentrations: 0.0001, 0.001, 0.01, 0.1 and 1 mg/L plus control. At the tested concentrations there was a reduction of algal cell biomass by 0.0, 0.2, 10.5, 67.4 and 81.9%, respectively.

Table 10.2.1-03.1 Average cell biomass, preliminary test (non-GLP)

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (yield)	% inhibition after 72 h of exposure (growth rate)
Control	0.0	0.0
0.0001	-21.9*	-3.6*
0.001	1.0	0.2
0.01	41.1	10.5
0.1	97.2	67.4
1.0	99.0	81.9

*calculated inhibition values are lower than 0%, what means that the algal cell density at exposure termination is higher than the algal cell density in the control

Definitive test
In the definitive test, the algae, *Pseudokirchneriella subcapitata*, with an initial cell density of 1 x 10^4 cells/mL were exposed to the test item concentrations: 1.0, 0.33, 0.11, 0.037, 0.012 and 0.0041 mg/L plus the control. The results are summarized in the table below.

Table 10.2.1-03.2 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	0.0	0.0-
0.0041	-0.3*	-1.3*

0.012	-0.4*	-2.5*
0.037	17.9	59.0
0.11	64.7	96.6
0.33	66.5	97.0
1.0	80.0	98.8

Conclusion

The endpoint values determined on the basis of the nominal test item concentrations:
The concentration causing a 50% inhibition of the growth rate of Raphidocelis subcapitata (formerly Pseudokirchneriella subcapitata), i.e. the ErC_{50}/72 h value is 0.1230 mg/L (95% confidence interval: 0.1167 – 0.1296).
The concentration causing a 50% inhibition of yield of Raphidocelis subcapitata (formerly Pseudokirchneriella subcapitata), i.e. the EyC_{50}/72 h value is 0.0324 mg/L (95% confidence interval: 0.0298 – 0.0350).
The LOEC/72 h value for growth rate and yield is 0.037 mg/L.
The NOEC/72 h value for growth rate and yield is 0.012 mg/L.

Comments of zRMS: The study is considered valid. All validity criteria were met.

In the growth inhibition test on *Lemna gibba*, the endpoint values were determined on the basis of the nominal test item concentrations and the nominal concentrations of flufenacet and pendimethalin in the test item. Results are summarized in the table below:

	The endpoint values based on the nominal test item concentrations			
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	0.1596 (0.1482-0.1717)	**0.6532** (0.5853-0.7286)	0.3735 (0.3218-0.4324)	8.1935 (6.5828-10.4440)
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	0.0484 (0.0427-0.0540)	0.0723 (0.0597-0.0861)	0.0412 (0.0312-0.0523)	0.3646 (0.2588-0.4870)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	0.0259 (0.0219-0.0300)	0.0229 (0.0176-0.0289)	0.0130 (0.0089-0.0179)	0.0717 (0.0427-0.1095)
LOEC/7d (mg/l)	0.095	0.095	0.095	0.095
NOEC/7d (mg/l)	0.030	**0.030**	0.030	0.030
	The endpoint values based on the nominal concentrations of flufenacet			
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	0.0090 (0.0084-0.0097)	0.0370 (0.0331-0.0413)	0.0212 (0.0182-0.0245)	0.4638 (0.3727-0.5912)
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	0.0027 (0.0024-0.0031)	0.0041 (0.0034-0.0049)	0.0023 (0.0018-0.0030)	0.0206 (0.0147-0.0276)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	0.0015 (0.0012-0.0017)	0.0013 (0.0010-0.0016)	0.0007 (0.0005-0.0010)	0.0041 (0.0024-0.0062)
LOEC/7d (mg/l)	0.0054	0.0054	0.0054	0.0054
NOEC/7d (mg/l)	0.0017	0.0017	0.0017	0.0017

		The endpoint values based on the nominal concentrations of pendimethalin			
		Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
	EyC_{50}/7d/ ErC_{50}/7d (mg/l)	0.0452 (0.0420-0.0486)	0.1849 (0.1657-0.2062)	0.1057 (0.0911-0.1224)	2.3190 (1.8631-2.9559)
	EyC_{20}/7d/ ErC_{20}/7d (mg/l)	0.0137 (0.0121-0.0153)	0.0205 (0.0169-0.0244)	0.0117 (0.0088-0.0148)	0.1032 (0.0733-0.1379)
	EyC_{10}/7d/ ErC_{10}/7d (mg/l)	0.0073 (0.0062-0.0085)	0.0065 (0.0050-0.0082)	0.0037 (0.0025-0.0051)	0.0203 (0.0121-0.0310)
	LOEC/7d (mg/l)	0.0269	0.0269	0.0269	0.0269
	NOEC/7d (mg/l)	0.0085	0.0085	0.0085	0.0085

Reference:	KCP 10.2.1 - 04
Report:	"Flufenacet 6% + Pendimethalin 30% EC. *Lemna gibba* CPCC 310, Growth Inhibition Test". xxx
Guideline(s):	OECD Guideline No. 221 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:

Description:	Flufenacet 6% + Pendimethalin 30% EC
Batch number:	SCL-78154
A.i. content:	flufenacet 60 g/l Pendimethalin 300 g/l

Test system:

Species:	*Lemna gibba* L. CPCC 310
Strain:	-
Age:	-
Source:	Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada
Medium:	20X AAP nutrient solution

Experimental conditions:

Temperature:	23.0 – 23.2ºC
pH values:	7.41 – 8.90
Mean light intensity:	7728 – 7800 lux, constant illumination
Test vessels:	Glass crystallizers containing 150 mL of a given test item concentration or control
Initial frond number:	9 (i.e. 3 plants per 3 fronds)

Experimental period: 7 d

Test design: Semi-static system with daily renewals; three replicates for each test item concentration and six replicates for control.
The test item concentrations in definitive test were: 32, 10, 3.13, 0.98, 0.31, 0.095, 0.030 mg/L plus the control. The concentrations of flufenacet and pendimethalin were determined using a validated gas chromatographic method with TSD detection.

Samples of each fresh test item concentration and the control collected at exposure initiation and at each renewal, and each spent test item concentration and the control collected at each renewal and at exposure termination were chemically analysed.
In fresh samples the determined concentrations of flufenacet were in the range of 96.3 – 104.5% of nominal concentration in the range of 0.095 – 32 mg/L. In the test item concentration of 0.030 mg/L analysed concentration of flufenacet was below LoD. The determined concentrations of pendimethalin were in the range of 96.0 – 108.1% of nominal concentration. The results confirm that the test item concentrations were prepared correctly.
In spent samples the determined concentrations of flufenacet were in the range of 95.7 – 102.2% of nominal concentration in the range of 0.095 – 32 mg/L. In the test item concentration of 0.030 mg/L analysed concentration of flufenacet was below LoD. The determined concentrations of pendimethalin were in the range of 85.8 – 94.7% of nominal concentration Therefore, the concentrations of flufenacet and pendimethalin were stable under test conditions between renewals. The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of flufenacet and pendimethalin.

The preliminary growth inhibition tests (non-GLP) and definitive test were performed under semi-static test design.
The number of fronds in each replicate was counted twice during exposure (day 2 and 5) and at exposure termination. At the same time observations of plant development were performed. Growth of plant cultures in the test item concentrations was compared with that of the control. The dry weight was measured after exposure initiation and after exposure termination.

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.

Results: In the growth inhibition test on *Lemna gibba*, the endpoint values were determined on the basis of the nominal test item concentrations and the nominal concentrations of flufenacet and pendimethalin in the test item. Results are summarized in the table below:

	The endpoint values based on the nominal test item concentrations			
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	0.1596 (0.1482-0.1717)	0.6532 (0.5853-0.7286)	0.3735 (0.3218-0.4324)	8.1935 (6.5828-10.4440)
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	0.0484 (0.0427-0.0540)	0.0723 (0.0597-0.0861)	0.0412 (0.0312-0.0523)	0.3646 (0.2588-0.4870)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	0.0259 (0.0219-0.0300)	0.0229 (0.0176-0.0289)	0.0130 (0.0089-0.0179)	0.0717 (0.0427-0.1095)
LOEC/7d (mg/l)	0.095	0.095	0.095	0.095
NOEC/7d (mg/l)	0.030	0.030	0.030	0.030
	The endpoint values based on the nominal concentrations of flufenacet			

	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	0.0090 (0.0084-0.0097)	0.0370 (0.0331-0.0413)	0.0212 (0.0182-0.0245)	0.4638 (0.3727-0.5912)
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	0.0027 (0.0024-0.0031)	0.0041 (0.0034-0.0049)	0.0023 (0.0018-0.0030)	0.0206 (0.0147-0.0276)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	0.0015 (0.0012-0.0017)	0.0013 (0.0010-0.0016)	0.0007 (0.0005-0.0010)	0.0041 (0.0024-0.0062)
LOEC/7d (mg/l)	0.0054	0.0054	0.0054	0.0054
NOEC/7d (mg/l)	0.0017	0.0017	0.0017	0.0017
	The endpoint values based on the nominal concentrations of pendimethalin			
	Yield inhibition based on the frond number	**Growth rate inhibition based on the frond number**	**Yield inhibition based on the dry weight**	**Growth rate inhibition based on the dry weight**
EyC_{50}/7d/ ErC_{50}/7d (mg/l)	0.0452 (0.0420-0.0486)	0.1849 (0.1657-0.2062)	0.1057 (0.0911-0.1224)	2.3190 (1.8631-2.9559)
EyC_{20}/7d/ ErC_{20}/7d (mg/l)	0.0137 (0.0121-0.0153)	0.0205 (0.0169-0.0244)	0.0117 (0.0088-0.0148)	0.1032 (0.0733-0.1379)
EyC_{10}/7d/ ErC_{10}/7d (mg/l)	0.0073 (0.0062-0.0085)	0.0065 (0.0050-0.0082)	0.0037 (0.0025-0.0051)	0.0203 (0.0121-0.0310)
LOEC/7d (mg/l)	0.0269	0.0269	0.0269	0.0269
NOEC/7d (mg/l)	0.0085	0.0085	0.0085	0.0085

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. - The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%). - The 24-hour LD_{50} of the reference item (dimethoate) was 0.114 µg/bee (criterion:

	0.10 - 0.35 µg a.i./bee) **Agreed endpoints:** 48 h $LD_{5\ (oral)\ 0}$ >400 µg test item/honeybee (> 113.2 µg of pendimethalin + 22.6 µg of flufenacet /honeybee).

Reference: KCP 10.3.1.1.1

Report "Flufenacet 6% + Pendimethalin 30% SC. Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test". Elżbieta Kulec-Płoszczyca, 2017, Study code B/160/16

Guideline(s): OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)

Deviations: In the final report a deviation from the study plan occurred, concerning the change of the address of the Sponsor.
This deviation had no impact on the study results

GLP: Yes

Acceptability: Yes

Materials and methods

The acute oral toxicity study of Flufenacet 6% + Pendimethalin 30% SC (batch number: SCL-19159) was conducted to determine the LD_{50} values for honeybees. Five doses of the test item were used. These included: 25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee (i.e. 7.1 µg of pendimethalin + 1.4 µg of flufenacet /honeybee, 14.2 µg of pendimethalin + 2.8 µg of flufenacet /honeybee, 28.3 µg of pendimethalin + 5.7 µg of flufenacet /honeybee, 56.6 µg of pendimethalin + 11.3 µg of flufenacet /honeybee, 113.2 µg of pendimethalin + 22.6 µg of flufenacet /honeybee) 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 100 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

Table 10.3.1.1.1-01: Acute oral toxicity on honeybees (*Apis mellifera L.*)

Dose			**Nº of tested bees**	**Mortality after 48 h**		**LD_{50}**		
				Total				
[µg /bee] [a]	**[µg a.i./bee] [b]**			**[no.]**	**[%]**	**[µg /bee] [a]**	**[µg a.i./bee] [b]**	
	a.i. [c]	**a.i. [d]**					**a.i. [c]**	**a.i. [d]**
0.0 (Control)			30	0	0.0	>400.0	>113.2	>22.6
25.0	7.1	1.4	30	0	0.0			
50.0	14.2	2.8	30	0	0.0			
100.0	28.3	5.7	30	2	6.7			
200.0	56.6	11.3	30	4	13.3			
400.0	113.2	22.6	30	9	30.0			

a: µg test item/ bee
b: µg active ingredient /bee
c: pendimethalin
d: flufenacet

Findings

- The mortality in the test item treatments after 48 hours was lower than 50% when compared to the control.
- The median lethal doses of Flufenacet 6% + Pendimethalin 30% SC (LD_{50}) after 24 and 48 hours of the exposure are higher than the highest dose used in the study, i.e. 400 µg test item/bee (> 113.2 µg of pendimethalin + 22.6 µg of flufenacet /honeybee).
- Sublethal toxicity effects (behavioural abnormalities) such paralysis in the group treated with the test item at the rate of 400 µg/honeybee were observed after 4 hours of exposure and after 24 hours of exposure in the group treated with the test item at the rate of 200 µg/honeybee. After 48 hours no sublethal toxicity effects were observed.
- The reduction during 48 h ranged from (-2.01) to 46.05% as compared to the control. The negative values indicate higher sucrose solution consumption in groups treated with the test item compared to the control group.

Validity criteria

The following validity criteria were met during the test:

- The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%).
- The 24-hour LD_{50} of the reference item (dimethoate) was 0.114 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee)

Conclusion

The median lethal doses (LD50) after 24 and 48 hours of exposure are higher than the maximum used dose, i.e. 400 µg test item/honeybee (> 113.2 µg of pendimethalin + 22.6 µg of flufenacet /honeybee).

With respect to the test results, it can be concluded that the test item, Flufenacet 6% + Pendimethalin 30% SC had no adverse effect on mortality of honeybees (*Apis mellifera* L.).

No behavioural abnormalities or any signs of paralysis with respect to the test item and the control were observed over the 48 hours exposure.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. • The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%). • The 24-hour LD_{50} of the reference item (dimethoate) was 0.28 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee). **Agreed endpoints:** 48 $LD_{50(contact)}$ > 400.0 µg/honeybee (113.2 µg pendimethalin/bee, 22.6 µg flufenacet/bee).

Reference:	KCP 10.3.1.1.2
Report	"Flufenacet 6% + Pendimethalin 30% SC. Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test", Elżbieta Kulec-Płoszczyca, 2017, Study code B/161/16
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method

C.17. (2008)

Deviations: In the final report a deviation from the study plan occurred, concerning the change of the address of the Sponsor.
This deviation had no impact on the study results.

GLP: Yes

Acceptability: Yes

Materials and methods

The acute contact toxicity study of Flufenacet 6% + Pendimethalin 30% SC (batch No. SCL-19159) was conducted to determine the effects on honeybees. Five doses of the test item were used. These included: 25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee (7.1, 1.4 µg a.i./bee; 14.2, 2.8µg a.i./bee; 28.3, 5.7 µg a.i./bee; 56.6, 11.3 µg a.i./bee; and 113.2 µg pendimethalin/bee, 22.6 µg flufenacet/bee). 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

Table 10.3.1.1.2-01: Acute contact toxicity on honeybees (*Apis mellifera* L.)

Dose			**Nº of tested bees**	**Mortality after 48 h**		**LD_{50}**		
				Total				
[µg /bee] [a]	**[µg a.i./bee] [b]**			**[no.]**	**[%]**	**[µg /bee] [a]**	**[µg a.i./bee] [b]**	
	a.i. [c]	**a.i. [d]**					**a.i. [c]**	**a.i. [d]**
0.0 (Control)			30	0	0.0	>400.0	>113.2	>22.6
25.0	7.1	1.4	30	0	0.0			
50.0	14.2	2.8	30	0	0.0			
100.0	28.3	5.7	30	0	0.0			
200.0	56.6	11.3	30	0	0.0			
400.0	113.2	22.6	30	1	3.3			

a: µg test item/ bee
b: µg active ingredient /bee
c: pendimethalin
d: flufenacet

Findings

- Mortality of the control group after 48 hours of exposure was 0%.
- Mortality of the treated groups was lower than 50% when compared to the control.
- No sublethal toxicity effects (behavioural abnormalities) such as excitement (uncoordinated movement, increased activity, intensive cleaning) or any signs of paralysis with respect to the test item and the control were observed over the 48 hours exposure.

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 LD_{50} of the reference item (dimethoate) was 0.28 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

Conclusion

The median lethal doses (LD_{50}/24 h and LD_{50}/48 h contact) are higher than the highest dose used in the test, i.e. 400.0 µg/honeybee (113.2 µg pendimethalin/bee, 22.6 µg flufenacet/bee).

With respect to the test results, it can be concluded that the test item, Flufenacet 6% + Pendimethalin 30% SC had no adverse effect on mortality of honeybees (*Apis mellifera* L.).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS: The study is considered valid. All validity criteria were met.
- Mortality observed in control treatment was equal or less than 15% for the duration of the test
- Mean mortality in the reference item concentration was ≥ 50% at the end of the test

The endpoints determined are shown in the table below.

Endpoints (D10)	Test item: Flufenacet technical (active substance: Flufenacet)	
	Concentration	Dose
NOEC / NOEDD	840.3 mg a.s./kg food	23.44 µg a.s./bee/day
LC_{50} / LDD_{50} (95 % Confidence limits)	>840.3 mg a.s./kg food	>23.44 µg a.s./bee/day

Reference Report:	KCP 10.3.1.2-01 Ansaloni, T., 2016 Chronic toxicity of Flufenacet technical on honeybees (Apis mellifera L.)
Source:	Trialcamp S.L.U. Poligon Industrial l'Alter. Avda. Antic Regne de Valencia, 25, 46290 Alcasser (Valencia). Spain. Unpublished report No.: TRC16-116BA. Issued: 2016.
Guidelines:	Based on CEB (2012) method, adaptions of OECD Guidelines nº 213 (1998), publications of Decourty et al. (2005) and Suchail et al (2001), recommendations of the german ring test group (2013) and EPPO 170
Deviations to Guidelines:	None to the guideline. - Temperature in the climatic chamber was slighlty above 35ºC (max. 35.74ºC) during one period of more than two consecutive hours.
GLP:	Yes (certified laboratory).
Study Objective:	To determine the chronic toxicity of Flufenacet technical to adult worker honeybees.
Test item:	Flufenacet technical; Batch code: SWL-8454; active substance: Flufenacet; content of a.s. determined by certificate of analysis: 98.26 %;w/w expiry date: 20th Dec 2016.
Reference product:	BAS 152 11 I; Batch number FRE-001226; active ingredient: Dimethoate; content of a.i. analysed: 420.3 g/L density: 1.072 g/cm^3.
Test organisms:	Test species: *Apis mellifera L. var. iberica* (Hymenoptera, Apidae)

	Life Stage:	Young adult worker bees (not older than 24 hours).
	Source:	Commercial apiary about 18 km from Trialcamp facilities.
	Preparation of test organism:	The bees were kept in stainless steel cages (8.5 x 6.5 x 4.5 cm) with several small ventilation holes at their bottom and a glass sliding door on the front side which enabled easy handling of the bees and providing clear vision for the assessments. Two circular holes were present in the upper surface of the cages of which one was used for solutions provisioning. Treatment solutions consisted of a 50% (w/v) sucrose solution either with sucrose only (control) or with a required amount of the test or reference substance) and they were provided by means of 5 ml disposable syringes. The inner surface of each cage was covered with filter paper to avoid accumulation of moisture. During the acclimatization period, the bees were feed with untreated 50% aqueous sucrose solution ad libitum. Each cage was considered as a replicate and it contained a group of ten bees.
Test design:		A single dose of 100 µg Flufenacet/bee/day was assessed. A stock solution was prepared daily by mixing a defined amount of the test item in a defined amount of acetone. The test dose was prepared daily by mixing an aliquot of the stock solution with a defined amount of a 50% w/v aqueous sucrose solution. Two control groups, one with untreated sucrose solution 50% w/v only and one with sucrose solution mixed with acetone, and the reference item Dimethoate 40% EC at a daily dose of 0.107 µg a.i./bee/day were concurrently tested. Five replicates per treatment each enclosing at least ten bees, were group fed with one feeder per cage containing 1000 µl of test solution, thus providing 100 µl of test solution per bee per day. Feeders were weighed prior to their placement in the test cages and were changed on a daily basis with new feeders containing fresh test solutions. When removed each feeder was re-weighed and the mean dose consumed per bee was calculated taking in account the surviving individuals at the moment of replacement. Five additional cages with syringes with the feeding solution but no bees were maintained in the climatic chamber. Syringes of these additional cages were changed daily in concomitance with the test syringes and were weighed before and after each replacement for the calculation of sucrose solution evaporation. Daily consumption of the test solutions (control and treatments with the test and the reference items) were adjusted taking in account the daily evaporation.
Test concentrations / doses:	Control:	C: 50 % (w/v) aqueous sucrose solution.
	Test Item:	a single concentration of 100 µg Flufenacet/bee/day.
	Reference Item:	R: 0.107 µg dimethoate/bee/day.
Test conditions:	Temperature:	32.4 – 35.74 °C
	Relative humidity:	50.03 – 66.46 %
	Exposure to light:	Constant darkness except during application and assessments.
Sampling:		Four treatments were assayed daily in the test: One limit concentration of the test item, two control groups (pure sucrose solution and sucrose solution + acetone) and one treatment with the reference item. Five replicates per treatment were set up
Analytical verification:		A method was validated and specimens of aqueous solution were analysed for concentration determination of Flufenacet. Quantification was performed by ionic HPLC. The limit of quantification (LOQ) of the analytical method was 3.96 µg/L, with a limit of detection (LOD) set at 1.19 µg/L (30% of the LOQ). Analytical study was performed to verify the concentration of the samples taken. For the analytical concentration verification, Flufenacet residues were determined. The measured concentration in the samples was within 20 % of nominal test concentration used, Thus the concentrations of the test item were confirmed and the endpoints are based on nominal concentrations.

Analytical recoveries for Flufenacet

Sample code	Timing	Matrix	Replicate	Nominal Concentration [mg/mL]	Analysed Concentration [mg/mL]	% of Nominal

TRC16-116BA 1S	D9	50 % (w/v) aqueous sucrose solution	M1	20.40	17.07	83.68
TRC16-116BA 1S	D9		M2	20.40	17.08	83.73

Statistics: Mean daily consumptions of the two controls (negative and solvent control) were compared by means of a parametric pair wise test (t- test; $\alpha = 0.05$). Mean daily consumptions of the pooled controls and of the test item were compared between them by means of a parametric pair wise test (t- test; $\alpha = 0.05$). Mean cumulative mortality of the two control groups at 240h were compared by means of a pair-wise non parametric test (Mann-Whitney exact test, $\alpha = 0.05$). Mean daily consumptions of the pooled controls and of the test item were compared between them by means of a pair-wise non parametric test (Mann-Whitney exact test, $\alpha = 0.05$).

Findings: Results are shown in the tables below.
The estimated consumed chronic LDD50-value (Lethal Dietary Dose that kills 50% of the exposed individuals) for Flufenacet technical was higher than the mean consumed dose of 23.44 µg Flufenacet/bee/day. Based on the mortality data, the NOEDD (No Observed Effect Dietary Dose) was determined to correspond to a daily consumed dose of 23.44 µg Flufenacet/bee/day, equivalent to a NOEC of 840.34 mg a.i./kg food. A total of five idividuals of those exposed to the test item, two at 48h and 3 at 216h, were observed to be affected throughout the study. No affected individuals were observed in the control groups at any of the assessments.

Treatment	10 day cumulative mortality	Corrected mortality	Overall mean consumption of feeding solution	Daily dietary dose	Accumulated mean uptake
Control:					
	[%]		[µL/bee/day]	-	-
C	8.00	-	20.73	-	-
Reference item: BAS 152 11 I:					
(µg dimethoate/bee/d) [a]	[%]		[µL/bee/day]	[µg a.i./bee/day]	[µg a.i./bee]
R (0.107)	100.00	100.00	18.08	1.93E-02	0.097(°°)
Test item: Flufenacet technical:					
(µg Flufenacet/bee/day) [a]	[%]		[µL/bee/day]	[µg a.s.bee/day]	[µg a.s./bee]
T1 (100)	18.00	10.87	23.44	23.44	234.39

(°°) Cumulative over 5 days of application

Conclusion: All validity criteria were met and the study was deemed valid. The endpoints determined are shown in the table below.
No statistically significant differences were observed in mean daily consumption between any of the test item treatments and the control group.

Endpoints (D10)	Test item: Flufenacet technical (active substance: Flufenacet)	
	Concentration	Dose
NOEC / NOEDD	840.3 mg a.s./kg food	23.44 µg a.s./bee/day
LC_{50} / LDD_{50} (95 % Confidence limits)	>840.3 mg a.s./kg food	>23.44 µg a.s./bee/day

Comments of zRMS:	The study is considered valid. All validity criteria were met. The endpoints determined are shown below: **The LDD_{50} value, is 56.58 µg/bee/day** The NOEDD is 25.8 µg/bee/day The LC_{50} is 1533.1 mg/kg The NOEC is 666.7 mg/kg

Reference Report	KCP 10.3.1.2-02 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 LDD_{50}, LC_{50}, 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						LC_{50}	LDD_{50}
					Number of dead bees [no.] replicates			Total				
[mg/kg]	[µg/bee/day] [µg/30 mg/day]	[mg/kg]	[µg/bee/day] [µg/30 mg/day] [a]		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 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 LDD_{50} value, is 56.58 µg/bee/day. The LC_{50} 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).

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	The study is considered valid. All validity criteria were met. The endpoint determined is shown below: The NOEC D22 = 311.69 mg Flufenacet/kg diet, equivalent 48 µg Flufenacet/larva (NOED).

Reference: KCP 10.3.1.3-01

Report "Flufenacet Technical – Honey Bee Larval (Apis mellifera L.) Toxicity Test following Repeated Exposure under laboratory conditions", Marcial Marín, 2019, Study code S17-08182. Trialcamp S.L.U.

Guideline(s): Yes, OECD Guidance Document 239 (2016), SANCO/3029/99 rev.4 (July 2000)

Deviations: None to guidance.

- On 27, 28 and 30 September (larval stage) and from 08 to 15 October 2018 (pupation and emergence phases), temperatures out of the target range were recorded for more than 30 minutes once every 24 h. Maximum recorded temperature was 35.2 °C and minimum recorded temperature was 26.4 °C.
- On 30 September and 01 October 2018 (larval stage) air relative humidity below the target range was recorded for more than 2 hours. Minimum recorded relative humidity was 60.4 %.
- On 26 January, 27 and 28 May 2018, temperatures above the target range were recorded during the product storage period. Maximum recorded temperature was 20.4 °C.
- On 28 September and 02 October 2018, temperatures above -18 °C and below -15 °C for more than 2 hours were recorded during samples storage. Maximum recorded temperature for these deviations was -17.42 °C (maximum recorded temperature for the storage period: -17.33 °C).
- Time Study Schedule for reporting was June 2019 instead of December 2018.
- The commercial royal jelly used in this study was collected more than 12 months previously to study start.

GLP: Yes

Acceptability: Yes

Materials and methods

The objective of this study was to determine the effects of Flufenacet Technical (batch SCL-64456) on the honey bee larvae, *Apis mellifera* L., from repeated feeding exposure in an 22 day in vitro test and to determine the No Observed Effect Dose/Concentration (NOED, NOEC), the Lowest Observed Effect Dose / Concentration (LOED,

LOEC) and the corresponding Median Effect Dose/Concentration (ED_{50}, EC_{50}) for adult emergence (from D3 to D22), where possible.

The test species was honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae originating from commercial beehives from the in-house test facility stock, adequately fed, healthy and as far as possible disease-free and queen-right. The hives from which the larvae were obtained were not previously exposed to any chemical treatments within four weeks of test initiation.

At D-3, the queen from at least three colonies was isolated for one day within a queen excluder placed on a single frame with empty cells in their own hive, to provide known-aged eggs and subsequent larvae.
At D-2, maximum 30 hours after isolation, the queens were released. Frames containing eggs were left in the excluder cages until hatching (D1). Three frames from different hives, containing the highest number of synchronized larvae, were selected for grafting in the laboratory.

The study was conducted as a dose response test with duration of 22 days from grafting on day 1 to the final assessment on day 22. From day 3 until day 6 of the test, 5 different concentrations of Flufenacet Technical were applied to the larvae of the test item groups and one single concentration of the reference item was applied to the larvae of the reference item group. Both, test and reference item, were supplied in diet B and C. The daily feeding volume increased from 20 µL to 50 µL diet per larva over the application period. The cumulative feeding volume from day 3 until day 6 of 140 µL diet per larva and the density of the diet (1.1 g/mL) were considered for the calculation of the cumulative doses per larva. Two control groups (negative and solvent control) were included in the test and exposed for the same period of time under identical exposure conditions to the treatments. Each treatment group consisted of 48 larvae; 16 from each of three different colonies (each colony representing a replicate). Larval mortality assessments were on days 4, 5, 6, 7, and 8. The presence of uneaten food was qualitatively recorded on day 8. Assessment of mortality during pupation phase was on day 15 and assessment of emergence on day 22.

The test item was applied at rates 19.48, 38.96, 77.92, 155.84 and 311.69 mg Flufenacet/kg diet, equivalent to 3.05, 6.11, 12.21, 24.42 and 48.84 µg Flufenacet/larva). Just before feeding, from day 3 until day 6, the test solutions were added to the diet using a micropipette. The volume of application solution in the diet did not exceed 10 % of the final diet volume. The amount of acetone represented the 1 % of the final diet volume. The diet was homogenized using a vortex mixer.
Dimethoate was used as reference item at a rate of 52.80 mg Dimethoate/L diet (equivalent to 48.0 mg Dimethoate/kg diet and 7.39 µg Dimethoate/larva).

The test conditions were: Air Temperature: Min: 26.3* / Max: 35.2 °C; Relative humidity: Min: 45.6 / Max: 97 %; Exposure to light: Constant darkness except during feeding and assessments.
* Deviation (≥ 30 minutes)

Assessment of larval mortality was conducted before feeding on D4, D5, D6, D7 and D8. With assistance of a stereo microscope, larvae were recorded as dead if no respiration (movement of spiracles) was observed. On D8, during the assessment of mortality, the presence of uneaten food was qualitatively recorded. Assessment of mortality during pupation phase was conducted on day D15 and assessment of emergence on D22. Other observations (larval appearance and size) were recorded to aid in the interpretation of mortality in comparison to the control groups. At each assessment time, dead larvae and pupae were removed for sanitary reasons.

Analytical phase was performed to verify the concentration of the samples taken. A method was validated and samples of treated solutions were analysed for concentration determination of Flufenacet. Quantification was performed by HPLC. The limit of quantification (LOQ) of the analytical method was 10.26 µg/mL with a limit of detection (LOD) set at 3.08 µg/mL (≤ 30 % of the LOQ).

The measured concentration in the samples was within 20 % of nominal test concentration used. Thus the concentrations of the active ingredient were confirmed and the endpoints are based on nominal concentrations.

Statistical calculations were made with the statistical software ToxRat® Professional 3.2.1. All tests were performed using α = 0.05. Mortality in the negative control was compared with mortality in the solvent control by Fisher's Exact Binomial Test (two-sided). For NOED determination, treatments were compared with control by multiple Fisher's Exact Binomial Test with Bonferroni correction (one-sided greater). NOEC was determined as the concentration corresponding to the NOED. No statistical analysis was performed to determine ED50/EC50 because no emergence below 50% was recorded.

Results and discussions

Table 2.3.1.1.2-1: Endpoints

Endpoints	**Period**	**Dose** [a]		**Concentration**
		µg a.i./larva	mg a.i./kg diet[b]	µg t.i./larva
NOED/NOEC	D3-D22	48.00	311.69	48.84
LOED/LOEC	D3-D22	n.d.	n.d.	n.d.
ED_{50} / EC_{50}	D3-D22	n.d.	n.d.	n.d.

t.i.: test item (Flufenacet Technical); a.i.: active ingredient (Flufenacet).
n.d.: not determined
[a] Based on the density of the diet (1.1 g/mL) and the cumulative feeding volume from day 3 until day 6 of 140 µL diet/larva.

Findings:

- On day 8, the cumulative larval mortality in both control groups was 6.25 %.On day 22, the adult emergence rate of the initial grafted larvae was 89.58 % in the negative control group (Co) and 91.67 % in the solvent control group (Cs). Therefore the validity criteria for the control group were met for both test periods: the D8 mortality was lower than 15.00 % and the D22 days emergence rate was greater than 70.00 %, across all replicates. Cumulative mortality in the Reference Item group also met the validity criteria (>50 % on day 8, actual value 93.75 %).

Conclusion

All validity criteria were met and sensitivity of the test organisms was confirmed.
Accordingly, the study was deemed valid.
The NOEC values for D22 were determined to be 311.69 mg Flufenacet/kg diet (step-down Cochran-Armitage test procedure, α = 0.05, one-sided greater), equivalent 48 µg Flufenacet/larva (NOED). Under the conditions of this study, the LOEC/LOED could not be determined.
Since no mortalities above 50 % were recorded, the EC_{50} values could not been calculated.
No affected emerged bees (i.e. malformation) were observed at the D22 emergence assessment.

Comments of zRMS:	The study is considered valid. All validity criteria were met. ED_{10} (D22) 0.5 µg a.i./larva (reliable based on the criteria set in EFSA Supporting publication 2019:EN-1673; suitable for consideration in the risk assessment). NOED 0.64 µg a.i./larva The endpoints determined are shown in the table below:

ED_{50}	5.8 [µg a.i./larva]	
ED_{20}	1.3 [µg a.i./larva]	
ED_{10}	**0.5 [µg a.i./larva]**	

	NOED	**0.64 [µg a.i./larva]**	
	EC_{50}	36.7 [mg a.i./kg food]	
	EC_{20}	8.0 [mg a.i./kg food]	
	EC_{10}	2.9 [mg a.i./kg food]	
	NOEC	4.0 [mg a.i./kg food]	

Reference Report KCP 10.3.1.3-02
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/$EC_{10/20/50}$ 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 [µg a.i./larva]	Concentration [mg a.i./kg food]	On day 8: Larval mortality Day 3 – Day 8 [%] abs.	On day 8: Larval mortality Day 3 – Day 8 [%] corr.	On day 8: Mean OO [%]	On day 22: Pupal mortality Day 8 – Day 22 [%] abs.	On day 22: Pupal mortality Day 8 – Day 22 [%] corr.	On day 22: Total mortality Day 3 – Day 22 [%] abs.	On day 22: Total mortality Day 3 – Day 22 [%] corr.	On day 22: Adult emergence rate [%] 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	ED_{50} [µg a.i./larva] [2] (95% CL)	5.8 (3.9 – 8.7)
	ED_{20} [µg a.i./larva] [2] (95% CL)	1.3 (0.8 – 2.2)
	ED_{10} [µg a.i./larva] [2] (95% CL)	0.5 (0.2 – 1.1)
	NOED [µg a.i./larva] [1]	0.64
Test item concentrations	EC_{50} [mg a.i./kg food] [2] (95% CL)	36.7 (24.7 – 54.6)
	EC_{20} [mg a.i./kg food] [2] (95% CL)	8.0 (4.7 – 13.6)
	EC_{10} [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 ED_{50} (successful adult emergence up to D22) was calculated to be 5.8 µg a.i./larva, which is equivalent to an EC_{50} of 36.7 mg a.i./kg food.
The ED_{10} and ED_{20} (D22) was determined to be 0.5 and 1.3 µg product/larva, respectively, which is equivalent to an EC_{10} and EC_{20} (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.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.4.1.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

A 2.4.1.2 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: – mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%), – corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 95.0% on day 7 of exposure (criterion: a minimum of 50%), – the mean number of eggs per female in the control group was 6.0 (required: ≥ 4 eggs per female). **Agreed endpoints:** LR50 >2.5 L/ha

	ER_{50} = 0.92 Lf.p./ha $NOER_{mortality}$ = 0.16 L/ha $NOER_{reproduction}$ = 0.06 L/ha

Reference: KCP 10.3.2.2-01

Report "An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the predatory mite, *Typhlodromus pyri* (Scheuten)". Monika Stalmach, 2018, B/163/16. Institute of Industrial Organic Chemistry, Branch Pszczyna

Guideline(s): ESCORT 1 Guidance Document (Barrett K.L. et al., 1994)
ESCORT 2 Guidance Document (Candolfi M.P. et al., 2001)
Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Blumel S. et al., 2000)

Deviations: According to study plan, study B/163/16 should be completed in December 2017, but it was completed in May 2018, which had no impact on the results. During the study formulation of the test item has changed also Study Director has changed. This deviation had no impact on the study results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on mortality and reproduction of the predatory mite, *T. pyri* (Sch.) was conducted for Sharda Cropchem Ltd, India at Institute of Industrial Organic Chemistry, Branch Pszczyna.
The study was carried out based on the Sponsor recommended rates for the test item as the definite test. There were 0.06, 0.16, 0.4, 1.0 and 2.5 L/ha. A 24 hours old (protonymphal stage) of predatory mites *T. pyri* were exposed to the test item applied to plastic discs (*Pinus* sp.) during the experimental period.
To verify the sensitivity of the mites and the precision of the test procedure, the insecticide, Danadim 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 9.0 mL/ha (3.6 g a.i./ha). The control group was treated with distilled water.
Mortality was observed after 7 days of post treatment of the test item. Observations of reproduction in the control and other groups treated with the test item were made after 8, 11 and 14 days post treatment of the test item.
Endpoints based on mortality of T. *pyri* was 7 days and reproduction reduction (Pr) was 14 days post-test item treatment.

Results
The effects of Flufenacet 6% + Pendimethalin 30% EC on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Mortality and reproduction of *T. pyri* in the laboratory test

Study group (application rate) [kg/ha]	**Parameter (endpoint)**				
	Mortality		**Fecundity**		
	Total [%]	**LR_{50}**	**Mean no. of mummies/female (Rr) [No]**	**Reproduction reduction Pr [%]**	**ER_{50}**
Control	0.0	-	6.011	-	-
Flufenacet 6% + Pendimethalin 30% EC					
0.06	0.0	**>2.5 L/ha**	6.141	-2.2	**0.92 L/ha**
0.16	0.0		3.741	37.7*	
0.4	6.7*		3.535	41.2*	
1.0	11.7*		3.628	39.6*	
2.5	40.0*		2.100	65.5*	
$NOER_{mortality}$		**0.16 L/ha**	$NOER_{reproduction}$		**0.06 L/ha**

Reference item	Danadim 400 EC			
9.0 mL/ha	95.0	-	-	-

* - statistically significant differences at $p < 0.05$

Findings

- Mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to Flufenacet 6% + Pendimethalin 30% EC at rates of 0.06, 0.16, 0.4, 1.0 and 2.5 L/ha, the percentages of *T. pyri* mortalities were 0.0, 0.0, 6.7, 11.7 and 40.0%, respectively.
- There were statistically significant differences in mortality between group treated with the test item at rates of 0.4, 1.0 and 2.5L/ha, and the control group.
- On the basis of the obtained mortality results, the LR_{50} is 3.579 L/ha. The $NOER_{mortality}$ is 0.16 L/ha.
- For the reference item Danadim 400 EC, the mortality of mites after 7 days of exposure at the rate of 9.0 mL/ha, was 95.0%, 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 6.0 eggs/female. The mean reproduction rates (Rr) after 14 days of exposure to Flufenacet 6% + Pendimethalin 30% EC at rates 0.06, 0.16, 0.4, 1.0 and 2.5 L/ha were 6.1, 3.7, 3.5, 3.6 and 2.1 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by rates of 0.06, 0.16, 0.4, 1.0 and 2.5 L/ha were -2.2, 37.8. 41.2, 39.6 and 65.5%, respectively.
- There were statistically significant differences in reproduction between group treated with the test item at rates of 0.16, 0.4, 1.0 and 2.5 L/ha and the control group.
- On the basis of the obtained results, the ER_{50} is 0.92 L/ha. The NOER value could not be estimated. It can only be concluded that the $NOER_{reproduction}$ is lower than 0.06 L/ha

Conclusion
On the basis of the obtained results it can be concluded that Flufenacet 6% + Pendimethalin 30% EC at the rates of 0.06 and 0.16 L/ha has no adverse effect on mortality. However, at the rate of 0.4, 1.0 and 2.5 L/ha such an effect is observed. The test item at all tested rates has an adverse effect on reproduction of the mites.

Comments of zRMS:	The study is considered valid. All validity criteria were met. • after 48 hours, mortality in 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 5.0 mL/ha was 60.0% (criterion: a minimum of 50%), • all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity), • the mean number of mummies per female in the control group was 21.7 (criterion: a minimum of 5.0 mummies/female), • all wasps in the control group gave offwinter (criterion: a maximum of 2 females giving no off winter). **Agreed endpoints:** LR_{50} > 4.2 L f.p./ha **ER_{50} = 2.14 L f.p./ha** NOER value could not be estimated. It can only be concluded that the **$NOER_{śmiertelność} \geq$ 4.2 L/ha**

Reference: KCP 10.3.2.2-02

Report: "An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendi-

	methalin 30% EC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez)". Monika Stalmach, 2018, B/162/16. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 200 documents and the guidelines developed by the IOBC, BART, and EPPO Joi (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)
Deviations:	According the Amendment No. 2 to the Study Plan B/162/16, study should be completed in December 2018, but it was completed in January 2019, which had no impact on the results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

SUMMARY

The laboratory test involved the evaluation of the effects of the test item, Flufenacet 6% + Pendimethalin 30% EC on mortality and fecundity of the parasitic wasp, *A. rhopalosiphi.* Five rates of the test item were used in the definitive test i.e., 0.5, 0.85, 1.45, 2.47 and 4.2 L/ha.

Adult female wasps were exposed to the test item applied to barley plants. The parasitoids were confined for 48 h and their condition was assessed after 2, 24, and 48 hours. Then, females which survived the 48-hour exposure to Flufenacet 6% + Pendimethalin 30% EC and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, 15 female wasps from the groups treated with the test item at rates of 0.5, 0.85, 1.45, 2.47 and 4.2 L/ha and the ones from 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 sensitivity of the test method, an insecticide, Danadim 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 5.0 mL/ha (2.0 g dimethoate/ha). The control group was comprised of wasps having contact with glass plates sprayed with distilled water.

Materials and methods:

Test item:	name: Flufenacet 6% + Pendimethalin 30% EC; content: flufenacet: 60 g/L and pendimethalin: 300 g/L; batch no.: SCL-19159; manufacturing date: May 15th, 2016; expiry date: May 14th, 2018.
Biological test system:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae.
– age:	adult females (24 - 48 hours after emerging from mummies)
– source:	a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Katz Biotech AG (Baruth, Germany)
Experimental design:	7 study groups: - a control group (0.0 L/ha) - Flufenacet 6% + Pendimethalin 30% EC at the rate of 0.5 L/ha - Flufenacet 6% + Pendimethalin 30% EC at the rate of 0.85 L/ha - Flufenacet 6% + Pendimethalin 30% EC at the rate of 1.45 L/ha - Flufenacet 6% + Pendimethalin 30% EC at the rate of 2.47 L/ha - Flufenacet 6% + Pendimethalin 30% EC at the rate of 4.2 L/ha - Danadim 400 EC at the rate of 5.0 mL/ha mortality assessment: 6 replicates/group; 5 females/replicate
Test conditions:	
– temperature:	19-22°C
– relative air humidity:	69-81%

– photoperiod: 16 hours light (mortality assessment and oviposition: 1237 lx; fecundity assessment: 4947 lx): 8 hours dark

Statistical analyses: Chi2 2x2 Table test with Bonferroni correction, Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Analysis of Variance (ANOVA), Dunnett's test, Duncan's test, Multiple Sequentially-rejective Welsh t-test after Bonferroni-Holm.

Endpoints:

– wasp mortality after 48 hours of exposure

– fecundity reduction (Pr) of the surviving female wasps exposed to Alpha-cypermethrin 10% EC, recorded 12 days after the oviposition period

RESULTS AND DISCUSSION:

The validity criterion concerning mortality was met, because mortality of the control group was 0.0% (criterion: a maximum of 10.0%) after 48 hours of exposure.

Mortality of the wasps exposed to Flufenacet 6% + Pendimethalin 30% EC at the rates of 0.5, 0.85, 1.45, 2.47 and of 4.2 L/ha was 3.3, 3.3, 3.3, 6.7 and 13.3%., respectively. At the significance level of 0.05, there were no statistically significant differences in mortality between the wasps exposed to the test item in each dose used in the study and the control group. Mortality of the wasps exposed to Danadim 400 EC at the rate of 5.0 mL/ha was 60.0% after 48 hours. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate.

The fecundity assessment showed that the mean number of mummies per female in the control group was 21.7. As for the number of mummies/female in the group treated with Flufenacet 6% + Pendimethalin 30% EC at the rates of 0.5, 0.85, 1.45, 2.47 and of 4.2 L/ha was 21.5, 18.1, 13.8, 9.9 and 6.2, respectively. Fecundity reduction (Pr) caused by Flufenacet 6% + Pendimethalin 30% EC at the rate of 0.5, 0.85, 1.45, 2.47 and of 4.2 L/ha was equal to 0.9, 16.6, 36.5, 54.6 and 71.5%., respectively. At the significance level of 0.05, there were no statistically significant differences in fecundity between the wasps exposed to the test item at the rates of 0.5 and 0.85 L/h and the control group.

Parametr (endpoint)								
Mortality (after 48 hours)				**Fecundity (12 days after oviposition)**				
Test item [application rate]		**Total [%]**	**LR_{50}**	**Test item [application rate]**		**Mean no. of mummies/ female**	**fecundity reduction Pr [%]**	**ER_{50}**
Test item [L/ha]	Active ingredients [kg/ha]		**[L/ha]**	**Test item [L/ha]**	Active ingredients [kg/ha]			**[L/ha]**
Control		**0**	**Above 4.2**	**Control**		21.7	–	**2.14 (1.62– 2.66)***
0.5	0.03[a] + 0.15[b]	**3.3**		**0.5**	0.03[a] + 0.15[b]	21.5	0.9	
0.85	0.05[a] + 0.26[b]	**3.3**		**0.85**	0.05[a] + 0.26[b]	18.1	16.6	
1.45	0.09[a] + 0.44[b]	**3.3**		**1.45[+]**	0.09[a] + 0.44[b]	13.8	36.5	
2.47	0.15[a] + 0.74[b]	**6.7**		**2.47[+]**	0.15[a] + 0.74[b]	9.9	54.6	
4.2	0.25[a] + 1.26[b]	**13.3**		**4.2[+]**	0.25[a] + 1.26[b]	6.2	71.5	
$NOER_{mortality}$ ≥ 4.2 L/ha				**$NOER_{fecundity}$: 0.85 L/ha**				
Reference item: Danadim 400 EC								
Reference item [mL/ha]		**5.0**						
Active ingredient dimethoate [g/ha]		2.0						
Mortality (after 48 h)								
Total [%]		**60.0**						

[a]: flufenacet
[b]: pendimethalin
[+]: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.2.1. software [9], [SOP/B/67]
*: ER_{50} with confidence limit

TEST VALIDITY CRITERIA

The following validity criteria were met during the study:
– after 48 hours, mortality in 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 5.0 mL/ha was 60.0% (criterion: a minimum of 50%),
– all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
– the mean number of mummies per female in the control group was 21.7 (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: – Average mortality observed in the control treatment was 0 % (criterion: minimum ≤ 6.7 %) – Average mortality observed in the test reference at the rate of 9 mL/ha was 100 % (criterion: ≥ 65 ± 35 %)

MORTALITY	
LR_{50}	**4.27 L/ha** (256.6[a] + 1306.6[b] g a.i./ha)
NOER	2.0 L/ha (120.2[a] + 612[b] g a.i./ha)
FOOD CONSUMPTION	
ER_{50}	**4.11 L/ha** (247.0[a] + 1257.6[b] g a.i./ha)
NOER	2.0 L/ha (120.2[a] + 612[b] g a.i./ha)

Report	KCP 10.3.2.2-03
Title	An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the carabid beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae). V. Angayarkanni. 2021. Report No. 8903/2021. Bioscience research foundation.
Guidelines	ESCORT 1 and ESCORT 2 guidance documents and the guidelines developed by the IOBC, BART and EPPO Joint Initiative.
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Summary

An extended laboratory study was carried out to determine the effects of Flufenacet 6% + Pendimethalin 30% EC on mortality of the carabid beetle *Poecilus cupreus* (Coleoptera: carabidae) and its food consumption under laboratory conditions. In the definitive test, the test substance was tested in a range of 5 different rates in a geometric series, with a spacing factor of 2 (1.0, 2.0, 4.0, 8.0 and 16.0 L/ha). The natural standard soil was used as test substrate.

Each tested group consisted of 30 test organisms, divided in 5 parallel replicates, each containing 3 adult female and 3 adult male. The conditions of the test organisms were recorded during 14 days. Mortality was assessed after 2 hours, and after 1, 2, 4, 7, 10 and 14 days. The toxicity effects of the test item were also observed. Food consumption was recorded on 2, 4, 7, 10 and 14 days after the exposure by evaluation of the fly pupae, which was consumed and untouched. Mortality and mean food consumption by the beetles after 14 days of exposure were the endpoints.

To verify the sensitivity of the biological test system and the precision of the test procedure, the insecticide Parathion (50% parathion, w/w) was used as a reference item. The rate of the reference item was 9 mL/ha (4.5 g parathion/ha). The control group was treated with distilled water.

Material and methods

Test item: Flufenacet 6% + Pendimethalin 30% EC: content: flufenacet 6.01% (w/v), pendimethalin 30.60% (w/v); Batch No.: SCL-39855; Date of production: 29th August 2019; expiry date: 28st August 2021.

Biological test system: *Poecilus cupreus* (Coleoptera, Carabidae)
– Age: Adults beetles (4 – 9 weeks after hatching from pupae)
– Source: BRF Insectary

Experimental design: 7 test groups:

Groups	Rates of test item (L/ha)	Rates of flufenacet[a] (g/ha)	Rates of pendimethalin[b] (g/ha)
Control group	0.0	0.0	0.0
Test item group 1	1.0	60.1	306
Test item group 2	2.0	120.2	612
Test item group 3	4.0	240.4	1224
Test item group 4	8.0	480.8	2448
Test item group 5	16.0	961.6	4896
Reference item	9 mL/ha	4.5 g parathion/ha[c]	

a based on flufenacet content in the test item, i.e. 6.01% w/v
b based on pendimehtalin content in the test item, i.e. 30.60% w/v
c based on parathion content in reference item, i.e. 50%

Test conditions:
– Temperature: 19.5 ºC to 21.3 ºC
– Relative air humidity: 70% of the WHC
– Photoperiod: 16:8 light/dark, light intensity between 880 to 1552 lux

Statistics: The LR_{50} and NOER for mortality and the ER_{50} and NOER for consumption were determined by using 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:
Mortality: LR_{50}, NOER.
Food consumption: ER_{50}, NOER

Results

Mortality of the beetles after exposure to Flufenacet 6% + Pendimethalin 30% EC at rates of 1.0, 2.0, 4.0, 8.0 and 16.0 L/ha was 10.00, 20.00, 43.33, 73.33 and 93.33%, respectively. There were no statistically significant differences in mortality between group treated with the test item at rates of 1.0, 2.0 L/ha and control group.

The mean number of consumed flies per beetles in the control group during the experimental period was 1.0, whereas in the group treated with Flufenacet 6% + Pendimethalin 30% EC at rates of 1.0, 2.0, 4.0, 8.0 and 16.0 L/ha, were

0.80, 0.69, 0.54, 0.32 and 0.18, respectively. Reduction in food consumption in the groups treated with Flufenacet 6% + Pendimethalin 30% EC during the experimental period were 19.7, 30.6, 46.4, 68.1 and 81.9%, respectively in comparison with the control group. There were statistically significant differences in food consumed between group treated with the test item at rates of 4.0, 8.0 and 16.0 L/ha and control group.

MORTALITY							
Day after treatment	**Study group – application rate (L/ha)**						
	Control (0.0)	**T1 (1.0)**	**T2 (2.0)**	**T3 (4.0)**	**T4 (8.0)**	**T5 (16.0)**	**Parathion (9 mL/ha)**
Mortality in 1st week (%)	0.00	10.00	20.00	40.00	70.00	90.00	100
Corrected mortality (%)	-	-	-	-	-	-	-
Mortality in 2nd week (%)	0.00	0.00	0.00	3.33	3.33	3.33	-
Corrected mortality (%)	-	-	-	-	-	-	-
Mortality in the experiment (%)	0.00	10.00	20.00	43.33	73.33	93.33	100
Corrected mortality (%)	-	-	-	-	-	-	-
LR_{50}	**4.27 L/ha** (256.6[a] + 1306.6[b] g a.i./ha)						
NOER	**2.0 L/ha** (120.2[a] + 612[b] g a.i./ha)						
FOOD CONSUMPTION							
Day after treatment	**Study group – application rate (L/ha)**						
	Control (0.0)	**T1 (1.0)**	**T2 (2.0)**	**T3 (4.0)**	**T4 (8.0)**	**T5 (16.0)**	**Parathion (9 mL/ha)**
Mean number of consumed flies/beetle in 1st week	1.00	0.92	0.86	0.69	0.42	0.31	0.33
Reduction in consumption in 1st week (%)	-	7.8	14.4	31.1	57.8	68.9	67
Mean number of consumed flies/beetle in 2nd week	1.00	0.68	0.53	0.38	0.22	0.05	-
Reduction in consumption in 2nd week (%)	-	31.7	46.7	61.7	78.3	95.0	-
Mean number of consumed flies/beetle in the experiment	1.00	0.80	0.69	0.54	0.32	0.18	0.33
Reduction in consumption in the experiment (%)	-	19.7	30.6	46.4	68.1	81.9	67.0
ER_{50}	**4.11 L/ha** (247.0[a] + 1257.6[b] g a.i./ha)						
NOER	**2.0 L/ha** (120.2[a] + 612[b] g a.i./ha)						

a: flufenacet
b: pendimethalin

Test validity criteria

The following validity criteria were met during the study:

– Average mortality observed in the control treatment was 0 % (criterion: minimum ≤ 6.7 %).
– Average mortality observed in the test reference at the rate of 9 mL/ha was 100 % (criterion: ≥ 65 ± 35 %).

Comments of zRMS:	The study is considered valid. All validity criteria were met: - pre-imaginal mortality of the control group was 10.0% (criterion: a maximum of 30.0%), - mean corrected mortality of the reference item group was 100.0% (criterion: a minimum of 40%), -fertility (the mean number of fertile eggs/female/day) in the control group was 8.6 (criterion: ≥ 2 fertile eggs/female).

	LR_{50} = 4.05 (3.11-5.64) L/ha **$NOER_{mortality}$ = 0.512 L/ha** The correct ER_{50} is set to **> 0.512 L f.p./ha**. This toxicity value should be considered in the risk assessment.

Reference:	KCP 10.3.2.2-04.
Report	"An extended laboratory test for evaluating the effects of Flufenacet 6% + Pendimethalin 30% EC on the ladybird beetle, *Coccinella septempunctata* L". Agnieszka Fulczyk. 2022. Study code B-45-22. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland
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 (Schmuck et al., 2000)
Deviations:	Yes 1. In the experimental part of the study a deviation from the guidelines developed by the IOBC, BART and EPPO Joint initiative (Schmuck V., et al., 2000) occurred. This deviation is to use leaf discs as a surface instead of plastic discs, however, did not have influence the study course and results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	NA

Study objective

The aim of the study was to determine the rate-effect relationship (LR_{50}) of Flufenacet 6% + Pendimethalin 30% EC on mortality and impact on reproductive capacity of the ladybird beetle, *Coccinella septempunctata* L., in the laboratory condition.

Summary

The extended laboratory test involved the evaluation of the effects of the test item, Flufenacet 6% + Pendimethalin 30% EC on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata*. In a definitive test, four test item application rates of 0.512, 1.28, 3.2 and 8.0 L/ha were used.
To assess mortality of the ladybird beetles, *Coccinella septempunctata* L., 4-day-old larvae were exposed to the test item applied to leaf discs. There were 40 replicates of each treated group. Each replicate contained 1 larva of *C. septempunctata* L. The larvae were fed with the fresh aphids, *Acyrthosiphon pisum* until pupation. During the exposure phase, survival, condition and development of the ladybird beetles were regularly assessed until the end of pupation. After emergence of the adults, pre-imaginal mortality was calculated on the basis of the numbers of dead larvae, pupae, and adults which died during emergence.
After completion of mortality assessment, healthy hatched beetles from the control group and from group treated with the test item at the rates of application rates of 0.512, 1.28 and 3.2 L/ha were subjected to evaluate the reproductive performance. Mortality in the group treated with the test item at the rate of 8.0 L/ha, after Abbott's correction, was > 50%, the criterion of reproduction assessment was not met. To allow egg-laying, adult ladybirds were transferred to separate reproduction units. The beetles had continuous access to food in the form of a honey-water solution (2:1), pine pollen (*Pinus sp*.) and the broad bean plants infested with the aphid, *A. pisum*. Reproductive performance observations, concerning the numbers of eggs laid and their fertility were made over a period of 9 days.
To check the relative susceptibility of the test system and the sensitivity of the test method, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 3.2 g/ha. Control beetles had contact with leaf discs sprayed with distilled water.

Materials and methods

Test item:	**Flufenacet 6% + Pendimethalin 30% EC** batch number: SCL-44652

Date of manufacture: 10.02.2021
Date of expiry: 09.02.2023
Active substance: flufenacet 6.01% (w/v), pendimethalin 30.20% (w/v)

Biological test system:
the ladybird beetle, *C. septempunctata* L. (Arthropoda: *Coccinellidae*)
age: 4-day-old larvae
source: breeding of ladybird beetle at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; beetles were obtained from commercial breeder (Katz Biotech AG, Germany)

Test design:
6 study groups:
- a control group (0.0 L/ha)
- Flufenacet 6% + Pendimethalin 30% EC at the rates of:
- 0.512 L/ha
- 1.28 L/ha
- 3.2 L/ha
- 8.0 L/ha
- dimethoate at the rate of 3.2 g/ha

number of replicates: 40 replicates/group
number of larvae: 1 larva of *Coccinella septempunctata* /replicate

Test conditions:
– temperature: 23.0 – 27.0°C
– relative air humidity: 60.0 - 89.4%
– photoperiod: 16 hours light : 8 hours dark
– light intensity 2893 lux

Endpoints:
– preimaginal mortality of the ladybird beetles
– LR_{50}
– $NOER_{mortality}$
– reproductive performance of the moulted beetles over a period of 9 days (the mean number of fertile eggs/female/day) reproduction reduction (Pr)

Statistics:
Probit analysis using linear max. likelihood regression, Step-down Cochran-Armitage Test Procedure.
Calculations were made using the ToxRat Professional 3.3.0. software.

Results

The effects of the test item, Flufenacet 6% + Pendimethalin 30% EC on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata* L. in the laboratory test are summarized below.

Study group	**Parameters (endpoints)**					
	Mortality			**Reproduction**		
Test item [L/ha]	**[%]**	**[%][a]**	**LR_{50} [L/ha]**	**Mean no. of eggs/female/day**	**Mean no. of fertile eggs/female/day**	**Reproduction reduction Pr [%]**
Control (0.0)	10.0	-	4.05 (3.11-5.64)	11.1	8.6	-
0.512	12.5	2.8		12.4	9.0	-4.7*
1.28[+]	25.0	16.7		18.7	16.1	-87.2*
3.2[+]	47.5	41.7		16.4	14.0	-62.8*
8.0[+]	75.0	72.2		-	-	-
$NOER_{mortality}$	0.512 [L/ha]					
dimethoate						
Reference item [g/ha]	100.0	100.0	-			
3.2						

(-) – 95% confidence interval
: mortality was corrected according Abbott's equation
+: statistically significant differences between control and groups exposed to test item
*: the negative value means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group

Conclusions

The validity criterion concerning mortality was met, because mortality of the ladybird beetle, *Coccinella septempunctata* L. in the control group was equal to 10.0% (≤ 30.0%). The mortality of the ladybird beetles exposed to the test item at the rates of 0.512, 1.28, 3.2 and 8.0 L/ha, after Abbott's correction, were 2.8, 16.7, 41.7 and 72.2%, respectively.
At the significance level of 0.05, there were no statistically significant differences in mortality between the ladybirds exposed to the test item at the rate of 0.512 L/ha of Flufenacet 6% + Pendimethalin 30% EC and the control group (Step-down Cochran- Armitage Test Procedure, (Alpha=0.05, p(trend)>Alpha)). At the significance level of 0.05, there were statistically significant differences in mortality between the ladybirds exposed to the test item at the rates of 1.28, 3.2, 8.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC and the control group (Step-down Cochran-Armitage Test Procedure, (Alpha=0.05, p(trend)<Alpha)).
The LR_{50} value is 4.05 L/ha (95% confidence limits: 3.11 – 5.64 L/ha) of Flufenacet 6% + Pendimethalin 30% EC.
The $NOER_{mortality}$ is equal to 0.512 L/ha of Flufenacet 6% + Pendimethalin 30% EC.
The mortality of the ladybird beetles exposed to the reference item at the rate of 3.2 g of dimethoate/ha, after Abbott's correction, was equal to 100.0%. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate.
The mean number of fertile eggs/female/day in the control group was 8.6 (criterion: ≥ 2 eggs/female/day). The mean numbers of fertile eggs/female/day in the group treated with the Flufenacet 6% + Pendimethalin 30% EC at the rates of 0.512, 1.28 and 3.2 L/ha were equal to 9.0, 16.1 and 14.0, and it refers to -4.7, -87.2 and -62.8% reproduction reduction, respectively. The negative value means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group.
It can be concluded that Flufenacet 6% + Pendimethalin 30% EC at the rates of 0.512, 1.28 and 3.2 L/ha had no adverse effect on the reproduction capacity of the ladybird beetle.

A 2.5 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.5.1 KCP 10.4.1 Earthworms

A 2.5.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS: The study is considered valid.

All validity criteria were met:
- each replicate produced 125.1 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 12.0% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 0%

(criterion: ≤ 10%).

Agreed endpoints:

Parameter	Value (mg test item/kg dry soil)	Value (mg flufenacet/kg dry soil)
EC_{50}	37.17 (32.05-43.13)	18.60 (16.03-21.56)
EC_{20}	25.39 (18.27-29.88)	12.70 (9.13-14.94)
EC_{10}	20.81 (13.13-25.60)	10.40 (6.56-12.80)
LOEC	32	16
NOEC	18	9
LC_{50}	284.49	142.24

Reference: KCP 10.4.1.1-01

Report "Flufenacet 50% SC Earthworm Reproduction Test (*Eisenia fetida*). Gierbuszewska A., 2014, G/22/14.

Guideline(s): OECD Guideline 222

Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Materials

Test item:	
Description:	Flufenacet 50% SC
Production batch:	SWE-62631
Active ingredients content:	Flufenacet 50% w/w
Vehicle and control:	Artificial soil
Test system:	
Species:	*Eisenia fetida* (Savigny 1826)
Strain:	-
Age:	adult (6 months old) with clitellum
Body weight:	264-326 mg
Source:	In house breeding at the Test Facility
Acclimation period:	24h in the artificial soil
Diet:	During the experiment, the earthworms were fed on air-dried finely ground cow manure. At the beginning of the experiment, it was mixed with the soil substrate (5 g food/ 500 g dry soil). The food prepared in this way was provided once a week during the four-week period (5 g food/container). After 4 weeks (when the adult earthworms were removed from the soil), the juvenile worms were fed only once (5 g food/container).
Experimental conditions:	
Test medium:	The test was performed in Soil (5% sphagnum peat, 20% kaolin clay, 75% industrial sand) in plastic containers (500 g dry soil/container).
Temperature:	19.5 – 22.0°C
Humidity:	15.00 – 15.90% (48.75 – 51.68% MWHC, beginning); 15.00 – 15.80% (48.75 – 51.35% MWHC, end)
pH:	6.12 – 6.19 (beginning); 6.25 – 6.32 (end)
Light and photoperiod:	545 - 683 lux (16 hours light and 8 hours dark)

Study design and methods

Experimental period:	03/07/14 - 28/08/2014

Test design and treatment:	The test item in the form of a water solution was mixed with the artificial soil. The concentrations of the test item were 10, 18, 32, 56, 100, 180, 320 and 560 mg/kg dry soil. Each of them was divided into four replicates. There was also an untreated control group divided into eight replicates. 10 earthworms per replicate. The experiment lasted 8 weeks. After 4 weeks, all adult worms were removed from the test containers and observed. All changes in their behaviour and morphology were recorded. The number of earthworms and their body weights were also determined. The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment. In order to provide assurance that the laboratory test conditions were adequate and to verify that the response of the test organisms would not change statistically over time, a test with a reference substance, carbendazim was conducted. Five concentrations of the reference substance were used. These included: 1, 1.5, 2.25, 3.37, and 5 mg/kg dry soil. The impact on reproduction was assessed after 8 weeks of the experiment. The obtained results served as a basis for the determination of the NOEC and the LOEC
Statistics:	NOEC and LOEC: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity and Williams Multiple Sequential t-test Procedure. EC_{50}, EC_{20}, EC_{10}: probit method.

Results and discussions

After 4 weeks of the experiment, Flufenacet 50% SC caused mortality of the adult earthworms in the concentration 320 mg/kg dw of artificial soil (87.5%) and in the concentration 560 mg/kg dw of artificial soil (100.0%). In the other concentrations no mortality was observed.
After 4 weeks, the treated earthworms did not exhibit any changes in appearance and behaviour.

After the application of the test item at the concentrations ranging from 10 to 100 mg/kg dry soil, the body weight increase was between 19.7 – 44.1%. As for the control group it was equal to 26.6%. At the concentrations ranging from 180 to 560 mg/kg dry soil, the body weight decrease was between 2.9 – 100.0%.

The obtained results made it possible to conclude that Flufenacet 50% has a significant impact on reproduction of the earthworms.

The results are considered valid because the following criteria were satisfied in the controls: each replicate produced 125.1 juveniles (mean) at the end of the experiment (criterion ≥ 30); the coefficient of variation of reproduction was 12.0% (criterion ≤ 30%); adult mortality over the initial 4 weeks of the experiment was 0% (criterion ≤ 10%).
The NOEC for the reference substance was 2.25 mg/kg dry soil. This value is in line with the range recommended by the guideline OECD 222 (1 to 5 mg carbendazim/kg soil dry weight).

Conclusion

Endpoints values are in the table below:

Parameter	Value (mg test item/kg dry soil)	Value (mg flufenacet/kg dry soil)
EC_{50}	37.17 (32.05-43.13)	18.60 (16.03-21.56)
EC_{20}	25.39 (18.27-29.88)	12.70 (9.13-14.94)
EC_{10}	20.81 (13.13-25.60)	10.40 (6.56-12.80)
LOEC	32	16
NOEC	18	9
LC_{50}	284.49	142.24

Comments of zRMS:	The study is considered valid. All validity criteria were met. - Control mortality < 10% - Production of juveniles in the control ≥ 30 per unit (163.8) - Coefficient of variation of reproduction in the control ≤ 30% (5.8%) **Agreed endpoints:** NOEC (mortality) ≥ 300.4 mg test item/kg dry soil LC_{10}, LC_{20} and LC_{50} (mortality) > 300.4 mg test item/kg dry soil NOEC (biomass) = 168.2 mg test item/kg dry soil LOEC (biomass) = 300.4 mg test item/kg dry soil NOEC (reproduction) = 168.2 mg test item/kg dry soil LOEC (reproduction) = 300.4 mg test item/kg dry soil EC_{10} = 188.9 mg test item/kg dry soil EC_{20} and EC_{50} > 300.4 mg test item/kg dry soil

Reference:	KCP 10.4.1.1-02
Report	Earthworm reproduction test with Pendimetalin 40% SC. Servajean, E. Report No.: 17-99-135-ES. Phytosafe s.a.r.l.
Guideline(s):	OECD Guideline No. 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item	Pendimethalin 40% SC, Batch No.SCL-58726
Artificial soil	5 % w/w sphagnum peat (grounded and sieved), 20 % w/w kaolinite clay, 75 % w/w fine sand (50% particles between 50 and 200 µm)
Test organism	Earthworm, *Eisenia fetida*. Origin: adult specimens born at the Phytosafe site, of the same generation.
Test design	Test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicates
Concentration of the test item	Control; 4.8; 9.0; 15.0; 30.0; 51.0; 93.1; 168.2 and 300.4 mg/kg dry soil
Test conditions	Temperature: 18.5 – 22.3 °C; pH at the beginning of the experiment: 6.2 - 6.5; pH at the end of the experiment: 6.0 - 6.6; soil moisture content at the end of the experiment: 40.2 - 44.8%; light-dark cycle: 16h : 8h; light intensity: 400-800 lux

Endpoints EC_{10}, EC_{20}, EC_{50}, NOEC

Results

Mortality

Percent mortality was 2.5% as maximum at 15.0 mg product/kg dry soil and 1.3% in the control.

Biomass changes

In the control group, mean body weight of the adults was increased by 107.3% as compared to the initial value. In the test item treatments, mean body weight was increased as compared to the initial values. Increase in biomass was similar to that of the control except for treatment 300.4 mg test item/kg soil since gain in biomass was significantly reduced.

For the reference item treatments, the gain of biomass was considered as similar to that of the controls for the 0.5 and 1.0 mg/kg soil, but significantly reduced at 2.5 mg/kg dry soil.

Juveniles number

In the control group, the mean number of juveniles was 163.8 per unit and coefficient of variation amounted to 5.8% of the mean.

The reproductive performance in the test item treatments was similar to the controls up to and including 168.2 mg/kg dry soil, but significantly reduced at 300.4 mg/kg dry soil.

The test was considered valid as the results fulfilled the following conditions:

- Control mortality < 10%
- Production of juveniles in the control ≥ 30 per unit (163.8)
- Coefficient of variation of reproduction in the control ≤ 30% (5.8%)

Conclusions

NOEC (mortality) ≥ 300.4 mg test item/kg dry soil
LC_{10}, LC_{20} and LC_{50} (mortality) > 300.4 mg test item/kg dry soil
NOEC (biomass) = 168.2 mg test item/kg dry soil
LOEC (biomass) = 300.4 mg test item/kg dry soil
NOEC (reproduction) = 168.2 mg test item/kg dry soil
LOEC (reproduction) = 300.4 mg test item/kg dry soil
EC_{10} = 188.9 mg test item/kg dry soil
EC_{20} and EC_{50} > 300.4 mg test item/kg dry soil

Comments of zRMS: The study is considered valid. All validity criteria were met.

Parameter	Value [mg test item / kg dry weight of artificial soil]
EC_{10}	**43.107** (5.544 – 87.161)
EC_{20}	78.951 (19.258 – 136.852)
EC_{50}	251.264 (147.855 – 457.629)
NOEC (reproduction)	**18.000**
LOEC (reproduction)	32.000
LC_{50}	470.292 (429.939 – 512.990)
NOEC (survival)	320.000
LOEC (survival)	560.000

Reference:	KCP 10.4.1.1
Report	"Flufenacet 6% + Pendimethalin 30% EC. Earthworm Reproduction Test (*Eisenia andrei*)", Aneta Gierbuszewska (2020), Study code: G/68/17
Guideline(s):	OECD Guideline No. 222 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

The aims of the study were to assess the impact of Flufenacet 6% + Pendimethalin 30% EC on reproduction of the earthworm, *Eisenia andrei* and to determine EC_{10}, EC_{20}, EC_{50} and NOEC.

The test item in the form of an aqueous emulsion was mixed with a suitable amount of the artificial soil. The concentrations of the test item were: 1.8, 3.2, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil. Each of them was divided into four replicates. There were also one untreated control group with the deionised water only. Control group was divided into eight replicates. The experiment lasted 8 weeks. After 4 weeks, all adult earthworms were removed from the test containers and observed. All changes in their behavior and morphology were recorded. The number of earthworms and their body weights were also determined.

The impact of the test item on reproduction was evaluated after an additional 4 week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Results and discussions

- ***Observation of the earthworms***

After 8 weeks of the experiment, the juveniles of earthworms did not exhibit any changes in appearance and behaviour.

- ***Mortality data***

The impact of the test item on mortality of the earthworms is presented in the table below.

Table 1. Mortality of the adult earthworms (*Eisenia andrei*) after 4 weeks of the experiment.

Concentration [mg/kg dry weight of the artificial soil]	Number of tested earthworms [no.]	Total Mortality	
		No.	%
0 (control)	80	2	2.5
1.8	40	0	0.0
3.2	40	1	2.5
5.6	40	1	2.5
10.0	40	0	0.0
18.0	40	0	0.0
32.0	40	0	0.0
56.0	40	1	2.5
100.0	40	1	2.5
180.0	40	1	2.5
320.0	40	3	7.5
560.0	40	31^{+}	77.5
1000.0	40	40^{+}	100.0

+ - statistically significant difference (Fisher's Exact Binomial Test with Bonferroni Correction, alpha = 0.05)

- ***Body weight***

Table 2. Body weight change in the adult earthworms (*Eisenia andrei*) after 4 weeks.

Concentration [mg/kg dry weight of the artificial soil]	Number of tested earth-worms [no.]	Mean body weight decrease	
		mg	%
0 (control)	80	41.2	9.0
1.8	40	21.3	4.7
3.2	40	55.6	12.6
5.6	40	29.1	6.7
10.0	40	67.5	15.3
18.0	40	49.3	11.5
32.0	40	56.5	12.8
56.0	40	42.4	9.7
100.0	40	27.6	6.3
180.0	40	83.5	19.0
320.0	40	62.6	14.9
560.0	40	63.3	14.7
1000.0	40	-	-

❖ ***Impact of the test item on reproduction of the earthworms***

The results concerning the impact of the test item on reproduction are shown in the table below.

Table 3. Number of juvenile worms (*Eisenia andrei*) after 8 weeks of the experiment

Concentration [mg/kg dry weight of the artificial soil]	Mean ±SD	Comparison to the control [%]	CV* [%]
0 (control)	191.6 ± 41.6	-	21.7
1.8	186.0 ± 36.9	97.1	19.8
3.2	189.0 ± 63.9	98.6	33.8
5.6	170.8 ± 36.5	89.1	21.4
10.0	162.3 ± 10.9	84.7	6.7
18.0	157.3 ± 29.0	82.1	18.4
32.0	151.5+ ± 30.5	79.1	20.1
56.0	144.0 ± 28.5	75.1	19.8
100.0	168.3 ± 39.6	87.8	23.5
180.0	136.0+ ± 6.2	71.0	4.5
320.0	98.5+ ± 6.1	51.4	6.2
560.0	40.5+ ± 16.6	21.1	41.0
1000.0	0.0+ ± 0.0	0.0	-

* - coefficient of variation
+ - statistically significant difference (Williams Multiple Sequential t-test Procedure, alpha = 0.05)

Validity criteria

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

- Each replicate produced 191.6 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment)
- The coefficient of variation of reproduction was 21.7% (criterion: ≤ 30%)
- Adult mortality over the initial 4 weeks of the experiment was 2.5% (criterion: ≤ 10%)

Conclusion

After the application of the test item at the concentrations ranging from 1.8 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 0.0 – 189.0 per replicate. The mean number of juveniles in the control group was equal to 191.6 per replicate.

After 8 weeks of the experiment, it was concluded that **Flufenacet 6% + Pendimethalin 30% EC** had no statistically significant impact on reproduction of the earthworms at the concentrations ranging from 1.8 to 18.0 mg/kg dry weight of the artificial soil and 56.0 to 100.0 mg/kg dry weight of the artificial soil.

The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below.

Parameter	Value [mg test item / kg dry weight of artificial soil]
EC_{10}	43.107 (5.544 – 87.161)
EC_{20}	78.951 (19.258 – 136.852)
EC_{50}	251.264 (147.855 – 457.629)
NOEC (reproduction)	18.000
LOEC (reproduction)	32.000
LC_{50}	470.292 (429.939 – 512.990)
NOEC (survival)	320.000
LOEC (survival)	560.000

A 2.5.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.5.1.3 KCP 10.4.2.2 Higher tier testing

Comments of zRMS:	All validity criteria were met. The mean abundance of earthworms of the test field at trial start was 242.9 ind./m2, thus fulfilling the guideline recommendation (60 ind./m² for arable soils). At least one representative of endogeic and anecic earthworms was present at the field site in a sufficient number (>10 % of total earthworms or at least 10 - 15 ind./m2), with abundances of 159.7 ind./m2 for *Aporrectodea caliginosa* (endogeic) and 33.9 ind./m² for *Lumbricus terrestris* (anecic; pre-sampling values). The study meets all criteria required for a valid earthworm field study as requested by the available guidance for earthworm field studies (ISO 11268-3, 2014; KULA *et al.*, 2006). It can be concluded that Flufenacet 6% + Pendimethalin 30% EC tested at an application rate of 4.5 L/h (corresponding to 0.27 kg flufenacet/ha + 1.35 kg pendimethalin/ha) had no adverse effects on single species, ecological groups (represented by dominant endogeic and anecic earthworm species), morphological classes (represented by dominant epilobous and tanylobous earthworm species) and total earthworm abundance and biomass about one year after application.

Reference Report	KCP 10.4.2.2-1. „Effects of Flufenacet 6% + Pendimethalin 30% EC on earthworms under field conditions". Lennart Schulz. 2022, Study code: 21 48 FEW 0002. BioChem agrar. Germany.
Guideline(s):	Yes ISO 11268-3 (2014): Soil quality - Effects of pollutants on earthworms

	Part 3: Guidance of the determination of effects in field situations, KULA, C. et al. (2006): Technical Recommendations for the Update of the ISO Earthworm Field Test Guideline (ISO 11268-3)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	NA

Study objective

The objective of this field study was to investigate potential effects and potential recovery of field populations of earthworms after the application of the test item Flufenacet 6% + Pendimethalin 30% EC. Therefore, a field experiment lasting about one year was performed and the effects of the test item with regard to species composition, biomass and abundance were compared to an untreated control and to a reference item (MAYPON FLOW).

Materials and methods

The study design was based on the ISO guidance document (Anonymous, 2014: ISO 11268-3, 2014: Soil quality – Effects of pollutants on earthworms, Part 3: Guidance on the determination of effects in field situations). The following recommendations were taken into account: KULA et al. (2006): Technical recommendations for the update of the ISO earthworm field test guideline (ISO 11268-3) and DE JONG et al. (2006): Guidance for summarizing earthworm field studies - A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies.

Test item:	**Flufenacet 6% + Pendimethalin 30% EC** Batch No.: SCL-44822 Expiration date: 03 March 2023 Active ingredient/content: flufenacet 6 % w/v (nominal) pendimethalin 30 % w/v (nominal)
Reference item:	The reference item MAYPON FLOW is toxic to earthworms and was tested to verify the sensitivity of the test system. Batch No.: 2150/13 Formulation type: SC Active ingredient/content: carbendazim 50 % w/v (nominal) Application rate: 20 L reference item/ha in 600 L water/ha (nominally equivalent to 10 kg a.s./ha) Number of applications: 1 (in parallel to the test item application)
Equipment:	Calibrated plot sprayers (spray width 2.5 m), Schachtner, PSG-F5.3 B 01.25.19 with 10 nozzles TEEJET DG80015VS and Baumann / agrotop GmbH, PL 2 with 10 nozzles Lechler IDK 90-015c.
Test conditions:	Natural field conditions, soil textural class: sandy loamy silt (DIN 4220) / loam (USDA), mean pH ($CaCl_2$) 5.9, mean total organic carbon content 1.12 % and mean maximum water holding capacity 37.8 g/100 g soil dry weight.
Endpoints:	Total abundance, total biomass, total adult and total juvenile abundance and biomass, total adult and total juvenile abundance and biomass of epilobous and tanylobous, total adult and total juvenile abundance and biomass of endogeic and anecic, total adult and total juvenile abundance and biomass of single species.
Test design:	The trial was placed on arable land near Machern in Saxony/Germany. The test item Flufenacet 6% + Pendimethalin 30% EC (flufenacet 6 % w/v (nominal), 6.0 % w/v (analysed) + pendimethalin 30 % w/v (nominal), 30.0 % w/v (analysed) was applied once on bare soil at an application rate of 4.5 L test item/ha corresponding to 270 g flufenacet/ha (nominal) + 1350 g pendimethalin/ha (nominal). MAYPON FLOW (carbendazim 50 % w/v (nominal) was applied once to the plots as ref-

erence item at a rate of 20 L/ha, corresponding to 10 kg carbendazim/ha, in parallel to the test item application. The control plots were left untreated.
The fodder crop "Landsberger Gemenge" (clover grass mixture) was seeded about 4 weeks after application and stayed on the field until the end of the study.
The test was performed in combination with further field tests on a test field with 36 plots. The plots, each 10 m x 10 m, were arranged in 6 x 6 formation, each plot surrounded by a 2 m wide path, between the plots. The set-up was a completely randomised design with 6 replicates per treatment group (total number of plots used for the test: 18). The assignment of the treatment groups to the plots was based on the results of a pre-sampling. The pre-sampling was conducted to determine the density, diversity and homogeneity of earthworm
populations at the site. Defined areas were sampled to assess earthworm populations before application, i.e., about 1 month before test item application and three times after the test item applications, i.e., about 1, 5 and 12 months after application. Earthworms were sampled from four 0.125 m² sampling areas per plot per sampling occasion by combining hand sorting with AITC (Allyl-isothiocyanate) extraction in the excavated hole.

Statistic:

Pre-treatment sampling:
With the Shapiro-Wilk's-test or Kolmogorov-Smirnoff-test data were analysed for normal distribution. Afterwards, data were analysed with a two-factorial analysis of variance (ANOVA) with treatment as fixed factor and block as random factor.
If necessary, followed by two-sided t-test.
Post-treatment sampling:
With the Shapiro-Wilk's-test or Kolmogorov-Smirnoff-test data were analysed for normal distribution and with the Levene's test data were analysed for homogeneity in variance. Afterwards data were analysed as follows:
The data were analysed by a one-sided Student-t-test or Welch-t-test with test item treatment group < control as well as with reference item treatment group < control at the 5 % significance level. Test item and reference item were analysed in separate analyses.

Results

No measurable residues (< LOD) of flufenacet and pendimethalin were determined in the soil samples of the control plots taken immediately after application as well as in the untreated soil used for the spray targets. The mean recovery of flufenacet in the soil samples from the treated plots of the test item treatment group taken immediately after application was 86.1 % of the corresponding nominal level of 0.18 mg a.s./kg soil d.w. (assuming a bulk density of 1.5 g/cm³ and a soil depth of 10 cm).
A mean residue value of 99.4 % of the application rate was found in the soil of the spray targets. The mean recovery of pendimethalin in the soil samples from the treated plots of the test item treatment group taken immediately after application was 82.0 % of the corresponding nominal level of 0.90 mg a.s./kg soil d.w. (assuming a bulk density of 1.5 g/cm³ and a soil depth of 10 cm).
A mean residue value of 96.0 % of the application rate was found in the soil of the spray targets.

The results of the spray target analyses confirmed that the test item was accurately applied to the assigned plots. Since the average residue levels of the active substances in the soil samples taken immediately after application as well as in the soil of the spray targets were within the recommended range of 50 % to 150 % of the nominal value, the correct application of the test item was verified.
The mean earthworm abundance in the control plots was 238.7 ind./m² at pre-sampling, 168.3 ind./m² at 1st sampling, 295.7 ind./m² at 2nd sampling and 197.3 ind./m² at 3rd sampling.

Earthworm species found in the plots of the field site at pre-sampling were the endogeic species *Aporrectodea caliginosa* (65.7 % of total earthworms) and *Aporrectodea rosea* (15.3 % of total earthworms) as well as the anecic species *Aporrectodea longa* (4.2 % of total earthworms) and *Lumbricus terrestris* (14.0 % of total earthworms). The presence of the dominant species *Aporrectodea caliginosa* and *Lumbricus terrestris*, representing different ecological groups, indicated the suitability of the field site.

The toxic reference item reduced the total earthworm abundance by 50.9 % at 1st sampling, 15.0 % at 2nd sampling and 33.6 % at 3rd sampling. *Lumbricus terrestris* was the most sensitive species and was reduced in total abundance by 62.1 %, 58.7 % and 65.4 % on these sampling dates.
The total earthworm biomass was reduced by the reference item by 59.9 % at 1st sampling, 6.4 % at 2nd sampling and 46.9 % at 3rd sampling. *Lumbricus terrestris* was the most sensitive species and was reduced in total biomass by 67.5 %, 51.6 % and 73.8 % on these sampling dates. These results clearly indicated the effect of the toxic reference item and thus the validity of the field study.

The surface monitoring on days 1 - 3 after application showed that there were no acute primary effects on earthworms by Flufenacet 6% + Pendimethalin 30% EC. No alive, moribund or dead earthworms were found on the soil surface neither in the test item nor in the control monitoring areas.

No statistically significant reductions in total earthworm abundance and biomass could be observed for the tested application rate of 4.5 L test item/ha about 1, 5 and 12 months after application. Furthermore, no statistically significant reductions in abundance and biomass of the different earthworm species (*Aporrectodea caliginosa*, *Aporrectodea rosea*, *Aporrectodea longa* and *Lumbricus terrestris*) and ecological groups (endogeic and anecic earthworms) could be observed for the tested application rate about 1, 5 and 12 months after application.

Conclusions

The current study meets all criteria required for a valid earthworm field study as requested by the available guidance for earthworm field studies (ISO 11268-3, 2014; KULA et al., 2006).
The mean abundance of earthworms of the test field at trial start was 242.9 ind./m², thus fulfilling the guideline recommendation (60 ind./m² for arable soils).
At least one representative of endogeic and anecic earthworms was present at the field site in a sufficient number (>10 % of total earthworms or at least 10 - 15 ind./m²), with abundances of 159.7 ind./m² for *Aporrectodea caliginosa* (endogeic) and 33.9 ind./m² for *Lumbricus terrestris* (anecic; pre-sampling values).
In the reference item treatment group, the total earthworm abundance was reduced by 50.9 % and the total earthworm biomass was reduced by 59.9 % at 1st sampling (about 1 month after application), respectively, fulfilling the guideline re-commendation (reduction of the earthworm abundance and / or biomass of > 50 % compared to the control).

It can be concluded that Flufenacet 6% + Pendimethalin 30% EC tested at an application rate of 4.5 L/ha (corresponding to 0.27 kg flufenacet/ha + 1.35 kg pendimethalin/ha) had no adverse effects on single species, ecological groups (represented by dominant endogeic and anecic earthworm species), morphological classes (represented by dominant epilobous and tanylobous earthworm species) and total earthworm abundance and biomass about one year after application.

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

A 2.5.1.4 KCP 10.4.2.1 Species level testing

Comments of zRMS: The study is considered valid. All validity criteria were met.

Slight deviations were found, however did not affect the course of the experiment or the results.

Agreed endpoints:

Parameter	Value (mg test item/kg dry soil)	Value (mg flufenacet/kg dry soil)
Survival of adult collembolans		
EC_{50}	367.7 (285.1-501.1)	183.9 (142.6-250.6)
EC_{20}	103.8 (74.0-135.4)	51.9 (37.0-67.7)
EC_{10}	53.6 (33.3-75.0)	26.8 (16.6-37.5)
LOEC	32.0	16.0

	NOEC	18.0	9.0
	Reproduction of collembolans		
	EC_{50}	152.9 (129.2-180.6)	76.4 (64.0-90.3)
	EC_{20}	89.4 (63.4-108.8)	44.7 (31.7-54.4)
	EC_{10}	67.5 (42.0-86.8)	33.7 (21.0-43.4)
	LOEC	100.0	50.0
	NOEC	56.0	28.0

Reference: KCP 10.4.2.1-01

Report "Flufenacet 50% SC Collembolan (*Folsomia candida*) Reproduction Test. Arendarczyk A., 2015, G/28/15.

Guideline(s): OECD Guideline 232

Deviations: Yes. The temperature during the experiment was 18 – 23 ºC and it should have been between 18 – 22 ºC. The deviation was recorded during the last week of the test, it lasted 12 h (6 h 22.5ºC and 6 hours 23ºC), i.e. 1.8% of the total test time. It was a short-term deviation which did not affect the course of the experiment or the results.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Materials

Test item:
- Description: Flufenacet 50% SC
- Production batch: SWE-62631
- Active ingredients content: Flufenacet 50% w/w

Vehicle and control: Artificial soil (5% peat, 20% clay and 75% sand)

Test system:
- Species: *Folsomia candida*
- Age: 11 – 12 days old (synchronized culture)
- Source: Standard laboratory culture at the Test Facility
- Diet: During the experiment, the collembolans were fed with granulated dried baker´s yeast. The amount of food was 2 mg/container. The collembolans were fed at the beginning of the experiment and after 2 weeks of incubation.

Experimental conditions:
- Test medium: The test was performed in artificial soil (5% sphagnum peat, 20% kaolin clay, 75% industrial sand) in plastic containers (30 g moistened soil/container).
- Temperature: 18.0 – 23.0°C
- Soil Humidity: 10.1 – 11.5% (beginning); 10.0 – 11.6% (end)
- pH: 6.43 – 6.50 (beginning); 5.68 – 6.12 (end)
- Light and photoperiod: 470 - 595 lux (12 hours light and 12 hours dark)

Study design and methods

Experimental period:	18/03/15 - 15/04/2015
Test design and treatment:	The test item in the dorm of a water suspension was mixed with the artificial soil. Eight concentrations of the test item were used: 18, 32, 56, 100, 180, 320, 560 and 1000 mg/kg dry weight of artificial soil. Each concentration was prepared in four replicates, 10 collembolans per replicate. An untreated control group (8 replicates) was conducted. The pH of one control sample and one sample of each concentration was measured at the beginning and at the end of the test. The soil moisture content was checked at the beginning and at the end of the test. Water loss was replenished by adding 1 mL of distilled water per container (after 2 weeks of the experiment). The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The number of adult and juvenile collembolans was determined separately. In order to determine the sensitivity of the test organisms to chemical substance and to verify that the response of the test organisms would not change over time, a test with a reference substance, boric acid, was conducted. Twelve concentrations of the reference substance were used. These included: 15, 22, 32, 46, 68, 100, 150, 220, 320, 460, 680 and 1000 mg/kg dry soil. The impact on reproduction was assessed after 28 days of the experiment. The obtained results served as a basis for the determination of the EC_{50} value.
Statistics:	NOEC: Fisher´s Exact Binomial Test with Bonferroni Correction (survival), the Shapiro-Wilk Test on Normal Distribution (offspring number), the Levene´s Test on Variance Homogeneity (offspring number) and the Williams Multiple Sequential t-test Procedure (offpring number). EC_{50}, $EC_{20,}$ EC_{10}: probit method.

Results and discussions

After the application of the test item at the concentrations ranging from 18 to 1000 mg/kg dry weight of soil, survival of the collembolans was between 100.0% - 17.5%. In the control group, survival was equal to 98.8%.
The mean number of juveniles after the application of the test item at the concentrations ranging from 18 to 560 mg/kg dry weight of soil was between 326.0 – 7.3 per replicate. There were no juveniles noticed after application of the test item at concentration equal 1000 mg/kg dry weight of soil. The mean number of juveniles in the control group was equal to 311.1 per replicate.
The concentration of boric acid causing a 50% reduction in the number of juveniles produced within the exposure period (EC_{50}) is 98.1 mg/kg dry weight of soil. According to the OECD Guideline 232 the EC_{50} should be about 100 mg/kg dry weight of soil; hence, the sensitivity of the test organisms was proper.

The results are considered valid because the following criteria were satisfied in the controls: mean adult mortality was 1.2% (criterion ≤ 20%); the mean number of juveniles per vessel was 311.1 at the end (criterion ≥ 100 juveniles); the coefficient of variation calculated for the number of juveniles was 20.4% (criterion ≤ 30%).

Conclusion

Endpoints values are in the table below:

Parameter	Value (mg test item/kg dry soil)	Value (mg flufenacet/kg dry soil)
Survival of adult collembolans		
EC_{50}	367.7 (285.1-501.1)	183.9 (142.6-250.6)
EC_{20}	103.8 (74.0-135.4)	51.9 (37.0-67.7)
EC_{10}	53.6 (33.3-75.0)	26.8 (16.6-37.5)
LOEC	32.0	16.0
NOEC	18.0	9.0
Reproduction of collembolans		
EC_{50}	152.9 (129.2-180.6)	76.4 (64.0-90.3)
EC_{20}	89.4 (63.4-108.8)	44.7 (31.7-54.4)
EC_{10}	67.5 (42.0-86.8)	33.7 (21.0-43.4)
LOEC	100.0	50.0
NOEC	56.0	28.0

Comments of zRMS:	The study is considered valid. All validity criteria were met: - Mean percent mortality in the control group is ≤ 20% at the end of the test (1.3%) - Reproduction rate in the control group is ≥ 100 juveniles per unit at the end of test (149.8) - Standard deviation of the reproduction rate within the control group is ≤ 30% of mean value (8.6%) **Agreed endpoints:** NOEC (mortality) = 167.2 mg/kg dry soil (64.7 mg a.i./kg dry soil) LC_{50} (mortality) = 410.8 mg/kg (159.0 mg a.i./kg dry soil) 95%-confidence interval: 393.9-427.8 mg/kg dry soil NOEC (reproduction) = 97 mg/kg dry soil (37.5 mg a.i./kg dry soil) EC_{10} (reproduction) = 111.7 mg/kg (43.2 mg a.i./kg dry soil) 95%-confidence interval: 93.0-130.4 mg/kg dry soil EC_{20} (reproduction) = 133.2 mg/kg (51.6 mg a.i./kg dry soil) 95%-confidence interval: 114.5-151.9 mg/kg dry soil EC_{50} (reproduction) = 181.6 mg/kg (70.3 mg a.i./kg dry soil) 95%-confidence interval: 162.9-200.2 mg/kg dry soil

Reference: KCP 10.4.2.1-02

Report Collembolan reproduction test in soil with Pendimethalin 40% SC. Servajean, E. Report No.: 17-99-128-ES. Phytosafe s.a.r.l.

Guideline(s): OECD Guideline No. 232

Deviations: Yes. The pH of the control soil (6.8) was slightly higher than the recommended threshold value of 6.5. This change did not adversely affect the quality and integrity of the study

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:	Pendimethalin 40% SC, batch no.SCL-58726
Test species:	Collembolans: Folsomia candida, 9-12-day old juveniles born at the Phytosafe site.
Soil:	Artificial soil: 5% w/w sphagnum peat (grounded and sieved), 20% w/w kaolinite clay, 75% fine sand, 0.3% w/w $CaCO_3$
Study design:	Number of replicates: 4 replicates / concentration + 8 replicates / control Number of collembolans: 10 / replicate Test duration: 28 days
Application rates:	Control, 16.7, 30.1, 53.5, 97.0, 167.2, 317.7, 568.5 and 1003.3 mg/kg dry soil
Test conditions:	Temperature: 19.2 – 21.3 °C; pH at the beginning of the experiment: 6.8 – 6.9; pH at the end of the experiment: 6.9; lighting: 12 h light / 12 h dark; light intensity: 400-800 lux
Statistical analysis:	SigmaStat 4.0 was used for statistical analysis and NOEC determination. NOEC determination: the Shapiro-Wilk's Test on Normal Distribution, Brown-Forsythe test on Variance Homogeneity, Student's t-test for parametric pairwise comparison, Welch's t-test (normal distribution observed, variance homogeneity failed), Mann-Whitney Rank Sum Test (when normal distribution failed)
Endpoints:	EC_{10}, EC_{20}, EC_{50}, LC_{50}, NOEC

Results

Test item	Pendimethalin 40% SC		
Test object	*Folsomia candida*		
Exposure	Artificial soil		
Concentration [mg/kg soil (dw)]	**Adult mortality [%]**	**Number of Juveniles/test vessel [mean ± sd]**	**Reproduction [% of control]**
Control	1.3	149.8 ± 12.9	-
16.7	2.5	150.0 ± 17.3	-0.2
30.1	2.5	145.0 ± 13.3	3.2
53.5	0.0	147.0 ± 25.3	1.8
97.0	0.0	149.0 ± 7.5	0.5
167.2	7.5	85.3 ± 18.5	43.1
317.7	32.5	25.3 ± 14.6	83.1
568.5	72.5	13.0 ± 9.1	91.3
1003.3	92.5	5.5 ± 3.0	96.3

	Mortality	**Reproduction**
NOEC (mg a.s./kg soil (dw))	167.2 mg/kg dry soil (64.7 mg a.i./kg soil))	97.0 mg/kg dry soil (37.5 mg a.i./kg dry soil)
LC/EC_{10} (mg a.s./kg soil (dw))	200.6 mg/kg dry soil (77.7 mg a.i./kg soil)	117 mg/kg dry soil (43.2 mg a.i./kg soil)
LC/EC_{20} (mg a.s./kg soil (dw))	261.0 mg/kg dry soil (101.0 mg a.i./kg soil)	133.2 mg/kg dry soil (51.6 mg a.i./kg soil)
LC/EC_{50} (mg a.s./kg soil (dw))	410.8 mg/kg dry soil (159.0 mg a.i./kg soil)	181.6 mg/kg soil (70.3 mg a.i./kg dry soil)

The test is considered valid since:

- Mean percent mortality in the control group is ≤ 20% at the end of the test (1.3%)
- Reproduction rate in the control group is ≥ 100 juveniles per unit at the end of test (149.8)
- Standard deviation of the reproduction rate within the control group is ≤ 30% of mean value (8.6%)

Conclusions

NOEC (mortality) = 167.2 mg/kg dry soil (64.7 mg a.i./kg dry soil)
LC_{50} (mortality) = 410.8 mg/kg (159.0 mg a.i./kg dry soil) 95%-confidence interval: 393.9-427.8 mg/kg dry soil
NOEC (reproduction) = 97 mg/kg dry soil (37.5 mg a.i./kg dry soil)
EC_{10} (reproduction) = 111.7 mg/kg (43.2 mg a.i./kg dry soil) 95%-confidence interval: 93.0-130.4 mg/kg dry soil

EC_{20} (reproduction) = 133.2 mg/kg (51.6 mg a.i./kg dry soil) 95%-confidence interval: 114.5-151.9 mg/kg dry soil
EC_{50} (reproduction) = 181.6 mg/kg (70.3 mg a.i./kg dry soil) 95%-confidence interval: 162.9-200.2 mg/kg dry soil

Comments of zRMS:	The study has been evaluated according to OECD 232 (2016) and is considered acceptable. All validity criteria are met. NOEC reproduction 18 mg formulation /kg soil dry weight EC_{10} 23.79 mg formulation /kg soil dry weight

Reference:	KCP 10.4.2.1
Report	"Flufenacet 6% + Pendimethalin 30% EC. Collembolan (*Folsomia candida*) Reproduction Test". Aneta Gierbuszewska. 2020. Study code: G/69/17. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 232 (2016)
Deviations:	Yes. 1. At the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016). 2. Physiological or pathological symptoms or distinct changes in behavior were not described. 3. Culturing of collembolans takes place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232 (2016) (3.3). 4. In order to verify the nominal soil concentration of the test item, the analytical measurements of the artificial soil treated with the test item at the lower, middle and the highest concentrations (5.6, 100 and 1000 mg/kg dry weight of the artificial soil) was performed. According to the Study Plan the analytical measurements at the concentrations equal to 1.8, 32.0 and 1000 mg/kg dry weight of the artificial soil should be performed. The above deviations did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Flufenacet 6% + Pendimethaline 30% EC Batch no.: SCL – 78154 Active substance: flufenacet: 60 g/L, pendimethalin: 300 g/L
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Biological test system :	the collembolan, *Folsomia candida* obtained from a standard laboratory culture at the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology
Test design:	The test item in form of water emulsion was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. Test duration: 28 days
Test doses:	A control, 5.6, 10, 18, 32, 56, 100, 180, 320, 560, and 1000 mg of the test item/kg dry weight of artificial soil. There were 4 replicates of each test concentration and a concurrent control group divided into eight replicates. Ten 12-day-old collembolans were introduced into each test container.
Test conditions:	temperature: 18.5 – 19.5°C; pH at the beginning of the test: 6.25 – 6.35; pH at the end of the test: 5.50 – 5.57;

soil moisture content at the beginning of the test: 13.3 – 14.1% (46.1 – 48.9% of the maximum water holding capacity);
soil moisture content at the end of the test: 12.5 – 13.4% (43.3 – 46.4% of the maximum water holding capacity);
lighting: 16 h light and 8h dark;
light intensity at the beginning of the experiment: 603,1 – 708,6 lux
light intensity at the end of the experiment: 656,6 – 725,1 lux
The collembolans were fed at the beginning of the experiment and after 2 weeks of incubation

Endpoints: EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC
LC_{10}, LC_{20}, LC_{50}, NOEC

Results and discussions

Mortality at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil ranged from 2.5 to 100.0%. As for the control group, it was equal to 10.0%. The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the table given below.

Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of flufenacet/kg dry weight of artificial soi]	Value [mg of pendimethalin/kg dry weight of artificial soi]
LC_{10}	**34.31** (1.46 – 58.34)	**1.94** (0.08 – 3.30)	**9.71** (0.41 – 16.51)
LC_{20}	**48.07** (5.70 – 75.00)	**2.72** (0.32 – 4.25)	**13.60** (1.61 – 21.23)
LC_{50}	**79.97** (35.24 – 138.59)	**4.53** (1.99 – 7.84)	**22.63** (9.97 – 39.22)
NOEC	**32.0**	**1.81**	**9.06**
LOEC	**56.0**	**3.17**	**15.85**

(-) – 95% confidence interval

After the exposure of the adult collembolans to the test item at the concentrations ranging from 5.6 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 0 and 988 per replicate. As for the control group, the mean number of juveniles was equal to 902 per replicate. The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of flufenacet/kg dry weight of artificial soi]	Value [mg of pendimethalin/kg dry weight of artificial soi]
EC_{10}	**23.79** (21.97 – 25.47)	**1.35** (1.24 – 1.44)	**6.73** (6.22 – 7.21)
EC_{20}	**30.40** (28.66 – 32.01)	**1.72** (1.62 – 1.81)	**8.60** (8.11 – 9.06)
EC_{50}	**48.60** (46.91 – 50.36)	**2.75** (2.66 – 2.85)	**13.75** (13.28 – 14.25)
NOEC	**18.0**	**1.02**	**5.09**
LOEC	**32.0**	**1.81**	**9.06**

(-) – 95% confidence interval

Conclusions

- The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 10% reduction in the number of juveniles produced within the exposure period (**EC_{10}**) is equal to **23.79 mg/kg dry weight of the artificial soil** (i.e. 1.35 mg of flufenacet + 6.73 mg of pendimethalin/kg dry weight of the artificial soil).
- The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 20% reduction in the number of juveniles produced within the exposure period (**EC_{20}**) is equal to **30.40 mg/kg dry weight of the artificial soil** (i.e. 1.72 mg of flufenacet + 8.60 mg of pendimethalin/kg dry weight of the artificial soil).
- The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 50% reduction in the number of juveniles produced within the exposure period (**EC_{50}**) is equal to **48.60 mg/kg dry weight of the artificial**

soil (i.e. 2.75 mg of flufenacet + 13.75 mg of pendimethalin/kg dry weight of the artificial soil).

- The lowest concentration at which the test item is observed to have statistically significant effects on collembolan reproduction (**LOEC**) is equal to **32.0 mg/kg dry weight of the artificial soil** (i.e. 1.81 mg of flufenacet + 9.06 mg of pendimethalin/kg dry weight of the artificial soil).
- The highest concentration at which the test item is observed to have no statistically significant effects on collembolan reproduction (**NOEC**) is equal to **18.0 mg/kg dry weight of the artificial soil** (i.e. 1.02 mg of flufenacet + 5.09 mg of pendimethalin/kg dry weight of the artificial soil).

Comments of zRMS:	The study has been evaluated according to OECD 226 (2016) and is considered acceptable. All validity criteria are met. NOEC reproduction 95.26 mg formulation /kg soil dry weight EC_{10} 128.62 mg formulation /kg soil dry weight

Reference:	KCP 10.4.2.1-02
Report	"Effects of Flufenacet 6% + Pendimethalin 30% EC on the reproductive output of the predatory soil mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in artificial soil". Dr. V. Angayarkanni. 2022. Study No.: 10416/2022. Bioscience Research Foundation.
Guideline(s):	OECD 226 (2016): OECD Guidelines for the testing of chemicals, No. 226; Predatory mite (*Hypoaspis* (*Geolaelaps*) *aculeifer*) reproduction test in soil.
Deviations:	None
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Flufenacet 6% + Pendimethalin 30% EC Batch No.: SCL-401203 Active substance: - Flufenacet 6.01 (% w/v) - Pendimethalin 30.60 (% w/v)
Artificial soil	5% sphagnum peat (a particle size of 2 ± 1 mm); 20% kaolin clay; 75% air-dried industrial sand with more than 50 % of the particles between 50 and 200 microns.
Biological test system:	*Hypoaspis aculeifer* Canestrini (Acari, Laelapidae), from Bioscience Research Foundation insectary, adult female 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 8 replicates; 10 adult females were exposed per replicate. 6 additional replicates (T1, T6 and T10

only) for analytical purposes (without test organisms).

Test doses: 0 (control), 10 Test item groups (T1 – T10), i.e. 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.

Test conditions: Temperature during exposure: 20.5 °C to 21.2 °C
pH at the beginning of the test: 5.95 to 6.05
pH at the end of the test: 5.92 to 6.07
Soil moisture content at the beginning of the test: 20.25% to 21.42% (corresponding to 51.34 – 52.42 % of the WHCmax)
Soil moisture content at the end of the test: 19.90% to 21.15% (corresponding to 50.01 – 52.25% of the WHCmax)
Lighting: 16 h light and 8 h dark (long day conditions); light intensity: 580 lux to 700 lux

Endpoints: LOEC and NOEC for mortality and $EC_{10, 20, 50}$ for reproductive output, where possible.

Results and discussions

After the application of the test item at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, mortality was between 0.00 and 50.0%. As for the control group, it was 0.0%.

No behavioural abnormalities or any pathological symptoms of the test organisms were 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 5.05 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 71.75 and 130.75 per replicate. As for the control group, the mean number of juveniles was equal to 131.00 per replicate.

Validity criteria

- Mean adult mortality: 0.0% (criterion: ≤ 20%).
- The mean number of juveniles per replicate at the end of the test: 131.00 (criterion: ≥ 50 juveniles at the end of the test).
- The coefficient of variation for the number of juveniles: 1.73 (criterion: ≤ 30%).

Mortality of adult females of *H. aculeifer* after 14 of exposure to the test soil.

Sample	Concentration [mg of test item/kg d.w. soil]	Total number of adults females introduced	Total number of non-recovered adult females	Mean Mortality [%]	SD	SE	Mortality corrected for control [%]*
Control	0	80	0	0	0.0	0.0	0.0
T1	5.04	40	0	0	0.0	0.0	0.0
T2	9.07	40	0	0	5.0	2.5	0.0
T3	16.33	40	1	2.5	5.0	2.5	2.5
T4	29.40	40	2	5.0	5.0	2.5	5.0
T5	52.92	40	3	7.5	5.0	2.5	7.5
T6	95.26	40	3	7.5	5.0	2.5	7.5
T7	171.47	40	10	25.0	5.8	2.9	25.00+
T8	308.64	40	13	32.5	5.0	2.5	32.50+
T9	555.56	40	16	40.0	8.2	4.1	40.00+
T10	1000	40	20	50.0	0.0	0.0	50.00+

Endpoint	Value [mg test item/kg d.w. soil]	Value [mg of active substance/kg d.w. soil]
LC_{10}	**71.04** (61.29 – 80.79)	**4.30[a] + 21.91[b]** (3.71 - 4.89) + (18.60 – 24.52)
LC_{20}	**169.37** (151.15 – 187.59)	**10.24[a] + 52.24[b]** (9.14 – 11.35) + (45.88 – 56.94)
LC_{50}	**892.74** (749.74 - >1000)	**54.00[a] + 275.38[b]** (45.35 ->60.38) + (227.59 - >308.47)
NOEC	**95.26**	**5.76[a] + 29.38[b]**
LOEC	**171.47**	**10.37[a] + 52.89[b]**

a: Flufenacet
b: Pendimethalin
*: 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 $p < 0.05$

Reproductive output of *H. aculeifer* after 14 of exposure to the test soil.

Sample	Concentration [mg of test item/kg d.w. soil]	Mean number of juveniles	SD	SE	CV [%]	Reduction in reproduction output compared to control [%]*
Control	0	131.00	2.27	0.80	1.73	-
T1	5.04	130.75	1.26	0.63	0.96	0.19
T2	9.07	129.25	0.96	0.48	0.74	1.34
T3	16.33	128.50	0.58	0.29	0.45	1.91
T4	29.40	127.75	0.96	0.48	0.75	2.48
T5	52.92	126.25	2.22	1.11	1.76	3.63
T6	95.26	124.25	1.26	0.63	1.01	5.15
T7	171.47	116.50	1.73	0.87	1.49	11.07+
T8	308.64	108.75	2.99	1.49	2.75	16.98+
T9	555.56	91.25	4.50	2.25	4.9	30.34+
T10	1000	71.75	9.25	4.63	12.89	45.23+

Endpoint	Value [mg test item/kg d.w. soil]	Value [mg of active substance/kg d.w. soil]
EC_{10}	**128.62** (111.38 – 145.86)	**7.78[a] + 39.67[b]** (6.74 – 8.82) + (33.81 – 44.28)
EC_{20}	**305.32** (269.17 – 341.47)	**18.47[a] + 94.18[b]** (16.28 – 20.65) + (81.71 – 103.65)
EC_{50}	**>1000**	**> 60.48[a] + >308.47[b]**
NOEC	**95.26**	**5.76[a] + 29.38[b]**
LOEC	**171.47**	**10.37[a] + 52.89[b]**

a: Flufenacet
b: Pendimethalin
CV: coefficient of variation
+: statistically significant difference between the control and the treatment group $p < 0.05$

Conclusion

The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 50% mortality of adults within the exposure period (LC_{50}) is 892.74 mg/kg dry weight of the artificial soil, i.e. **(54.0 mg Flufenacet + 275.38 mg Pendimethalin /kg dry weight of the artificial soil).**

The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 10% reduction in the number of juveniles produced within the exposure period (EC_{10}) is 128.62 mg/kg dry weight of the artificial soil, i.e. **(7.78 mg Flufenacet + 39.67 mg Pendimethalin /kg dry weight of the artificial soil).**

The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 10% reduction in the number of juveniles produced within the exposure period (EC_{20}) is 305.32 mg/kg dry weight of the artificial soil, i.e. **(18.47 mg Flufenacet + 94.18 mg Pendimethalin /kg dry weight of the artificial soil).**

The concentration of **Flufenacet 6% + Pendimethalin 30% EC** causing a 10% reduction in the number

of juveniles produced within the exposure period (EC_{50}) is >1000 mg/kg dry weight of the artificial soil, i.e. **(60.48 mg Flufenacet + 308.47 mg Pendimethalin /kg dry weight of the artificial soil).**

The lowest concentration at which **Flufenacet 6% + Pendimethalin 30% EC** is observed to have statistically significant effects on reproductive output (**LOEC**) is 171.47 mg/kg dry weight of the artificial soil, i.e. **(5.76 mg Flufenacet + 29.38 mg Pendimethalin /kg dry weight of the artificial soil).**

The highest concentration at which **Flufenacet 6% + Pendimethalin 30% EC** is observed to have no statistically significant effects on reproductive output (**NOEC**) is 95.26 mg/kg dry weight of the artificial soil, i.e. **(10.37 mg Flufenacet + 52.89 mg Pendimethalin /kg dry weight of the artificial soil).**

A 2.5.1.5 KCP 10.4.2.2 Higher tier testing

A 2.6 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered valid. All validity criteria were met. - The coefficients of variation (CV) in the control group were 5.5, 6.5, 9.4, 5.5, 0.9 and 3.2 %, after 0, 7, 14, 28, 42 and 56 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%. **Agreed endpoints:** On the basis of the results, it was concluded that Flufenacet 6% + Pendimethalin 30% EC at the concentration corresponding to the PEC: 28.27 mg of test item/kg of dry weight soil (i.e. 1.62 mg of flufenacet + 8.1 mg of pendimethalin/kg of dry weight soil) and 5 x PEC: 141.35 mg of test item/kg of dry weight soil (i.e. 7.98 mg of flufenacet + 39.9 mg of pendimethalin/kg of dry weight soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference: KCP 10.5-01

Report "Flufenacet 6% + Pendimethalin 30% EC. Soil Microorganisms: Nitrogen Transformation Test" Aneta Gierbuszewska, Feb, 2020, G/67/17

Guideline(s): OECD Guideline No. 216 (2000) / EU Method C.21.

Deviations: Deviations from the OECD Guideline No. 216 (2000), the EU Method C.21. :
According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer.
The predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the substances with the mobility in soil KFoc > 500 mL/g. Thus, the applied soil depth is a deviation from OECD Guideline No. 216 (2000), EU Method C.21 where the PEC is calculated by using 5 cm of the soil depth.
Deviations from the Study Plan:
The study finished in February 2020, not in December 2019, as it was planned.
These deviations did not affect the results of the study.

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:

Description:	Flufenacet 6% + Pendimethalin 30% EC
Production batch:	SCL- 78154
Active ingredients content:	Flufenacet: 60 g/l, Pendimethalin: 300 g/l
Vehicle and control:	Distilled water

Test system:

Species:	Microorganisms
Source:	Agricultural soil collected from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry, Branch Pszczyna..

Experimental conditions:

Temperature:	20.4 – 22.0°C
Humidity:	52.3% – 59.7% MWHC incubation in darkness.

Study design and methods

Test design and treatment:	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 56 days. Concentrations of the test item: control, PEC: 28.27 mg of test item/kg of dry weight soil (i.e. 1.62 mg of flufenacet + 8.1 mg of pendimethalin/kg of dry weight soil) and 5 x PEC: 141.35 mg of test item/kg of dry weight soil (i.e. 7.98 mg of flufenacet + 39.9 mg of pendimethalin/kg of dry weight soil)

Results

The difference in the nitrates formation rate between the control soil and the one treated with the test item at the concentration corresponding to the control, PEC: 28.27 mg of test item/kg of dry weight soil (i.e. 1.62 mg of flufenacet + 8.1 mg of pendimethalin/kg of dry weight soil) and 5 x PEC: 141.35 mg of test item/kg of dry weight soil (i.e. 7.98 mg of flufenacet + 39.9 mg of pendimethalin/kg of dry weight soil) did not exceed 25% on 56 day of analysis.

Deviations from the control based on nitrates formation rate for selected time interval [%]:

Time interval [d]	**PEC 28.27 mg of test item/kg of dry weight soil (i.e. 1.62 mg of flufenacet + 8.1 mg of pendimethalin/kg of dry weight soil)**	**5 x PEC 141.35 mg of test item/kg of dry weight soil (i.e. 7.98 mg of flufenacet + 39.9 mg of pendimethalin/kg of dry weight soil)**
0 - 7	34.6	-42.8
0 - 14	-22.2	-113.7
0 - 28	-0.7	-34.7
0-42	-10.0	-31.3
0-56	7.9	-22.7

Validity

The coefficients of variation (CV) in the control group were 5.5, 6.5, 9.4, 5.5, 0.9 and 3.2 %, after 0, 7, 14, 28, 42 and 56 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.

Conclusion

On the basis of the results, it was concluded that Flufenacet 6% + Pendimethalin 30% EC at the concentration corresponding to the PEC: 28.27 mg of test item/kg of dry weight soil (i.e. 1.62 mg of flufenacet + 8.1 mg of pendimethalin/kg of dry weight soil) and 5 x PEC: 141.35 mg of test item/kg of dry weight soil (i.e. 7.98 mg of flufenacet + 39.9 mg of pendimethalin/kg of dry weight soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

A 2.7 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.7.1 KCP 10.6.1 Summary of screening data

A 2.7.2 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: 100.0% – sunflower, 95.2% – cabbage, 100.0% – pea, 90.0% – carrot, 80.0% – perennial ryegrass, 95.0% – oats,, - the mean survival of the emerged control seedlings was 100% for sunflower, cabbage, pea, carrot and perennial ryegrasss and 105.6% for

oats (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:

Flufenacet 6% + Pendimethalin 30% EC: ER_{50}, and NOER values.

Endpoint value		**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	545.46 (394.30-760.48)	>4000
	g/ha[a]	>240	>240	>240	>240	32.73 (23.66-45.63)	>240
	g/ha[b]	>1200	>1200	>1200	>1200	163.64 (118.29-228.14)	>1200
NOER	mL/ha	≥4000	≥4000	≥4000	≥4000	148.15	≥4000
	g/ha[a]	≥ 240	≥ 240	≥ 240	≥ 240	8.89	≥ 240
	g/ha[b]	≥1200	≥1200	≥1200	≥1200	44.45	≥1200
Shoot length (plants without roots)							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	725.79 (375.53-2464.93)	2302.52 (2085.49-2548.59)
	g/ha[a]	>240	>240	>240	>240	43.55 (22.53-147.90)	138.15 (125.13-152.92)
	g/ha[b]	>1200	>1200	>1200	>1200	217.74 (112.66-739.48)	690.76 (625.65-764.58)
NOER	mL/ha	≥ 4000	444.44	≥ 4000	≥ 4000	49.38	444.44
	g/ha[a]	≥ 240	26.67	≥ 240	≥ 240	2.96	26.67
	g/ha[b]	≥1200	133.33	≥1200	≥1200	14.81	133.33
Plant dry weight (plants without roots)							
ER_{50}	mL/ha	>4000	3063.21	>4000	>4000	545.57 (396.45-758.40)	1750.87 (1417.06-2192.74)
	g/ha[a]	>240	183.79	>240	>240	32.73 (23.79-45.50)	105.05 (85.02-131.56)
	g/ha[b]	>1200	918.96	>1200	>1200	163.67 (118.93-227.52)	525.26 (425.12-657.82)
NOER	mL/ha	≥4000	444.44	≥4000	≥4000	148.15	444.44
	g/ha[a]	≥ 240	26.67	≥ 240	≥ 240	8.89	26.67
	g/ha[b]	≥1200	133.33	≥1200	≥1200	44.45	133.33

a: Flufenacet

b: Pendimethalin

Reference:	KCP 10.6.2-01
Report:	"Flufenacet 6% + Pendimethalin 30% EC. Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test". Aneta Gierbuszewska,., G/71/17, 2020 Institute of Industrial Organic Chemistry, Branch Pszcyna
Guideline(s):	OECD No. 208 (2006)
Deviations:	Deviations from OECD Guideline No. 208: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50μE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 88.8 and 144.7 μE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. Deviation from the study plan: The study was finished in June 2020 and not in October 2019 as it had been planned. All deviations did not affect results of the experiment.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Flufenacet 6% + Pendimethaline 30% EC 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, ten application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots 3 (sunflower, pea, cabbage) or 5 (carrot, perennial, ryegrass, oats) seeds/pot). 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 (every day and then every 2 – 3 days) 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 ER_{10}, ER_{25}, ER_{50}, and NOER.

Material and methods

Test item:	Flufenacet 6% + Pendimethalin 30% EC Batch number: SCL-78154 Production date: March 23, 2018 Expiry date: March 22, 2020
Test species:	sunflower (Helianthus annuus), cabbage (Brassica oleracea var. capitata), pea (Pisum sativum), carrot (Daucus carota), perennial ryegrass (Lolium perenne), oats (Avena sativa).
Test design:	number of rates: 10 + control; number of replicates/rate: 4 (carrot, perennial ryegrass, oats) or 7 (sunflower, cabbage, pea). the total number of seeds per application rate – 20 (carrot, perennial ryegrass, oats) or 21 (sunflower, cabbage, pea). test termination: 14 days after the emergence of 50% of the control seedlings

Test duration: 14 days after 50 % emergence of the control seedlings.
Application rates: a control, 0.20, 0.61, 1.83, 5.49, 16.46, 49.38, 148.15, 444.44, 1333.33, and 4000.00 mL of test item/ha,

volume of deionized water used to prepare the highest rate corresponded 300 L water/ha

Soil: sandy loam

Endpoints: ER_{10}, ER_{25}, ER_{50}, NOER

Test conditions: Temperature: 20.7 – 27.8°C
Humidity: 48.1– 86.7%
Photoperiod – 16h day:8h night
Light intensity: 88.8 – 144.7 µE/m^2/s
Carbon dioxide concentration: 351– 397 ppm

Statistical analysis: ER_{10}, ER_{25}, ER_{50} – probit or logit analysis using linear max. likelihood regression,
NOER:
In order to determine the NOER values for the emergence the following statistical tests were used:
Fisher's Exact Binomial Test with Bonferroni Correction;
Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure
In order to determine the NOER values for the shoot length and the plant weight at the end of the experiment (shoots cut down above the ground), the following statistical tests were used:
Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals) or Bartlett's Test Procedure on Variance Homogenity, Williams Multiple Sequential t-test Procedure

Validity criteria: - the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100.0% – sunflower,
95.2% – cabbage,
100.0% – pea,
90.0% – carrot,
80.0% – perennial ryegrass,
95.0% – oats,,
- the mean survival of the emerged control seedlings was 100% for sunflower, cabbage, pea, carrot and perennial ryegrasss and 105.6% for oats (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

Flufenacet 6% + Pendimethalin 30% EC: ER_{50}, and NOER values.

Endpoint value		**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number at the end of the experiment							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	545.46 (394.30-760.48)	>4000
	g/ha[a]	>240	>240	>240	>240	32.73 (23.66-45.63)	>240
	g/ha[b]	>1200	>1200	>1200	>1200	163.64 (118.29-228.14)	>1200
NOER	mL/ha	≥4000	≥4000	≥4000	≥4000	148.15	≥4000
	g/ha[a]	≥ 240	≥ 240	≥ 240	≥ 240	8.89	≥ 240

	g/ha[b]	≥1200	≥1200	≥1200	≥1200	44.45	≥1200
Shoot length (plants without roots)							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	725.79 (375.53-2464.93)	2302.52 (2085.49-2548.59)
	g/ha[a]	>240	>240	>240	>240	43.55 (22.53-147.90)	138.15 (125.13-152.92)
	g/ha[b]	>1200	>1200	>1200	>1200	217.74 (112.66-739.48)	690.76 (625.65-764.58)
NOER	mL/ha	≥ 4000	444.44	≥ 4000	≥ 4000	49.38	444.44
	g/ha[a]	≥ 240	26.67	≥ 240	≥ 240	2.96	26.67
	g/ha[b]	≥1200	133.33	≥1200	≥1200	14.81	133.33
Plant dry weight (plants without roots)							
ER_{50}	mL/ha	>4000	3063.21	>4000	>4000	545.57 (396.45-758.40)	1750.87 (1417.06-2192.74)
	g/ha[a]	>240	183.79	>240	>240	32.73 (23.79-45.50)	105.05 (85.02-131.56)
	g/ha[b]	>1200	918.96	>1200	>1200	163.67 (118.93-227.52)	525.26 (425.12-657.82)
NOER	mL/ha	≥4000	444.44	≥4000	≥4000	148.15	444.44
	g/ha[a]	≥ 240	26.67	≥ 240	≥ 240	8.89	26.67
	g/ha[b]	≥1200	133.33	≥1200	≥1200	44.45	133.33

a: Flufenacet

b: Pendimethalin

Comments of zRMS:

The study is considered valid.

All validity criteria were met:
- the seedling emergence of plants (validity criterion: at least 70%) was as follows:
78.6 – 95.2– sunflower,
81.0 – 92.9 – cabbage,
81.0 – 92.9 – pea,
72.5 – 87.5 – carrot,
77.5 – 92.5 – perennial ryegrass,
82.5 – 90.0 – oats,
- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%),
- the control plants did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identica.

Agreed endpoints:

Endpoint value		**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	>4000	>4000
	g/ha[a]	>240	>240	>240	>240	>240	>240
	g/ha[b]	>1200	>1200	>1200	>1200	>1200	>1200
NOER	mL/ha	≥4000	≥4000	≥4000	≥4000	≥4000	≥4000
	g/ha[a]	≥240	≥240	≥240	≥240	≥240	≥240
	g/ha[b]	≥1200	≥1200	≥1200	≥1200	≥1200	≥1200
Shoot length (plants without roots)							

	ER_{50}	mL/ha	>4000	>4000	>4000 (3302.34 -4000)	>4000	965.99	>4000
		g/ha[a]	>240	>240	>240 (198.14-240)	>240	57.96	>240
		g/ha[b]	>1200	>1200	>1200 (990.70-1200)	>1200	289.80	>1200
	NOER	mL/ha	≥4000	444.44	148.15	1333.33	444.44	444.44
		g/ha[a]	≥240	26.67	8.89	80.0	26.67	26.67
		g/ha[b]	≥1200	133.33	44.45	400.0	133.33	133.33
	Plant dry weight (plants without roots)							
	ER_{50}	mL/ha	>4000	>4000	>4000	>4000	**515.16**	>4000
		g/ha[a]	>240	>240	>240	>240	30.91	>240
		g/ha[b]	>1200	>1200	>1200	>1200	154.55	>1200
	NOER	mL/ha	≥4000	148.15	148.15	1333.33	444.44	444.44
		g/ha[a]	≥200	8.89	8.89	80.0	26.67	26.67
		g/ha[b]	≥1200	44.45	44.45	400.0	133.33	133.33
	a: flufenacet b: pendimethalin ER_{50} of the most sensitive species (Perennial ryegrass (Lolium perenne)) 515.16 ml product/ha. During the experiment the plant damages were observed: stunted growth, wilting, chlorosis, spots, deformations, necrosis. The following order of the test plant sensitivity was noticed: pea > cabbage > perennial ryegrass > oats > carrot > sunflower							

Reference: KCP 10.6.2-02

Report "Flufenacet 6% + Pendimethaline 30% EC: Terrestial Plant Test: Vegetative Vigour Test". Aneta Gierbuszewska, 2020, Report number G/72/17. Institute of Industrial Organic Chemistry, Branch Pszczyna

Guideline(s): OECD Guideline No. 227 (2006)

Deviations: Deviation from OECD Guideline No. 227:
According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 59.9 and 144.0 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.
All above mentioned deviations did not affect the results of the study.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item: Flufenacet 6% + Pendimethalin 30% EC; Batch Number SCL-78154; active substance: flufenacet – 60 g/L, pendimethalin – 300 g/L

Test species:	pea (*Pisum sativum*), cabbage (*Brassica oleracea var. capitata*), carrot (*Daucus carota*), sunflower (*Helianthus annuus*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*).
Soil:	Sandy loam soil containing 1.2% organic carbon
Study design:	number of rates: 10 + control; number of replicates/rate: 4 (carrot, perennial ryegrass, oats) or 7 (sunflower, cabbage, pea). The total number of plants per application rate – 20 (carrot, perennial ryegrass, oats) or 21 (cabbage, pea, sunflower) test termination: 21 days after the spraying
Application rates:	a control, 0.20, 0.61, 1.83, 5.49, 16.46, 49.38, 148.15, 444.44, 1333.33, and 4000.00 mL/ha. Volume of deionised water used to prepare the highest rate: 300 L water/ha
Test conditions:	temperature: 17.4 – 24.2°C, humidity: 49.2 – 90.5%, lighting: 16 h light: 8 h dark; light intensity: 59.9 – 144.0 µE/m2/s; carbon dioxide concentration: 322 – 364 ppm
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit analysis using linear max. likelihood regression or logit analysis using linear max. likelihood regression or the nonlinear regression using the 4-parameter logistic. NOER: In order to determine the NOER value for the plant number at the end of the experiment any computations had been perfomed because of no change in mortality of plants. In order to determine the NOER values for the shoot length at the end of the experiment (shoots cut down above the ground) and for the plant weight at the end of the experiment (shoots cut down above the ground), the following statistical tests were used: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals) or Bartlett´s Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment
Endpoints:	ER_{10}, ER_{25}, ER_{50} and NOER

Results and Conclusions

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethaline 30% EC had no influence on the plant number.
On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethaline 30% EC had influence on shoot length and shoot dry weight of cultovation of cabbage, pea, carrot, perennial ryegrass and oats at the end of the experiment. The impact depended on the rate and species. During the experiment the plant damages were observed: stunted growth, wilting, chlorosis, spots, deformations, necrosis.
The following order of the test plant sensitivity was noticed:
pea > cabbage > perennial ryegrass > oats > carrot > sunflower
The endpoint values showing the impact of the test item on vegetative vigour of the plant species tested are presented in table given below:

Endpoint value		**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
Plant number							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	>4000	>4000
	g/ha[a]	>240	>240	>240	>240	>240	>240
	g/ha[b]	>1200	>1200	>1200	>1200	>1200	>1200
NOER	mL/ha	≥4000	≥4000	≥4000	≥4000	≥4000	≥4000
	g/ha[a]	≥240	≥240	≥240	≥240	≥240	≥240
	g/ha[b]	≥1200	≥1200	≥1200	≥1200	≥1200	≥1200
Shoot length (plants without roots)							
ER_{50}	mL/ha	>4000	>4000	>4000 (3302.34-4000)	>4000	965.99	>4000
	g/ha[a]	>240	>240	>240 (198.14-240)	>240	57.96	>240
	g/ha[b]	>1200		>1200		289.80	

			>1200	(990.70-1200)	>1200		>1200
NOER	mL/ha	≥4000	444.44	148.15	1333.33	444.44	444.44
	g/ha[a]	≥240	26.67	8.89	80.0	26.67	26.67
	g/ha[b]	≥1200	133.33	44.45	400.0	133.33	133.33
Plant dry weight (plants without roots)							
ER_{50}	mL/ha	>4000	>4000	>4000	>4000	515.16	>4000
	g/ha[a]	>240	>240	>240	>240	30.91	>240
	g/ha[b]	>1200	>1200	>1200	>1200	154.55	>1200
NOER	mL/ha	≥4000	148.15	148.15	1333.33	444.44	444.44
	g/ha[a]	≥200	8.89	8.89	80.0	26.67	26.67
	g/ha[b]	≥1200	44.45	44.45	400.0	133.33	133.33

a: flufenacet
b: pendimethalin

A 2.7.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.8 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.9 KCP 10.8 Monitoring data