FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: JMD-HER 387 OD

Product name: Jockey 387 OD

Chemical active substances:
2,4-D, 250 g/L (as 2,4-D 2EHE, 377 g/L)
Iodosulfuron-methyl-sodium, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: ~~December 2022~~ October 2023

MS Finalisation date: December 2023; March 2024, August 2024

Version history

When	What
12.2023	Assessment by zRMS
03.2024	Final version of RR after commenting period
08.2024	zRMS addition (ecotoxicology)

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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: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Winter wheat, Winter rye, Winter triticale	F	weeds (for details please refer to Section B0 and B3)	spraying	Spring BBCH 23-31	1	n.a	0.8-1.0 L/ha	8-10 g iodosulfuron-methyl-sodium 301.6-377 g 2,4-D	200-300 L/ha	not relevant	not relevant	A	A	R	A	A	A	R
2	PL	Spring wheat, Spring triticale	F	weeds (for details please refer to Section B0 and B3)	spraying	Spring BBCH 23-31	1	n.a	0.8-1.0 L/ha	8-10 g iodosulfuron-methyl-sodium 301.6-377 g 2,4-D	200-300 L/ha	not relevant	not relevant	A	A	R	A	A	A	R
3	BG	Winter wheat	F	weeds (for details please refer to Section B0 and B3)	spraying	Spring BBCH 23-31	1	n.a	0.8-1.0 L/ha	8-10 g iodosulfuron-methyl-sodium 301.6-377 g 2,4-D	200-300 L/ha	not relevant	not relevant	A	A	R	A	A	A	R
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
-	-	-	-	-	-	-	-	-	-	-	-	-	-							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Minor uses according to Article 51 (field uses)																				
-	-	-	-	-	-	-	-	-	-	-	-	-	-							
Minor uses according to Article 51 (interzonal uses)																				
-	-	-	-	-	-	-	-	-	-	-	-	-	-							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 "Conclusion"

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

Remarks table:

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

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

9.1.1 Overall conclusions

9.1.1.1

9.1.1.2 zRMS Comments: The listed metabolites are in agreement with the EFSA conclusion on iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453. Metabolites of 2,4-D are in line with EU agreed endpoints as reported in EFSA Report of 2,4-D (EFSA Journal 2014;12(9):3812).

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

Birds

Effects on birds for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. However further data on JMD-HER 387 OD is not relevant as data for each active substance on toxicity to birds are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for JMD-HER 387 OD with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of JMD-HER 387 OD to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substances, as well as SV_{90} and SV_m. Since JMD-HER 387 OD contains two active substances, combine risk assessment was performed as well.

Drinking water exposure leaf scenario and puddle scenario has not been estimated since not relevant.

Exposure for earthworm-eating birds and fish-eating birds via secondary poisoning was assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substances as well as exposure estimated from predicted environmental concentration of 2,4-D and iodosulfuron-methyl-sodium in earthworms and fishes.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of JMD-HER 387 OD. No risk management measures are required.

Terrestrial vertebrates (other than birds)

Effects on mammals for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. However further data on JMD-HER 387 OD is not relevant as data for each active substance on toxicity to mammals are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for JMD-HER 387 OD with the proposed use pattern and EU agreed endpoints have been provided and are

considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of JMD-HER 387 OD to terrestrial vertebrates other than birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with 2,4-D and iodosulfuron-methyl-sodium, as well as SV_{90} and SV_m. Since JMD-HER 387 OD contains two active substances, combine risk assessment was performed as well.

Drinking water exposure puddle scenario has not been performed since not relevant.

Exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning was assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with 2,4-D and iodosulfuron-methyl-sodium as well as exposure estimated from predicted environmental concentration of 2,4-D and iodosulfuron-methyl-sodium in earthworms and fishes.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use. No risk mitigations are required.

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

Effects on aquatic organisms for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. Acute toxicity studies of JMD-HER 387 OD to invertebrates, algae and aquatic plants as well as literature data for metabolite 4-CP were submitted in this dossier.

Risk assessments for JMD-HER 387 OD with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PECsw/RAC values were calculated with PECsw values obtained for active substances and their metabolites calculated in Step 1, 2, 3 and 4. Most of the PECsw/RAC values were below 1 for acute and long-term risk using Step 3 and Step 4 PECsw indicating no unacceptable risk to aquatic organisms at application rate of 1 L/ha provided the appropriate risk mitigations are applied. Summary of proposed risk mitigations for each scenario are in table below.

Scenario	Winter cereals, application rate: 1 L/ha	Spring cereals, application rate: 1 L/ha
D1/ditch	risk mitigation at national level	75% nozzle reduction or 5m buffer zone
D1/stream	risk mitigation at national level	risk mitigation at national level
D2/ditch	risk mitigation at national level	not relevant
D2/stream	risk mitigation at national level	not relevant
D3/ditch	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D4/pond	no risk mitigation needed	no risk mitigation needed
D4/stream	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D5/pond	no risk mitigation needed	no risk mitigation needed

D5/stream	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D6/ditch	risk mitigation at national level	75% nozzle reduction or * 5m buffer zone
R1/pond	no risk mitigation needed	no risk mitigation needed *
R1/stream	5m vegetated buffer zone	5m vegetated buffer zone *
R2/stream	not relevant	5m vegetated buffer zone *
R3/stream	5m vegetated buffer zone	5m vegetated buffer zone *
R4/stream	75% nozzle reduction or 5m buffer zone	5m vegetated buffer zone

For Poland D3, D4 and R1 scenarios are relevant. R1 scenario is not available for spring cereals but it can be assumed that risk assessment is covered by R1 risk assessment for winter cereals and maize. In case of Poland, it can be concluded that JMD-HER 387 OD used at the max. rate of 1 L/ha to protect cereals according to proposed GAP does not pose unacceptable risk to aquatic organisms under condition that 5m vegetated buffer strip is applied.

Classification of JMD-HER 387 OD was done on the basis of formulation test results as well as active substances properties. The proposed classification of the product JMD-HER 387 OD is:

Aquatic Acute 1, H400
Aquatic Chronic 1, H410

9.1.1.5 Effects on bees (KCP 10.3.1)

Effects on bees for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. Toxicity studies of JMD-HER 387 OD to bees were submitted in this dossier.

Risk assessments for JMD-HER 387 OD with the proposed use pattern was carried out according to the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and the latest Draft EFSA Guidance for risk assessment for bees EFSA Journal 2013; 11(7):3295.

The risks of JMD-HER 387 OD to honeybees was assessed from Hazard Quotients (HQ) and Exposure Toxicity Ratio (ETR) between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product as well as the maximum single application rate.

All the hazard quotients were considerably less than the respective triggers, indicating that JMD-HER 387 OD at maximum rate of 1 L/ha poses a low risk to bees. No risk management measures are required.

9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

Effects on non-target arthropods for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. Toxicity studies of JMD-HER 387 OD to non-target arthropods were submitted in this dossier.

Risk assessments for JMD-HER 387 OD with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods "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.

The in-field and off-field risk of JMD-HER 387 OD to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from studies with active ingredient and the formulated product JMD-HER 387 OD as well as in-field and off-field predicted environmental rate. No risk was determined in-field and off-field after application of JMD-HER 387 OD at maximum rate of 1 L/ha. No risk management measures are required.

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

Effects on earthworms and other soil micro-organisms for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. The earthworm, *Folsomia candida* and *Hypoaspis aculeifer* chronic toxicity studies as well as nitrogen transformation test for JMD-HER 387 OD were submitted in this dossier.

Risk assessments for JMD-HER 387 OD with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

Earthworms, *Folsomia candida* and *Hypoaspis aculeifer*
The risk of JMD-HER 387 OD to earthworms, *Folsomia candida* and *Hypoaspis aculeifer* was assessed from acute toxicity exposure ratios (TERs) between the selected toxicity endpoint for the active ingredient, metabolites and the formulated product JMD-HER 387 OD as well as the maximum soil PECs.

The acute and chronic TER values were greater than the trigger of 10 and 5 respectively, indicating an acceptable risk to earthworms, *Folsomia candida* and *Hypoaspis aculeifer* following application of JMD-HER 387 OD at maximum rate of 1 L/ha. No risk management measures are required.

Micro-organisms
The risk of JMD-HER 387 OD to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for active substances, metabolites and the formulated product JMD-HER 387 OD with predicted application concentrations (PECs) obtained for active substances, metabolites and the formulation.

According to the performed risk assessment it was assessed that the application of JMD-HER 387 OD at maximum rate of 1 L/ha does not pose unacceptable risk to soil micro-organisms. No risk management measures are required.

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

Effects on non-target terrestrial plants for JMD-HER 387 OD were not evaluated as part of the EU review of 2,4-D and iodosulfuron-methyl-sodium. The studies on seedling emergence and vegetative vigour for JMD-HER 387 OD were submitted in this dossier.

The risk of JMD-HER 387 OD to non-target plants was assessed from toxicity exposure ratios between toxicity endpoints for the formulation JMD-HER 387 OD and predicted environmental rate. The TER values were greater than the trigger of 5, indicating an acceptable risk to non-target terrestrial plants following application of JMD-HER 387 OD at maximum rate of 1 L/ha provided the following risk mitigations are applied:

- 10m buffer zone
or
- 5 m buffer zone with 50% drift reducing spray nozzles.

~~- 5m buffer zone or~~
~~- 75% nozzle reduction.~~

9.1.1.9 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).

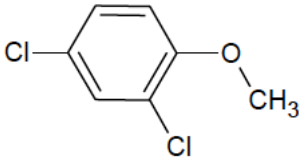
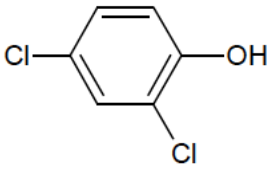
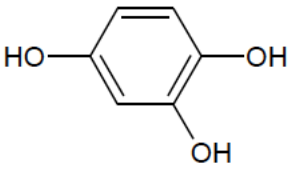
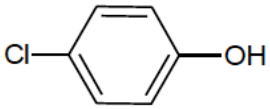
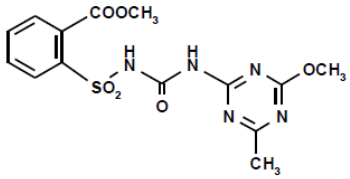
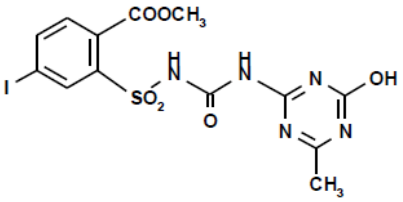
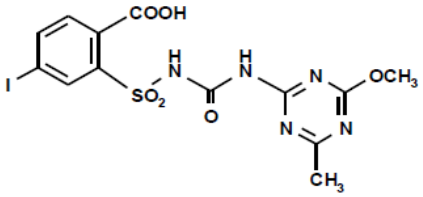
Table 9.1-2: Critical use pattern of JMD-HER 387 OD

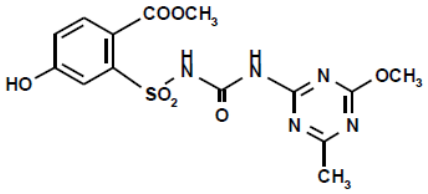
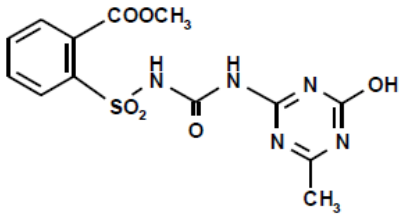
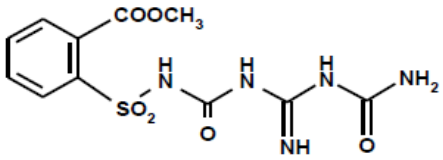
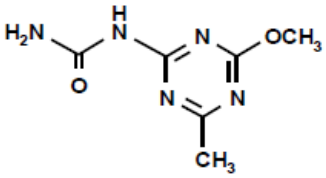
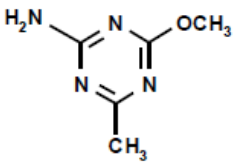
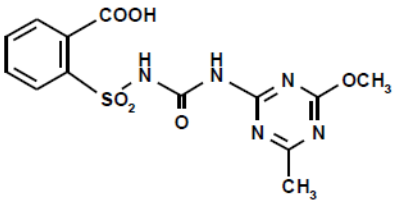
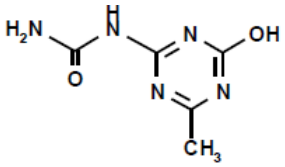
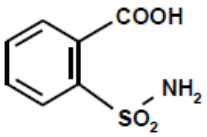
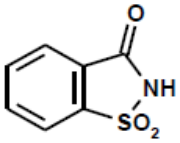
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
risk assessment to birds/mammals acute and long term/reproductive			
spring cereals, winter cereals	spring cereals, winter cereals	max. application rate	SV_{90}, SV_m
risk assessment of secondary poisoning for earthworm-eating birds/mammals			
spring cereals, winter cereals	spring cereals, winter cereals	max. 21-d twa PECs	NR
risk assessment of secondary poisoning for fish-eating birds/mammals			
spring cereals, winter cereals	spring cereals, winter cereals	max. PECsw	NR
risk assessment to aquatic organisms			
spring cereals, winter cereals	spring cereals, winter cereals	max. application rate	NR
risk assessment to bees			
spring cereals, winter cereals	spring cereals, winter cereals	max. application rate	NR
risk assessment to non-target arthropods			
spring cereals, winter cereals	spring cereals, winter cereals	max. application rate	NR
risk assessment to soil macro-organisms			
spring cereals, winter cereals	spring cereals, winter cereals	max. PECs	NR
risk assessment to soil microorganisms			
spring cereals, winter cereals	spring cereals, winter cereals	max. PECs	NR
risk assessment to non-target plants			
spring cereals, winter cereals	spring cereals, winter cereals	max. application rate	NR

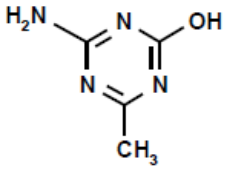
9.1.3 Consideration of metabolites

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 JMD-HER 387 OD is indicated in the table.

Table 9.1-3 Metabolites of 2,4-D and iodosulfuron-methyl-sodium

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
2,4-D				
2,4-DCA		177	Soil: 15% Water/sediment: 5.3%	yes
2,4-DCP		163	Soil: 8.7% Water/sediment: 32.1%	yes
1,2,4-ben-zenetriol		126.1	Soil: NR Water/sediment: 31.7%	yes
4-CP		128.6	Soil: 33% Water/sediment: 6.9%	yes
iodosulfuron-methyl-sodium				
AE F075736		381.4	Soil: 88.5% (aerobic), 67.9% (anaerobic) Water: 57.0% Sediment: 15.9% Water/sediment: 67.8%	yes
AE F145741		493.2	Soil: 6.9% (aerobic) Water: 7.0% Sediment: 1.9% Water/sediment: 8.7%	yes
AE F145740		493.2	Soil: 8.7% (aerobic) Water: 9.2% Sediment: 3.5% Water/sediment: 12.6%	yes

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
AE 0002166		397.4	Soil: 20.0% (photolysis) Water: 25.1% (photolysis in natural water)	yes
AE F161778		367.3	Soil: 14.5% (aerobic) Water/sediment: 2.6%	yes
BCS-CW81253		343.3	Soil: 35.1% (aerobic) Water/sediment: 0.0001%	yes
AE 0000119		183.2	Soil: 19.9% (aerobic) Water: 17.7% Sediment: 15.0% Water/sediment: 24.9%	yes
AE F059411		140.2	Soil: 40.9% (aerobic), 23.6% (anaerobic) Water: 19.3% Sediment: 8.3 Water/sediment: 27.5%	yes
AE 0014966		367.3	Water: 11.8% Sediment: 5.9% Water/sediment: 15.5%	yes
AE 0034855		169.1	Water: 16.7% Sediment: 10.7% Water/sediment: 24.2%	yes
AE 1234964		201.2	Water: 6.8% Sediment: 0.6% Water/sediment: 7.4%	yes
AE F159737		183.2	Water: 6.1% Sediment: 1.6% Water/sediment: 7.8%	yes

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
AE F154781		126.1	Water: 8.7% (aerobic mineralisation in surface water)	yes

zRMS Comments: The listed metabolites are in agreement with the EFSA conclusion on iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453. Metabolites of 2,4-D are in line with EU agreed endpoints as reported in EFSA Report of 2,4-D (EFSA Journal 2014;12(9):3812).

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with 2,4-D and iodosulfuron-methyl-sodium. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of JMD-HER 387 OD were not evaluated as part of the EU assessment. However, the provision of further data on the JMD-HER 387 OD is not considered essential, because it is possible to extrapolate data from the active substances. Additionally, vertebrates' studies should be avoided.

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
2,4-D				
Canary (*Serinus canaria*)	2,4-D	Oral, Acute	LD_{50} = 633 mg/kg bw	EFSA Journal 2014;12(9):3812
Japanese quail (*Coturnix coturnix japonica*)	2,4-D	Oral, Acute	LD_{50} = 617.3 mg/kg bw	
Bobwhite quail (*Colinus virginianus*)	2,4-D	Oral Acute	LD_{50} = 500 mg/kg bw	
-	-	Oral Acute	**LD_{50} = 580.3 mg/kg bw** (geometric mean, n=3)	
Northern Bobwhite Mallard duck	2,4-D	Dietary Short-term	LC_{50} > 5620 mg/kg diet	
Bobwhite quail (*Colinus virginianus*)	2,4-D	Dietary Long-term	NOEC > 1000 mg/kg diet (NOEL = 100 mg/kg bw/d based on generic conversion factor of 0.1)	
Bobwhite quail	2,4-D	Dietary	NOEC = 1000 mg/kg diet	

(*Colinus virginianus*)		Long-term	(NOEL > 101 mg/kg bw/d based on study results)	
Japanese quail (*Coturnix coturnix japonica*)	2,4-D	Dietary Long-term	NOEC = 1000 mg/kg diet (NOEL = 100 mg/kg bw/d based on study results)	
-	-	Dietary Long-term	**NOEL = 58 mg/kg bw/d** (geometric mean LD_{50}/10)	-
Iodosulfuron-methyl-sodium				
Japanese quail (*Coturnix coturnix japonica*)	iodosulfuron-methyl-sodium	Oral Acute	**LD_{50} >2000 mg/kg bw**	EFSA Journal 2016;14(4):4453
Bobwhite quail (*Colinus virginianus*)	iodosulfuron-methyl-sodium	Oral Acute	LD_{50} >2000 mg/kg bw	
Mallard duck (*Anas plathyrhyn-chos*)	iodosulfuron-methyl-sodium	Oral Acute	LD_{50} >2000 mg/kg bw	
Bobwhite quail (*Colinus virginianus*)	iodosulfuron-methyl-sodium	Dietary Long-term	**NOEL = 78 mg/kg bw/d**	
Mallard duck (*Anas plathyrhyn-chos*)	iodosulfuron-methyl-sodium	Dietary Long-term	NOEL = 125 mg/kg bw/d	

zRMS comment: zRMS confirms that the reported toxicity data in table 9.2-1 are in accordance with the EU agreed end-points and will be used for risk assessment.

9.2.1.1 Justification for new endpoints

Not relevant. No new endpoints were 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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for birds from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

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 JMD-HER 387 OD in cereals (2,4-D endpoints)

Intended uses	spring cereals, winter cereals				
Active substance	2,4-D				
Application rate (kg/ha)	1 × 0.250				
Acute toxicity (mg/kg bw)	580.3				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
NR, screening	Small omnivorous bird	158.8	1	39.7	14.6
BBCH 10-29	Large herbivorous bird “goose”	30.5	1	7.63	76.1
BBCH 10-29	Small omnivorous bird “lark”	24.0	1	6	96.7
BBCH 30-39	Small omnivorous bird “lark”	12.0	1	3	193.4
Reprod. toxicity (mg/kg bw/d)	58				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
NR, screening	Small omnivorous bird	64.8	1 × 0.53	8.59	6.8
BBCH 10-29	Large herbivorous bird “goose”	16.2	1 × 0.53	2.15	27
BBCH 10-29	Small omnivorous bird “lark”	10.9	1 × 0.53	1.44	40.3
BBCH 30-39	Small omnivorous bird “lark”	5.4	1 × 0.53	0.72	80.6

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.

Combined risk assessment - consideration of acute mixture toxicity

According to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438), combined risk assessment must be considered for formulations containing more than one active substance.

For the assessment of acute exposure, a surrogate LD_{50} can be calculated for a mixture of active substances with known toxicity assuming dose additivity:

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

where:
$X\,(a.s._i)$ - fraction of active substance (i) in the formulation mixture
$LD_{50}\,(a.s._i)$ - acute toxicity for the active substance (i)

Table 9.2-3: Acute LD_{50} for the mixture of active substances

Test substance	Concentration of active substance in formulation (g/L)	Fraction of active substance in the formulation mixture	Acute toxicity endpoint (mg/kg bw)	Fraction of active substance/LD_{50} for the active substance	LD_{50} mix (mg/kg bw)	Tox per fraction (a.s.)	Deviation "tox per fraction a.s." and "tox per fraction mix" > 10%?
2,4-D	250	0.962	580.3	0.0016578	596.37	603.2	no 1.13
iodosulfuron-methyl-sodium	10	0.038	2000	0.0000190		52631.6	yes 98.87
Total	260	1.0	-	0.0016768		-	-

If the two quotients 'tox per fraction (a.s.)' and 'tox per fraction (mix)' deviate by less than 10%, this indicates that articular substance will contribute at least 90% to mixture toxicity. This is the case of JMD-HER 387 OD and further combined risk is not necessary since risk assessment performed with 2,4-D toxicity data covers combined risk. Nevertheless, combined risk assessment with the calculated LD_{50} mix is provided below.

Table 9.2-4: First-tier assessment of the acute risk for birds due to the use of JMD-HER 387 OD in cereals (combined risk assessment)

Intended uses	spring cereals, winter cereals				
Active substance	2,4-D + iodosulfuron-methyl-sodium-sodium				
Application rate (kg/ha)	0.250 + 0.010				
Acute toxicity (mg/kg bw)	596.37				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
NR, screening	Small omnivorous bird	158.8	1	41.29	14.4
BBCH 10-29	Large herbivorous bird "goose"	30.5	1	7.93	75.2

BBCH 10-29	Small omnivorous bird “lark”	24.0	1	6.24	95.6
BBCH 30-39	Small omnivorous bird “lark”	12.0	1	3.12	191.1

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.

Similar approach was applied for chronic toxicity. NOELmix was calculated and combined risk assessment has been performed.

Table 9.2-5: Chronic NOEL for the mixture of active substances

Test substance	**Concentration of active substance in formulation (g/L)**	**Fraction of active substance in the formulation mixture**	**Chronic toxicity endpoint (mg/kg bw/day)**	**Fraction of active substance/NOEL for the active substance**	**NOEL mix (mg/kg bw)**	**Tox per fraction (a.s.)**	**Deviation “tox per fraction a.s.” and “tox per fraction mix" > 10%?**
2,4-D	250	0.962	580.3	0.0165862	58.57	60.3	no 2.87
iodosulfuron-methyl-sodium	10	0.038	2000	0.0004872		2052.6	yes 97.15
Total	260	1.0	-	0.0170734		-	-

If the two quotients ‘tox per fraction (a.s.)’ and ‘tox per fraction (mix)’ deviate by less than 10%, this indicates that articular substance will contribute at least 90% to mixture toxicity. This is the case of JMD-HER 387 OD and further combined risk is not necessary since risk assessment performed with 2,4-D toxicity data covers combined risk. Nevertheless, combined risk assessment with the calculated NOELmix is provided below.

Table 9.2-6: First-tier assessment of the long-term/reproductive risk for birds due to the use of JMD-HER 387 OD in cereals (combined risk assessment)

Intended use	spring cereals, winter cereals				
Active substance	2,4-D + iodosulfuron-methyl-sodium-sodium				
Application rate (kg/ha)	0.250 + 0.010				
Reprod. toxicity (mg/kg bw/d)	58.57				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
NR, screening	Small omnivorous bird	64.8	1 × 0.53	8.93	6.6
BBCH 10-29	Large herbivorous bird “goose”	16.2	1 × 0.53	2.23	26.3
BBCH 10-29	Small omnivorous bird “lark”	10.9	1 × 0.53	1.5	39
BBCH 30-39	Small omnivorous bird “lark”	5.4	1 × 0.53	0.74	79.1

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 comment: The risk assessment at screening and Tier 1 is considered acceptable. 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). For transparency, the acute and long-term risk assessment for iodosulfuron-methyl-sodium was performed by zRMS.

First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of JMD-HER 387 OD in cereals (iodosulfuron-methyl-sodium endpoints)

Intended uses	spring cereals, winter cereals				
Active substance	iodosulfuron-methyl-sodium				
Application rate (kg/ha)	1 × 0.010				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
NR, screening	Small omnivorous bird	158.8	1	1.588	1259
BBCH 10-29	Large herbivorous bird “goose”	30.5	1	0.305	6557
BBCH 10-29	Small omnivorous bird “lark”	24.0	1	0.24	8333
BBCH 30-39	Small omnivorous bird “lark”	12.0	1	0.12	16666
Reprod. toxicity (mg/kg bw/d)	78				
TER criterion	5+				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
NR, screening	Small omnivorous bird	64.8	1 × 0.53	0.34	229
BBCH 10-29	Large herbivorous bird “goose”	16.2	1 × 0.53	0.08586	908
BBCH 10-29	Small omnivorous bird “lark”	10.9	1 × 0.53	0.05777	1350
BBCH 30-39	Small omnivorous bird “lark”	5.4	1 × 0.53	0.029	2689

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.

Safe use of active substance for birds such as 2,4-D and iodosulfuron-methyl-sodium were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable. In the case of **Jockey 387 OD** and further combined risk is not necessary since risk assessment performed with 2,4-D toxicity data covers combined risk. Nevertheless, combined risk assessment with the calculated LD_{50mix} and $NOEL_{mix}$ was provided by Applicant. Combined acute and log-term risk assessment for birds was accepted by RMS. Refinement risk assessment for birds are not necessary

9.2.2.2 Higher-tier risk assessment

Not relevant. First-tier risk assessment confirmed that JMD-HER 387 OD does not pose unacceptable acute and long term/reproductive risk to birds.

Agree with the presented risk assessment.

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 JMD-HER 387 OD is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario must not 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 58.6 2,4-D belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	250		
Acute toxicity (mg/kg bw)	=	580.3	quotient	= 0.43
Reprod. toxicity (mg/kg bw/d)	=	58	quotient	= 4.31

With a K(f)oc of 50.6 iodosulfuron-methyl-sodium belongs to the group of less sorptive substances.

Effective application rate (g/ha)	=	10		
Acute toxicity (mg/kg bw)	=	2000	quotient	= 0.005
Reprod. toxicity (mg/kg bw/d)	=	78	quotient	= 0.128

zRMS comment: Agree with the presented risk assessment.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of 2,4-D and iodosulfuron-methyl-sodium are blow the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required. However secondary poisoning assessments are required for the two metabolites of 2,4-D for which log P_{ow} are higher than the trigger value of 3 i.e. 3.06 for 2,4-DCP and 3.36 for 2,4-DCA. Risk assessments of secondary poisoning is based on an assumed toxicity i.e. NOEL of 5.8 mg/kg bw/d (ten times higher than toxicity of the parent).

Agree with the presented risk assessment.

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 measured/predicted concentrations in soil/porewater / is based on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for birds from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure 2,4-DCP via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

Parameter	2,4-DCP	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.011	21-TWA PECsoil
log P_{ow} / P_{ow}	3.06 / 1148.15	EFSA Journal 2014;12(9):3812
Koc	512	arithmetic mean (n = 7)
foc	0.02	default
BCF_{worm}	1.43	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.02	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.02	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	5.8	value ten times higher than toxicity of the parent
TER_{lt}	290	-

TER values shown in bold fall below the relevant trigger.

Table 9.2-8: Assessment of the risk for earthworm-eating birds due to exposure 2,4-DCA via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

Parameter	2,4-DCA	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.021	21-TWA PECsoil
log P_{ow} / P_{ow}	3.36 / 2290.87	EFSA Journal 2014;12(9):3812
Koc	1028	arithmetic mean (n = 7)
foc	0.02	default
BCF_{worm}	1.38	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.03	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.04	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	5.8	value ten times higher than toxicity of the parent
TER_{lt}	193.33	-

TER values shown in bold fall below the relevant trigger.

zRMS comment: Agree with the presented risk assessment.

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 / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of 2,4-DCP and 2,4-DCA in water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for birds from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.2-9: Assessment of the risk for fish-eating birds due to exposure to 2,4-DCP via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

Parameter	2,4-DCP	comments
PEC_{sw} (mg/L)	0.0154	Initial PECsw (Step 1)
TWA	0.53	DAR, February 2014
BCF_{fish}	340	EFSA Journal 2014;12(9):3812
BMF	NR	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	2.78	$PEC_{fish} = PEC_{water} \times TWA \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.441	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	5.8	value ten times higher than toxicity of the parent
TER_{lt}	13.15	-

TER values shown in bold fall below the relevant trigger.

Table 9.2-10: Assessment of the risk for fish-eating birds due to exposure to 2,4-DCA via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

Parameter	2,4-DCA	comments
PEC_{sw} (mg/L)	0.0058	Initial PECsw (Step 1)
TWA	0.53	DAR, February 2014
BCF_{fish}	31	EFSA Journal 2014;12(9):3812
BMF	NR	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.10	$PEC_{fish} = PEC_{water} \times TWA \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.015	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	5.8	value ten times higher than toxicity of the parent
TER_{lt}	386.67	-

TER values shown in bold fall below the relevant trigger.

zRMS comment: Agree with the presented risk assessment.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

All the TER values exceed the trigger values of 10 for acute and 5 for reproductive/long-term risk. JMD-HER 387 OD used at max. application rate of 1 L/ha to protect cereals according to proposed GAP, does not pose unacceptable risk to birds.

zRMS comment: Agree with the presented risk assessment.

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 2,4-D and iodosulfuron-methyl-sodium. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of JMD-HER 387 OD were not evaluated as part of the EU assessment. However, the provision of further data on the JMD-HER 387 OD is not considered essential, because it is possible to extrapolate data from the active substances. Additionally, vertebrates' studies should be avoided.

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
2,4-D				
Rat	2,4-D	Oral Acute	LD_{50} = 669 mg/kg bw	EFSA Journal 2014; 12(9):3812
Rat	2,4-D	Oral Acute	LD_{50} = 486 mg/kg bw	
Rat	2,4-D	Oral Acute	LD_{50} > 500 mg/kg bw	
Geometric mean to be used in the risk assessment		Oral Acute	**LD_{50} > 554 mg/kg bw** (geometric mean)	
Rat	2,4-D	Dietary Long-term	**NOAEL = 20.6 mg/kg bw/d**	
iodosulfuron-methyl-sodium				
Wistar rat	iodosulfuron-methyl-sodium	Oral Acute	**LD_{50} = 2678 mg/kg bw**	EFSA Journal 2016;14(4):4453
Wistar rat	IMS + MPR OD 400	Oral Acute	LD_{50} > 2000 mg product/kg bw	

Species	Substance	Exposure System	Results	Reference
2,4-D				
Wistar rat	iodosulfuron-methyl-sodium	Long-term Combined chronic toxicity and oncogenicity study (2 years)	**NOAEL = 2.96 mg/kg bw/d (male)** NOAEL = 3.91 mg/kg bw/d (female)	

zRMS comment: zRMS confirms that the reported toxicity data in table 9.3-1 are in accordance with the EU agreed end-points and will be used for risk assessment.

9.3.1.1 Justification for new endpoints

Not relevant. No new endpoints were 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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for mammals from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

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 JMD-HER 387 OD in cereals (2,4-D endpoints)

Intended use	spring cereals, winter cereals				
Active substance/product	2,4-D				
Application rate (kg/ha)	1 × 0.250				
Acute toxicity (mg/kg bw)	>554				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
NR, screening	Small herbivorous mammal	118.4	1	29.6	18.7
Reprod. toxicity (mg/kg bw/d)	20.6				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
NR, screening	Small herbivorous mammal	48.3	1 × 0.53	6.4	**3.2**
BBCH ≥20	Small insectivorous mammal “shrew”	1.9	1 × 0.53	0.3	68.7
BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1 × 0.53	1	20.6
BBCH 30-39	Small omnivorous mammal “mouse”	3.9	1 × 0.53	0.5	41.2

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 JMD-HER 387 OD in cereals (iodosulfuron-methyl-sodium endpoints)

Intended use	spring cereals, winter cereals

Active substance/product	iodosulfuron-methyl-sodium				
Application rate (kg/ha)	1 × 0.010				
Acute toxicity (mg/kg bw)	2678				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
NR, screening	Small herbivorous mammal	118.4	1	1.2	2231.7
Reprod. toxicity (mg/kg bw/d)	2.96				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
NR, screening	Small herbivorous mammal	48.3	1 × 0.53	0.3	9.9

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.

Combined risk assessment - consideration of mixture toxicity

According to Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438), combined risk assessment must considered for formulations containing more than one active substance.

For the assessment of acute exposure, a surrogate LD_{50} can be calculated for a mixture of active substances with known toxicity assuming dose additivity:

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

where:
$X\,(a.s._i)$ - fraction of active substance (i) in the formulation mixture
$LD_{50}\,(a.s._i)$ - acute toxicity for the active substance (i)

The LD_{50} of the mix is summarised in the table below.

Table 9.3-4: Acute LD_{50} for the mixture of active substances

Test substance	Concentration of active substance in formulation (g/L)	Fraction of active substance in the formulation mixture	Acute toxicity endpoint (mg/kg bw)	Fraction of active substance/LD_{50} for the active substance	LD_{50} mix (mg/kg bw)	Tox per fraction (a.s.)	Deviation "tox per fraction a.s." and "tox per fraction mix" > 10%?
2,4-D	250	0.962	>554	0.0017365	571.2	575.9	no 0.55
iodosulfuron-methyl-sodium	10	0.038	2678	0.0000142		70473.7	yes 99.45
Total	260	1.0	-	0.0017507		-	-

If the two quotients 'tox per fraction (a.s.)' and 'tox per fraction (mix)' deviate by less than 10%, this indicates that articular substance will contribute at least 90% to mixture toxicity. This is the case of JMD-HER 387 OD and further combined risk is not necessary since risk assessment performed with 2,4-D toxicity data covers combined risk. Nevertheless, combined risk assessment with the calculated LD_{50} mix is provided below.

Table 9.3-5: First-tier assessment of the acute risk for mammals due to the use of JMD-HER 387 OD in cereals (combined risk assessment)

Intended use	spring cereals, winter cereals				
Active substance/product	2,4-D + iodosulfuron-methyl-sodium-sodium				
Application rate (kg/ha)	0.250 + 0.010				
Acute toxicity (mg/kg bw)	571.2				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
NR, screening	Small herbivorous mammal	118.4	1	30.8	18.5

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

Similar approach was applied for chronic toxicity. NOELmix was calculated and combined risk assessment has been performed.

Table 9.3-6: Chronic NOEL for the mixture of active substances

Test substance	Concentration of active substance in formulation (g/L)	Fraction of active substance in the formulation mixture	Chronic toxicity endpoint (mg/kg bw/day)	Fraction of active substance/NOEL for the active substance	NOEL mix (mg/kg bw)	Tox per fraction (a.s.)	Deviation "tox per fraction a.s." and "tox per fraction mix" > 10%?
2,4-D	250	0.962	20.6	0.0466990	16.8	21.4	no 21.5

iodosulfuron-methyl-so-dium	10	0.038	2.96	0.0128378		77.9	no 78.43
Total	260	1.0	-	0.0595368		-	-

If the two quotients 'tox per fraction (a.s.)' and 'tox per fraction (mix)' deviate by less than 10%, this indicates that articular substance will contribute at least 90% to mixture toxicity. This is not the case of JMD-HER 387 OD and further combined risk is necessary.

Table 9.3-7: First-tier assessment of the long-term/reproductive risk for mammals due to the use of JMD-HER 387 OD in cereals (combined risk assessment)

Intended use	spring cereals, winter cereals				
Active substance/product	2,4-D + iodosulfuron-methyl-sodium-sodium				
Application rate (kg/ha)	0.250 + 0.010				
Reprod. toxicity (mg/kg bw/d)	16.8				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**$MAF_m \times$ TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
NR, screening	Small herbivorous mammal	48.3	1 × 0.53	6.7	**2.5**
BBCH ≥20	Small insectivorous mammal "shrew"	1.9	1 × 0.53	0.3	56
BBCH 10-29	Small omnivorous mammal "mouse"	7.8	1 × 0.53	1.1	15.3
BBCH 30-39	Small omnivorous mammal "mouse"	3.9	1 × 0.53	0.5	33.6

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.

The risk assessment at screening and Tier 1 is considered acceptable. 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). Safe use of active substance for birds such as 2,4-D and iodosulfuron-methyl-sodium were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable. Combined acute and log-term risk assessment for mammals was accepted by RMS.

9.3.2.2 Higher-tier risk assessment

Not relevant. First-tier risk assessment confirmed that JMD-HER 387 OD does not pose unacceptable acute and long term/reproductive risk to mammals.

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 58.6 2,4-D belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	250		
Acute toxicity (mg/kg bw)	=	554	quotient =	0.45
Reprod. toxicity (mg/kg bw/d)	=	20.6	quotient =	12.14

With a K(f)oc of 50.6iodosulfuron-methyl-sodium belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	10		
Acute toxicity (mg/kg bw)	=	2678	quotient =	0.004
Reprod. toxicity (mg/kg bw/d)	=	2.96	quotient =	3.38

The ratios of effective application rates to relevant endpoints do not exceed 50 so further risk assessment for mammals due to uptake of contaminated drinking water (puddle scenario) is not necessary.

zRMS comment: Agree with the presented risk assessment.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of 2,4-D and iodosulfuron-methyl-sodium are blow the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required. However secondary poisoning assessments are required for the two metabolites of 2,4-D for which log P_{ow} are higher than the trigger value of 3 i.e. 3.06 for 2,4-DCP and 3.36 for 2,4-DCA. Risk assessments of secondary poisoning is based on an assumed toxicity i.e. NOEL of 2.06 mg/kg bw/d (ten times higher than toxicity of the parent).

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for mammals from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.3-8: Assessment of the risk for earthworm-eating mammals due to exposure to 2,4-DCP via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

Parameter	2,4-DCP	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.011	21-TWA PECsoil
log P_{ow} / P_{ow}	3.06 / 1148.15	EFSA Journal 2014;12(9):3812
Koc	512	Arythmetic mean (n = 7)
foc	0.02	default

Parameter	2,4-DCP	comments
BCF_{worm}	1.43	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.02	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.03	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	2.06	value ten times higher than toxicity of the parent
TER_{lt}	68.67	-

TER values shown in bold fall below the relevant trigger.

Table 9.3-9: Assessment of the risk for earthworm-eating mammals due to exposure to 2,4-DCA via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

Parameter	2,4-DCA	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.021	21-TWA PECsoil
log P_{ow} / P_{ow}	3.36 / 2290.87	EFSA Journal 2014;12(9):3812
Koc	1028	Arythmetic mean (n = 7)
foc	0.02	Default
BCF_{worm}	1.38	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.03	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.04	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	2.06	value ten times higher than toxicity of the parent
TER_{lt}	51.5	-

TER values shown in bold fall below the relevant trigger.

zRMS comment: Agree with the presented risk assessment.

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 / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of 2,4-DCP and 2,4-DCA in water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for mammals from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.3-10: Assessment of the risk for fish-eating mammals due to exposure to 2,4-DCP via bioaccumulation in fish (secondary poisoning) for the intended use cereals

Parameter	2,4-DCP	comments
PEC_{sw} (mg/L)	0.0154	Initial PECsw (Step 2)
TWA	0.53	DAR, February 2014
BCF_{fish}	340	EFSA Journal 2014;12(9):3812

BMF	NR	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	2.775	$PEC_{fish} = PEC_{water} \times TWA \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.39	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	2.06	value ten times higher than toxicity of the parent
TER_{lt}	5.23	-

TER values shown in bold fall below the relevant trigger.

Table 9.3-11: Assessment of the risk for fish-eating mammals due to exposure to 2,4-DCA via bioaccumulation in fish (secondary poisoning) for the intended use cereals

Parameter	**2,4-DCA**	**comments**
PEC_{sw} (mg/L)	0.0058	Initial PECsw (Step 1)
TWA	0.53	DAR, February 2014
BCF_{fish}	31	EFSA Journal 2014;12(9):3812
BMF	NR	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.095	$PEC_{fish} = PEC_{water} \times TWA \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.01	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	2.06	value ten times higher than toxicity of the parent
TER_{lt}	158.46	-

TER values shown in bold fall below the relevant trigger.

zRMS comment: Agree with the presented risk assessment.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

All the TER values exceed the trigger values of 10 for acute and 5 for reproductive/long-term risk. JMD-HER 387 OD used at max. application rate of 1 L/ha to protect cereals according to proposed GAP, does not pose unacceptable risk to mammals.

zRMS comment: Agree with the presented risk assessment.

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

Not relevant.

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 2,4-D, iodosulfuron-methyl-sodium and their relevant metabolites. Full details of these studies are provided in the respective EU DAR.

Effects on aquatic organisms of JMD-HER 387 OD were not evaluated as part of the EU assessment. New data for metabolites 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 – 2,4-D and its metabolites

Species	Substance	Exposure System	Results	Reference
2,4-D				
Pimephales promelas	2,4-D	96 h, f	Mortality **LC_{50}=100 mg/L $_{nom}$**	EFSA Journal 2014;12(9):3812
Pimephales promelas	2,4-D	32 d (ELS), f	Growth **NOEC=63.4mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
Cyprinus carpio	2,4-D-DMA 600 SL	96 h, s	Mortality LC_{50}>59.9 mg/L $_{mm}$ (LC_{50}>100 mg prod./L $_{nom}$)	EFSA Journal 2014;12(9):3812
Daphnia magna	2,4-D	48 h, s	Mortality **EC_{50} = 134.2 mg/L $_{nom}$**	EFSA Journal 2014;12(9):3812
Daphnia magna	2,4-D	21 d, ss	Reproduction **NOEC = 38.4 mg/L $_{nom}$** (NOEC=46.2 mg DMA salt/L $_{nom}$)	EFSA Journal 2014;12(9):3812
Daphnia magna	2,4-D	21 d, f	Reproduction NOEC = 79 mg/L $_{mm}$	EFSA Journal 2014;12(9):3812
Daphnia magna	2,4-D-DMA 600 SL	48 h, s	Mortality LC_{50}=50.6 mg/L $_{mm}$ (LC_{50}>100 mg prod./L $_{nom}$)	EFSA Journal 2014;12(9):3812
Pseudokirchneriella subcapitata	2,4-D	72 h, s	Growth rate: **E_rC_{50}>78 mg/L $_{mm}$** Yield: E_rC_{50}>78 mg/L $_{mm}$	EFSA Journal 2014;12(9):3812
Navicula pelliculosa	2,4-D	72 h	Yield: E_yC_{50}>100 mg/L $_{nom}$ Growth rate: E_rC_{50}>100 mg/L $_{nom}$	EFSA Journal 2014;12(9):3812
Desmodesmus subspicat	2,4-D	72 h	Yield: E_yC_{50}>582.2 mg/L $_{mm}$ Growth rate: E_rC_{50}>582.2 mg/L $_{mm}$	EFSA Journal 2014;12(9):3812

Skeletonema costatum	2,4-D	72 h, s	**Yield: E_yC_{50}= 0.68 mg/L $_{nom}$** Growth rate: E_rC_{50}=4.58 mg/L $_{nom}$	EFSA Journal 2014;12(9):3812
Pseudokirchneriella subcapitata	2,4-D-DMA 600 SL	72 h, s	Yield: E_yC_{50}>115.35 mg/L (EyC50> 186.65 mg prod./L $_{mm}$) Growth rate: E_rC_{50}> 197.8 mg/L (E_rC_{50}> 320 mg/L)	EFSA Journal 2014;12(9):3812
Lemna minor	2,4-D	7 d, s	Fronds, E_yC_{50}=10.66 mg/L $_{nom}$ **Fronds, E_rC_{50}=17.51 mg/L $_{nom}$** Dry weight, E_yC_{50}=18.50 mg/L $_{nom}$ Dry weight, E_rC_{50}>100 mg/L $_{nom}$	EFSA Journal 2014;12(9):3812
Myriophyllum spicatum	2,4-D	14 d	Total root length, **EC_{50}=0.011 mg/L^1 $_{nom}$** Total root length, NOEC=0.0047 mg/L^1 $_{nom}$	EFSA Journal 2014;12(9):3812
Lemna minor	2,4-D-DMA 720 SL	7 d	Fronds, E_yC_{50}=2.7 mg/L$_{nom}$ (E_yC_5=4.6 mg prod./L$_{nom}$) Growth rate, E_yC_{50}= 14.4 mg/L$_{nom}$ (E_yC_{50}= 24.6 mg prod./L$_{nom}$)	EFSA Journal 2014;12(9):3812
2,4-DCA				
Oncorthynchus mykiss	2,4-DCA	96 h	Mortality **LC_{50}>1.4 mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
Daphnia magna	2,4-DCA	48 h, s	Mortality **LC_{50}=6.4 mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
Pseudokirchneriella subcapitata	2,4-DCA	72 h, s	**Yield: EyC50= 2.2 mg/L $_{mm}$** Growth rate: ErC50=4.3 mg/L $_{mm}$	EFSA Journal 2014;12(9):3812
Lemna gibba	2,4-DCA	7 d	Fronds, **EC50=2.1 mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
Myriophyllum aquaticum	2,4-DCA	10 d, s	Shoot length, **EC50=1.16 mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
2,4-DCP				
Daphnia magna	2,4-DCP	48 h, s	Mortality **LC_{50}=2.8 mg/L $_{nom}$**	EFSA Journal 2014;12(9):3812
Pseudokirchneriella subcapitata	2,4-DCP	72 h, s	Yield: **EyC50= 1.13 mg/L $_{mm}$** Growth rate: ErC50=3.44 mg/L $_{mm}$	EFSA Journal 2014;12(9):3812
Lemna gibba	2,4-DCP	10 d	Fronds, **EC50=1.5 mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
Myriophyllum aquaticum	2,4-DCP	10 d, s	Fresh weight, **EC50=12.4 mg/L $_{mm}$**	EFSA Journal 2014;12(9):3812
4-CP				
Oncorhynchus mykiss	4-CP	96 h	**LC_{50} = 1.9 mg/L**	KCP 10.2.1.1/01 Hodson, P.V. *et al.* (1984)
Daphnia magna	4-CP	48 h	**EC_{50} = 2.5 mg/L**	KCP 10.2.1.2/01 Kühn, R. *et al.* (1989)
Skeletonema costatum	4-CP	-	**E_rC_{50} = 13.8 mg/L**	KCP 10.2.1.3/01 Cowgill, U.M. *et al.*

				(1989)
Higher-tier studies (micro- or mesocosm studies)				
Not submitted.				

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

[1]endpoint agreed at the Pesticides Peer Review Meeting 111 (04 – 07 February 2013) and it is the geometric mean value for root length from the available 6 ring test studies with *Myriophyllum*.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – iodosulfuron-methyl-sodium and its metabolites

Species	Substance	Exposure System	Results/Toxicity [a]	Reference
Iodosulfuron-methyl-sodium				
Oncorhynchus mykiss, *Lepomis macrochirus*, *Cyprinodon variegatus*	iodosulfuron-methyl-sodium	96 h, s	**$LC_{50,\ nom}$>100 mg/L**	EFSA Journal 2016;14(4):4453
Oncorhynchus mykiss	iodosulfuron-methyl-sodium	28 d, ft	**$NOEC_{mm}$ = 7.79 mg/L**	
Pimephales promelas	iodosulfuron-methyl-sodium	35 d, ft	NOEC >9.8 mg/L	
Oncorhynchus mykiss	IMS+MPR OD 400	96 h, s	$LC_{50,}$ prep = 7.75 mg/L (0.684 mg as/L)	
Daphnia magna	iodosulfuron-methyl-sodium	48 h, s	**$EC_{50,\ nom}$>100 mg/L**	
Americamysis bahia	iodosulfuron-methyl-sodium	96 h, s	$LC_{50,\ nom}$>100 mg/L	
Daphnia magna	iodosulfuron-methyl-sodium	21 d, ss	**$EC_{10,\ nom}$=7.9 mg/L**	
Daphnia magna	IMS+MPR OD 400	48 h, s	$EC_{50,}$ prep = 8.3 mg/L (0.732 mg as/L)	
Pseudokirchneriella subcapitata	iodosulfuron-methyl-sodium	96 h, s	**E_rC_{50nom}= 0.152 mg/L** E_bC_{50nom}= 0.064 mg/L NOECnom=0.018 mg/L	
Navicula pelliculosa	iodosulfuron-methyl-sodium	72 h, s	E_rC_{50nom}>100 mg/L E_bC_{50nom}>100 mg/L $NOEC_{nom}$=100 mg/L	
Pseudokirchneriella subcapitata	IMS+MPR OD 400	72 h, s	$E_rC_{50,prep}$=6.71 mg/L (0.592 mg as/L) $E_bC_{50,prep}$=7.48 mg/L (0.66 mg as/L) $NOEC_{prep}$<0.1 mg/L (<0.0088 mg as/L)	

Lemna gibba	iodosulfuron-methyl-sodium	14 d, ss	Frond number 7d EC_{50nom}=0.00079 mg/L 14d EC_{50nom}=0.00083 mg/L 7d ErC_{50nom}=0.00134 mg/L $NOEC_{nom}$=0.00040 mg/L	
Lemna gibba	iodosulfuron-methyl-sodium + metsulfuron-methyl	6 weeks, ss	Frond number **7d $E_rC_{50nom,}$=0.00108 mg as/L** 6w $E_rC_{50nom,}$=0.000679 mg as/L $NOEC_{nom}$=0.000400 mg as/L Frond area 7d $E_rC_{50nom,}$=0.00112 mg as/L 6w $E_rC_{50nom,}$=0.000609 mg as/L $NOEC_{nom}$=0.000400 mg as/L	
Myriophyllum spicatum	iodosulfuron-methyl-sodium	10 d, s	NOECnom=0.0010 mg/L[b]	
Elodea Canadensis	iodosulfuron-methyl-sodium	10 d, s	NOECnom=0.00022 mg/L[b] NOECnom biomass=0.00046 mg/L	
Myriophyllum spicatum	iodosulfuron-methyl-sodium	14 d, s	Shoot lenght E_yC_{50nom}=0.00203 mg/L Wet weight E_yC_{50nom}=0.00251 mg/L Dry weight E_yC_{50nom}>0.00845 mg/L NOEC=0.00089 mg/L	
Lemna gibba	IMS+MPR OD 400	7d, s	Frond number $E_rC_{50nom,prep}$=0.0084 mg/L (0.00074 mg as/L) Biomass $E_rC_{50nom,prep}$>0.1 mg/L (>0.0088 mg as/L)	
AE 1234964				
Oncorhynchus mykiss	AE1234964	96 h, s	**LC_{50nom}>100 mg/L**	EFSA Journal 2016;14(4):4453
Daphnia magna	AE1234964	48 h, s	**$EC_{50, nom}$>100 mg/L**	
Lemna gibba	AE1234964	7 d, s	frond number **ErC_{50nom}>100 mg/L** biomass EbC_{50nom}>100 mg/L NOEC=0.32 mg/L	
AE F159737				
Oncorhynchus mykiss	AE F159737	96 h, s	**LC_{50nom}>100 mg/L**	EFSA Journal 2016;14(4):4453
Daphnia magna	AE F159737	48 h, s	**$EC_{50, nom}$>100 mg/L**	
Lemna gibba	AE F159737	7 d, s	frond number **ErC_{50nom}>100 mg/L** biomass EbC_{50nom}>100 mg/L NOEC=0.32 mg/L	
AE F059411				
Daphnia magna	AE F059411	48 h, s	**$EC_{50, nom}$>100 mg/L**	EFSA Journal

Pseudokirchneriella subcapitata	AE F059411	72 h, s	**E_rC_{50nom}>100 mg/L** $NOErC_{nom}$=100 mg/L	2016;14(4):4453
Lemna gibba	AE F059411	7 d, ss	frond number **ErC_{50nom}>100 mg/L** biomass EbC_{50nom}>100 mg/L NOEC=56 mg/L	
Lemna gibba	AE F059411	7 d, ss	frond number ErC_{50nom}>100 mg/L biomass EbC_{50nom}>100 mg/L NOEC=32 mg/L	
AE F145741				
Pseudokirchneriella subcapitata	AE F145741	72 h, s	**E_rC_{50nom}>10 mg/L** $NOErC_{nom}$<0.625mg/L	EFSA Journal 2016;14(4):4453
Lemna gibba	AE F145741	7 d, s	frond number ErC_{50nom}=4.69 mg/L NOErC=0.76 mg/L frond area **ErC_{50nom}=3.84 mg/L** NOErC=0.76 mg/L biomass EbC_{50nom}>11.4 mg/L NOErC=1.60 mg/L	
AE F145740				
Pseudokirchneriella subcapitata	AE F145740	72 h, s	**E_rC_{50nom}>10 mg/L** $NOErC_{nom}$=10 mg/L	EFSA Journal 2016;14(4):4453
Lemna gibba	AE F145740	7 d, s	frond number **ErC_{50nom}>10 mg/L** NOErC=10 mg/L frond area ErC_{50nom}>10 mg/L NOErC=10 mg/L	
AE 0002166				
Pseudokirchneriella subcapitata	AE 0002166	72 h, s	**E_rC_{50nom}>10 mg/L** $NOErC_{nom}$<10 mg/L	EFSA Journal 2016;14(4):4453
Lemna gibba	AE 0002166	7 d, ss	frond number **ErC_{50nom}=0.0230 mg/L** biomass EbC_{50nom}=0.0583 mg/L NOEC=0.00769 mg/L	
AE F161778				
Pseudokirchneriella subcapitata	AE F161778	72 h, s	**E_rC_{50nom}>10 mg/L** $NOErC_{nom}$<10 mg/L	EFSA Journal 2016;14(4):4453
Lemna gibba	AE F161778	7 d, ss	frond number **ErC_{50nom}=0.0281 mg/L** biomass EbC_{50nom}=0.0305 mg/L NOEC=0.010 mg/L	
BCS-CW81253				
Pseudokirchneriella subcapitata	BCS-CW81253	72 h, s	**E_rC_{50nom}>10 mg/L** $NOEC_{nom}$=10 mg/L	EFSA Journal 2016;14(4):4453

Lemna gibba	BCS-CW81253	7 d, s	frond number **ErC_{50nom}>10 mg/L** NOErC=10 mg/L frond area ErC_{50nom}>10 mg/L NOErC=10 mg/L	
AE F154781				
Pseudokirchneri-ella subcapitata	AE F154781	72 h, s	**E_rC_{50nom}>10 mg/L** $NOEC_{nom}$=10 mg/L	EFSA Journal 2016;14(4):4453
Lemna gibba	AE F154781	7 d, s	frond number **ErC_{50nom}>10 mg/L** NOErC=10 mg/L frond area ErC_{50nom}>10 mg/L NOErC=10 mg/L	EFSA Journal 2016;14(4):4453
AE F075736				
Lemna gibba	AE F075736	7 d, ss	frond number 7d ErC_{50nom}=0.00112 mg/L[c] 7d NOEC=0.00032 mg/L[c] biomass 7d ErC_{50nom}=0.00131 mg/L[c] 7d NOEC=0.00032 mg/L[c]	EFSA Journal 2016;14(4):4453
Lemna gibba	AE F075736	7 d, s	frond number **7d ErC_{50nom}=0.00057 mg/L** 7d NOEC=0.00025 mg/L biomass 7d ErC_{50nom}=0.000365 mg/L 7d NOEC=0.00025 mg/L	
AE 0000119				
Lemna gibba	AE 0000119	7 d, ss	frond number **ErC_{50nom}>100 mg/L** biomass EbC_{50nom}>100 mg/L NOEC=100 mg/L	EFSA Journal 2016;14(4):4453
AE 0014966				
Lemna gibba	AE 0014966	7 d, ss	frond number **ErC_{50nom}=0.575 mg/L** biomass EbC_{50nom}=0.380 mg/L NOEC=0.18 mg/L	EFSA Journal 2016;14(4):4453
AE 0034855				
Lemna gibba	AE 0034855	7 d, ss	frond number **ErC_{50nom}>100 mg/L** biomass EbC_{50nom}>100 mg/L NOEC=100 mg/L	EFSA Journal 2016;14(4):4453
Higher-tier studies (micro- or mesocosm studies)				
Further testing on aquatic organisms Outdoor pond study with eight species of aquatic macrophytes exposed for six weeks (Hoberg, 2011, Report No 13798.6259) combined with the 6 week endpoint on *Lemna gibba* from the laboratory study (Bruns, 2013, Report No EBIML025). As no intermediate biological measurements were performed over 6 weeks, it cannot be excluded that a certain recovery might have taken place. Therefore, the only endpoints derived from this study are NOEAECs, based on the assumption that some recovery might have occurred during the 6 weeks. NOEAEC based on measured initial test concentration 0.27 µg a.s./L compared with FOCUS exposure profiles or geomean				

measured concentration 0.16 µg a.s./L compared with PECmax should be used for the risk assessment, along with an assessment factor of 3.

Potential endocrine disrupting properties:
No indications on the potential for endocrine disrupting properties have been identified.

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
a) (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance
b) Endpoint based on non-standard endpoints not suitable for risk assessment since these can be difficult to interpret as also the substance itself may influence such parameters
c) A minor contamination was observed in the control samples which may have a small influence on the EC50 values.

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – JMD-HER 387 OD

Species	Substance	Exposure System	Results	Reference
Daphnia magna	JMD-HER 387 OD	48 h, ss	**$EC_{50,nom}$ >100 mg/L**	KCP 10.2.1.2/02/ Czarnecka M/2021/ Study code: W-02-21
Chironomus riparius	JMD-HER 387 OD	48 h, ss	**$EC_{50,nom}$ >100 mg/L**	KCP 10.2.1.2/03/ Czarnecka M/2021/ Study code: W-01-21
Raphidocelis subcapitata (Pseudokirchneriella subcapitata)	JMD-HER 387 OD	72 h, s	**$E_rC_{50,nom}$ = 9.207 mg/L** $E_yC_{50,nom}$ = 1.698 mg/L	KCP 10.2.1.3/02 Czarnecka M/2021/ Study code: W-03-21
Lemna gibba	JMD-HER 387 OD	7 d, ss	Frond number: $E_rC_{50,nom}$ = 0.186 mg/L $E_yC_{50,nom}$ = 0.032 mg/L Dry weight: **$E_rC_{50,nom}$ = 1.054mg/L** $E_yC_{50,nom}$ = 0.041 mg/L	KCP 10.2.1.4/01/ Czarnecka M/2021/ Study code: W-04-21
Myriophyllum spicatum	JMD-HER 387 OD	14 d, s	**Shoots length** **$E_rC_{50,nom}$ = 0.139 mg/l** $E_yC_{50,nom}$ = 0.100 mg/l **Fresh weight** E_rC_{50} = 4.976 mg/l E_yC_{50} = 0.689 mg/l **Dry weight** $E_rC_{50,nom}$ = 10.988 mg/l $E_yC_{50,nom}$ = 1.885 mg/l	KCP 10.2.1.4/02/ Turek-Lipka T/2021/ Study code: W-05-21
Higher-tier studies (micro- or mesocosm studies)				
Not available.				

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

New endpoints are provided for the formulated product JMD-HER 387 OD and the metabolite 4-CP (literature data). Details of studies and results are included in Table 9.5-1 and Table 9.5-2. Summary of the

studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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).

For metabolite 1,2,4-benzenetriol, no toxicity studies are available. Therefore, for the risk assessment, it was assumed that the metabolite is 10x more toxic than the active substance (worst case approach) and acute toxicity endpoints were calculated.

The relevant global maximum FOCUS Step 1, 2, 3 and 4 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

Even though for few scenarios risk assessment with Step 3 PECsw was acceptable, PEC/RAC with Step 4 PECsw was calculated since those valued were needed in combine risk assessment.

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 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 2,4-D for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Algae**	**Higher plants**	**Higher plants**
Test species		***Pimephales promelas***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Skeletonema costatum***	***Lemna minor***	***Myriophyllum spicatum***
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	E_yC_{50}	E_yC_{50}	**E_yC_{50}**	EC_{50}
		100000	63400	134200	38400	78000	680	17510	11
AF		100	10	100	10	10	10	10	10
RAC (µg/L)		1000	6340	1342	3840	7800	68	1751	1.1
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1 & 2 – winter cereals (250 g a.s./ha)									
Step 1	79.5933	0.08	0.01	0.06	0.02	0.01	1.17	0.05	**72.36**
Step 2 NEU	10.1080	0.01	0.00	0.01	0.00	0.00	0.15	0.01	**9.19**
Step 2 SEU	18.3402	0.02	0.00	0.01	0.00	0.00	0.27	0.01	**16.67**
Step 3 – winter cereals (250 g a.s./ha)									
D1/ditch	12.77	0.01	0.00	0.01	0.00	0.00	0.19	0.01	**11.61**
D1/stream	8.00	0.01	0.00	0.01	0.00	0.00	0.12	0.00	**7.27**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Algae	Higher plants	Higher plants
D2/ditch	21.46	0.02	0.00	0.02	0.01	0.00	0.32	0.01	**19.51**
D2/stream	13.77	0.01	0.00	0.01	0.00	0.00	0.20	0.01	**12.52**
D3/ditch	1.583	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.44**
D4/pond	0.05466	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.05
D4/stream	1.171	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.06**
D5/pond	0.05467	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.05
D5/stream	1.256	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.14**
D6/ditch	1.615	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.47**
R1/pond	0.06061	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.06
R1/stream	1.388	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.26**
R3/stream	1.466	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.33**
R4/stream	1.034	0.00	0.00	0.00	0.00	0.00	0.02	0.00	0.94
Step 1 & 2 – spring cereals (250 g a.s./ha)									
Step 1	79.5933	0.08	0.01	0.06	0.02	0.01	**1.17**	0.05	**72.36**
Step 2 NEU	10.1080	0.01	0.00	0.01	0.00	0.00	0.15	0.01	**9.19**
Step 2 SEU	18.3402	0.02	0.00	0.01	0.00	0.00	0.27	0.01	**16.67**
Step 3 – spring cereals (250 g a.s./ha)									
D1/ditch	1.62	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.47**
D1/stream	1.403	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.28**
D3/ditch	1.584	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.44**
D4/pond	0.0547	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.05
D4/stream	1.296	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.18**
D5/pond	0.05467	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.05
D5/stream	1.259	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.14**
R4/stream	5.564	0.01	0.00	0.00	0.00	0.00	0.08	0.00	**5.06**
Step 3 – maize as a surrogate for spring cereals (250 g a.s./ha)									
D6/ditch	1.304	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.19**
R1/pond	0.1682	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.15
R1/stream	1.204	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.09**
R2/stream	1.219	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.11**
R3/stream	1.282	0.00	0.00	0.00	0.00	0.00	0.02	0.00	**1.17**

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

Table 9.5-5: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for 2,4-D based on FOCUS Step 4 calculations and toxicity data for *Myriophyllum spicatum* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in winter cereals

Intended use		winter cereals						
Active substance		2,4-D						
Application rate (g as/ha)		250						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	12.77	12.77	12.77	-	12.77	12.77	12.77
50 %		12.77	12.77	-	-	-	-	-
75 %		12.77	-	-	-	-	-	-
90 %		12.77	-	-	-	-	-	-
None	D1 stream	8.000	8.000	8.000	-	8.000	8.000	8.000
50 %		8.000	8.000	-	-		-	-
75 %		8.000	-	-	-	-	-	-
90 %		8.000	-	-	-	-	-	-
None	D2 ditch	21.46	21.46	21.46	-	21.46	21.46	21.46
50 %		21.46	21.46	-	-	-	-	-
75 %		21.46	-	-	-	-	-	-
90 %		21.46	-	-	-	-	-	-
None	D2 stream	13.77	13.77	13.77	-	13.77	13.77	13.77
50 %		13.77	13.77	-	-	-	-	
75 %		13.77	-	-	-	-	-	-
90 %		13.77	-	-	-	-	-	-
None	D3 ditch	1.583	0.4291	0.2276	-	0.4291	0.2276	0.2276
50 %		0.9630	0.2145	-	-	-	-	-
75 %		0.4817	-	-	-	-	-	-
90 %		0.1926	-	-	-	-	-	-
None	D4 pond	0.05466	0.04729	0.03400	-	0.04729	0.03400	0.03400
50 %		0.04413	0.02364	-	-	-	-	-
75 %		0.02206	-	-	-	-	-	-
90 %		0.008825	-	-	-	-	-	-
None	D4 stream	1.171	0.4277	0.2269	-	0.4277	0.2269	0.2269
50 %		0.9603	0.2139	-	-	-	-	-
75 %		0.4801	-	-	-	-	-	-
90 %		0.1920	-	-	-	-	-	-
None	D5 pond	0.05467	0.04730	0.03401	-	0.04730	0.03401	0.03401
50 %		0.04414	0.02365	-	-	-	-	-

75 %		0.02207	-	-	-	-	-	-
90 %		0.008828	-	-	-	-	-	-
None	D5 stream	1.256	0.4589	0.2434	-	0.4589	0.2434	0.2434
50 %		1.030	0.2295	-	-	-	-	-
75 %		0.5151	-	-	-	-	-	-
90 %		0.2060	-	-	-	-	-	-
None	D6 ditch	1.615	1.615	1.615	-	1.615	1.615	1.615
50 %		1.615	1.615	-	-	-	-	-
75 %		1.615	-	-	-	-	-	-
90 %		1.615	-	-	-	-	-	-
None	R1 pond	0.06061	0.05665	0.04952	-	0.04730	0.03401	0.03401
50 %		0.05495	0.04396	-	-	-	-	-
75 %		0.04311	-	-	-	-	-	-
90 %		0.03603	-	-	-	-	-	-
None	R1 stream	1.388	1.388	1.388	-	0.3812	0.2022	0.5712
50 %		1.388	1.388	-	-	-	-	-
75 %		1.388	-	-	-	-	-	-
90 %		1.388	-	-	-	-	-	-
None	R3 stream	1.466	1.044	1.044	-	0.5355	0.3443	0.4765
50 %		1.202	1.044	-	-	-	-	-
75 %		1.044	-	-	-	-	-	-
90 %		1.044	-	-	-	-	-	-
None	R4 stream	1.034	0.3776	0.2003	-	0.3776	0.2003	0.2003
50 %		0.8477	0.1888	-	-	-	-	-
75 %		0.4238	-	-	-	-	-	-
90 %		0.1695	-	-	-	-	-	-
RAC (µg/L) 1.1		**PEC/RAC ratio**						
None	D1 ditch	**11.61**	**11.61**	**11.61**	-	**11.61**	**11.61**	**11.61**
50 %		**11.61**	**11.61**	-	-	-	-	-
75 %		**11.61**	-	-	-	-	-	-
90 %		**11.61**	-	-	-	-	-	-
None	D1 stream	**7.27**	**7.27**	**7.27**	-	**7.27**	**7.27**	**7.27**
50 %		**7.27**	**7.27**	-	-	-	-	-
75 %		**7.27**	-	-	-	-	-	-
90 %		**7.27**	-	-	-	-	-	-
None	D2 ditch	**19.51**	**19.51**	**19.51**	-	**19.51**	**19.51**	**19.51**
50 %		**19.51**	**19.51**	-	-	-	-	-
75 %		**19.51**	-	-	-	-	-	-

90 %		**19.51**	-	-	-	-	-	-
None	D2 stream	**12.52**	**12.52**	**12.52**	-	**12.52**	**12.52**	**12.52**
50 %		**12.52**	**12.52**	-	-	-	-	-
75 %		**12.52**	-	-	-	-	-	-
90 %		**12.52**	-	-	-	-	-	-
None	D3 ditch	**1.44**	0.39	0.21	-	0.39	0.21	0.21
50 %		0.88	0.2	-	-	-	-	-
75 %		0.44	-	-	-	-	-	-
90 %		0.18	-	-	-	-	-	-
None	D4 pond	0.05	0.04	0.03	-	0.04	0.03	0.03
50 %		0.04	0.02	-	-	-	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D4 stream	**1.06**	0.39	0.21	-	0.39	0.21	0.21
50 %		0.87	0.19	-	-	-	-	-
75 %		0.44	-	-	-	-	-	-
90 %		0.17	-	-	-	-	-	-
None	D5 pond	0.05	0.04	0.03	-	0.04	0.03	0.03
50 %		0.04	0.02	-	-	-	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D5 stream	**1.14**	0.42	0.22	-	0.42	0.22	0.22
50 %		0.94	0.21	-	-	-	-	-
75 %		0.47	-	-	-	-	-	-
90 %		0.19	-	-	-	-	-	-
None	D6 ditch	**1.47**	**1.47**	**1.47**	-	**1.47**	**1.47**	**1.47**
50 %		**1.47**	**1.47**	-	-	-	-	-
75 %		**1.47**	-	-	-	-	-	-
90 %		**1.47**	-	-	-	-	-	-
None	R1 pond	0.06	0.05	0.05	-	0.04	0.03	0.03
50 %		0.05	0.04	-	-	-	-	-
75 %		0.04	-	-	-	-	-	-
90 %		0.03	-	-	-	-	-	-
None	R1 stream	**1.26**	**1.26**	**1.26**	-	0.35	0.18	0.52
50 %		**1.26**	**1.26**	-	-	-	-	-
75 %		**1.26**	-	-	-	-	-	-
90 %		**1.26**	-	-	-	-	-	-
None	R3 stream	**1.33**	0.95	0.95	-	0.49	0.31	0.43
50 %		**1.09**	0.95	-	-	-	-	-

75 %		0.95	-	-	-	-	-	-
90 %		0.95	-	-	-	-	-	-
None	R4 stream	0.94	0.34	0.18	-	0.34	0.18	0.18
50 %		0.77	0.17	-	-	-	-	-
75 %		0.39	-	-	-	-	-	-
90 %		0.15	-	-	-	-	-	-

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: PEC calculation and acceptability of risk (PEC/RAC < 1) for 2,4-D based on FOCUS Step 4 calculations and toxicity data for *Myriophyllum spicatum* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in spring cereals

Intended use		spring cereals						
Active substance		2,4-D						
Application rate (g as/ha)		250						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	1.620	0.4516	0.2475	-	0.4516	0.2475	0.2475
50 %		0.9925	0.2343	-	-	-	-	-
75 %		0.5049	-	-	-	-	-	-
90 %		0.2121	-	-	-	-	-	-
None	D1 stream	1.403	0.5123	0.2718	-	0.5123	0.2718	0.2718
50 %		1.150	0.2563	-	-	-	-	-
75 %		0.5751	-	-	-	-	-	-
90 %		0.2300	-	-	-	-	-	-
None	D3 ditch	1.584	0.4295	0.2278	-	0.4295	0.2278	0.2278
50 %		0.9638	0.2147	-	-	-	-	-
75 %		0.4821	-	-	-	-	-	-
90 %		0.1928		-	-	-	-	-
None	D4 pond	0.05470	0.04733	0.03403	-	0.04733	0.03403	0.03403
50 %		0.04416	0.02366	-	-	-	-	-
75 %		0.02208	-	-	-	-	-	-
90 %		0.008837	-	-	-	-	-	-
None	D4 stream	1.296	0.4735	0.2512	-	0.4735	0.2512	0.2512
50 %		1.063	0.2368	-	-	-	-	-
75 %		0.5315	-	-	-	-	-	-
90 %		0.2126	-	-	-	-	-	-
None	D5 pond	0.05467	0.04730	0.03401	-	0.04730	0.03401	0.03401
50 %		0.04414	0.02365	-	-	-		-

75 %		0.02207	-	-	-	-	-	-
90 %		0.008827	-	-	-	-	-	-
None	D5 stream	1.259	0.4598	0.2439	-	0.4598	0.2439	0.2439
50 %		1.032	0.2300	-	-	-	-	-
75 %		0.5161	-	-	-	-	-	-
90 %		0.2064	-	-	-	-	-	-
None	R4 stream	5.564	5.564	5.564	-	0.3829	0.2031	2.511
50 %		5.564	5.564	-	-	-	-	-
75 %		5.564	-	-	-	-	-	-
90 %		5.564	-	-	-	-	-	-
None	D6 ditch (maize as a surrogate for spring cereals)	1.304	0.4273	0.2266	-	0.4273	0.2266	0.2266
50 %		0.9589	0.2136	-	-		-	-
75 %		0.4796	-	-	-	-	-	-
90 %		0.1918	-	-	-	-	-	-
None	R1 pond (maize as a surrogate for spring cereals)	0.1682	0.1649	0.1573	-	0.05525	0.03401	0.07531
50 %		0.1631	0.1514	-	-	-	-	-
75 %		0.1505	-	-	-	-	-	-
90 %		0.1430	-	-	-	-	-	-
None	R1 stream (maize as a surrogate for spring cereals)	1.204	1.204	1.204	-	0.3829	0.2031	0.5482
50 %		1.204	1.204	-	-	-	-	-
75 %		1.204	-	-	-	-	-	-
90 %		1.204	-	-	-	-	-	-
None	R2 stream (maize as a surrogate for spring cereals)	1.219	1.058	1.058	-	0.5133	0.2723	0.4802
50 %		1.152	1.058	-	-	-	-	-
75 %		1.058	-	-	-	-	-	-
90 %		1.058	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	1.282	0.6134	0.6134	-	0.5398	0.2863	0.2863
50 %		1.212	0.6134	-	-	-	-	-
75 %		0.6134	-	-	-	-	-	-
90 %		0.6134	-	-	-	-	-	-
RAC (µg/L) 1.1		**PEC/RAC ratio**						
None	D1 ditch	**1.47**	0.41	0.23	-	0.41	0.23	0.23
50 %		0.9	0.21	-	-	-	-	-
75 %		0.46	-	-	-	-	-	-
90 %		0.19	-	-	-	-	-	-
None	D1 stream	**1.28**	0.47	0.25	-	0.47	0.25	0.25
50 %		**1.05**	0.23	-	-	-	-	-
75 %		0.52	-	-	-	-	-	-

90 %		0.21	-	-	-	-	-	-
None	D3 ditch	**1.44**	0.39	0.21	-	0.39	0.21	0.21
50 %		0.88	0.2	-	-	-	-	-
75 %		0.44	-	-	-	-	-	-
90 %		0.18	0	-	-	-	-	-
None	D4 pond	0.05	0.04	0.03	-	0.04	0.03	0.03
50 %		0.04	0.02	-	-	-	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D4 stream	**1.18**	0.43	0.23	-	0.43	0.23	0.23
50 %		0.97	0.22	-	-	-	-	-
75 %		0.48	-	-	-	-	-	-
90 %		0.19	-	-	-	-	-	-
None	D5 pond	0.05	0.04	0.03	-	0.04	0.03	0.03
50 %		0.04	0.02	-	-	-	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D5 stream	**1.14**	0.42	0.22	-	0.42	0.22	0.22
50 %		0.94	0.21	-	-	-	-	-
75 %		0.47	-	-	-	-	-	-
90 %		0.19	-	-	-	-	-	-
None	R4 stream	**5.06**	**5.06**	**5.06**	-	0.35	0.18	**2.28**
50 %		**5.06**	**5.06**	-	-	-	-	-
75 %		**5.06**	-	-	-	-	-	-
90 %		**5.06**	-	-	-	-	-	-
None	D6 ditch (maize as a surrogate for spring cereals)	**1.19**	0.39	0.21	-	0.39	0.21	0.21
50 %		0.87	0.19	-	-	-	-	-
75 %		0.44	-	-	-	-	-	-
90 %		0.17	-	-	-	-	-	-
None	R1 pond (maize as a surrogate for spring cereals)	0.15	0.15	0.14	-	0.05	0.03	0.07
50 %		0.15	0.14	-	-	-	-	-
75 %		0.14	-	-	-	-	-	-
90 %		0.13	-	-	-	-	-	-
None	R1 stream (maize as a surrogate for spring cereals)	**1.09**	**1.09**	**1.09**	-	0.35	0.18	0.5
50 %		**1.09**	**1.09**	-	-	-	-	-
75 %		**1.09**	-	-	-	-	-	-
90 %		**1.09**	-	-	-	-	-	-
None	R2 stream	**1.11**	0.96	0.96	-	0.47	0.25	0.44
50 %		**1.05**	0.96	-	-	-	-	-

75 %	(maize as a surrogate for spring cereals)	0.96	-	-	-	-	-	-
90 %		0.96	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	**1.17**	0.56	0.56	-	0.49	0.26	0.26
50 %		**1.1**	0.56	-	-	-	-	-
75 %		0.56	-	-	-	-	-	-
90 %		0.56	-	-	-	-	-	-

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

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 2,4-DCP for each organism group based on FOCUS Steps 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**	**Higher plants**
Test species		-	-	***Daphnia magna***	-	***Pseudokirchn. subcapitata***	***Lemna gibba***	***Myriophyllum aquaticum***
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	E_yC_{50}	EC_{50}	EC_{50}
		10000*	-	2800	-	1130	1500	12400
AF		100	10	100	10	10	10	10
RAC (µg/L)		1000	-	28	-	113	150	1240
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-
Step 1 & 2 – spring cereals (250 g a.s./ha)								
Step 1	15.4474	0.02	-	0.55	-	0.14	0.10	0.01
Step 1 & 2 – winter cereals (250 g a.s./ha)								
Step 1	15.4474	0.02	-	0.55	-	0.14	0.10	0.01

* The endpoint used for risk assessment for the metabolite 2,4-DCP is the EC_{50} of parent molecule / 10, according to SANCO Guidance Document on Aquatic Ecotoxicology p.49 (European Commission, 2002b)

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 2,4-DCA for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group	**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**	**Higher plants**
Test species	***Oncorthynchus mykiss***	-	***Daphnia magna***	-	***Pseudokirchn. subcapitata***	***Lemna gibba***	***Myriophyllum aquaticum***
Endpoint (µg/L)	LC_{50}	NOEC	EC_{50}	NOEC	E_yC_{50}	EC_{50}	EC_{50}

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants	Higher plants
		1400	-	6400	-	2200	2100	1160
AF		100	10	100	10	10	10	10
RAC (µg/L)		14	-	64	-	220	210	116
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	-	-	-	-	-	-	-
Step 1 & 2 – spring cereals (250 g a.s./ha)								
Step 1	5.8127	0.42	-	0.09	-	0.03	0.03	0.05
Step 1 & 2 – winter cereals (250 g a.s./ha)								
Step 1	5.8127	0.42	-	0.09	-	0.03	0.03	0.05

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 4-CP for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants	-
Test species		***Oncorthynchus mykiss***	-	***Daphnia magna***	-	***Skeletonema costatum***	-	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	E_yC_{50}	EC_{50}	-
		1900	-	2500	-	2200	-	-
AF		100	10	100	10	10	10	-
RAC (µg/L)		19	-	25	-	220	-	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	-	-	-	-	-	-	-
Step 1 & 2 – spring cereals (250 g a.s./ha)								
Step 1	17.7888	0.94	-	0.71	-	0.08	-	-
Step 2 NEU	1.5945	0.08	-	0.06	-	0.01	-	-
Step 2 SEU	3.1023	0.16	-	0.12	-	0.01	-	-
Step 1 & 2 – winter cereals (250 g a.s./ha)								
Step 1	17.7888	0.94	-	0.71	-	0.08	-	-
Step 2 NEU	1.5945	0.08	-	0.06	-	0.01	-	-
Step 2 SEU	3.1023	0.16	-	0.12	-	0.01	-	-

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 1,2,4-benzenetriol for each organism group based on FOCUS Step 1, 2 and 3 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**	**-**
Test species		***Pimephales promelas***	**-**	***Daphnia magna***	**-**	***Pseudo-kirchn. subcapitata***	***Myriophyl-lum spi-catum***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	E_yC_{50}	EC50	-
		10000	-	13420	-	7800	1.1	-
AF		100	10	100	10	10	10	-
RAC (µg/L)		100	-	134.2	-	780	0.11	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-
Step 1 & 2 – winter cereals (250 g a.s./ha)								
Step 1	0.14	0.11	-	0.02	-	**130.88**	0.14	-
Step 2 NEU	0.02	0.01	-	0.00	-	**16.62**	0.02	-
Step 2 SEU	0.03	0.02	-	0.00	-	**30.16**	0.03	-
Step 3 – winter cereals (250 g a.s./ha)								
D1/ditch	2.3098	0.02	-	0.02	-	0.00	**21.00**	-
D1/stream	1.447	0.01	-	0.01	-	0.00	**13.15**	-
D2/ditch	3.8816	0.04	-	0.03	-	0.00	**35.29**	-
D2/stream	2.4907	0.02	-	0.02	-	0.00	**22.64**	-
D3/ditch	0.2863	0.00	-	0.00	-	0.00	**2.60**	-
D4/pond	0.0099	0.00	-	0.00	-	0.00	0.09	-
D4/stream	0.2118	0.00	-	0.00	-	0.00	**1.93**	-
D5/pond	0.0099	0.00	-	0.00	-	0.00	0.09	-
D5/stream	0.2272	0.00	-	0.00	-	0.00	**2.07**	-
D6/ditch	0.2921	0.00	-	0.00	-	0.00	**2.66**	-
R1/pond	0.011	0.00	-	0.00	-	0.00	0.10	-
R1/stream	0.2511	0.00	-	0.00	-	0.00	**2.28**	-
R3/stream	0.2652	0.00	-	0.00	-	0.00	**2.41**	-
R4/stream	0.187	0.00	-	0.00	-	0.00	**1.70**	-
Step 1 & 2 – spring cereals (250 g a.s./ha)								
Step 1	14.3966	0.14	-	0.11	-	0.02	**130.88**	-
Step 2 NEU	1.8283	0.02	-	0.01	-	0.00	**16.62**	-
Step 2 SEU	3.3173	0.03	-	0.02	-	0.00	**30.16**	-
Step 3 – spring cereals (250 g a.s./ha)								

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants	-
D1/ditch	0.293	0.00	-	0.00	-	0.00	**2.66**	-
D1/stream	0.2538	0.00	-	0.00	-	0.00	**2.31**	-
D3/ditch	0.2865	0.00	-	0.00	-	0.00	**2.60**	-
D4/pond	0.0099	0.00	-	0.00	-	0.00	0.09	-
D4/stream	0.2344	0.00	-	0.00	-	0.00	**2.13**	-
D5/pond	0.0099	0.00	-	0.00	-	0.00	0.09	-
D5/stream	0.2277	0.00	-	0.00	-	0.00	**2.07**	-
R4/stream	1.0064	0.01	-	0.01	-	0.00	**9.15**	-
Step 3 – maize as a surrogate for spring cereals (250 g a.s./ha)								
D6/ditch	0.2359	0.00	-	0.00	-	0.00	**2.14**	-
R1/pond	0.0304	0.00	-	0.00	-	0.00	0.28	-
R1/stream	0.2178	0.00	-	0.00	-	0.00	**1.98**	-
R3/stream	0.2205	0.00	-	0.00	-	0.00	**2.00**	-
R4/stream	0.2319	0.00	-	0.00	-	0.00	**2.11**	-

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: PEC calculation and acceptability of risk (PEC/RAC < 1) for 1,2,4-benzenetriol based on FOCUS Step 4 calculations and toxicity data for *Myriophyllum spicatum* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in winter cereals

Intended use		winter cereals						
Active substance		1,2,4-benzenetriol						
Application rate (g as/ha)		250						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	2.3098	2.3098	2.3098	-	2.3098	2.3098	2.3098
50 %		2.3098	2.3098	-	-	-	-	-
75 %		2.3098	-	-	-	-	-	-
90 %		2.3098	-	-	-	-	-	-
None	D1 stream	1.4470	1.4470	1.4470	-	1.4470	1.4470	1.4470
50 %		1.4470	1.4470	-	-	-	-	-
75 %		1.4470	-	-	-	-	-	-
90 %		1.4470	-	-	-	-	-	-
None	D2 ditch	3.8816	3.8816	3.8816	-	3.8816	3.8816	3.8816
50 %		3.8816	3.8816	-	-	-	-	-
75 %		3.8816	-	-	-	-	-	-
90 %		3.8816	-	-	-	-	-	-

None	D2 stream	2.4907	2.4907	2.4907	-	2.4907	2.4907	2.4907
50 %		2.4907	2.4907	-	-	-	-	-
75 %		2.4907	-	-	-	-	-	-
90 %		2.4907	-	-	-	-	-	-
None	D3 ditch	0.2863	0.0776	0.0412	-	0.0776	0.0412	0.0412
50 %		0.1742	0.0388	-	-	-	-	-
75 %		0.0871	-	-	-	-	-	-
90 %		0.0348	-	-	-	-	-	-
None	D4 pond	0.0099	0.0086	0.0061	-	0.0086	0.0061	0.0061
50 %		0.0080	0.0043	-	-	-	-	-
75 %		0.0040	-	-	-	-	-	-
90 %		0.0016	-	-	-	-	-	-
None	D4 stream	0.2118	0.0774	0.0410	-	0.0774	0.0410	0.0410
50 %		0.1737	0.0387	-	-	-	-	-
75 %		0.0868	-	-	-	-	-	-
90 %		0.0347	-	-	-	-	-	-
None	D4 pond	0.0099	0.0086	0.0062	-	0.0086	0.0062	0.0062
50 %		0.0080	0.0043	-	-	-	-	-
75 %		0.0040	-	-	-	-	-	-
90 %		0.0016	-	-	-	-	-	-
None	D5 stream	0.2272	0.0830	0.0440	-	0.0830	0.0440	0.0440
50 %		0.1863	0.0415	-	-	-	-	-
75 %		0.0932	-	-	-	-	-	-
90 %		0.0373	-	-	-	-	-	-
None	D6 ditch	0.2921	0.2921	0.2921	-	0.2921	0.2921	0.2921
50 %		0.2921	0.2921	-	-	-	-	-
75 %		0.2921	-	-	-	-	-	-
90 %		0.2921	-	-	-	-	-	-
None	R1 pond	0.0110	0.0102	0.0090	-	0.0086	0.0062	0.0062
50 %		0.0099	0.0080	-	-	-	-	-
75 %		0.0078	-	-	-	-	-	-
90 %		0.0065	-	-	-	-	-	-
None	R1 stream	0.2511	0.2511	0.2511	-	0.0690	0.0366	0.1033
50 %		0.2511	0.2511	-	-	-	-	-
75 %		0.2511	-	-	-	-	-	-
90 %		0.2511	-	-	-	-	-	-
None	R3 stream	0.2652	0.1888	0.1888	-	0.0969	0.0623	0.0862
50 %		0.2174	0.1888	-	-	-	-	-
75 %		0.1888	-	-	-	-	-	-

90 %		0.1888	-	-	-	-	-	-
None	R4 stream	0.1870	0.0683	0.0362	-	0.0683	0.0362	0.0362
50 %		0.1533	0.0341	-	-	-	-	-
75 %		0.0767	-	-	-	-	-	-
90 %		0.0307	-	-	-	-	-	-
RAC (µg/L) 0.11		**PEC/RAC ratio**						
None	D1 ditch	**21.00**	**21.00**	**21.00**	-	**21.00**	**21.00**	**21.00**
50 %		**21.00**	**21.00**	-	-	-	-	-
75 %		**21.00**	-	-	-	-	-	-
90 %		**21.00**	-	-	-	-	-	-
None	D1 stream	**13.15**	**13.15**	**13.15**	-	**13.15**	**13.15**	**13.15**
50 %		**13.15**	**13.15**	-	-	-	-	-
75 %		**13.15**	-	-	-	-	-	-
90 %		**13.15**	-	-	-	-	-	-
None	D2 ditch	**35.29**	**35.29**	**35.29**	-	**35.29**	**35.29**	**35.29**
50 %		**35.29**	**35.29**	-	-	-	-	-
75 %		**35.29**	-	-	-	-	-	-
90 %		**35.29**	-	-	-	-	-	-
None	D2 stream	**22.64**	**22.64**	**22.64**	-	**22.64**	**22.64**	**22.64**
50 %		**22.64**	**22.64**	-	-	-	-	-
75 %		**22.64**	-	-	-	-	-	-
90 %		**22.64**	-	-	-	-	-	-
None	D3 ditch	**2.60**	0.71	0.37	-	0.71	0.37	0.37
50 %		**1.58**	0.35	-	-	-	-	-
75 %		0.79	-	-	-	-	-	-
90 %		0.32	-	-	-	-	-	-
None	D4 pond	0.09	0.08	0.06	-	0.08	0.06	0.06
50 %		0.07	0.04	-	-	-	-	-
75 %		0.04	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D4 stream	**1.93**	0.70	0.37	-	0.70	0.37	0.37
50 %		**1.58**	0.35	-	-	-	-	-
75 %		0.79	-	-	-	-	-	-
90 %		0.32	-	-	-	-	-	-
None	D5 pond	0.09	0.08	0.06	-	0.08	0.06	0.06
50 %		0.07	0.04	-	-	-	-	-
75 %		0.04	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-

None	D5 stream	**2.07**	0.75	0.40	-	0.75	0.40	0.40
50 %		**1.69**	0.38	-	-	-	-	-
75 %		0.85	-	-	-	-	-	-
90 %		0.34	-	-	-	-	-	-
None	D6 ditch	**2.66**	**2.66**	**2.66**	-	**2.66**	**2.66**	**2.66**
50 %		**2.66**	**2.66**	-	-	-	-	-
75 %		**2.66**	-	-	-	-	-	-
90 %		**2.66**	-	-	-	-	-	-
None	R1 pond	0.10	0.09	0.08	-	0.08	0.06	0.06
50 %		0.09	0.07	-	-	-	-	-
75 %		0.07	-	-	-	-	-	-
90 %		0.06	-	-	-	-	-	-
None	R1 stream	**2.28**	**2.28**	**2.28**	-	0.63	0.33	0.94
50 %		**2.28**	**2.28**	-	-	-	-	-
75 %		**2.28**	-	-	-	-	-	-
90 %		**2.28**	-	-	-	-	-	-
None	R3 stream	**2.41**	**1.72**	**1.72**	-	0.88	0.57	0.78
50 %		**1.98**	**1.72**	-	-	-	-	-
75 %		**1.72**	-	-	-	-	-	-
90 %		**1.72**	-	-	-	-	-	-
None	R4 stream	**1.70**	0.62	0.33	-	0.62	0.33	0.33
50 %		**1.39**	0.31	-	-	-	-	-
75 %		0.70	-	-	-	-	-	-
90 %		0.28	-	-	-	-	-	-

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

Table 9.5-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for 1,2,4-benzenetriol based on FOCUS Step 4 calculations and toxicity data for *Myriophyllum spicatum* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in spring cereals

Intended use		spring cereals						
Active substance		1,2,4-benzenetriol						
Application rate (g as/ha)		250						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	0.2930	0.0817	0.0448	-	0.0817	0.0448	0.0448
50 %		0.1795	0.0424	-	-	-	-	-
75 %		0.0913	-	-	-	-	-	-
90 %		0.0384	-	-	-	-	-	-

None	D1 stream	1.403	0.5123	0.2718	-	0.5123	0.2718	0.2718
50 %		1.150	0.2563	-	-	-	-	-
75 %		0.5751	-	-	-	-	-	-
90 %		0.2300	-	-	-	-	-	-
None	D3 ditch	0.2865	0.0777	0.0412	-	0.0777	0.0412	0.0412
50 %		0.1743	0.0388	-	-	-	-	-
75 %		0.0872	-	-	-	-	-	-
90 %		0.0349	-	-	-	-	-	-
None	D4 pond	0.0099	0.0086	0.0062	-	0.0086	0.0062	0.0062
50 %		0.0080	0.0043	-	-	-	-	-
75 %		0.0040	-	-	-	-	-	-
90 %		0.0016	-	-	-	-	-	-
None	D4 stream	0.2344	0.0856	0.0454	-	0.0856	0.0454	0.0454
50 %		0.1923	0.0428	-	-	-	-	-
75 %		0.0961	-	-	-	-	-	-
90 %		0.0385	-	-	-	-	-	-
None	D5 pond	0.0099	0.0086	0.0062	-	0.0086	0.0062	0.0062
50 %		0.0080	0.0043	-	-	-	-	-
75 %		0.0040	-	-	-	-	-	-
90 %		0.0016	-	-	-	-	-	-
None	D5 stream	0.2277	0.0832	0.0441	-	0.0832	0.0441	0.0441
50 %		0.1867	0.0416	-	-	-	-	-
75 %		0.0934	-	-	-	-	-	-
90 %		0.0373	-	-	-	-	-	-
None	R4 stream	1.0064	1.0064	1.0064	-	0.0693	0.0367	0.4542
50 %		1.0064	1.0064	-	-	-	-	-
75 %		1.0064	-	-	-	-	-	-
90 %		1.0064	-	-	-	-	-	-
None	D6 ditch (maize as a surrogate for spring cereals)	0.2359	0.0773	0.0410	-	0.0773	0.0410	0.0410
50 %		0.1734	0.0386	-	-	-	-	-
75 %		0.0867	-	-	-	-	-	-
90 %		0.0347	-	-	-	-	-	-
None	R1 pond (maize as a surrogate for spring cereals)	0.0304	0.0298	0.0285	-	0.0100	0.0062	0.0136
50 %		0.0295	0.0274	-	-	-	-	-
75 %		0.0272	-	-	-	-	-	-
90 %		0.0259	-	-	-	-	-	-
None	R1 stream (maize as a surrogate for	0.2178	0.2178	0.2178	-	0.0693	0.0367	0.0992
50 %		0.2178	0.2178	-	-	-	-	-
75 %		0.2178	-	-	-	-	-	-

90 %	spring cereals)	0.2178	-	-	-	-	-	-
None	R2 stream (maize as a surrogate for spring cereals)	0.2205	0.1914	0.1914	-	0.0928	0.0493	0.0869
50 %		0.2084	0.1914	-	-	-	-	-
75 %		0.1914	-	-	-	-	-	-
90 %		0.1914	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	0.2319	0.1109	0.1109	-	0.0976	0.0518	0.0518
50 %		0.2192	0.1109	-	-	-	-	-
75 %		0.1109	-	-	-	-	-	-
90 %		0.1109	-	-	-	-	-	-
RAC (µg/L) 0.11		**PEC/RAC ratio**						
None	D1 ditch	**2.66**	0.74	0.41	-	0.74	0.41	0.41
50 %		**1.63**	0.39	-	-	-	-	-
75 %		0.83	-	-	-	-	-	-
90 %		0.35	-	-	-	-	-	-
None	D1 stream	**12.75**	**4.66**	**2.47**	-	**4.66**	**2.47**	**2.47**
50 %		**10.45**	**2.33**	-	-	-	-	-
75 %		**5.23**	-	-	-	-	-	-
90 %		**2.09**	-	-	-	-	-	-
None	D3 ditch	**2.60**	0.71	0.37	-	0.71	0.37	0.37
50 %		**1.58**	0.35	-	-	-	-	-
75 %		0.79	-	-	-	-	-	-
90 %		0.32	-	-	-	-	-	-
None	D4 pond	0.09	0.08	0.06	-	0.08	0.06	0.06
50 %		0.07	0.04	-	-	-	-	-
75 %		0.04	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D4 stream	**2.13**	0.78	0.41	-	0.78	0.41	0.41
50 %		**1.75**	0.39	-	-	-	-	-
75 %		0.87	-	-	-	-	-	-
90 %		0.35	-	-	-	-	-	-
None	D5 pond	0.09	0.08	0.06	-	0.08	0.06	0.06
50 %		0.07	0.04	-	-	-	-	-
75 %		0.04	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D5 stream	**2.07**	0.76	0.40	-	0.76	0.40	0.40
50 %		**1.70**	0.38	-	-	-	-	-
75 %		0.85	-	-	-	-	-	-

90 %		0.34	-	-	-	-	-	-
None	R4 stream	**9.15**	**9.15**	**9.15**	-	0.63	0.33	**4.13**
50 %		**9.15**	**9.15**	-	-	-	-	-
75 %		**9.15**	-	-	-	-	-	-
90 %		**9.15**	-	-	-	-	-	-
None	D6 ditch (maize as a surrogate for spring cereals)	**2.14**	0.70	0.37	-	0.70	0.37	0.37
50 %		**1.58**	0.35	-	-	-	-	-
75 %		0.79	-	-	-	-	-	-
90 %		0.32	-	-	-	-	-	-
None	R1 pond (maize as a surrogate for spring cereals)	0.28	0.27	0.26	-	0.09	0.06	0.12
50 %		0.27	0.25	-	-	-	-	-
75 %		0.25	-	-	-	-	-	-
90 %		0.24	-	-	-	-	-	-
None	R1 stream (maize as a surrogate for spring cereals)	**1.98**	**1.98**	**1.98**	-	0.63	0.33	0.90
50 %		**1.98**	**1.98**	-	-	-	-	-
75 %		**1.98**	-	-	-	-	-	-
90 %		**1.98**	-	-	-	-	-	-
None	R2 stream (maize as a surrogate for spring cereals)	**2.00**	**1.74**	**1.74**	-	0.84	0.45	0.79
50 %		**1.89**	**1.74**	-	-	-	-	-
75 %		**1.74**	-	-	-	-	-	-
90 %		**1.74**	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	**2.11**	**1.01**	**1.01**	-	0.89	0.47	0.47
50 %		**1.99**	**1.01**	-	-	-	-	-
75 %		**1.01**	-	-	-	-	-	-
90 %		**1.01**	-	-	-	-	-	-

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

In accordance with the EFSA Journal 2016;14(4):4453, endpoints used for acute risk assessment for fish, invertebrates and algae has been obtained with representative formulation hence JMD-HER 387 OD first-tier risk assessment was calculated with toxicity endpoints obtained with iodosulfuron-methyl-sodium.

The higher tier risk assessment endpoints in EFSA Journal 2016;14(4):4453 are:
- 0.27 µg/L (NOEAEC based on measured initial test concentration) with AF of 3 resulting in RAC = 0.09 µg/L and
- 0.16 µg/L (geomean measured concentration) with AF of 3 resulting in RAC = 0.053 µg/L.

However, in accordance with Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290) the geomean E_rC_{50} value is:
- 1.02 µg/L based on three *Lemna minor* studies (E_rC_{50}=0.00134 mg/L, E_rC_{50}=0.00108 mg as/L and E_rC_{50}=0.00074 mg as/L) with AF of 10 resulting in RAC = 1.2 µg/L and
- 1.2 µg/L based on two *Lemna minor* studies with active substance (E_rC_{50}=0.00134 mg/L and E_rC_{50}=0.00108 mg as/L) with AF of 10 resulting in RAC = 0.12 µg/L.

Above RAC = 1.2 µg/L and RAC = 0.12 µg/L were used in Step 1, 2 and 3 risk assessment as additional

endpoints. In Step 4 RAC = 0.053 µg/L based on NOEAEC (geomean measured) of 0.16 µg/L for aquatic macrophytes with AF of 3 from mesocosm studies was used.

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**	**Higher tier test**			
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna minor***	***Lemna minor***		**aquatic macrophytes**	
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	geomean EC_{50}		NOEAEC	
		100000	7790	100000	7900	152	1.08	1.02	1.2	0.27 (measured initial)	0.16 (geomean measured)
AF		100	10	100	10	10	10	10	10	3	3
RAC (µg/L)		1000	779	1000	790	15.2	0.108	0.102	0.12	0.09	0.053
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-	-	-
Step 1 & 2– winter cereals (10 g a.s./ha)											
Step 1	3.2832	0.00	0.00	0.00	0.00	0.22	**30.40**	**32.19**	**27.36**	**36.48**	**61.95**
Step 2 NEU	0.2605	0.00	0.00	0.00	0.00	0.02	**2.41**	**2.55**	**2.17**	**2.89**	**4.92**
Step 2 SEU	0.4434	0.00	0.00	0.00	0.00	0.03	**4.11**	**4.35**	**3.70**	**4.93**	**8.37**
Step 3 – winter cereals (10 g a.s./ha)											
D1/ditch	**0.5076**	0.00	0.00	0.00	0.00	0.03	**4.70**	**4.98**	**4.23**	**5.64**	**9.58**
D1/stream	**0.3177**	0.00	0.00	0.00	0.00	0.02	**2.94**	**3.11**	**2.65**	**3.53**	**5.99**
D2/ditch	**0.7067**	0.00	0.00	0.00	0.00	0.05	**6.54**	**6.93**	**5.89**	**7.85**	**13.33**
D2/stream	**0.4504**	0.00	0.00	0.00	0.00	0.03	**4.17**	**4.42**	**3.75**	**5.00**	**8.50**
D3/ditch	**0.06331**	0.00	0.00	0.00	0.00	0.00	0.59	0.62	0.53	0.70	**1.19**
D4/pond	0.002186	0.00	0.00	0.00	0.00	0.00	0.02	0.02	0.02	0.02	0.04

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants	Higher tier test			
D4/stream	0.04684	0.00	0.00	0.00	0.00	0.00	0.43	0.46	0.39	0.52	0.88
D5/pond	0.002187	0.00	0.00	0.00	0.00	0.00	0.02	0.02	0.02	0.02	0.04
D5/stream	0.05025	0.00	0.00	0.00	0.00	0.00	0.47	0.49	0.42	0.56	0.95
~~D6/ditch~~	~~**0.06394**~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.59~~	~~0.63~~	~~0.53~~	~~0.71~~	~~**1.21**~~
R1/pond	0.002187	0.00	0.00	0.00	0.00	0.00	0.02	0.02	0.02	0.02	0.04
R1/stream	0.04889	0.00	0.00	0.00	0.00	0.00	0.45	0.48	0.41	0.54	0.92
R3/stream	**0.05864**	0.00	0.00	0.00	0.00	0.00	0.54	0.57	0.49	0.65	**1.11**
R4/stream	0.04135	0.00	0.00	0.00	0.00	0.00	0.38	0.41	0.34	0.46	0.78
Step 1 & 2 – spring cereals (10 g a.s./ha)											
Step 1	3.2832	0.00	0.00	0.00	0.00	0.22	**30.40**	**32.19**	**27.36**	**36.48**	**61.95**
Step 2 NEU	0.2605	0.00	0.00	0.00	0.00	0.02	**2.41**	**2.55**	**2.17**	**2.89**	**4.92**
Step 2 SEU	0.4434	0.00	0.00	0.00	0.00	0.03	**4.11**	**4.35**	**3.70**	**4.93**	**8.37**
Step 3 – spring cereals (10 g a.s./ha)											
~~D1/ditch~~	~~**0.06455**~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.60~~	~~0.63~~	~~0.54~~	~~0.72~~	~~**1.22**~~
~~D1/stream~~	~~**0.05610**~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.00~~	~~0.52~~	~~0.55~~	~~0.47~~	~~0.62~~	~~**1.06**~~
D3/ditch	**0.06337**	0.00	0.00	0.00	0.00	0.00	0.59	0.62	0.53	0.70	**1.20**
D4/pond	0.002188	0.00	0.00	0.00	0.00	0.00	0.02	0.02	0.02	0.02	0.04
D4/stream	0.05185	0.00	0.00	0.00	0.00	0.00	0.48	0.51	0.43	0.58	0.98
D5/pond	0.002187	0.00	0.00	0.00	0.00	0.00	0.02	0.02	0.02	0.02	0.04
D5/stream	0.05035	0.00	0.00	0.00	0.00	0.00	0.47	0.49	0.42	0.56	0.95
R4/stream	**0.2027**	0.00	0.00	0.00	0.00	0.01	**1.88**	**1.99**	**1.69**	**2.25**	**3.82**
Step 3 – maize as a surrogate for spring cereals (10 g a.s./ha)											
D6/ditch	0.05215	0.00	0.00	0.00	0.00	0.00	0.48	0.51	0.43	0.58	0.98
R1/pond	0.004681	0.00	0.00	0.00	0.00	0.00	0.04	0.05	0.04	0.05	0.09

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Higher plants	Higher tier test			
R1/stream	0.03639	0.00	0.00	0.00	0.00	0.00	0.34	0.36	0.30	0.40	0.69
R2/stream	0.04877	0.00	0.00	0.00	0.00	0.00	0.45	0.48	0.41	0.54	0.92
R3/stream	0.05129	0.00	0.00	0.00	0.00	0.00	0.47	0.50	0.43	0.57	0.97

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

Table 9.5-14: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium based on FOCUS Step 4 calculations and toxicity data for *Aquatic macrophytes* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in winter cereals

Intended use		winter cereals						
Active substance		iodosulfuron-methyl-sodium						
Application rate (g as/ha)		10						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	**0.5076**	**0.5076**	0.5076	-	**0.5076**	0.5076	0.5076
50 %		**0.5076**	**0.5076**	-	-	**0.5076**	-	-
75 %		**0.5076**	-	-	-	-	-	-
90 %		**0.5076**	-	-	-	-	-	-
None	D1 stream	**0.3177**	**0.3177**	**0.3177**	-	**0.3177**	**0.3177**	**0.3177**
50 %		**0.3177**	**0.3177**	-	-	**0.3177**	-	-
75 %		**0.3177**	-	-	-	-	-	-
90 %		**0.3177**	-	-	-	-	-	-
None	D2 ditch	**0.7067**	**0.7067**	**0.7067**	-	**0.7067**	**0.7067**	**0.7067**
50 %		**0.7067**	**0.7067**		-	**0.7067**	-	-
75 %		**0.7067**	-		-	-	-	-
90 %		**0.7067**	-		-	-	-	-
None	D2 stream	**0.4504**	**0.4504**	**0.4504**	-	**0.4504**	**0.4504**	**0.4504**
50 %		**0.4504**	**0.4504**		-	**0.4504**	-	-
75 %		**0.4504**	-	-	-	-	-	-
90 %		**0.4504**	-	-	-	-	-	-
None	D3 ditch	**0.06331**	0.01716	0.009104	-	0.01716	0.009104	0.009104
50 %		0.03854	0.008582	-	-	0.008582	-	-
75 %		0.01926	-	-	-	-	-	-
90 %		0.007704	-	-	-	-	-	-
None	D4 pond	0.002186	0.001892	0.001360	-	0.001892	0.001360	0.001360
50 %		0.001765	0.000946	-	-	0.000946	-	-
75 %		0.04019	-	-	-	-	-	-
90 %		0.000353	-	-	-	-	-	-
None	D4 stream	0.04684	0.01711	0.009076	-	0.01711	0.009076	0.009076
50 %		0.03840	0.008557	-	-	0.008557	-	-
75 %		0.01920	-	-	-	-	-	-
90 %		0.007681	-	-	-	-	-	-

None	D5 pond	0.002187	0.001892	0.001360	-	0.001892	0.001360	0.001360
50 %		0.001766	0.000946	-	-	0.000946	-	-
75 %		0.000883	-	-	-	-	-	-
90 %		0.000353	-	-	-	-	-	-
None	D5 stream	0.05025	0.01836	0.009737	-	0.01836	0.009737	0.009737
50 %		0.04120	0.009181	-	-	0.009181	-	-
75 %		0.02060	-	-	-	-	-	-
90 %		0.008241	-	-	-	-	-	-
None	D6 ditch	**0.06394**	0.02852	0.02852	-	0.02852	0.02852	0.02852
50 %		0.03892	0.02852	-	-	0.02852	-	-
75 %		0.02852	-	-	-	-	-	-
90 %		0.02852	-	-	-	-	-	-
None	R1 pond	0.002187	0.001955	0.001360	-	0.001892	0.001360	0.001360
50 %		0.001884	0.001424	-	-	0.000946	-	-
75 %		0.001389	-	-	-	-	-	-
90 %		0.001092	-	-	-	-	-	-
None	R1 stream	0.04889	0.04889	0.008089	-	0.01525	0.008089	0.02013
50 %		0.04889	0.04889	-	-	0.007627	-	-
75 %		0.04889	-	-	-	-	-	-
90 %		0.04889	-	-	-	-	-	-
None	R3 stream	**0.05864**	0.02839	0.01136	-	0.02142	0.01136	0.01296
50 %		0.04808	0.02839	-	-	0.01405	-	-
75 %		0.02839	-	-	-	-	-	-
90 %		0.02839	-	-	-	-	-	-
None	R4 stream	0.04135	0.01510	0.008012	-	0.01510	0.008012	0.008012
50 %		0.03390	0.007554	-	-	0.007554	-	-
75 %		0.01695	-	-	-	-	-	-
90 %		0.006780	-	-	-	-	-	-
RAC (µg/L) 0.053		**PEC/RAC ratio**						
None	D1 ditch	**9.58**	**9.58**	**9.58**	-	**9.58**	**9.58**	**9.58**
50 %		**9.58**	**9.58**	-	-	**9.58**	-	-
75 %		**9.58**	-	-	-	-	-	-
90 %		**9.58**	-	-	-	-	-	-
None	D1 stream	**5.99**	**5.99**	**5.99**	-	**5.99**	**5.99**	**5.99**
50 %		**5.99**	**5.99**	-	-	**5.99**	-	-
75 %		**5.99**	-	-	-	-	-	-
90 %		**5.99**	-	-	-	-	-	-
None	D2 ditch	**13.33**	**13.33**	**13.33**	-	**13.33**	**13.33**	**13.33**

50 %		**13.33**	**13.33**	-	-	**13.33**	-	-
75 %		**13.33**	-	-	-	-	-	-
90 %		**13.33**	-	-	-	-	-	-
None	D2 stream	**8.50**	**8.50**	**8.50**	-	**8.50**	**8.50**	**8.50**
50 %		**8.50**	**8.50**	-	-	**8.50**	-	-
75 %		**8.50**	-	-	-	-	-	-
90 %		**8.50**	-	-	-	-	-	-
None	D3 ditch	**1.19**	0.32	0.17	-	0.32	0.17	0.17
50 %		0.73	0.16	-	-	0.16	-	-
75 %		0.36	-	-	-	-	-	-
90 %		0.15	-	-	-	-	-	-
None	D4 pond	0.04	0.04	0.03	-	0.04	0.03	0.03
50 %		0.03	0.02	-	-	0.02	-	-
75 %		0.76	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D4 stream	0.88	0.32	0.17	-	0.32	0.17	0.17
50 %		0.72	0.16	-	-	0.16	-	-
75 %		0.36	-	-	-	-	-	-
90 %		0.14	-	-	-	-	-	-
None	D5 pond	0.04	0.04	0.03	-	0.04	0.03	0.03
50 %		0.03	0.02	-	-	0.02	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D5 stream	0.95	0.35	0.18	-	0.35	0.18	0.18
50 %		0.78	0.17	-	-	0.17	-	-
75 %		0.39	-	-	-	-	-	-
90 %		0.16	-	-	-	-	-	-
None	D6 ditch	**1.21**	0.54	0.54	-	0.54	0.54	0.54
50 %		0.73	0.54	-	-	0.54	-	-
75 %		0.54	-	-	-	-	-	-
90 %		0.54	-	-	-	-	-	-
None	R1 pond	0.04	0.04	0.03	-	0.04	0.03	0.03
50 %		0.04	0.03	-	-	0.02	-	-
75 %		0.03	-	-	-	-	-	-
90 %		0.02	-	-	-	-	-	-
None	R1 stream	0.92	0.92	0.15	-	0.29	0.15	0.38
50 %		0.92	0.92	-	-	0.14	-	-
75 %		0.92	-	-	-	-	-	-
90 %		0.92	-	-	-	-	-	-

None	R3 stream	**1.11**	0.54	0.21	-	0.40	0.21	0.24
50 %		0.91	0.54	-	-	0.27	-	-
75 %		0.54	-	-	-	-	-	-
90 %		0.54	-	-	-	-	-	-
None	R4 stream	0.78	0.28	0.15	-	0.28	0.15	0.15
50 %		0.64	0.14	-	-	0.14	-	-
75 %		0.32	-	-	-	-	-	-
90 %		0.13	-	-	-	-	-	-

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: PEC calculation and acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium based on FOCUS Step 4 calculations and toxicity data for *Aquatic macrophytes* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in spring cereals

Intended use		spring cereals						
Active substance		iodosulfuron-methyl-sodium						
Application rate (g as/ha)		10						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	**0.06455**	0.01780	0.009632	-	0.01780	0.009632	0.009632
50 %		0.03945	0.009103	-	-	0.009103	-	-
75 %		0.01992	-	-	-	-	-	-
90 %		0.008214	-	-	-	-	-	-
None	D1 stream	**0.05610**	0.02050	0.01087	-	0.02050	0.01087	0.01087
50 %		0.04600	0.01025	-	-	0.01025	-	-
75 %		0.02300	-	-	-	-	-	-
90 %		0.009201	-	-	-	-	-	-
None	D3 ditch	**0.06337**	0.01718	0.009112	-	0.01718	0.009112	0.009112
50 %		0.03857	0.008589	-	-	0.008589	-	-
75 %		0.02300	-	-	-	-	-	-
90 %		0.009201	-	-	-	-	-	-
None	D4 pond	0.002188	0.001893	0.001361	-	0.001893	0.001361	0.001361
50 %		0.001766	0.000946	-	-	0.000946	-	-
75 %		0.000883	-	-	-	-	-	-
90 %		0.000353	-	-	-	-	-	-
None	D4 stream	0.05185	0.01894	0.01005	-	0.01894	0.01005	0.01005
50 %		0.04251	0.009472	-	-	0.009472	-	-
75 %		0.02126	-	-	-	-	-	-
90 %		0.008503	-	-	-	-	-	-

None	D5 pond	0.002187	0.001892	0.001360	-	0.001892	0.001360	0.001360
50 %		0.001766	0.000946	-	-	0.000946	-	-
75 %		0.000883	-	-	-	-	-	-
90 %		0.000353	-	-	-	-	-	-
None	D5 stream	0.05035	0.01840	0.009756	-	0.01840	0.009756	0.009756
50 %		0.04129	0.009199	-	-	0.009199	-	-
75 %		0.02064	-	-	-	-	-	-
90 %		0.008257	-	-	-	-	-	-
None	R4 stream	**0.2027**	**0.2027**	0.2027	-	0.01532	0.008124	0.09149
50 %		**0.2027**	0.2027	-	-	0.008335	-	-
75 %		0.2027	-	-	-	-	-	-
90 %		0.2027	-	-	-	-	-	-
None	D6 ditch (maize as a surrogate for spring cereals)	0.05215	0.01709	0.009066	-	0.01709	0.009066	0.009066
50 %		0.03838	0.008546	-	-	0.008546	-	-
75 %		0.01918	-	-	-	-	-	-
90 %		0.007672	-	-	-	-	-	-
None	R1 pond (maize as a surrogate for spring cereals)	0.004681	0.004547	0.004230	-	0.001893	0.001361	0.002200
50 %		0.004471	0.003983	-	-	0.001308	-	-
75 %		0.003945	-	-	-	-	-	-
90 %		0.003630	-	-	-	-	-	-
None	R1 stream (maize as a surrogate for spring cereals)	0.03639	0.02983	0.02983	-	0.01532	0.008126	0.01358
50 %		0.03438	0.02983	-	-	0.007661	-	-
75 %		0.02983	-	-	-	-	-	-
90 %		0.02983	-	-	-	-	-	-
None	R2 stream (maize as a surrogate for spring cereals)	0.04877	0.02310	0.02310	-	0.02053	0.01089	0.01089
50 %		0.04609	0.02310	-	-	0.01027	-	-
75 %		0.02310	-	-	-	-	-	-
90 %		0.02310	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	0.05129	0.02159	0.01665	-	0.02159	0.01145	0.01145
50 %		0.04846	0.01665	-	-	0.01080	-	-
75 %		0.02423	-	-	-	-	-	-
90 %		0.01665	-	-	-	-	-	-
RAC (µg/L) 0.053		**PEC/RAC ratio**						
None	D1 ditch	**1.22**	0.34	0.18	-	0.34	0.18	0.18
50 %		0.74	0.17	-	-	0.17	-	-
75 %		0.38	-	-	-	-	-	-
90 %		0.15	-	-	-	-	-	-
None	D1 stream	**1.06**	0.39	0.21	-	0.39	0.21	0.21

50 %		0.87	0.19	-	-	0.19	-	-
75 %		0.43	-	-	-	-	-	-
90 %		0.17	-	-	-	-	-	-
None	D3 ditch	**1.20**	0.32	0.17	-	0.32	0.17	0.17
50 %		0.73	0.16	-	-	0.16	-	-
75 %		0.43	-	-	-	-	-	-
90 %		0.17	-	-	-	-	-	-
None	D4 pond	0.04	0.04	0.03	-	0.04	0.03	0.03
50 %		0.03	0.02	-	-	0.02	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D4 stream	0.98	0.36	0.19	-	0.36	0.19	0.19
50 %		0.80	0.18	-	-	0.18	-	-
75 %		0.40	-	-	-	-	-	-
90 %		0.16	-	-	-	-	-	-
None	D5 pond	0.04	0.04	0.03	-	0.04	0.03	0.03
50 %		0.03	0.02	-	-	0.02	-	-
75 %		0.02	-	-	-	-	-	-
90 %		0.01	-	-	-	-	-	-
None	D5 stream	0.95	0.35	0.18	-	0.35	0.18	0.18
50 %		0.78	0.17	-	-	0.17	-	-
75 %		0.39	-	-	-	-	-	-
90 %		0.16	-	-	-	-	-	-
None	R4 stream	**3.82**	**3.82**	**3.82**	-	0.29	0.15	**1.73**
50 %		**3.82**	**3.82**	-	-	0.16	-	-
75 %		**3.82**	-	-	-	-	-	-
90 %		**3.82**	-	-	-	-	-	-
None	D6 ditch (maize as a surrogate for spring cereals)	0.98	0.32	0.17	-	0.32	0.17	0.17
50 %		0.72	0.16	-	-	0.16	-	-
75 %		0.36	-	-	-	-	-	-
90 %		0.14	-	-	-	-	-	-
None	R1 pond (maize as a surrogate for spring cereals)	0.09	0.09	0.08	-	0.04	0.03	0.04
50 %		0.08	0.08	-	-	0.02	-	-
75 %		0.07	-	-	-	-	-	-
90 %		0.07	-	-	-	-	-	-
None	R1 stream (maize as a surrogate for spring cereals)	0.69	0.56	0.56	-	0.29	0.15	0.26
50 %		0.65	0.56	-	-	0.14	-	-
75 %		0.56	-	-	-	-	-	-
90 %		0.56	-	-	-	-	-	-

None	R2 stream (maize as a surrogate for spring cereals)	0.92	0.44	0.44	-	0.39	0.21	0.21
50 %		0.87	0.44	-	-	0.19	-	-
75 %		0.44	-	-	-	-	-	-
90 %		0.44	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	0.97	0.41	0.31	-	0.41	0.22	0.22
50 %		0.91	0.31	-	-	0.20	-	-
75 %		0.46	-	-	-	-	-	-
90 %		0.31	-	-	-	-	-	-

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) AE F075736 for each organism group based on FOCUS Step 1, 2 and 3 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inver-teb. acute**	**Inver-teb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		-	-	-	-	-	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	-	-	0.57	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	-	-	0.057	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1 & 2– winter cereals (10 g a.s./ha)									
Step 1	3.7303	-	-	-	-	-	-	**65.44**	-
Step 2 NEU	0.4337	-	-	-	-	-	-	**7.61**	-
Step 2 SEU	0.8240	-	-	-	-	-	-	**14.46**	-
Step 3 – winter cereals (10 g a.s./ha)									
D1/ditch	**0.3600**							**6.32**	
D1/stream	**0.2417**	-	-	-	-	-	-	**4.24**	-
D2/ditch	**0.5219**	-	-	-	-	-	-	**9.16**	-
D2/stream	**0.3973**	-	-	-	-	-	-	**6.97**	-
D3/ditch	0.01942	-	-	-	-	-	-	0.34	-
D4/pond	0.04019	-	-	-	-	-	-	0.71	-
D4/stream	0.02139	-	-	-	-	-	-	0.38	-
D5/pond	0.007938	-	-	-	-	-	-	0.14	-
D5/stream	0.004277	-	-	-	-	-	-	0.08	-
D6/ditch	**0.1688**							**2.96**	
R1/pond	0.000386	-	-	-	-	-	-	0.01	-

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
R1/stream	0.02187	-	-	-	-	-	-	0.38	-
R3/stream	0.03323	-	-	-	-	-	-	0.58	-
R4/stream	0.000113	-	-	-	-	-	-	0.00	-
Step 1 & 2– spring cereals (10 g a.s./ha)									
Step 1	3.7303	-	-	-	-	-	-	**65.44**	-
Step 2 NEU	0.4337	-	-	-	-	-	-	**7.61**	-
Step 2 SEU	0.8240	-	-	-	-	-	-	**14.46**	-
Step 3 – spring cereals (10 g a.s./ha)									
D1/ditch	0.05407	-	-	-	-	-	-	0.95	-
D1/stream	0.03806	-	-	-	-	-	-	0.67	-
D3/ditch	0.02329	-	-	-	-	-	-	0.41	-
D4/pond	0.04483	-	-	-	-	-	-	0.79	-
D4/stream	0.02312	-	-	-	-	-	-	0.41	-
D5/pond	0.008192	-	-	-	-	-	-	0.14	-
D5/stream	0.004291	-	-	-	-	-	-	0.08	-
R4/stream	**0.05845**	-	-	-	-	-	-	**1.03**	-
Step 3 – maize as a surrogate for spring cereals (10 g a.s./ha)									
D6/ditch	0.004222	-	-	-	-	-	-	0.07	-
R1/pond	0.003329	-	-	-	-	-	-	0.06	-
R1/stream	0.02873	-	-	-	-	-	-	0.50	-
R2/stream	**0.06243**	-	-	-	-	-	-	**1.10**	-
R3/stream	**0.06214**	-	-	-	-	-	-	**1.09**	-

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: PEC calculation and acceptability of risk (PEC/RAC < 1) for AE F075736 based on FOCUS Step 4 calculations and toxicity data for *Lemna gibba* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in winter cereals

Intended use		winter cereals						
Active substance		AE F075736						
Application rate (g as/ha)		10						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	D1 ditch	0.3600	0.3600	0.3600	-	0.3600	0.3600	0.3600
50 %		0.3600	0.3600	-	-	0.3600	-	-
75 %		0.3600	-	-	-	-	-	-

90 %		0.3600	-	-	-	-	-	-
None	D1 stream	0.2417	0.2417	0.2417	-	0.2417	0.2417	0.2417
50 %		0.2417	0.2417	-	-	0.2417	-	-
75 %		0.2417	-	-	-	-	-	-
90 %		0.2417	-	-	-	-	-	-
None	D2 ditch	0.5219	0.5219	0.5219	-	0.5219	0.5219	0.5219
50 %		0.5219	0.5219	-	-	-	-	-
75 %		0.5219	-	-	-	-	-	-
90 %		0.5219	-	-	-	-	-	-
None	D2 stream	0.3973	0.3973	0.3973	-	0.3973	0.3973	0.3973
50 %		0.3973	0.3973	-	-	0.3973	-	-
75 %		0.3973	-	-	-	-	-	-
90 %		0.3973	-	-	-	-	-	-
None	D6 ditch	0.1688	0.1688	0.1688	-	0.1688	0.1688	0.1688
50 %		0.1688	0.1688	-	-	0.1688	-	-
75 %		0.1688	-	-	-	-	-	-
90 %		0.1688	-	-	-	-	-	-
RAC (µg/L) 0.057		**PEC/RAC ratio**						
None	D1 ditch	**6.32**	**6.32**	**6.32**	-	**6.32**	**6.32**	**6.32**
50 %		**6.32**	**6.32**	-	-	**6.32**	-	-
75 %		**6.32**	-	-	-	-	-	-
90 %		**6.32**	-	-	-	-	-	-
None	D1 stream	**4.24**	**4.24**	**4.24**	-	**4.24**	**4.24**	**4.24**
50 %		**4.24**	**4.24**	-	-	**4.24**	-	-
75 %		**4.24**	-	-	-	-	-	-
90 %		**4.24**	-	-	-	-	-	-
None	D2 ditch	**9.16**	**9.16**	**9.16**	-	**9.16**	**9.16**	**9.16**
50 %		**9.16**	**9.16**	-	-	**9.16**	-	-
75 %		**9.16**	-	-	-	-	-	-
90 %		**9.16**	-	-	-	-	-	-
None	D2 stream	**6.97**	**6.97**	**6.97**	-	**6.97**	**6.97**	**6.97**
50 %		**6.97**	**6.97**	-	-	**6.97**	-	-
75 %		**6.97**	-	-	-	-	-	-
90 %		**6.97**	-	-	-	-	-	-
None	D6 ditch	**2.96**	**2.96**	**2.96**	-	**2.96**	**2.96**	**2.96**
50 %		**2.96**	**2.96**	-	-	**2.96**	-	-
75 %		**2.96**	-	-	-	-	-	-
90 %		**2.96**	-	-	-	-	-	-

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

Table 9.5-18: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for AE F075736 based on FOCUS Step 4 calculations and toxicity data for *Lemna gibba* with mitigation of spray drift and run-off for the use of JMD-HER 387 OD in spring cereals

Intended use		spring cereals						
Active substance		AE F075736						
Application rate (g as/ha)		10						
Nozzle reduction	**Vegetated filter strip (m)**	None	None	None	None	5 VFSmod	10 VFSmod	10-12
	No-spray buffer (m)	1/3	5	10	20	5	10	10
None	R4 stream	0.05845	0.05845	0.05845	-	0.000571	0.000309	0.02639
50 %		0.05845	0.05845	-	-	0.000571	-	-
75 %		0.05845	-	-	-	-	-	-
90 %		0.05845	-	-	-	-	-	-
None	R2 stream (maize as a surrogate for spring cereals)	0.06243	0.06243	0.06243	-	0.000002	0.000001	0.02833
50 %		0.06243	0.06243	-	-	0.000002	-	-
75 %		0.06243	-	-	-	-	-	-
90 %		0.06243	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	0.06214	0.06214	0.06214	-	0.01731	0.000001	0.02834
50 %		0.06214	0.06214	-	-	0.01731	-	-
75 %		0.06214	-	-	-	-	-	-
90 %		0.06214	-	-	-	-	-	-
RAC (µg/L)		**PEC/RAC ratio**						
0.057								
None	R4 stream	**1.03**	**1.03**	**1.03**	-	0.01	0.01	0.46
50 %		**1.03**	**1.03**	-	-	0.01	-	-
75 %		**1.03**	-	-	-	-	-	-
90 %		**1.03**	-	-	-	-	-	-
None	R2 stream (maize as a surrogate for spring cereals)	**1.1**	**1.1**	**1.1**	-	0.00	0.00	0.50
50 %		**1.1**	**1.1**	-	-	0.00	-	-
75 %		**1.1**	-	-	-	-	-	-
90 %		**1.1**	-	-	-	-	-	-
None	R3 stream (maize as a surrogate for spring cereals)	**1.09**	**1.09**	**1.09**	-	0.30	0.00	0.50
50 %		**1.09**	**1.09**	-	-	0.30	-	-
75 %		**1.09**	-	-	-	-	-	-
90 %		**1.09**	-	-	-	-	-	-

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: acceptability of risk (PEC/RAC < 1) for AE 1234964 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		***On-corhyn-chus mykiss***	-	***Daphnia magna***	-	-	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	-
		100000	-	100000	-	-	-	100000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		1000	-	1000	-	-	-	10000	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.0964	0.00	-	0.00	-	-	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.0964	0.00	-	0.00	-	-	-	0.00	-

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

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AE F159737 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		***On-corhyn-chus mykiss***	-	***Daphnia magna***	-	-	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		100000	-	100000	-	-	-	100000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		1000	-	1000	-	-	-	10000	-
FOCUS Scenario	-	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.0925	0.00	-	0.00	-	-	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.0925	0.00	-	0.00	-	-	-	0.00	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant

trigger of 1 are shown in bold

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE F059411 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		-	-	***Daphnia magna***	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	100000	-	100000	-	100000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	1000	-	10000	-	10000	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1 – spring cereals (10 g a.s./ha)									
-	0.5756	-	-	0.00	-	0.00	-	0.00	-
Step 1 – winter cereals (10 g a.s./ha)									
-	0.5756	-	-	0.00	-	0.00	-	0.00	-

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

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE F145741 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		-	-	-	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	10000	-	3840	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	1000	-	384	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.4920	-	-	-	-	0.00	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.4920	-	-	-	-	0.00	-	0.00	-

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

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE F145740 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Test species		-	-	-	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	10000	-	10000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	1000	-	1000	-
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.6570	-	-	-	-	0.00	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.6570	-	-	-	-	0.00	-	0.00	-

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

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AE 0002166 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group	Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Test species	-	-	-	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	-
		-	-	-	-	10000	-	23	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	1000	-	2.3	-
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	1.1460	-	-	-	-	0.00	-	0.50	-
Step 1– winter cereals (10 g a.s./ha)									
-	1.1460	-	-	-	-	0.00	-	0.50	-

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

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE F161778 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Test species		-	-	-	-	***Pseudo-kirchneri-ella sub-capitata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	10000	-	28.1	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	1000	-	2.81	-
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.3821	-	-	-	-	0.00	-	0.14	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.3821	-	-	-	-	0.00	-	0.14	-

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

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) BCS-CW81253 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		-	-	-	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	10000	-	10000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	1000	-	1000	-
FOCUS Sce-nario	**PEC gl-max (µg/L)**	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.7189	-	-	-	-	0.00	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.7189	-	-	-	-	0.00	-	0.00	-

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

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE F154781 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. pro-longed**	**Higher plants**	**-**
Test species		-	-	-	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	10000	-	10000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	1000	-	1000	-
FOCUS Sce-nario	**PEC gl-max (µg/L)**	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.0710	-	-	-	-	0.00	-	0.00	-

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.0710	-	-	-	-	0.00	-	0.00	-

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

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE 0000119 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Test species		-	-	-	-	-	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	-	-	100000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	-	-	10000	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.4549	-	-	-	-	0.00	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.4549	-	-	-	-	0.00	-	0.00	-

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

Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE 0014966 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Test species		-	-	-	-	-	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	-	-	575	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	-	-	57.5	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**	-	-	-	-	-	-	-	-

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.3684	-	-	-	-	-	-	0.01	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.3684	-	-	-	-	-	-	0.01	-

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

Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) AE 0034855 for each organism group based on FOCUS Step 1 calculations for the use of JMD-HER 387 OD in spring cereals and winter cereals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed	Higher plants	-
Test species		-	-	-	-	***Pseudo-kirch-neriella subcapi-tata***	-	***Lemna gibba***	-
Endpoint (µg/L)		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	-
		-	-	-	-	-	-	100000	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		-	-	-	-	-	-	10000	-
FOCUS Sce-nario	**PEC $_{gl-max}$ (µg/L)**	-	-	-	-	-	-	-	-
Step 1– spring cereals (10 g a.s./ha)									
-	0.2648	-	-	-	-	-	-	0.00	-
Step 1– winter cereals (10 g a.s./ha)									
-	0.2648	-	-	-	-	-	-	0.00	-

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

Mixture toxicity

Mixture toxicity evaluation has been performed in accordance with point 2.5 of Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290). The evaluation was based on calculated toxicity for fish, invertebrates, algae and macrophytes. Calculation were performed with "AGD_AquaMix_v1.15" tool.

Input values for each species are presented below. In case of fish no studies were available for formulation while studies available for active substances were performed for different species of fishes. Nonetheless, mixture toxicity was calculated and used for risk assessment. In Tier I for algae and macrophytes the same species were used i.e. *Pseudokirchneriella subcapitata* and *Lemna minor,* in order to get reliable results of comparison of toxicity calculated and measured. However, additional data i.e. the most sensitive species (*Skeletonema costatum* and *Myriophyllum spicatum*) were taken into account as well. The print screens of input values and in-between calculations including $EC_{xmix\text{-}CA,}$ EC_{xPPP} and MDR are provided below. For each organism separate evaluation has been performed.

Product data	
Product name	**JMD-HER 387 OD**
Density of product [g/cm^3]	1.04
LC_{50}fish [mg prod./L]	
LC_{50}fish a.s. based [mg sum of a.s/L]	
EC_{50}invertrebrates [mg prod./L]	100
LC_{50}invertrebrates a.s. based [mg sum of a.s/L]	37.2115
EC_{50}algae [mg prod./L]	9.207
EC_{50}algae a.s. based [mg sum of a.s/L]	3.4261
EC_{50}macrophytes [mg prod./L]	1.054
EC_{50}macrophytes a.s. based [mg sum of a.s/L]	0.3922

Calculated mixture toxicity (Eq. 13) based on Tier 1 data only	[mg/L]
$ECx_{mix\text{-}Ca}$fish	100
$ECx_{mix\text{-}Ca}$invertrebrates	133.0244352
$ECx_{mix\text{-}Ca}$algae	5.479816172
$ECx_{mix\text{-}Ca}$macrophytes	0.041699037

Calculated mixture toxicity (Eq. 13) based also on additional data	[mg/L]
$ECx_{mix\text{-}Ca}$fish	100
$ECx_{mix\text{-}Ca}$invertrebrates	133.0244352
$ECx_{mix\text{-}Ca}$algae	0.623991015
$ECx_{mix\text{-}Ca}$macrophytes	0.008890015

Options

Hide Species

Unlock sum of a.s. for product data

Active Substance (a.s.) standard data (Tier 1 EP)								
Active substance names		**2,4D**		**iodosulfuron**				
Concentration in Product [g a.s./L or g a.s./kg]	2,4D	377	iodosulfuron	10				
p(X) (fraction in product)	Species	0.97	Species	0.03	Species		Species	
LC_{50}fish [mg a.s./L]	*Pimephales promelas*	100	*Oncorhynchus mykiss*	100				
LC_{50}invertrebrates [mg a.s./L]	*Daphnia magna*	134.2	*Daphnia magna*	100				
EC_{50}algae [mg a.s./L]	*Pseudokirchneriella*	78	*Pseudokirchneriella*	0.152				
EC_{50}macrophytes [mg a.s./L]	*Lemna minor*	17.51	*Lemna minor*	0.00108				
Additional a.s. data (i.e. most sensitive species tested as Tier 1 data or refinements Tier 2A/B EP)								
LC_{50}fish [mg a.s./L]								
LC_{50}invertrebrates [mg a.s./L]								
EC_{50}algae [mg a.s./L]	*Skeletonema*	0.68						
EC_{50}macrophytes [mg a.s./L]	*Myriophyllum*	0.011						
AF for RAC								
Fish	Pimephales promelas	100	Oncorhynchus mykiss	100		100		100
Invertrebrates	Daphnia magna	100	Daphnia magna	100		100		100
Algae	Skeletonema	10	Pseudokirchneriella	10		10		10
Macrophytes	Myriophyllum	10	Lemna minor	10		10		10
RAC								
Fish	Pimephales promelas	1	Oncorhynchus mykiss	1				
Invertrebrates	Daphnia magna	1.342	Daphnia magna	1				
Algae	Skeletonema	0.068	Pseudokirchneriella	0.0152				
Macrophytes	Myriophyllum	0.0011	Lemna minor	0.000108				

Data used for calculation (after Step 3)								
Active substances		**2,4D**		**iodosulfuron**				
Concentration in Product [g a.s./L]	2,4D	377	iodosulfuron	10				
p(X) (fraction in product)	Species	0.97	Species	0.03	Species		Species	
LC_{50}fish [mg a.s./L]	Pimephales promelas	100	Oncorhynchus mykiss	100				
LC_{50}invertrebrates [mg a.s./L]	Daphnia magna	134.2	Daphnia magna	100				
EC_{50}algae [mg a.s./L]	Skeletonema	0.68	Pseudokirchneriella	0.152				
EC_{50}macrophytes [mg a.s./L]	Myriophyllum	0.011	Lemna minor	0.00108				

Species	Substance	Concentration (C_i) in formulation (g a.s./L)	P_i	ECxi (mg a.s./L)	ECx_{mix-CA} (mg sum a.s. /L)	ECx_{PPP} (mg sum a.s. /L)	MDR
Fish, acute toxicity							
Pimephales promelas	2,4D	377	0.97	100	100.00		
Oncorhynchus mykiss	iodosulfuron	10	0.03	100			
Invertebrates, acute toxicity							
Daphnia magna	2,4D	377	0.97	134.2	133.02	37.21153846	3.57
Daphnia magna	iodosulfuron	10	0.03	100			
Skeletonema	2,4D	377	0.97	78	5.48	3.426066346	1.60
Pseudokirchneriella	iodosulfuron	10	0.03	0.152			
Macrophytes							
Myriophyllum	2,4D	377	0.97	17.51	0.04	0.392209615	0.11
Lemna minor	iodosulfuron	10	0.03	0.00108			

Fishes – combined risk assessment

The formulation studies for are not available so fishes combined risk assessment was based on the calculated mixture toxicity since formulation studies are not available. It was assumed that 2,4-D and iodosulfuron-methyl-sodium does not have synergistic or antagonistic effect, so mixture toxicity calculation is feasible. $ETR_{mix\text{-}CA}$ values calculated in Step 8 were below the relevant trigger indicating acceptable risk for all scenarios. The print-screens for winter and spring cereals with $ETR_{mix\text{-}CA}$ values are below.

Invertebrates – combined risk assessment

The formulation studies for invertebrates are available and MDR and $EC_{xmix\text{-}CA}$ (a.s. in PPP)/ $EC_{xmix\text{-}CA}$ (a.s. in PEC_{mix}) were calculated. MDR value was 3.57 and $EC_{xmix\text{-}CA}$ (a.s. in PPP)/ $EC_{xmix\text{-}CA}$ (a.s. in PEC_{mix}) vales for each scenario equalled 1.0 indicating no antagonism or synergism effect and all scenarios can be assessed with formulation toxicity. $ETR_{mix\text{-}PPP}$ values calculated in Step 8 were below the relevant trigger indicating acceptable risk for all scenarios. The print-screens for winter and spring cereals with $ETR_{mix\text{-}PPP}$ values are below.

Algae – combined risk assessment

The formulation studies for algae are available and calculated MDR value was 1.60 indicating no antagonism or synergism effect and all scenarios can be assessed with formulation toxicity. Since for algae additional data i.e. study results for the most sensitive species *Skeletonema costatum* were taken into account, individual toxic units (TUs) approach was applied indicating that for D1, D2 and R1 2,4-D is a toxicity driver. Nonetheless, risk assessment for all scenarios was performed in Step 8 on the basis of RQ_{mix} as a worst case. RQ_{mix} values were below the relevant trigger indicating acceptable risk for all scenarios. The print-screens for winter and spring cereals with RQ_{mix} values are below.

Macrophytes – combined risk assessment

The formulation studies for macrophytes are available and calculated MDR value was 0.11 indicating antagonism effect hence the risk assessment for all scenarios was performed in Step 8 on the basis of RQ_{mix}. RQ_{mix} values were below the relevant trigger indicating acceptable risk for most scenarios in Step 3 or Step 4. For the other scenarios further risk mitigations are needed at national level. The print-screens for winter and spring cereals with RQ_{mix} values are below.

Print-screens for winter cereals are presented below.

Fish	
ETRmix-CA	
Step 1	0.00
Step 2	
N-Europe	0.00
S-Europe	0.00
Step 3	
D1 Ditch	0.00
D1 Stream	0.00
D2 Ditch	0.00
D2 Stream	0.00
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	0.00
R1 Pond	0.00
R1 Stream	0.00
R2 Stream	
R3 Stream	0.00
R4 Stream	0.00

Invertebrates	
RQmix	
Step 1	0.06
Step 2	
N-Europe	0.01
S-Europe	0.01
Step 3	
D1 Ditch	0.01
D1 Stream	0.01
D2 Ditch	0.02
D2 Stream	0.01
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	0.00
R1 Pond	0.00
R1 Stream	0.00
R2 Stream	
R3 Stream	0.00
R4 Stream	0.00

Algae	
RQmix	
Step 1	1.39
Step 2	
N-Europe	0.17
S-Europe	0.30
Step 3	
D1 Ditch	0.22
D1 Stream	0.14
D2 Ditch	0.36
D2 Stream	0.23
D3 Ditch	0.03
D4 Pond	0.00
D4 Stream	0.02
D5 Pond	0.00
D5 Stream	0.02
D6 Ditch	0.03
R1 Pond	0.00
R1 Stream	0.02
R2 Stream	
R3 Stream	0.03
R4 Stream	0.02

Macrophytes	
RQmix	
Step 1	102.76
Step 2	
N-Europe	11.60
S-Europe	20.78
Step 3	
D1 Ditch	16.31
D1 Stream	10.21
D2 Ditch	26.05
D2 Stream	16.69
D3 Ditch	2.03
D4 Pond	0.07
D4 Stream	1.50
D5 Pond	0.07
D5 Stream	1.61
D6 Ditch	2.06
R1 Pond	0.08
R1 Stream	1.71
R2 Stream	
R3 Stream	1.88
R4 Stream	1.32

Macrophytes										
FOCUS Step 4	Scenario	RQmix								
	Vegetative strip [m]	None	None	None	None	None	5 VFS	10 VFS	10-12	20
Nozzle reduction	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	10	20
None	D1 Ditch	16.31	16.31	16.31			16.31	16.31	16.31	
50%		16.31	16.31							
75%		16.31								
90%		16.31								
None	D1 Stream	10.21	10.21	10.21			10.21	10.21	10.21	
50%		10.21	10.21							
75%		10.21								
90%		10.21								
None	D2 Ditch	26.05	26.05	26.05			26.05	26.05	26.05	
50%		26.05	26.05							
75%		26.05								
90%		26.05								
None	D2 Stream	16.69	16.69	16.69			16.69	16.69	16.69	
50%		16.69	16.69							
75%		16.69								
90%		16.69								
None	D3 Ditch	2.03	0.55	0.29			0.55	0.29	0.29	
50%		1.23	0.27							
75%		0.62								
90%		0.25								
None	D4 Pond	0.07	0.06	0.04			0.06	0.04	0.04	
50%		0.06	0.03							
75%		0.39								
90%		0.01								
None	D4 Stream	1.50	0.55	0.29			0.55	0.29	0.29	
50%		1.23	0.27							
75%		0.61								
90%		0.25								
None	D5 Pond	0.07	0.06	0.04			0.06	0.04	0.04	
50%		0.06	0.03							
75%		0.03								
90%		0.01								
None	D5 Stream	1.61	0.59	0.31			0.59	0.31	0.31	
50%		1.32	0.29							
75%		0.66								
90%		0.26								
None	D6 Ditch	2.06	1.73	1.73			1.73	1.73	1.73	
50%		1.83	1.73							
75%		1.73								
90%		1.73								
None	R1 Pond	0.08	0.07	0.06			0.06	0.04	0.04	
50%		0.07	0.05							
75%		0.05								
90%		0.04								
None	R1 Stream	1.71	1.71	1.34			0.49	0.26	0.71	
50%		1.71	1.71							
75%		1.71								
90%		1.71								
None	R2 Stream									
50%										
75%										
90%										
None	R3 Stream	1.88	1.21	1.05			0.69	0.42	0.55	
50%		1.54	1.21							
75%		1.21								
90%		1.21								
None	R4 Stream	1.32	0.48	0.26			0.48	0.26	0.26	
50%		1.08	0.24							
75%		0.54								
90%		0.22								

Print-screens for spring cereals are presented below.

Fish	
ETRmix-CA	
Step 1	0.00
Step 2	
N-Europe	0.00
S-Europe	0.00
Step 3	
D1 Ditch	0.00
D1 Stream	0.00
D2 Ditch	
D2 Stream	
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	0.00
R1 Pond	0.00
R1 Stream	0.00
R2 Stream	0.00
R3 Stream	0.00
R4 Stream	0.00

Invertebrates	
RQmix	
Step 1	0.06
Step 2	
N-Europe	0.01
S-Europe	0.01
Step 3	
D1 Ditch	0.00
D1 Stream	0.00
D2 Ditch	
D2 Stream	
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	0.00
R1 Pond	0.00
R1 Stream	0.00
R2 Stream	0.00
R3 Stream	0.00
R4 Stream	0.00

Algae	
RQmix	
Step 1	1.39
Step 2	
N-Europe	0.17
S-Europe	0.30
Step 3	
D1 Ditch	0.03
D1 Stream	0.02
D2 Ditch	
D2 Stream	
D3 Ditch	0.03
D4 Pond	0.00
D4 Stream	0.02
D5 Pond	0.00
D5 Stream	0.02
D6 Ditch	0.02
R1 Pond	0.00
R1 Stream	0.02
R2 Stream	0.02
R3 Stream	0.02
R4 Stream	0.10

Macrophytes	
RQmix	
Step 1	102.76
Step 2	
N-Europe	11.60
S-Europe	20.78
Step 3	
D1 Ditch	2.07
D1 Stream	1.79
D2 Ditch	
D2 Stream	
D3 Ditch	2.03
D4 Pond	0.07
D4 Stream	1.66
D5 Pond	0.07
D5 Stream	1.61
D6 Ditch	1.67
R1 Pond	0.20
R1 Stream	1.43
R2 Stream	1.56
R3 Stream	1.64
R4 Stream	6.94

Macrophytes										
FOCUS Step 4	Scenario	RQmix								
	Vegetative strip [m]	None	None	None	None	None	5 VFS	10 VFS	10-12	20
Nozzle reduction	No spray buffer [m]	FOCUS default	5	10	15	20	5	10	10	20
None	D1 Ditch	**2.07**	0.58	0.31			0.58	0.31	0.31	
50%		**1.27**	0.30							
75%		0.64								
90%		0.27								
None	D1 Stream	**1.79**	0.66	0.35			0.66	0.35	0.35	
50%		**1.47**	0.33							
75%		0.74								
90%		0.29								
None	D2 Ditch									
50%										
75%										
90%										
None	D2 Stream									
50%										
75%										
90%										
None	D3 Ditch	**2.03**	0.55	0.29			0.55	0.29	0.29	
50%		**1.23**	0.27							
75%		0.65								
90%		0.26								
None	D4 Pond	0.07	0.06	0.04			0.06	0.04	0.04	
50%		0.06	0.03							
75%		0.03								
90%		0.01								
None	D4 Stream	**1.66**	0.61	0.32			0.61	0.32	0.32	
50%		**1.36**	0.30							
75%		0.68								
90%		0.27								
None	D5 Pond	0.07	0.06	0.04			0.06	0.04	0.04	
50%		0.06	0.03							
75%		0.03								
90%		0.01								
None	D5 Stream	**1.61**	0.59	0.31			0.59	0.31	0.31	
50%		**1.32**	0.29							
75%		0.66								
90%		0.26								
None	D6 Ditch	**1.67**	0.55	0.29			0.55	0.29	0.29	
50%		**1.23**	0.27							
75%		0.61								
90%		0.25								
None	R1 Pond	0.20	0.19	0.18			0.07	0.04	0.09	
50%		0.19	0.17							
75%		0.17								
90%		0.16								
None	R1 Stream	**1.43**	**1.37**	**1.37**			0.49	0.26	0.62	
50%		**1.41**	**1.37**							
75%		**1.37**								
90%		**1.37**								
None	R2 Stream	**1.56**	**1.18**	**1.18**			0.66	0.35	0.54	
50%		**1.47**	**1.18**							
75%		**1.18**								
90%		**1.18**								
None	R3 Stream	**1.64**	0.76	0.71			0.69	0.37	0.37	
50%		**1.55**	0.71							
75%		0.78								
90%		0.71								
None	R4 Stream	**6.94**	**6.94**	**6.94**			0.49	0.26	**3.13**	
50%		**6.94**	**6.94**							
75%		**6.94**								
90%		**6.94**								

The risk assessment performed for active substances, metabolites, formulation (combine risk) resulted in slightly different risk mitigations. Summary of risk mitigations and final proposal (bolded text) are included in table below. Taking summary into account it can be concluded that the main driver of aquatic toxicology is metabolite 1,2,4-benzenetriol and risk mitigations should be proposed basing on risk assessment with this compound.

Overall conclusions

PECsw/RAC values were calculated with PECsw values obtained for active substances and their metabolites calculated in Step 1, 2, 3 and 4. Most of the PECsw/RAC values were below 1 for acute and long-term risk using Step 3 and Step 4 PECsw indicating no unacceptable risk to aquatic organisms at application rate of 1 L/ha provided the appropriate risk mitigations are applied. Summary of proposed risk mitigations for each scenario are in table below.

Scenario	Winter cereals, application rate: 1 L/ha	Spring cereals, application rate: 1 L/ha
D1/ditch	risk mitigation at national level	75% nozzle reduction or 5m buffer zone
D1/stream	risk mitigation at national level	risk mitigation at national level
D2/ditch	risk mitigation at national level	not relevant
D2/stream	risk mitigation at national level	not relevant
D3/ditch	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D4/pond	no risk mitigation needed	no risk mitigation needed
D4/stream	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D5/pond	no risk mitigation needed	no risk mitigation needed
D5/stream	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D6/ditch	risk mitigation at national level	75% nozzle reduction or * 5m buffer zone
R1/pond	no risk mitigation needed	no risk mitigation needed *
R1/stream	5m vegetated buffer zone	5m vegetated buffer zone *
R2/stream	not relevant	5m vegetated buffer zone *
R3/stream	5m vegetated buffer zone	5m vegetated buffer zone *
R4/stream	75% nozzle reduction or 5m buffer zone	5m vegetated buffer zone

* maize as a surrogate scenario for spring cereals

For Poland D3, D4 and R1 scenarios are relevant. R1 scenario is not available for spring cereals but it can be assumed that risk assessment is covered by R1 risk assessment for winter cereals and maize. In case of Poland it can be concluded that JMD-HER 387 OD used at the max. rate of 1 L/ha to protect cereals according to proposed GAP does not pose unacceptable risk to aquatic organisms under condition that 5m vegetated buffer strip is applied.

zRMS comment: The evaluation of the risk for aquatic 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" (EFSA Journal 2013;11(7):3290). Acute toxicity studies of JMD-HER 387 OD to invertebrates, algae and aquatic plants as well as literature data for metabolite 4-CP were submitted in this dossier.

In Part B8 in the *Corre* the Evaluator agrees with modelling PECsw carried out by Applicant.

Due the fact that scenarios only D3, D4, D5, R1, R3, R4 are relevant for the Central Zone calculations the remaining scenarios have not been evaluated.

PECsw for active substances and their metabolites after application to winter and spring cereals were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1. Since for spring cereals some scenarios are not available, maize was used in modelling as a surrogate crop. PECsw values were used in aquatic risk assessment.

Risk assessment for combined toxicity for Jockey 387 OD was accepted by RMS.

PECsw/RAC values were calculated with PECsw values obtained for active substances and their metabolites calculated in Step 1, 2, 3 and 4. Most of the PECsw/RAC values were below 1 for acute and long-term risk using Step 3 and Step 4 PECsw indicating no unacceptable risk to aquatic organisms at application rate of 1 L/ha provided the appropriate risk mitigations are applied. Summary of proposed risk mitigations for each scenario are in table below.

Scenario	Winter cereals, application rate: 1 L/ha	Spring cereals, application rate: 1 L/ha
D3/ditch	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D4/pond	no risk mitigation needed	no risk mitigation needed
D4/stream	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
D5/pond	no risk mitigation needed	no risk mitigation needed
D5/stream	75% nozzle reduction or 5m buffer zone	75% nozzle reduction or 5m buffer zone
R1/pond	no risk mitigation needed	no risk mitigation needed *
R1/stream	5m vegetated buffer zone	5m vegetated buffer zone *
R2/stream	not relevant	5m vegetated buffer zone *
R3/stream	5m vegetated buffer zone	5m vegetated buffer zone *
R4/stream	75% nozzle reduction or 5m buffer zone	5m vegetated buffer zone

For Poland D3, D4 and R1 scenarios are relevant. R1 scenario is not available for spring cereals but it can be assumed that risk assessment is covered by R1 risk assessment for winter cereals and maize. In case of Poland, it can be concluded that JMD-HER 387 OD used at the max. rate of 1 L/ha to protect cereals according to proposed GAP does not pose unacceptable risk to aquatic organisms under condition that 5m vegetated buffer strip is applied.

Other approaches for simulating run-off mitigation reductions (e.g. VSFMod) are not recommended for the Core Assessment such approaches should only be presented in National Assessment.

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

The acceptable predicted environmental concentrations for active substance and their metabolites are appropriate to be used for the subsequent risk assessment.

In case the study: JMD-HER 387 OD Water-sediment *Myriophyllum spicatum* toxicity test; Turek-Lipka T.; 2021; Study Code: W-05-21 zRMS point out that the chemical analysis for the product Jockey 387 OD revealed, that the concentration of 2,4-D 2-EHE was below LOQ at the end of the test concentrations. Hence, it is concluded the toxicity endpoints from this studies may be questionable due to cannot be determined as exposure of the test compound was not maintained throughout the study. On the other hand, the combined risk assessment confirmed that it is clear that the calculated MDR value was 0.11 indicating antagonism effect hence the risk assessment for all scenarios was performed in Step 8 on the basis of

RQmix. RQmix values were below the relevant trigger indicating acceptable risk for most scenarios in Step 3 or Step 4. For the other scenarios further risk mitigations are needed at national level.

The risk assessment for 2,4-D and iodosulfuron-methyl-sodium alone and combined risk assessment is considered sufficient to cover the risk of exposure to the product based on step 4 and the iodosulfuron-methyl-sodium concentration were properly maintained throughout the studies for Myriophyllum. All validity criteria in the study was met. However, the reliable endpoint for the study and risk assessment for plant product protection Jockey 387 OD and *Myriophylum* should be considered at MSs level.

The risk assessment for aquatic organisms should be considered at MSs level.

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 2,4-D and iodosulfuron-methyl-sodium. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of JMD-HER 387 OD were not evaluated as part of the EU assessment. 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
2,4-D				
Bees	2,4-D	Acute Oral, 48h	LD_{50} = 94 µg/bee	EFSA Journal 2014; 12(9):3812
Bees	2,4-D	Acute Contact, 48h	LD_{50} > 100 µg/bee	EFSA Journal 2014; 12(9):3812
iodosulfuron-methyl-sodium				
Apis mellifera	iodosulfuron-methyl-sodium	Acute Oral, 72h	LD_{50} > 70 µg/bee	EFSA Journal 2016;14(4):4453
Apis mellifera	iodosulfuron-methyl-sodium	Acute Contact, 72h	LD_{50} > 131 µg/bee	
Apis mellifera	iodosulfuron-methyl-sodium	Acute Oral, 72h Acute Contact, 72h	LD_{50} > 107.6 µg/bee LD_{50} > 100 µg/bee	
Bombus terrestris	iodosulfuron-methyl-sodium	Acute Contact, 48h	LD_{50} > 100 µg/bee	
Apis mellifera	IMS + MPR OD 400	Acute Oral, 48h Acute Contact, 48h	LD_{50} =181.0 µg/ bee_{nom} (16.0 µg a.s./bee_{nom}) LD_{50} =317.6 µg/ bee_{nom} (28.0 µg a.s./bee_{nom})	

Apis mellifera	iodosulfuron-methyl-sodium	Chronic, 10d	LC_{50} >111.6 mg a.s./kg diet LD_{50} > 4.4 µg a.s./bee/d NOEC=111.6 mg a.s./kg diet NOEL=4.4 µg a.s./bee/d	
Apis mellifera	Iodosulfuron-methyl-sodium WG 10	21 d Feeding test Bee brood development	$NOEC_{mort, adult}$ < 25 mg a.s./L $NOEC_{mort, pupae}$ < 25 mg a.s./L $NOEC_{brood\ development}$ < 25 mg a.s./L $NOEC_{behaviour}$ = 25 mg a.s./L	
Apis mellifera	IMS + MPR OD 400	4 d exposure 18 days observation Semi-field Bee brood development	$NOEC_{mort, adult}$ = 10 g a.s./ha $NOEC_{mort, pupae}$ = 10 g a.s./ha $NOEC_{brood\ development}$ = 10 g a.s./ha $NOEC_{behaviour}$ = 10 g a.s./ha	
JMD-HER 387 OD				
Bees	JMD-HER 387 OD	Oral, 48h	LD_{50} > 100 µg/bee	KCP 10.3.1.1.1/01 Meler A/2021/Study code: 0005/0097/E
Bees	JMD-HER 387 OD	Contact, 48h	LD_{50} > 100 µg/bee	KCP 10.3.1.1.2/01 Meler A/2021/Study code: 0005/0098/E
Bumblebee	JMD-HER 387 OD	Oral, 48h	LD_{50} > 1000 µg/bee	KCP 10.3.1.1.1/02 Orzechowska U/2021/Study code: 0005/0101/E
Bumblebee	JMD-HER 387 OD	Contact, 48h	LD_{50} > 1000 µg/bee	KCP 10.3.1.1.2/02 Orzechowska U/2021/Study code: 0005/0104/E
Bees	JMD-HER 387 OD	Feeding, 10d	LDD_{50} >89.53 µg/bee/day	KCP 10.3.1.2/01 Orzechowska U/2021/Study code: 0005/0100/E
Bees larvae	JMD-HER 387 OD	Repeated exposure	LD_{50} = 199.398 µg/larva NOED = 11.11 µg/larva	KCP 10.3.1.4/01 Orzechowska U/2021/Study code: 0005/0103/E
Higher-tier studies (tunnel test, field studies)				
Not available.				

9.6.1.1 Justification for new endpoints

New endpoints are provided for the formulated product JMD-HER 387 OD. Details of studies and results are included in Table 9.6-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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) and "EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)" (EFSA Journal

2013;11(7):3295).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for bees from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

9.6.2.1 Hazard quotients for bees

Risk assessment acc. to SANCO/10329/2002 rev.2 (final), October 17, 2002

Table 9.6-2: First-tier acute assessment of the risk for bees and bumblebees due to the use of JMD-HER 387 OD in cereals (JMD-HER 387 OD endpoints)

Intended use	spring cereals, winter cereals		
Product	JMD-HER 387 OD		
Application rate (kg/ha)	1 × 1.044*		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Trigger HQ ≤ 50**
Bees			
Oral toxicity	>100	1044	<10.44
Contact toxicity	>100		<10.44
Bumblebees			
Oral toxicity	>1000	1044	<1.044
Contact toxicity	>1000		<1.044

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* application rate calculated on the basis of density 1.044 g/ml (see dRR Part B 0,1-4)

The acute risk to honeybees and bumblebees from use of JMD-HER 387 OD was assessed using the maximum single application rate and the oral and contact LD_{50} values. A Hazard Quotient (HQ) of less than 50 indicates a low risk to bees.

Risk assessment acc. to EFSA Journal 2013;11(7):3295

Table 9.6-3: Screening step assessment of the risk for bees due to the use JMD-HER 387 OD in cereals downward spray

Intended use	spring cereals, winter cereals				
Product	JMD-HER 387 OD				
Application rate (g/ha)	1 × 1.044*				
Test design	**LD_{50} (µg/bee) LDD_{50} (µg/bee/day) NOED (µg/larva)**	**Single application rate (g/ha)**	**SV**	**HQ/ ETR**	**Trigger**
Acute oral toxicity	>100	1044	7.6	< 0.08	0.2
Acute contact toxicity	>100	1044	-	< 10.4	42
Chronic adult oral toxicity	>89.53	1044	7.6	**0.09**	0.03
Larval development oral toxicity	11.11	1044	4.4	**0.41**	0.2

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure. HQ/ETR values shown in bold breach the relevant trigger.
* application rate calculated on the basis of density 1.044 g/ml (see dRR Part B 0,1-4)

Table 9.6-4: Screening step assessment of the risk for bumblebees due to the use of JMD-HER 387 OD in cereals downward spray

Intended use	spring cereals, winter cereals				
Product	JMD-HER 387 OD				
Application rate (g/ha)	1 × 1.044*				
Test design	**LD_{50} (µg/bee) LDD_{50} (µg/bee/day) NOED (µg/larva)**	**Single application rate (g/ha)**	**SV**	**HQ/ ETR**	**Trigger**
Acute oral toxicity	>1000	1044	11.2	< 0.01	0.036
Acute contact toxicity	>1000	1044	-	< 1.0	7

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure. HQ/ETR values shown in bold breach the relevant trigger.
*density of JMD-HER 387 OD is 1.044 g/ml

The screening step risk assessment above has indicated a potential chronic adult oral risk and therefore a Tier 1 assessment for treated crop has been provided.

Table 9.6-5: First-tier assessment of the chronic risk for bees and larvae due to the use of JMD-HER 387 OD in cereals

Intended use	spring cereals, winter cereals						
Active substance	JMD-HER 387 OD						
Application rate (g/ha)	1 × 1.044*						
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**SV**	**TWA**	**Ef**	**ETR**	**Trigger**
Chronic adult oral toxicity							
Cereals BBCH 10-29	>89.53	1044	2.9	0.72	1	0.024	0.03
Cereals BBCH 30-39	>89.53	1044	2.9	0.72	0.5	0.012	0.03
Larval development oral toxicity							
Cereals BBCH 10-29	11.11	1044	2.2	0.85	1	0.18	0.2
Cereals BBCH 30-39	11.11	1044	2.2	0.85	0.5	0.09	0.2

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

The Tier I ETR values are less than the trigger for downward sprays indicating that the risk to bees and larvae is acceptable.

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

The acute risk of JMD-HER 387 OD to honeybees and bumblebees was assessed from HQ and ETR between toxicity endpoints, estimated from acute oral and contact studies, chronic toxicity studies and larva toxicity with formulated product as well as the maximum single application rate. The HQ and ETR values were considerably less than the relevant triggers that means product JMD-HER 387 OD does not pose unacceptable acute oral and contact risk to honeybees and bumblebees. No risk mitigations are required.

zRMS comment: The risk assessment for bees was conducted in accordance with SANCO/10329/2002 rev. 2 final and the latest Draft EFSA Guidance for risk assessment for bees EFSA Journal 2013; 11(7):3295. The acute oral and contact toxicity data are available for the formulation Jockey 387 OD. In addition, the chronic study for adult bees and a study effects on honey bee development and other honey bee life stages was submitted by Applicant. The studies were accepted by zRMS. The risks of JMD-HER 387 OD to honeybees was assessed from Hazard Quotients (HQ) and Exposure Toxicity Ratio (ETR) between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product as well as the maximum single application rate.

All the hazard quotients were considerably less than the respective triggers, indicating that JMD-HER 387 OD at maximum rate of 1 L/ha poses a low risk to bees. No risk management measures are required.

Final decision for risk assessment for bees should be taken into account at MSs level.

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 2,4-D and iodosulfuron-methyl-sodium. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of JMD-HER 387 OD were not evaluated as part of the EU assessment. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Species	Substance	Exposure System	Results	Reference
2,4-D				
Aphidius rhopalosiphi	2,4-D DMA 600SL	Laboratory test, glass cover slides (2D)	LR_{50} > 3000 g as/ha	EFSA Journal 2014;12(9):3812
Typhlodromus pyri	2,4-D DMA 600SL	Laboratory test, glass plates (2D)	LR_{50} > 3000 g as/ha	
Poecilus cupreus	Herbizid Marks	Laboratory test, Arenas containing sand, plastic trays 14 days (3D)	Mortality 0% and 29.6% effect on feeding at rate 1000 g as/ha	
Aleochara bilineata	Herbizid Marks	Laboratory test, Arenas containing sand, glass Beakers 4 weeks + 5 weeks (3D)	Mortality 0% and 1.3% effect on beneficial capacity at rate 1000 g as/ha	
Pardosa ssp.	Herbizid Marks	Laboratory test, Arenas containing sand, plastic containers 14 days (3D)	Mortality 5% and 0% effect on food consumption at rate 1000 g as/ha	
iodosulfuron-methyl-sodium				
Aphidius rhopalosiphi	IMS + MPR OD 400	Laboratory test (2D)	LR_{50} = 300 ml/ha (30.3 g as/ha) ER_{50} = 300 ml/ha (30.3 g as/ha)	EFSA Journal 2016;14(4):4453
Aphidius rhopalosiphi	AE F115008 02 WG20 B002	Laboratory test	Mortality 86% at 0.2 kg/ha	
Typhlodromus pyri	IMS + MPR OD 400	Laboratory test (2D)	LR_{50} = 300 ml/ha (30.3 g as/ha) ER_{50} = 300 ml/ha (30.3 g as/ha)	
Typhlodromus pyri	AE F115008 02 WG20 B002	Laboratory test	Mortality 28% at 0.2 kg/ha Reproduction 16% at 0.2 kg/ha	
Poecilus cupreus	AE F115008 02 WG20 B002	Laboratory test	Mortality 0% at 0.2 kg/ha Food uptake 6% at 0.2 kg/ha	
Chrysoperla carnea	AE F115008 02 WG20 B002	Laboratory test	Mortality 0% at 0.2 kg/ha Reproduction 13-18% at 0.2 kg/ha	

JMD-HER 387 OD				
Aphidius rhopalosiphi	JMD-HER 387 OD	Extended laboratory test (3D)	Mortality: LR_{50} > 1 L/ha 0% at rate 1 L/ha Reproduction: ER_{50} > 1 L/ha 34% at rate 1 L/ha	KCP 10.3.2.2/01 Knapik M/2021/ Study code: B-41-21
Typhlodromus pyri	JMD-HER 387 OD	Extended laboratory test (2D)	Mortality: LR_{50} > 1 L/ha 13.8% at rate 1 L/ha Reproduction: ER_{50} > 1 L/ha 40.6% at rate 1 L/ha	KCP 10.3.2.2/02 Knapik M/2021/ Study code: B-40-21
Coccinella sep-tempunctata	JMD-HER 387 OD	Extended laboratory test (2D)	Mortality: LR_{50} > 1 L/ha 0% at rate 1 L/ha Reproduction: 2.2% at rate 1 L/ha	KCP 10.3.2.2/03 Knapik M/2021/ Study code: B-39-21
Aleochara bilineata	JMD-HER 387 OD	Extended laboratory test (2D)	Mortality: EC_{50} > 3000 mL/ha 0% at rate 1 L/ha Reproduction: NOEC ≥ 3000 mL/ha LOEC > 3000 mL/ha	KCP 10.3.2.2/04 Mautino G/2023/ Study code: 1185.H.SAG22/r
Field or semi-field tests				
Not available.				

9.7.1.1 Justification for new endpoints

New endpoints are provided for the formulated product JMD-HER 387 OD. Details of studies and results are included in Table 9.7-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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.

zRMS comment:
The studies on the effects of Jockey 387 OD on arthropods were provided by Applicant *(Aphidius rhopalosiphi, Thyprodromus pyri, Aleochara bilineata, Coccinella septempunctata)*. In this case, the studies were accepted by zRMS and used in te risk assessment. Risk assessments for JMD-HER 387 OD with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods "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.

The in-field and off-field risk of Jockey 387 OD to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from studies with active ingredient and the

formulated product Jockey 387 OD as well as in-field and off-field predicted environmental rate. No risk was determined in-field and off-field after application of Jockey 387 OD at maximum rate of 1 L/ha. No risk management measures are required.

The risk assessment for arthropods other than bees should be considered at MSs level.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for non-target arthropods from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

The risk assessment is calculated with units of ml/ha since recalculation with density does not chance anything as long as toxicity, rate and exposure is expressed in ml/ha.

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of JMD-HER 387 OD in cereals (JMD-HER 387 OD endpoints)

Intended use	spring cereals, winter cereals
Product	JMD-HER 387 OD
Application rate (ml/ha)	1 × 1000
MAF	1

Test species Tier I	**LR_{50} (lab.) (ml/ha)**	**$PER_{in\text{-}field}$ (ml/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**	**Rate with ≤ 50 % effect (ml/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	>1000	1000	<1	>1000	yes
Aphidius rhopalosiphi	>1000		<1	>1000	yes
Coccinella septempunctata	>1000		<1	>1000	Yes
Aleochara bilineata	>3000		<0.33	>3000	Yes

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

zRMS comment: Agreed.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for non-target arthropods from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

The risk assessment is calculated with units of ml/ha since recalculation with density does not chance anything as long as toxicity, rate and exposure is expressed in ml/ha.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of JMD-HER 387 OD in cereals (JMD-HER 387 OD endpoints)

Intended use	spring cereals, winter cereals
Active substance/product	JMD-HER 387 OD

Application rate (ml/ha)		1 × 1000							
MAF		1							
VDF / CF		10 (2D) & 1(3D) /10 (2D) & 5 (3D)							
Test species Tier II	**LR_{50} (lab.) (ml/ha)**	**Drift rate (%)**	**VDF**	**$PER_{off\text{-}field}$ (ml/ha)**	**CF**	**$PER_{off\text{-}field}$ (mL/ha)**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**	**Rate with ≤ 50 % effect (ml/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi (3D)	>1000	2.77	1	27.7	5	27.700	0.1385	>1000	yes
Typhlodromus pyri (2D)	>1000		10	277	10	2.770	0.0277	>1000	yes
Coccinella septempunctata (2D)	>1000			277		2.770	0.0277	>1000	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 comment: Agreed. Some Member states require the use of VDF 5 in off-field risk assessment for non-target arthropods other than bees. The risk assessment for non-target arthropods other than bees with VDF=5 was also added by zRMS.

Intended use		spring cereals, winter cereals							
Active substance/product		JMD-HER 387 OD							
Application rate (ml/ha)		1 × 1000							
MAF		1							
VDF / CF		5 (2D) & 1(3D) / 10 (2D) & 5 (3D)							
Test species Tier II	**LR_{50} (lab.) (ml/ha)**	**Drift rate (%)**	**VDF**	**$PER_{off\text{-}field}$ (ml/ha)**	**CF**	**$PER_{off\text{-}field}$ (mL/ha)**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**	**Rate with ≤ 50 % effect (ml/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi (3D)	>1000	2.77	1	27.7	5	27.700	0.1385	>1000	yes
Typhlodromus pyri (2D)	>1000		5	277	10	5.54	0.0554	>1000	yes
Coccinella septempunctata (2D)	>1000			277		5.54	0.0554	>1000	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.

The risk from the formulation Jockey 387 OD indicating an acceptable in–field and off-fiel risk as the HQ values are < 2. The risk assessment for non-target arthropods other than bees should be considered by MSs level.

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 risk of JMD-HER 387 OD to non-target arthropods was assessed from in-field and off-field HQ between toxicity endpoints, estimated from extended laboratory studies with formulated product as well as the maximum single application rate. The HQ values were considerably less than 2, indicating that the product poses a low risk to non-target arthropods. Additionally, $PER_{in\text{-}field}$ and $PER_{off\text{-}field}$ values were below rate with <50% effects indicating an acceptable risk. It can be concluded that JMD-HER 387 OD used at max. application rate of 1 L/ha to protect cereals according to proposed GAP, does not pose unacceptable in-field and off-field risk to non-target arthropods. No risk mitigations are required.

zRMS comment: Agreed.

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 2,4-D and iodosulfuron-methyl-sodium 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 JMD-HER 387 OD were not evaluated as part of the EU assessment. 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
2,4-D				
Eisenia fetida	2,4-D	14 d, acute	**LC_{50} = 350 mg/kg dw soil**	EFSA Journal 2014;12(9):3812
Eisenia fetida	2,4-D	56 d, chronic	**NOEC = 62.5 mg as/kg dw soil**	
Eisenia fetida	Aminopielik Standard 600 SL	14 d, acute	LC_{50} > 618 mg as/kg dw soil	
Eisenia fetida	2,4-DCA	14 d, acute	LC50 > 101.8 mg/kg soil **LC50corr > 50.9 mg/kg soil**	

Eisenia fetida	2,4-DCA	56 d, chronic	NOEC = 10 mg/kg soil **NOECcorr = 5 mg/kg soil**	
Eisenia fetida	2,4-DCP	56 d, chronic	NOEC = 10 mg/kg soil **NOECcorr = 5 mg/kg soil**	
Hypoaspis aculeifer	2,4-DCA	chronic	NOEC = 10 mg/kg dw soil **NOECcorr = 5 mg/kg soil**	
Hypoaspis aculeifer	2,4-DCP	chronic	NOEC = 5 mg/kg dw soil **NOECcorr = 2.5 mg/kg soil**	
Folsomia candida	2,4-DCA	chronic	NOEC = 10 mg/kg dw soil **NOECcorr = 5 mg/kg soil**	
Folsomia candida	2,4-DCP	chronic	NOEC = 1.25 mg/kg dw soil **NOECcorr = 0.625 mg/kg soil**	
iodosulfuron-methyl-sodium				
Eisenia fetida	Iodosulfuron-methyl-sodium	Chronic 56 d	**EC_{10} =7 mg as/kg dw soil**	EFSA Journal 2016;14(4):4453
Eisenia fetida	IMS + MPR OD 400	Chronic 56 d	NOEC = 56 mg/kg dw soil (4.63 mg as/kg dw soil)	
Eisenia fetida	AE F075736	Chronic 56 d	**EC_{10} = 0.7 mg/kg dw[1]**	
Eisenia fetida	AE F145741	Chronic 56 d	**NOAEC = 94.4 mg/kg dw soil**	
Eisenia fetida	AE F145740	Chronic 56 d	**NOEC = 97.5 mg/kg dw soil**	
Eisenia fetida	AE 0002166	Chronic 56 d	**NOEC = 95 mg/kg dw soil**	
Eisenia fetida	BCS-CW81253	Chronic 56 d	**NOEC = 99 mg/kg dw soil**	
Eisenia fetida	AE 0000119	Chronic 56 d	**NOEC = 97.8 mg/kg dw soil**	
Eisenia fetida	AE F059411	Chronic 56 d	**NOEC = 30 mg/kg dw soil**	
Folsomia candida	Iodosulfuron-methyl-sodium	Chronic 28 d	**NOEC = 316 mg/kg dw soil**	
Folsomia candida	IMS + MPR OD 400	Chronic 28 d	NOEC = 100 mg/kg dw soil (8.71 mg as/kg dw soil)	
Folsomia candida	AE F075736	Chronic 28 d	**NOEC = 9.86 mg/kg dw soil**	
Folsomia candida	BCS-CW81253	Chronic 28 d	**NOEC = 99 mg/kg dw soil**	
Folsomia candida	AE F059411	Chronic 28 d	**NOEC = 99.7 mg/kg dw soil**	
Folsomia candida	AE 0000119	Chronic 28 d	**NOEC = 97.8 mg/kg dw soil**	

Hypoaspis aculeifer	Iodosulfuron-methyl-sodium	Chronic 15 d	**NOEC = 1000 mg/kg dw soil**	
Hypoaspis aculeifer	IMS + MPR OD 400	Chronic 14 d	NOEC = 56 mg/kg dw soil (4.88 mg as/kg dw soil)	
Hypoaspis aculeifer	AE F075736	Chronic 14 d	**NOEC = 9.86 mg/kg dw soil**	
Hypoaspis aculeifer	AE F145741	Chronic 14 d	**NOEC = 100 mg/kg dw soil**	
Hypoaspis aculeifer	AE F145740	Chronic 14 d	**NOEC = 97.5 mg/kg dw soil**	
Hypoaspis aculeifer	AE 0002166	Chronic 14 d	**NOEC = 95.2 mg/kg dw soil**	
Hypoaspis aculeifer	BCS-CW81253	Chronic 14 d	**NOEC = 99 mg/kg dw soil**	
Hypoaspis aculeifer	AE F059411	Chronic 14 d	**NOEC = 98.7 mg/kg dw soil**	
Hypoaspis aculeifer	AE 0000119	Chronic 14 d	**NOEC = 97.8 mg/kg dw soil**	
JMD-HER 387 OD				
Eisenia fetida	JMD-HER 387 OD	56 d, chronic	**NOEC ≥1000 mg/kg dw soil (reproduction)** **NOEC ≥1000 mg/kg dw soil (survival)**	KCP 10.4.1.1/01 Arendarczyk A/2021; Study Code: G-03-21
Folsomia candida	JMD-HER 387 OD	28 d, chronic	**NOEC = 1.8 mg/kg dw**	KCP 10.4.2.1/01 Gierbuszewska A./ 2021/ Study Code: G-04-21
Hypoaspis aculeifer	JMD-HER 387 OD	14 d, chronic	**NOEC ≥1000 mg/kg dw soil (reproduction)** NOEC ≥1000 mg/kg dw soil (survival)	KCP 10.4.2.1/02 Gierbuszewska A./ 2021/ Study Code: G-05-21
Field studies				
Not available.				
Litter bag test				
Not available.				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.
[1] chronic toxicity value estimated i.e. 10 times lower than active substance toxicity endpoint

9.8.1.1 Justification for new endpoints

New endpoints are provided for the formulated product JMD-HER 387 OD. Details of studies and results are included in Table 9.8-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for soil organisms from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of JMD-HER 387 OD in spring cereals and winter cereals

Intended uses	spring cereals, winter cereals		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**$PEC_{soil, accum}$ (worst case) (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
2,4-D	350	0.286	1223.8
2,4-DCA	> 50.9	0.032	1590.6
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
2,4-D	62.5	0.286	218.5
2,4-DCA	5	0.032	156.3
2,4-DCP	5	0.017	294.1
iodosulfuron-methyl-sodium	7	0.011	636.4
AE F075736	0.7	0.007	100.0
AE F145741	94.4	0.001	94400
AE F145740	97.5	0.001	97500
AE 0002166	95	0.002	47500
BCS-CW81253	99	0.003	33000
AE 0000119	97.8	0.014	6985.7
AE F059411	30	0.025	1200.0
JMD-HER 387 OD	≥1000	1.148	871.1
Chronic effects on other soil macro- and mesofauna (*Hypoaspis aculeifer)*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
2,4-DCA	5	0.032	156.3
2,4-DCP	2.5	0.017	147.1

iodosulfuron-methyl-sodium	1000	0.011	90909.1
AE F075736	9.86	0.007	1408.6
AE F145741	100	0.001	100000
AE F145740	97.5	0.001	97500
AE 0002166	95.2	0.002	47600
BCS-CW81253	99	0.003	3300
AE F059411	98.7	0.025	3948
AE 0000119	97.8	0.014	6985.7
JMD-HER 387 OD	≥1000	1.148	871.1
Chronic effects on other soil macro- and mesofauna (*Folsomia candida)*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
2,4-DCA	5	0.032	156.3
2,4-DCP	0.625	0.017	36.8
Iodosulfuron-methyl-sodium	316	0.011	28727.3
AE F075736	9.86	0.007	1408.6
BCS-CW81253	99	0.003	33000
AE F059411	99.7	0.025	3988
AE 0000119	97.8	0.014	6985.7
JMD-HER 387 OD	1.8	1.148	1.6

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The risk of JMD-HER 387 OD to soil macro-organisms was assessed from in-field and off-field HQ between predicted concentrations in soil and the maximum single application rate toxicity endpoints. According to the performed risk assessment it was concluded that the application of JMD-HER 387 OD at maximum rate of 1 L/ha to protect cereals according to proposed GAP does not pose unacceptable risk to soil macro-organisms. No risk mitigations are required.

zRMS comment: The risk assessment for earthworms and other soil macroorganism for both a.s. (iodosulfuron-methyl-sodium and 2,4-D) and theit metabolites as well as, the product Jockey 387 OD was accepted by zRMS.

Risk assessments for Jockey 387 OD with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

The risk of Jockey 387 OD to earthworms, *Folsomia candida* and *Hypoaspis aculeifer* was assessed from acute toxicity exposure ratios (TERs) between the selected toxicity endpoint for the active ingredient, metabolites and the formulated product Jockey 387 OD as well as the maximum soil PECs.

The acute and chronic TER values were greater than the trigger of 10 and 5 respectively, indicating an acceptable risk to earthworms, *Folsomia candida* and *Hypoaspis aculeifer* following application of Jockey 387 OD at maximum rate of 1 L/ha. No risk management measures are required.

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 2,4-D and iodosulfuron-methyl-sodium their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of JMD-HER 387 OD were not evaluated as part of the EU assessment. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

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

Endpoint	Substance	Exposure System	Results	Reference
2,4-D				
N-mineralisation	2,4-D	-	**No effect at 3 mg/kg soil**	EFSA Journal 2014;12(9):3812
N-mineralisation	LAF-74	56 days	No effect at 29.9 mg as/kg soil	EFSA Journal 2014;12(9):3812
N-mineralisation	2,4-DCA	28 days	**No effect at 5 mg/kg soil**	EFSA Journal 2014;12(9):3812
N-mineralisation	2,4-DCP	42 days	**No effect at 5 mg/kg soil**	EFSA Journal 2014;12(9):3812
C-mineralisation	2,4-D	-	**No effect at 3 mg a.s./kg soil**	EFSA Journal 2014;12(9):3812
C-mineralisation	LAF-74	28 days	No effect at 29.9 mg a.s./kg soil	EFSA Journal 2014;12(9):3812
C-mineralisation	2,4-DCA	28 days	**No effect at 5 mg a.s./kg soil**	EFSA Journal 2014;12(9):3812
C-mineralisation	2,4-DCP	28 days	**No effect at 5 mg a.s./kg soil**	EFSA Journal 2014;12(9):3812
iodosulfuron-methyl-sodium				
N-mineralisation	Iodosulfuron-methyl-sodium	28 days	Nitrogen transformation rates /day was not reported in the study. On day 28, a maximum effect of 1% in comparison with the control was observed in total nitrogen at an application rate of up to	EFSA Journal 2016;14(4):4453

			0.067 mg/kg soil dw (50 g /ha). Overall, the maximum effect on total nitrogen was 4.8% and was observed at day 14.	
N-mineralisation	IMS + MPR OD 400	28 days	7.1% effect at day 28 at rates up to 0.067 mg a.s./kg soil dw	
N-mineralisation	AE F075736 (as formulated product 20 DP)	28 days	NOAEC 0.2 mg/kg (**0.04 mg a.s./kg soil dw**)[1]	
N-mineralisation	AE F145741	28 days	16.0% effect at day 28 at rates up to 0.063 mg/kg soil dw	
N-mineralisation	AE F145740	28 days	14.2% effect at day 28 at rates up to 0.063 mg/kg soil dw	
N-mineralisation	AE 0002166	28 days	17.3% effect at day 28 at rates up to 0.053 mg/kg soil dw	
N-mineralisation	AE F161778	28 days	16.3% effect at day 28 at rates up to 0.049 mg/kg soil dw	
N-mineralisation	BCS-CW81253	28 days	17.1% effect at day 28 at rates up to 0.043 mg/kg soil dw	
N-mineralisation	AE 0000119	28 days	2.9% effect at day 28 at rates up to 0.4 mg/kg soil dw	
N-mineralisation	AE F059411	28 days	22.9% effect at day 42 at rates up to 0.204 mg/kg soil dw	
JMD-HER 387 OD				
N-mineralisation	JMD-HER 387 OD	28 days	Effect -15.6% at **0.696 mg of test item/kg soil** Effect -21.9% at **3.480 mg of test item/kg soil**	KCP 10.5/01/ Pieczka P/2022/ Study Code: G-09-21

[1]SANCO 7593/VI/97-final from 14 Aug 2000

9.9.1.1 Justification for new endpoints

New endpoints are provided for the formulated product JMD-HER 387 OD. Details of studies and results are included in Table 9.9-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for soil microorganisms from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of JMD-HER 387 OD in spring cereals and winter cereals

Intended use	spring cereals, winter cereals		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
2,4-D	3	0.286	yes
2,4-DCA	5	0.032	yes
2,4-DCP	5	0.017	yes
iodosulfuron-methyl-sodium	0.067	0.011	yes
AE F075736	0.2	0.007	yes
AE F145741	0.063	0.001	yes
AE F145740	0.063	0.001	yes
AE 0002166	0.053	0.002	yes
AE F161778	0.049	0.001	yes
BCS-CW81253	0.043	0.003	yes
AE 0000119	0.4	0.014	yes
AE F059411	0.204	0.025	yes
JMD-HER 387 OD	3.480	1.148	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
2,4-D	3	0.286	yes
2,4-DCA	5	0.032	yes
2,4-DCP	5	0.017	yes

9.9.3 Overall conclusions

The risk of JMD-HER 387 OD to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for active substances, metabolites and JMD-HER 387 OD with appropriate predicted environmental concentrations in soil (PECs). According to the performed risk assessment it was concluded that the application of JMD-HER 387 OD at maximum rate of 1 L/ha to protect cereals according to proposed GAP does not pose unacceptable risk to soil micro-organisms. No risk mitigations are required.

zRMS comment: The risk assessment for soil microorganisms for both a.s. (iodosulfuron-methyl-sodium and 2,4-D) and theit metabolites as well as, the product Jockey 387 OD was accepted by zRMS.

The risk of Jockey 387 OD to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for active substances, metabolites and the formulated product Jockey 387 OD with predicted application concentrations (PECs) obtained for active substances, metabolites and the formulation.

According to the performed risk assessment it was assessed that the application of Jockey 387 OD at maximum rate of 1 L/ha does not pose unacceptable risk to soil micro-organisms.
No risk management measures are required.

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 2,4-D and iodosulfuron-methyl-sodium. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of JMD-HER 387 OD were not evaluated as part of the EU assessment. 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 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
2,4-D				
Lettuce Lactuca sativa	formulation LAF-74	Vegetative vigour & Seedling emergence	Vegetative vigour: ER_{50} = 19 g a.s./ha Emergence: ER_{50} = 27 g a.s./ha	EFSA Journal 2014;12(9):3812
iodosulfuron-methyl-sodium				
Allium cepa *Lolium perenne* *Zea mays* *Lycopersicon esculentum* *Pisum sativum* *Sinapis alba*	Iodosulfuron-methyl-sodium formulated as WG20	Vegetative vigour	Most sensitive species: *Sinapsis alba* ER_{50} = 0.042 g a.s./ha (height)	EFSA Journal 2016;14(4):4453
Allium cepa *Brassica oleracea* *Lolium perenne* *Zea mays*	Iodosulfuron-methyl-	Vegetative vigour	Most sensitive species with an appropriate dose-response: *Brassica oleracea* ER_{50} = 0.036 g a.s./ha (shoot weight)	

Cucumis sativus *Lactuca sativa* *Avena sativa* *Glycine max* *Lycopersicon esculentum* *Brassica rapa*	sodium formulated as WG20			
Zea mays *Avena sativa* *Allium cepa* *Brassica napus* *Raphanus sativus* *Beta vulgaris* *Cucumis sativus* *Helianthus annuus* *Lycopersicum esculentum* *Glycine max*	IMS + MPR OD 400	Vegetative vigour	Most sensitive species: *Helianthus annuus* ER_{50} = 2.43 ml product /ha (0.245 g a.s./ha) (shoot dry weight)	
	IMS + MPR OD 400	Seedling emergence	Most sensitive species: *Beta vulgaris* ER_{50} = 5.62 ml product /ha (0.567 g a.s./ha) (shoot dry weight)	
JMD-HER 387 OD				
Pea *Pisum sativum* Cabbage *Brassica oleracea var. capitata* Red clover *Trifolium pratense* Carrot *Daucus carota* Onion *Allium cepa* Corn *Zea mays*	JMD-HER 387 OD	21 d Seedling emergence	<u>Shoot length</u> *Pisum sativum* ER_{50} >1000mL/ha *Brassica oleracea var.capitata* ER_{50} =359.9 mL/ha *Trifolium pratense* ER_{50} = 97 mL/ha *Daucus carota* ER_{50} = 114.8 mL/ha *Allium cepa* ER_{50} = 175.3 mL/ha *Zea mays* ER_{50} > 1000 mL/ha <u>Plant dry weight</u> *Pisum sativum* ER_{50} = 880 mL/ha *Brassica oleracea var.capitata* ER_{50} = 244 mL/ha *Trifolium pratense* ER_{50} = 164.5 mL/ha *Daucus carota* ER_{50} = 104.8 mL/ha *Allium cepa* ER_{50} = 226 mL/ha *Zea mays* ER_{50} >1000 mL/ha	KCP 10.6.2/01/ Pieczka P /2021/Study Code: G-08-21
Pea *Pisum sativum* Cabbage *Brassica oleracea var. capitata* Red clover *Trifolium pratense* Carrot *Daucus carota* Onion *Allium cepa* Corn *Zea mays*	JMD-HER 387 OD	21 d Vegetative vigour	<u>Shoot length</u> *Pisum sativum* ER_{50} = 210.3 mL/ha *Brassica oleracea var.capitata* ER_{50} > 1000 mL/ha *Trifolium pratense* ER_{50} = 72.1 mL/ha *Daucus carota* ER_{50} = 396.9 mL/ha *Allium cepa* ER_{50} = 61 mL/ha *Zea mays* ER_{50} > 1000 mL/ha <u>Plant dry weight</u> *Pisum sativum* ER_{50} = 143.2 mL/ha *Brassica oleracea var.capitata* ER_{50} =622.7 mL/ha *Trifolium pratense* ER_{50} = 18.7 mL/ha *Daucus carota* ER_{50} = 26.4 mL/ha *Allium cepa* ER_{50} = 78.9 mL/ha *Zea mays* ER_{50} = 487.6 mL/ha	KCP 10.6.2/02/ Arendarczyk A /2021/Study Code: G-07-21

9.10.1.1 Justification for new endpoints

New endpoints are provided for the formulated product JMD-HER 387 OD. Details of studies and results are included in Table 9.10-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

As 6 species were available in seedling emergency and vegetative vigour, the HC5 value was calculated

using the Mosaic tool. Details concerning calculation of HC5 and Mosaic print screens are included in Appendix II (point A 2.6.2). The lowest HC5 value of 9.6 with AF factor of 1 were used in risk assessment.

Species	**Seedling emergence**		**Vegetative vigour**	
	E_rC_{50} (ml/ha) Shoot length	**E_rC_{50} (ml/ha) Plant dry weight**	**E_rC_{50} (ml/ha) Shoot length**	**E_rC_{50} (ml/ha) Plant dry weight**
Pisum sativum	1000	880	210.3	143.2
Brassica oleracea	359.9	244	1000	622.7
Trifolium pratense	97	164.5	72.1	18.7
Daucus carota	114.8	104.8	396.9	26.4
Allium cepa	175.3	226	61	78.9
Zea mays	1000	1000	1000	487.6
Median HC_5 (n = 6) Log-normal	62	76	42	12
Median HC_5 (n = 6) Log-logistic	50	62	35	**9.6**

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals covers the risk for non-target terrestrial plants from all intended uses i.e. spring cereals and winter cereals (see 9.1.2).

Table 9.10-2: Assessment of the risk for non-target plants due to the use of JMD-HER 387 OD in spring cereals and winter cereals

Intended uses	spring cereals, winter cereals
Product	JMD-HER 387 OD
Application rate (mL/ha)	1 × 1000
MAF	1

Test species	**ER_{50}/HC5 (mL/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour HC5	9.6	2.77	27.7	**0.3**

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 JMD-HER 387 OD in spring cereals and winter cereals considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use **Active substance/product** **Application rate (ml/ha)** **MAF**		spring cereals, winter cereals JMD-HER 387 OD 1 × 1000 1			
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	27.7	13.85	6.93	2.77
5	0.57	5.7	2.85	1.43	0.57
10	0.29	2.9	1.45	0.73	0.29
Toxicity value HC5 = 9.6 g/ha		**TER** **criterion: TER ≥ 1**			
1		**0.3**	**0.7**	1.4	3.5
5		1.7	3.4	6.7	16.8
10		3.3	6.6	13.2	33.1

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 risk of JMD-HER 387 OD to non-target plants was evaluated by comparison of the worst HC5 toxicity endpoint derived from laboratory tests for the formulation JMD-HER 387 OD and the highest application rate. According to the performed risk assessment it was assessed that the application of JMD-HER 387 OD at maximum rate of 1 L/ha at maximum rate of 1 L/ha to protect cereals according to proposed GAP does not pose unacceptable risk to non-target plants provided the following risk mitigations are applied:
- 5m buffer zone or
- 75% nozzle reduction.

zRMS comment: The studies on seedling emergence and vegetative vigour for Jockey 387 OD were accepted by zRMS. However, the risk assessment for non-target plants for product Jockey 387 OD was not accepted by zRMS.

The risk assessment using the HC_5 value was not accepted by zRMS. Sufficient representative toxicity data according to SANCO/10329/2002 rev 2 final must be available, the minimum requirement is n ≥ 6 for NTTP. We have only 6 points for each parameter without phytotoxicity effect. **Jockey 387 OD** is a herbicide due to in our opinion n should be at least 10 for SSD. There was not enough detailed information

regarding the statistical parameters of the determined of HC_5 value and SSD curve was not provided. **The risk assessment for HC_5 should be considered by MSs level.**

In reference to phytotoxicity effects observed in the studies it should be noted that, in the case of Jockey 387 OD, the highest phytotoxicity effects were assessed for carrot and red clover in the vegetative vigour study. For these species, 20% and 40% phytotoxicity was rated for the rate of 12.3 ml prod./ha. The lowest ER_{50} for Jockey 387 OD is 18.7 ml prod./ha for *Trifolium pratense* plant dry weight in the vegetative vigour test. Accordingly, an ER_{50} for phytotoxicity would be in the same range as the lowest ER_{50} for the vegetative endpoints. Due to the reasons mentioned above we agree that, the ER_{50} for vegetative endpoints should be chosen over a subjective ER_{50} for phytotoxicity.

Phytotoxicity parameter:
The phytotoxicity parameter was assessment by RMS based on data in the study report without statistical analysis (the Vegetative vigour test):
Pea ER_{50} > 111.1 mL formulation Jockey 387 OD/ha
Cabbage ER_{50} > 111.1 mL formulation Jockey 387 OD/ha
Red clover ER_{50} > 12.3 mL formulation Jockey 387 OD/ha
Carrot ER_{50} > 12.3 mL formulation Jockey 387 OD/ha
Onion ER_{50} > 37.0 mL formulation Jockey 387 OD/ha
Corn ER_{50} > 1000 mL formulation Jockey 387 OD/ha

The phytotoxicity parameter was assessment by RMS based on data in the study report without statistical analysis (Seedling Emergence and Seedling Growth Test):
Pea ER_{50} > 333.3 mL formulation Jockey 387 OD/ha
Cabbage ER_{50} > 333.3 mL formulation Jockey 387 OD/ha
Red clover ER_{50} > 37.0 mL formulation Jockey 387 OD/ha
Carrot ER_{50} > 111.1 mL formulation Jockey 387 OD/ha
Onion ER_{50} > 37.0 mL formulation Jockey 387 OD/ha
Corn = no phytotoxicity effect was observed

The deterministic risk assessment for non-target plants based on plant dry weight parameter was provided by zRMS below:

Plant dry weight parameter:

Intended use		spring cereals, winter cereals	
Active substance/product		Jockey 387 OD	
Application rate (ml/ha)		1 × 1000	
MAF		1	
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL product/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (mL product/ha)**
1	2.77	27.7	13.85
5	0.57	5.7	2.85
10	0.29	2.9	1.45
Toxicity value		**TER**	
ER_{50} = 18.7 mL formulation/ha		**criterion: TER ≥ 5**	
1		**0.68**	**1.35**
5		**3.3**	6.56
10		6.5	12.89

The risk of Jockey 387 OD to non-target plants was assessed from toxicity exposure ratios between toxicity

endpoints for the formulation Jockey 387 OD and predicted environmental rate. The TER values were greater than the trigger of 5, indicating an acceptable risk to non-target terrestrial plants following application of Jockey 387 OD at maximum rate of 1 L/ha provided the following risk mitigations are applied:

- 10m buffer zone or 5 m buffer zone with 50% drift reducing spray nozzles.

Risk assessment for non-target plants should be considered by MSs level.

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

Not available.

9.12 Monitoring data (KCP 10.8)

Not available.

9.13 Classification and Labelling

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to ecotoxicological data is proposed for the formulation:

Table 9.13-1: Justified proposals for classification and labelling for JMD-HER 387 OD according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Hazard pictograms or Code(s) for hazard pictogram(s):	 GHS09
Signal word:	Warning
Hazard statement(s):	Very toxic to aquatic life. [H400] Very toxic to aquatic life with long lasting effects. [H410]
Precautionary statement(s):	-
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). [SP 1] To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5m to surface water bodies. [SPe 3] To protect non-target plants respect an unsprayed vegetated buffer zone of 5m to non-agricultural land or 75% nozzle reduction. [SPe 3]* Collect spillage [P391]

Table 9.13-2: Summary of evaluation of the ecotoxicological studies for JMD-HER 387 OD

Type of test, species, model system (Guide-line)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Acute toxicity to aquatic organisms (lowest value)	$E_rC_{50,nom}$ =0.139 mg/l	Yes	Aquatic Acute 1, H400	KCP 10.2.1.4/02/ Turek-Lipka T/2021/ Study code: W-05-21
Chronic toxicity to aquatic organisms	no data, extrapola-tion form active substance data	Yes	Aquatic Chronic 1, H410	dRR Part C

zRMS comment: Agreed.

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**	**Verte-brate study Y/N**	**Owner**
KCP 10.2.1.1/01	[redacted]	[redacted]	Measurement of median lethal dose as a rapid indication of contaminant toxicity to fish [redacted] GLP: N Published: Y	Y	NR
KCP 10.2.1.2/01	Kühn, R. *et al.*	1989	Results of the harmful effects of selected water pollutants (anilines, phenols, aliphatic compounds) to D*aphnia magna* Wat. Res. Vol. 23, No. 4, pp. 495-499, 1989 GLP: N Published: Y	Y	NR
KCP 10.2.1.2/02	Czarnecka M.	2021	JMD-HER 387 OD *Daphnia magna*, Acute Immobilisation Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: W-02-21 GLP: Y Published: N	N	Pestila*
KCP 10.2.1.2/03	Czarnecka M.	2021	JMD-HER 387 OD *Chironomus* sp., Acute Immobilisation Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: W-01-21 GLP: Y Published: N	N	Pestila*

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	Owner
KCP 10.2.1.3/01	Cowgill, U. *et al.*	1989	Toxicity of nine benchmark chemicals to *Skeletonema costatum*, a marine diatom Environmenlal Toxicology and Chemisrry, Vol. 8, pp. 451-455, 1989 GLP: N Published: Y	N	NR
KCP 10.2.1.3/02	Czarnecka M.	2022	JMD-HER 387 OD *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: W-03-21 GLP: Y Published: N	N	Pestila*
KCP 10.2.1.4/01	Czarnecka M.	2021	JMD-HER 387 OD *Lemna gibba*, Growth Inhibition Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: W-04-21 GLP: Y Published: N	N	Pestila*
KCP 10.2.1.4/02	Turek-Lipka T.	2021	JMD-HER 387 OD Water-sediment *Myriophyllum spicatum* toxicity test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: W-05-21 GLP: Y Published: N	N	Pestila*
KCP 10.3.1.1.1/01	Meler A.	2021	Honeybees, Acute Oral Toxicity Test of the test item JMD-HER 387 OD according to OECD Guideline 213 SORBBOLAB Research Laboratory LLC, Poznań, Poland Study Code: 0005/0097/E GLP: Y Published: N	N	Pestila*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.3.1.1.1/02	Orzechowska U.	2021	Bumblebee, Acute Oral Toxicity Test of the test item JMD-HER 387 OD according to OECD guideline 247 SORBBOLAB Research Laboratory LLC, Poznań, Poland Study Code: 0005/0101/E GLP: Y Published: N	N	Pestila*
KCP 10.3.1.1.2/01	Meler A.	2021	Honeybees, Acute Contact Toxicity Test of the test item JMD-HER 387 OD according to OECD Guideline 214 SORBBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0098/E GLP: Y Published: N	N	Pestila*
KCP 10.3.1.1.2/02	Orzechowska U.	2021	Bumblebee, Acute Contact Toxicity Test of the test item JMD-HER 387 OD according to OECD guideline 246 SORBBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0104/E GLP: Y Published: N	N	Pestila*
KCP 10.3.1.2/01	Orzechowska U.	2021	Honey bee, chronic oral toxicity test of the test item JMD-HER 387 OD according to OECD 245 Guideline SORBBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0100/E GLP: Y Published: N	N	Pestila*
KCP 10.3.1.4/01	Orzechowska U.	2021	Honey Bee Larval Toxicity Test following Repeated Exposure to the test item JMD-HER 387 OD according to OECD GD 239 ENV/JM/MONO(2016)34 SORBBOLAB Research Laboratory LLC, Poznań, Poland Study code: 0005/0103/E GLP: Y Published: N	N	Pestila*

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	Owner
KCP 10.3.2.2/01	Knapik M.	2021	An extended laboratory test for evaluating the effects of JMD-HER 387 OD on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: B-41-21 GLP: Y Published: N	N	Pestila*
KCP 10.3.2.2/02	Knapik M.	2021	An extended laboratory test for evaluating the effects of JMD-HER 387 OD on the predatory mite, *Typhlodromus pyri* (Sch.); Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: B-40-2 GLP: Y Published: N	N	Pestila*
KCP 10.3.2.2/02	Knapik M.	2021	Amendment No. 1 to the Final Report An extended laboratory test for evaluating the effects of JMD-HER 387 OD on the predatory mite, Typhlodromus pyri (Sch.). Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study Code: B-40-2 GLP: Y Published: N	N	Pestila*
KCP 10.3.2.2/03	Knapik M.	2021	An extended laboratory test for evaluating effects of JMD-HER 387 OD on the ladybird beetle, *Coccinella septempunctata* (L.) Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: B-39-21 GLP: Y Published: N	N	Pestila*

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study Y/N**	Owner
KCP 10.3.2.2/04	Mautino G	2023	Effects of JMD-HER 387 OD (2,4-D-2EH + iodosulfuronmethylsodium) on the rove beetle *Aleochara bilineata* – extended laboratory test SAGEA Centro di Saggio s.r.l. Study Code: 1185.H.SAG22/r GLP: Y Published: N	N	Pestila*
KCP 10.4.1.1/01	Arendarczyk A.	2021	JMD-HER 387 OD Earthworm reproduction test (*Eisenia andrei*) Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-03-21 GLP: Y Published: N	N	Pestila*
KCP 10.4.2.1/01	Gierbuszewska A.	2021	JMD-HER 387 OD Collembolan (*Folsomia candida*) Reproduction Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-04-21 GLP: Y Published: N	N	Pestila*
KCP 10.4.2.1/02	Gierbuszewska A.	2021	Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-05-21 GLP: Y Published: N	N	Pestila*
KCP 10.5/01	Pieczka P.	2022	JMD-HER 387 OD Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-09-21 GLP: Y Published: N	N	Pestila*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 10.6.2/01	Pieczka P.	2021	JMD-HER 387 OD Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-08-21 GLP: Y Published: N	N	Pestila*
KCP 10.6.2/02	Arendarczyk A.	2021	JMD-HER 387 OD Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland Study code: G-07-21 GLP: Y Published: N	N	Pestila*

* Pestila Spółka z ograniczona odpowiedzialnością

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	Verte-brate 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	Verte-brate 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	Verte-brate 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

Not relevant. No studies submitted.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

Not relevant. No studies submitted.

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

Not relevant. No studies submitted.

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

A 2.2.1.1 KCP 10.2.1.1 Acute toxicity to fish

Comments of zRMS:	zRMS treated this publication as additional information.

Reference:	KCP 10.2.1.1/01
Report	Measurement of median lethal dose as a rapid indication of contaminant toxicity to fish, [redacted]
Guideline(s):	No
Deviations:	Not relevant
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

A new method was developed to measure the toxicity of chemicals to fish over 96 h. Tested substances were dissolved in 5% ethanol in saline or in cod-liver oil and injected at a rate of 1.0 ml per 100 g of fish.

The results of parallel bioassays to measure toxicity by oral intubation (OI-LD_{50}) or aqueous exposure (LC_{50}) were closely linked to IP-LD_{50} values. In this summary only data of the aqueous exposure test on p-chlorophenol are included.

MATERIALS AND METHODS

Test material:	
Test item:	p-Chlorophenol (= 4-chlorophenol)
Molecular weight	128.6 g/mol
Description:	analytical
Lot/Batch no.:	2450950
Purity:	not stated
Source:	BDH Chemicals
Vehicle and/or positive control:	no
Test system:	
Organism (Species):	rainbow trout (S*almo gairdneri / Oncorhynchus mykiss*)
Age:	not stated
Size:	4.6-6.4 cm
Body weight of the animals:	1.2 - 3.8g
Source:	Goosen's Trout Farm, R.R. #1, Otterville, ON, Canada
Diet/Food:	daily with Ewos trout pellets except on weekends
Acclimatisation period:	at least 1 week
Medium:	water from Lake Ontario, dechlorinated to less than 10 µg Cl/L with specific composition: acid capacity $K_{S4,3}$ 0f 0.8 mmol L^{-1}, total hardness of 2,4 mmol/L, a calcium to magnesium ratio of 4 : 1, a sodium to potassium ratio of 10 : 1
Environmental conditions:	
Temperature:	14.1 – 16.5 °C
Photoperiod:	16 h light and 8 h dark
pH:	7.6 – 8.19
Dissolved oxygen:	5.6 – 9.4
Conductivity:	340 µmhos/cm^2
Hardness:	86 mg $CaCO_3$/L

STUDY DESIGN

Based on the results of a preliminary range finding test at 1.0, 10, 100 and 1,000 mg/L, a definite test was performed using concentrations of 0 (control), 10, 18, 32, 56 and 100% of the maximum test concentration. Ten fish were exposed to each concentration and the bioassay was repeated three times (n= 10 fishes x 6 concentrations x 3 replicates = 180). Chemicals were added by a Hamilton syringe pump and dilutions were achieved by a Mount-Brungs diluter. Each bioassay tank contains 14 L of medium and flow per tank varied between tests from 21 to 111 mL/min. Size of test fish was chosen such that the flow rate was always greater than 2 L per gram of fish per day. During bioassay tanks were not aerated.

Observations
After 96 h the number of animals in the control and test solutions was assessed for mortality.

Statistical calculations
LC_{50} values were calculated from records of percent mortality by computerized probit analysis. When the number of partial mortalities was too low for probit analysis, a graphical method was chosen.
LC_{50} values are based on mean measured concentration.

RESULTS AND DISCUSSION

Findings

The determined LC50 values for rainbow trout are given in the table below.

Table KCP 10.2.1.1-1: Determined LC_{50} values for p-chlorophenol on rainbow trout

Tested substance	Test period in h	LC_{50}
p-chlorophenol	96	14.8 µmol/L corresponding to 1.9 mg/L

CONCLUSION

Taking into account the obtained results, toxicity of p-chlorophenol to rainbow trout resulted in an 96 h LC_{50} of 1.9 mg/L.

A 2.2.1.2 KCP 10.2.1.2 Acute toxicity to aquatic invertebrates

Comments of zRMS:	zRMS treated this publication as additional information.

Reference:	KCP 10.2.1.2/01
Report	Results of the harmful effects of selected water pollutants (anilines, phenols, aliphatic compounds) to D*aphnia magna* , Kühn, R. *et al.*, 1989 Wat. Res. Vol. 23, No. 4, pp. 495-499, 1989
Guideline(s):	DIN 38412, part II
Deviations:	Not relevant
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

In the acute *Daphnia* test, the EC_{50}, EC_0 and EC_{100} after 24 and 48 h were determined for 70 substances. The results of the tests are given in three tables according to substance group. Evaluation showed that the toxicity of the substances may be higher or even substantially greater when the test period is extended from 24 to 48 h. In this summary only data of the aqueous exposure test on p-chlorophenol are included.

MATERIALS AND METHODS

Test material:	
Test item:	p-Chlorophenol (= 4-chlorophenol)
Description:	analytical
Lot/Batch no.:	not stated
Purity:	not stated
Source:	not stated
Vehicle and/or positive control:	none
Test system:	
Organism (Species):	*Daphnia magna*
Source:	own culture
Medium:	water with specific composition: acid capacity $K_{S4,3}$ 0f 0.8 mmol L^{-1}, total hardness of 2,4 mmol L^{-1}, a calcium to magnesium ratio of 4:1, a sodium to potassium ratio of 10:1
Environmental conditions:	

Temperature:	20°C in an incubator
Photoperiod:	not stated
pH:	start of the test: 8.0 ± 0.2 end of the test: > 7.0
Dissolved oxygen:	end of the test: > 4.0 mg o^2/l
Conductivity:	not stated

STUDY DESIGN

The effects of p-chlorophenol on *Daphnia magna* were evaluated in a 48-hour static toxicity test. Twenty *Daphnia* (2 replicates of ten 6-24 h old animals per test beaker) were exposed per concentration and control. Concentrations were selected so that 3-4 EC values were in the range between EC_0 and EC_{100}, with at least one value below and one above EC_{50}. The ratio between concentrations was 1:1.4.

Observations
After 24 h and 48 h, the number of animals in the control and test solutions that could still swim were counted.

Statistical calculations
Not stated how data were statistical evaluated.

RESULTS AND DISCUSSION

Findings
The determined EC values for *Daphnia magna* are given in the table below.

Table KCP 10.2.1.2-1 Determined EC values for p-chlorophenol on *Daphnia magna*

Test period in h	EC_{50} [mg/L]	EC_0 [mg/L]	EC_{100} [mg/L]
24	3.4	1.5	11
48	2.5	1.5	4

CONCLUSION

Taking into account the obtained results, the toxicity of p-chlorophenol to *Daphnia magna* is 48 h EC_{50} = 2.5 mg/L.

Comments of zRMS:

The study was accepted by RMS.
The validity criteria:
- the percentage of immobilisation of Daphnia magna in the control was 0% (criterion: not more than 10%),
- the percentage of immobilisation of Daphnia magna in the control was 0% (criterion: not more than 10%).

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilised *Daphnia magna*								Total of immobilised *Daphnia magna* [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	0	0	0	0	0
100	20	0	0	0	0	0	0	0	0	0	0

Agreed endpoints based on nominal test concentrations:
48-h EC_{50} > 100 mg formulation Jockey 387 OD/L.

Reference:	KCP 10.2.1.2/02
Report	JMD-HER 387 OD *Daphnia magna*, Acute Immobilisation Test, Czarnecka M.; 2021; Study code: W-02-21
Guideline(s):	Yes, OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023
Stability of test compound:	The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using a high performance liquid chromatography (HPLC) with Diode Array Detection, whereas the concentrations of 2,4-D 2-EHE were determined by the gas chromatography (GC) with ECD.

2. Vehicle and/or positive control: vehicle control: Elendt M7 medium,
positive control: potassium dichromate

3. Test organism

Species:	*Daphnia magna* Straus
Source:	neonates collected from a laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Age:	no older than 24 h, not the first brood progeny
Feeding:	during the test daphnia were not fed
Test units:	glass beakers with a capacity of 150 mL

4. Environmental conditions:

Medium:	Elendt M7
pH:	7.30 – 7.39
Medium temperature:	20.9 – 21.7 °C
Lighting:	daily cycle 16 h light : 8 h dark, fluorescent light source

STUDY DESIGN AND METHOD

The acute *Daphnia magna* immobilisation test for JMD-HER 387 OD was conducted according to OECD Guideline 202. Immobilisation of *Daphnia magna* exposed to the test item, JMD-HER 387 OD was investigated during a 48-hour semi-static test. The definitive test was performed with a single test item concentration of 100 mg/L as a limit test. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. Four replicates were used for the test item concentration and the control, each with five *Daphnia magna*. The *Daphnia magna* were observed for immobilisation after 24 and 48 h of exposure and any abnormal behaviour or appearance. The Daphnia magna were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel. No immobilisation of Daphnia magna was observed during the period of exposure, neither in the control, nor in the test item concentration of 100 mg/L. Good condition of daphnia culture was confirmed by the study with the reference substance, potassium dichromate.

The concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE were chemically determined. The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using a high performance liquid chromatography (HPLC) with Diode Array Detection, whereas the concentrations of 2,4-D 2-EHE were determined by the gas chromatography (GC). In spent samples at renewal and at exposure termination, the determined concentrations of iodosulfuron-methyl-sodium were in the range of 99.2 – 101.8% of the nominal concentration, whereas the determined concentrations of 2,4-D 2-EHE were in the range of 92.7 – 94.2% of the nominal concentration. Therefore, the concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE were stable under test conditions. The endpoint value was determined based on the nominal test item concentration.

Test design:	definitive test: control and tested concentration prepared in 4 replicates each, with 5 daphnia introduced into each replicate
Type of the exposure:	semi-static
Exposure time:	2 days (48 hours)
Tested concentrations, definitive test:	control (0 mg/l), 100.0 mg/l (limit test)
Dates:	start of the study 14.05.2021 start of the experimental part: 08.06.2021 end of the experimental part: 10.06.2021 end of the study: 15.07.2021
Statistic:	ToxRat Professional Version 3.3.0 commercial software

Table KCP 10.2.1.2-2: Immobilization of daphnia after 24 h and 48 h– definitive test

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilised *Daphnia magna*								Total of immobilised *Daphnia magna* [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	0	0	0	0	0
100	20	0	0	0	0	0	0	0	0	0	0

CONCLUSION

The EC_{50}/48 h is higher than 100 mg/L.

Comments of zRMS:	The study was accepted by RMS. The validity criteria: **TEST VALIDITY CRITERIA** In the definitive test, the following validity criteria specified in the OECD Guideline No. 235 (2011) were met: – the immobilisation of *Chironomus riparius* larvae in the control was 5% (criterion: not more than 15%), – the dissolved oxygen concentrations in the control and test vessels were within the range of 7.1 – 9.3 mg/L (criterion: not less than 3 mg/L). **Agreed endpoints based on nominal test concentrations:** 48-h EC_{50} > 100 mg formulation Jockey 387 OD/L.

Reference:	KCP 10.2.1.2/03
Report	JMD-HER 387 OD *Chironomus* sp., Acute Immobilisation Test, Czarnecka M.; 2021; Study code: W-01-21
Guideline(s):	Yes, OECD 235
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023
Stability of test compound:	The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using a high performance liquid chromatography (HPLC) with Diode Array Detection, whereas the concentrations of 2,4-D 2-EHE were determined by the gas chromatography (GC) with ECD.

2. Vehicle and/or positive control: vehicle control: Elendt M7 medium,
positive control: potassium chloride

3. Test organism

Species:	freshwater dipteran midge *Chironomus riparius* Meigen 1804

Source:	neonates collected from a laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Poland
Age:	first instar larvae, two-three days after hatching
Feeding:	no feeding during test
Test units:	Petri dishes of 25 mL capacity

4. Environmental conditions:

Medium:	Elendt M7
pH:	6.92 – 7.50
Medium temperature:	20.9 – 21.7°C
Oxygen concentration:	8.7 – 9.3 mg/L
Lighting:	daily cycle 16 h light : 8 h dark, fluorescent light source, mean light intensity: 608.8 lux

STUDY DESIGN AND METHOD

The aim of the study was to demonstrate that the test item concentration causing 50% immobilisation of *Chironomus riparius*, i.e. the EC50 value after 48 h of exposure, is higher than the test item concentration of 100 mg/L (limit test). The definitive test was performed using a single test item concentration of 100 mg/L as a limit test plus the control.
The effect of the test item on immobilisation of Chironomus riparius larvae was assessed. The test item concentration used in the definitive test was determined on the basis of the preliminary test results. Larvae were considered as immobile if they showed inability to swim within 15 seconds after mechanical stimulation e.g. subjecting the larvae to a gentle stream of water from a Pasteur pipette or gentle agitation of the test vessel. At exposure termination, in the control, immobilisation of chironomid larvae was 5%, whereas in the test item concentration of 100 mg/L, the immobilisation of chironomid larvae was 10%. No abnormal behaviour of larvae was observed during exposure.
The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using a high performance liquid chromatography (HPLC) with Diode Array Detection, whereas the concentrations of 2,4-D 2-EHE were determined by the gas chromatography (GC) with ECD. In fresh samples at exposure initiation and at renewal, the determined concentrations of iodosulfuron-methyl-sodium were in the range of 99.4 – 99.9% of the nominal concentration, whereas the determined concentrations of 2,4-D 2-EHE were in the range of 98.3 – 99.8% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. In spent samples at renewal and at exposure termination, the determined concentrations of iodosulfuron-methyl-sodium were in the range of 99.7 – 99.8% of the nominal concentration, whereas the determined concentrations of 2,4-D 2-EHE were in the range of 85.5 – 95.7% of the nominal concentration. Therefore, the concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE were stable under test conditions.

Test design:	definitive test: control and tested concentration prepared in 4 replicates each, with larvae of *Chironimus riparius* introduced into each replicate
Type of the exposure:	semi-static
Exposure time:	48 hours of exposure with renewal after 24 hours
Tested concentrations, definitive test:	control (0 mg/l), 100.0 mg/l (limit test)

Dates:	start of the study 14.05.2021 start of the experimental part: 08.06.2021 end of the experimental part: 10.06.2021 end of the study: 15.07.2021
Statistic:	ToxRat Professional Version 3.3.0 commercial software

Table KCP 10.2.1.2-3: Immobilization of *Chironomus riparius* after 24 h and 48 h– definitive test

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilised *Chironomus riparius*								Total of immobilised *Chironomus riparius* [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	1	0	0	0	5
100	20	0	0	0	0	1	1	0	0	0	10

CONCLUSION

The EC_{50}/48 h is higher than 100 mg/L.

A 2.2.1.3 KCP 10.2.1.3 Effects on aquatic algae

Comments of zRMS:	zRMS treated this publication as additional information.

Reference:	KCP 10.2.1.3/01
Report	Toxicity of nine benchmark chemicals to *Skeletonema costatum*, a marine diatom, Cowgill, U., 1989 Environmenlal Toxicology and Chemisrry, Vol. 8, pp. 451-455, 1989
Guideline(s):	No
Deviations:	Not relevant
GLP:	No
Acceptability:	Yes
Duplication (if vertebrate study)	No

The purpose of this study was to determine the sensitivity of a *Skeletonema costatum* to eight common chemicals and one herbicide. The 50% reduction in the number of cells per milliliter and that of total cell volume × 10^4 μm^3/ml was estimated in relation to each of the nine chemicals. Nominal concentrations of triclopyr triethylamine salt (Garlon 3A), $K_2Cr_2O_7$, 4—chlorophenol and phenol were slightly toxic (>10 mg/L) according to the U.S. Environmental Protection Agency classificatory scheme, while diethanolamine, chlorobenzene, chloroform, acetone and ethanol were classified as practically nontoxic (>100 mg/L). No observed effect levels were found for each of the two cell measurements in relation to each of the chemicals tested for the 5—d period of the test. The range was found to be from 1 to 6,000 mg/L for total cell count and from 0.65 to 6,000 mg/L for total cell volume. Data on the sensitivities of other organisms

to the group of common chemicals are also included. The marine diatom proved to be less sensitive to $K_2Cr_2O_7$ and diethanolamine than the green alga *Selenastrum capricornutum*. In this summary only data of the aqueous exposure test on p-chlorophenol are included.

MATERIALS AND METHODS

Test material:	
Test item:	4 - chlorophenol
Description:	analytical
Lot:	AOD
Purity:	Not stated
Source:	Eastman Kodak, CAS No. 106-48-9
Vehicle and/or positive control:	none
Test system:	
Organism:	marine diatom (*Skeletonema costatum*)
Source:	Bigelow Laboratory for Ocean Sciences at West Boothbay Harbor, Maine
Medium:	Provasoli, revised ASP 12 medium. Revision consists of addition of SE (Na_2SeO_4, 0.00479 g/L) and Cu ($CuCl_2$ $2H_2O$, 0.06707 g/L) and doubling of the amount of cyanocobalamine (0.00040 g/L)
Environmental conditions:	
Temperature:	19.5-20.6 °C
Light:	4,296-4,318 lux
Photoperiod:	14h light/ 10 h dark

STUDY DESIGN

At the beginning of the experiment a range finding test was conducted. Concentrations were set an order of magnitude apart, 0.1, 1, 10, 100, 1,000 mg/L and so on. Cell density was 100,000 cells/mL at the beginning of the range finding test and in the definitive test. The definitive test consisted of 5 or more concentrations and a control replicated three times. For each concentration a counting blank was included. Total cell count and cell volume were measured by the use of a cell counter. Additionally, initial and final pHs of control, low, middle and high-test item rates were measured. Each test lasted 5 days.

Observations
In all tests temperature and light intensity was assessed daily until day 5.

Statistical calculations
Not stated how data were statistical evaluated.

RESULTS AND DISCUSSION

Findings
The determined EC_{50} and NOEL values for *Skeletonema costatum* are given in the table below.

Table KCP 10.2.1.3-1 Determined EC_{50} and NOEL values for 4 - chlorophenol

4 - chlorophenol	Total cell count	Total cell volume
120 EC_{50} (95 % CI)	13.8 mg/L (-16.0, 43.5)	11.6 mg/L (-18.9, 42.2)
120 NOEL	1.08 mg/L	0.39 mg/L

CONCLUSION

The toxicity of 4 - chlorophenol to *Skeletonema costatum* is EC_{50} = 13.8 mg/L and NOEL = 1.08 mg/L for total cell count and EC_{50} = 11.6 mg/L and NOEL = 0.39 mg/L.

Comments of zRMS:	The study was accepted by RMS. The validity criteria: **TEST VALIDITY CRITERIA** In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) and EU Method C.3 were met: - the biomass in the control increased by a factor of 98.8 within the 72-hour test period (criterion: at least a 16-fold growth), - the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 2.2% (criterion: it must not exceed 7%), - the mean coefficient of variation for the section-by-section growth rate in the control culture was 34.6% (criterion: it must not exceed 35%). Deviation of the study: none **Agreed endpoints based on nominal test concentrations:** 72h E_rC_{50} = 9.207 mg formulation Jockey 387 OD/L (95% confidence interval: 8.229 – 10.492). 72h E_rC_{20} = 2.308 mg formulation Jockey 387 OD/L (95% confidence interval: 1.998 – 2.607) 72-h E_rC_{10} = 1.120 mg formulation Jockey 387 OD/L (95% confidence interval: 0.892 – 1.345). 72-LOEC = 0.64 mg formulation Jockey 387 OD/L and the NOEC = 0.256 mg formulation Jockey 387 OD/L 72-h E_yC_{50} = 1.698 mg formulation Jockey 387 OD/L (95% confidence interval: 1.385 – 2.083) 72-h E_yC_{20} = 0.612 mg formulation Jockey 387 OD/L (95% confidence interval: 0.415 – 0.799) 72-h E_yC_{10} = 0.359 mg formulation Jockey 387 OD/L (95% confidence interval: 0.211 – 0.508) 72-LOEC = 0.64 mg formulation Jockey 387 OD/L and the NOEC = 0.256 mg formulation Jockey 387 OD/L

Reference:	KCP 10.2.1.3/02
Report	JMD-HER 387 OD *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudo-kirchneriella subcapitata*), Growth inhibition test; Czarnecka M.; 2022; Study Code: W-03-21
Guideline(s):	Yes, OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023
Chemical analysis/stability:	The concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE were chemically determined. The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using the high performance liquid chromatography (HPLC) with Diode Array Detection, whereas the concentrations of 2,4-D 2-EHE were determined by the gas chromatography (GC).

2. Vehicle and/or positive control: vehicle control: AAP medium,
positive control: 3,5-dichlorophenol

3. Test organism

Species:	freshwater green algae, *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*)
Source:	cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology, the algae were obtained from the Culture Collection of Algae at Göttingen University, Germany
Age:	three days old
Test units:	Erlenmeyer flasks with a capacity of 250 mL

4. Environmental conditions:

Medium:	AAP medium
Medium temperature:	22.7 – 23.1 ºC
pH:	7.18 – 7.60
Lighting:	6706 - 7610 lux

STUDY DESIGN AND METHOD

The growth of the green algae Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata) exposed to the test item, IMD-HER 387 OD was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration, or the control, per replicate. The initial density of the algae was 1 x 104 cells/mL. The definitive test was performed with the following test item concentrations: 10, 4, 1.6, 0.64, 0.256 mg/L plus the control.

The number of algal cells was determined with indirect method, which involves a spectrophotometric measurement of the absorbance of algal suspension at 670 nm and converting its value into the number of cells using a standard curve. The absorbance for each replicate of each test item concentration and the control were measured after 24, 48, and 72 h of exposure. Morphology observations of the algae cells were performed at exposure termination.

Test design:	tested concentrations in three replicates, control in six replicates
Type of the exposure:	static
Exposure time:	72 hours
Inoculum:	1 x 10^4 cells/mL
Tested concentrations, definitive test:	10, 4, 1.6, 0.64, 0.256 mg/L (0.097, 0.039, 0.016, 0.006, 0.002 mg iodosulfuron-methyl sodium /L, 3.555, 1.422, 0.569, 0.228, 0.091 mg 2,4-D 2-EHE /L)
Dates:	start of the study 11.05.2021 start of the experimental part: 11.06.2021 end of the experimental part: 14.06.2021 end of the study: 15.07.2021
Statistic:	Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential ttest Procedure

RESULTS

Calculated inhibition of growth rate for the test item concentrations ranging from 0.256 to 10 mg/L after 72 h of exposure was in the range of 0.7 – 51.8% when compared to the control. Inhibition of yield for the test item concentrations ranging from 0.256 to 10 mg/L after 72 h of exposure was in the range of 3.5 – 91.6% when compared to the control. Morphology observations of the algae cells were performed at exposure termination. In the test item concentrations of 0.256 and 0.64 mg/L no differences in shape, size and colour of algal cells were reported as compared to the algae cells in the control. In the test item concentration of 0.64 mg/L bigger cells were reported as compared to the algae cells in the control. In the test item concentrations of 4 and 10 mg/L bigger and opalescent cells were reported as compared to the algae cells in the control. Moreover, in the test item concentration of 10 mg/L swollen cells were reported.

In samples collected at exposure initiation, the determined concentrations of iodosulfuron-methyl-sodium were in the range of 91.9 – 110.3% of the nominal concentration, whereas the determined concentrations of 2,4-D 2-EHE were in the range of 96.5 – 107.1% of the nominal concentration. The results confirm that the test item concentration was prepared correctly. In samples collected at exposure termination, the determined concentrations of iodosulfuron-methyl-sodium were in the range of 95.0 – 102.6% of the nominal concentration, whereas the determined concentrations of 2,4-D 2-EHE were in the range of 0.8 – 6.6% of the nominal concentration. Therefore, the concentrations of iodosulfuron-methyl-sodium were stable under test conditions and 2,4-D 2-EHE were not stable under test conditions. The endpoint values were determined based on the nominal test item concentrations.

CONCLUSION

The endpoint values based on nominal test item concentrations are summarised in table below.

Table KCP 10.2.1.3-1: Freshwater alga growth inhibition test – final results

Parameter	Growth rate	Yield
EC_{50} – 72 h [mg/L]	9.207 (95% confidence interval: 8.229 – 10.492)	1.698 (95% confidence interval: 1.385 – 2.083)
LOEC – 72 h [mg/L]	0.64	0.64
NOEC – 72 h [mg/L]	0.256	0.256

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Comments of zRMS:	The study was accepted by RMS. The validity criteria: **VALIDITY CRITERIA** In the definitive test, the following validity criteria specified in the OECD Guideline No. 221/ EU method C.26. were met: - the doubling time of frond number in the control was 1.7 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 17.9), - the average specific growth rate in the control between day 0 and day 7 was 0.412 d^{-1} (minimum requirement: higher than 0.275 d^{-1}). Deviation of the study: none **Agreed endpoints based on nominal test concentrations:**

Results:

<u>The endpoint values based on the nominal test item concentrations:</u>

Endpoints based on the frond number:

The E_rC_{50}/7 d value is 0.186 mg/L (95% confidence interval 0.131 – 0.264).

The E_rC_{20}/7 d value is 0.02 mg/L (95% confidence interval 0.010 – 0.033).

The E_rC_{10}/7 d value is 0.006 mg/L (95% confidence interval 0.003 – 0.012).

The E_yC_{50}/7 d value is 0.032 mg/L (95% confidence interval 0.024 – 0.041).

The E_yC_{20}/7 d value is below 0.006 mg/L.

The E_yC_{10}/7 d value is below 0.006 mg/L.

For growth rate and yield, the NOEC/7 d value is lower than 0.006 mg/L, whereas LOEC/7 d value is lower or equal to 0.006 mg/L.

Endpoints based on the dry weight:

The E_rC_{50}/7 d value is 1.054 mg/L (95% confidence interval 0.639 – 1.723).

The E_rC_{20}/7 d value is 0.016 mg/L (95% confidence interval 0.006 – 0.034).

The E_rC_{10}/7 d value is below 0.006 mg/L.

For growth rate, the NOEC/7 d value is 0.006 mg//L, whereas the LOEC/7 d value is 0.032 mg/L.

The E_yC_{50}/7 d value is 0.041 mg/L (95% confidence interval 0.032 – 0.052).

The E_yC_{20}/7 d value is below 0.006 mg/L.

The E_yC_{10}/7 d value is below 0.006 mg/L.

For yield, the NOEC/7 d value is lower than 0.006 mg/L, whereas LOEC/7 d value is lower or equal to 0.006 mg/L.

<u>The endpoint values based on the nominal concentrations of iodosulfuron-methyl-sodium:</u>

Endpoints based on the frond number:

The E_rC_{50}/7 d value is 1.807 µg/L (95% confidence interval 1.268 – 2.564).

The E_rC_{20}/7 d value is 0.197 µg/L (95% confidence interval 0.102 – 0.321).

The E_rC_{10}/7 d value is 0.062 µg/L (95% confidence interval 0.025 – 0.117).

The E_yC_{50}/7 d value is 0.306 µg/L (95% confidence interval 0.235 – 0.394).

The E_yC_{20}/7 d value is below 0.0582 µg/L.

The E_yC_{10}/7 d value is below 0.0582 µg/L.For growth rate and yield, the NOEC/7 d value is lower than 0.0582 µg/L, whereas LOEC/7 d value is lower or equal to 0.0582 µg/L.

Endpoints based on the dry weight:

The E_rC_{50}/7 d value is 10.223 µg/L (95% confidence interval 6.198 – 16.709).

	The E_rC_{10}/7 d value is below 0.0582 µg/L. For growth rate, the NOEC/7 d value is 0.0582 µg/L, whereas the LOEC/7 d value is 0.310 µg/L. The E_yC_{50}/7 d value is 0.396 µg/L (95% confidence interval 0.309 – 0.501). The E_yC_{20}/7 d value is below 0.0582 µg/L. The E_yC_{10}/7 d value is below 0.0582 µg/L. For yield, the NOEC/7 d value is lower than 0.0582 µg/L, whereas LOEC/7 d value is lower or equal to 0.0582 µg/L. <u>The endpoint values based on the nominal concentrations of 2,4-D 2-EHE:</u> Endpoints based on the frond number: The E_rC_{50}/7 d value is 0.066 mg/L (95% confidence interval 0.047 – 0.094). The E_rC_{20}/7 d value is 0.007 mg/L (95% confidence interval 0.004 – 0.012). The E_rC_{10}/7 d value is 0.002 mg/L (95% confidence interval 0.001 – 0.004). The E_yC_{50}/7 d value is 0.011 mg/L (95% confidence interval 0.009 – 0.014). The E_yC_{20}/7 d value is below 0.00213 mg/L. The E_yC_{10}/7 d value is below 0.00213 mg/L. For growth rate and yield, the NOEC/7 d value is lower than 0.00213 mg/L, whereas LOEC/7 d value is lower or equal to 0.00213 mg/L. Endpoints based on the dry weight: The E_rC_{50}/7 d value is 0.375 mg/L (95% confidence interval 0.227 – 0.613). The E_rC_{20}/7 d value is 0.006 mg/L (95% confidence interval 0.002 – 0.012). The E_rC_{10}/7 d value is below 0.00213 mg/L. For growth rate, the NOEC/7 d value is 0.00213 mg/L, whereas the LOEC/7 d value is 0.0114 mg/L. The E_yC_{50}/7 d value is 0.015 mg/L (95% confidence interval 0.011 – 0.018). The E_yC_{20}/7 d value is below 0.00213 mg/L. The E_yC_{10}/7 d value is below 0.00213 mg/L. For yield, the NOEC/7 d value is lower than 0.00213 mg/L, whereas LOEC/7 d value is lower or equal to 0.00213 mg/L. <u>The endpoint values based on the geometric means of determined concentrations of 2,4-D 2-EHE:</u> Endpoints based on the frond number: The E_rC_{50}/7 d value is 0.021 mg/L (95% confidence interval 0.015 – 0.029). The E_rC_{20}/7 d value is 0.004 mg/L (95% confidence interval 0.002 – 0.006). The E_rC_{10}/7 d value is 0.002 mg/L (95% confidence interval 0.001 – 0.003). The E_yC_{50}/7 d value is 0.005 mg/L (95% confidence interval 0.004 – 0.007). The E_yC_{20}/7 d value is 0.001 mg/L (95% confidence interval 0.00 – 0.001). The E_yC_{10}/7 d value is below 0.001 mg/L. For growth rate and yield, the NOEC/7 d value is lower than 0.001 mg/L, whereas LOEC/7 d value is lower or equal to 0.001 mg/L. Endpoints based on the dry weight: The E_rC_{50}/7 d value is 0.154 mg/L (95% confidence interval 0.076 – 0.316). The E_rC_{20}/7 d value is 0.001 mg/L (95% confidence interval 0.00 – 0.004). The E_rC_{10}/7 d value is not determined. For growth rate, the NOEC/7 d value is 0.001 mg/L, whereas the LOEC/7 d value is 0.006 mg/L. The E_yC_{50}/7 d value is 0.006 mg/L (95% confidence interval 0.011 – 0.018). The E_yC_{20}/7 d value is 0.001 mg/L (95% confidence interval 0.001 – 0.002). The E_yC_{10}/7 d value is below 0.001 mg/L. For yield, the NOEC/7 d value is lower than 0.001 mg/L, whereas LOEC/7 d value is lower or equal to 0.001 mg/L.	

Reference:	KCP 10.2.1.4/01
Report	JMD-HER 387 OD *Lemna gibba*, Growth Inhibition Test; Czarnecka M.; 2021; Study Code: W-04-21
Guideline(s):	Yes, OECD 221

Deviations:	One deviation from the study plan concerning study completion date occurred. However, the deviation did not have any impact on the results generated during the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023
Stability of test compound:	The concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE were chemically determined. The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using the validated high performance liquid chromatographic method with MS/MS detection, whereas the concentrations of 2,4-D 2-EHE were determined by the validated gas chromatographic method with ECD detection.

2. Vehicle and/or positive control: vehicle: 20X AAP medium,
positive control: 3,5-dichlorophenol

3. Test organism

Species:	duckweed (*Lemna gibba*) specification CPCC 310
Source:	from the Institute of Industrial Organic Chemistry, Branch Pszczyna obtained from the University of Waterloo, Canadian Phycological Culture Centre, Ontario, Canada
Test units:	150 ml glass crystallizers

4. Environmental conditions:

Medium:	20X AAP medium
Medium temperature:	22.9 – 23.3ºC
pH:	7.40 – 8.09
Lighting:	7205 – 7388 lux

STUDY DESIGN AND METHOD

Lemna gibba growth inhibition test was performed according to OECD Guideline No 221. The aim of the study was to determine the influence of test item JMD-HER 387 OD, on growth of gibbous duckweed *Lemna gibba*. The growth of *Lemna gibba* exposed to the test item, JMD-HER 387 OD,, was investigated in a 7 day semi-static test with daily renewals. The test was performed in glass crystallizers containing 150 mL of either the test item concentration or the control. The initial frond number in each test item concentration and the control was nine. The following test item concentrations were used: 500, 100, 20, 4.0, 0.8, 0.16, 0.032, and 0.006 mg/L plus the control. The total number of fronds in each test vessel was counted twice during exposure (day 2 and 4) and at exposure termination. The observations of plant development, i.e. size of fronds, necrosis, chlorosis, colony break-up, gibbosity, changes in the appearance of roots were performed at the same time.
The concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE were chemically determined. The concentrations of iodosulfuron-methyl-sodium were chemically analyzed using the validated high performance liquid chromatographic method with MS/MS detection, whereas the concentrations of 2,4-D 2-EHE were determined by the validated gas chromatographic method with ECD detection. In spent samples at renewals and at exposure termination, the determined concentrations of iodosulfuron-methyl-sodium were in the range of 90.9 – 109.7% of the nominal concentration and the determined concentrations of 2,4-D 2-EHE were in the range of 5.3 – 71.4% of the nominal concentration. Therefore, the concentrations of iodosulfuron-methyl-sodium were stable under test conditions and 2,4-D 2-EHE were not stable under test conditions. The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of iodosulfuron-methyl-sodium, nominal concentrations of 2,4-D 2-EHE, and geometric means of determined concentrations of 2,4-D 2-EHE.

Test design:	tested concentrations in three replicates, control in six replicates, 9 fronds on every replicate
Type of the exposure:	semi-static
Exposure time:	7 days
Tested concentrations, definitive test:	500, 100, 20, 4.0, 0.8, 0.16, 0.032, and 0.006 mg/L (4850, 970, 194, 38.8, 7.76, 1.552, 0.310, 0.0582 µgiodosulfuron-methyl sodium/L, 177.75, 35.55, 7.11, 1.422, 0.284, 0.057, 0.0114, 0.00213 mg 2,4-D 2-EHE/L)
Dates:	start of the study 03.08.2021 start of the experimental part: 02.09.2021 end of the experimental part: 11.09.2021 end of the study: 20.10.2021
Statistic:	ToxRat Professional commercial software Version 3.3.0

CONCLUSION

The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of iodosulfuron-methyl-sodium, nominal concentrations of 2,4-D 2-EHE, and geometric means of determined concentrations of 2,4-D 2-EHE. They are given below.

Table KCP 10.2.1.4-1: *Lemna gibba* growth inhibition test-final results - nominal test item concentration

Rated value	ErC_{50} [mg/L]	LOEC [mg/l]	NOEC [mg/l]

Growth rate – frond number	0.186 (0.131 – 0.264)	≤0.006	<0.006
Growth rate – dry weight	1.054 (0.639 – 1.723)	0.032	0.006
Rated value	**EyC_{50} [mg/L]**	**LOEC [mg/l]**	**NOEC [mg/l]**
Yield – frond number	0.032 (0.024 – 0.041)	≤0.006	<0.006
Yield – dry weight	0.041 (0.032 – 0.052)	≤0.006	<0.006

Table KCP 10.2.1.4-2: *Lemna gibba* growth inhibition test-final results - nominal active substance concentration

iodosulfuron-methyl-sodium			
Rated value	**ErC_{50} [µg/L]**	**LOEC [µg/l]**	**NOEC [µg/l]**
Growth rate – frond number	0.186 (0.131 – 0.264)	≤0.0582	<0.0582
Growth rate – dry weight	10.223 (6.198 – 16.709)	0.310	0.0582
Rated value	**EyC_{50} [µg/L]**	**LOEC [µg/l]**	**NOEC [µg/l]**
Yield – frond number	0.306 (0.235 – 0.394)	≤0.0582	<0.0582
Yield – dry weight	0.396 (0.309 – 0.501)	≤0.0582	<0.0582
2,4-D 2-EH			
Rated value	**ErC_{50} [µg/L]**	**LOEC [µg/l]**	**NOEC [µg/l]**
Growth rate – frond number	0.066 (0.047 – 0.094)	≤0.00213	<0.00213
Growth rate – dry weight	0.375 (0.227 – 0.613)	0.0114	0.00213
Rated value	**EyC_{50} [µg/L]**	**LOEC [µg/l]**	**NOEC [µg/l]**
Yield – frond number	0.011 (0.009 – 0.014)	≤0.00213	<0.00213
Yield – dry weight	0.015 (0.011 – 0.018)	≤0.00213	<0.00213

Table KCP 10.2.1.4-3: *Lemna gibba* growth inhibition test-final results - geometric means of determined concentrations

2,4-D 2-EH			
Rated value	**ErC_{50} [µg/L]**	**LOEC [µg/l]**	**NOEC [µg/l]**
Growth rate – frond number	0.021 (0.015 – 0.029)	≤0.001	<0.001
Growth rate – dry weight	0.154 (0.076 – 0.316)	0.006	0.001
Rated value	**EyC_{50} [µg/L]**	**LOEC [µg/l]**	**NOEC [µg/l]**
Yield – frond number	0.005 (0.004 – 0.007)	≤0.001	<0.001

Yield – dry weight	0.006 (0.005 – 0.008)	≤0.001	<0.001

Comments of zRMS:

The study was accepted by RMS.
The validity criteria:
- the mean total shoot length in the control in comparison with the mean total shoot length at exposure initiation increased 3.6-fold. The criterion of at least doubling the total shoot length was met;
- the mean fresh weight in the control in comparison with the mean fresh weight for representative group at exposure initiation increased 9.4-fold. The criterion of at least doubling the fresh weight was met;
- the plants in the control were without visual symptoms of chlorosis and during the exposure phase no contamination with algae, fungi or bacteria on the plants, on the sediment surface or in the test medium was observed;
- the mean coefficient of variation for yield based on fresh weight in replicates of the control in a period from exposure initiation to termination was 25.8%; did not exceed 35%.

Deviation of the study: In the definitive test, the temperature during the rooting phase was in the range of 19.9 – 23.6ºC (not within the range of 20 ± 2°C). Therefore, range of the temperature was greater than stated in the OECD No. 239 (2014), SOP/W/87 and the study plan. However, the growth of plants in the control was sufficient and the validity criteria were met. Therefore, the impact of the higher temperature on the generated results is assumed not significant (negligible).

Results from analysis of 2,4-D 2-EHE (aqueous phase), definitive test

Date of sampling	Nominal test item concentration [mg/L]	Nominal concentration of 2,4-D 2-EHE [mg/L]	Average determined concentration of 2,4-D 2-EHE (n=3) in samples collected [mg/L]	Recovery [%]
Day 0 31.08.2021	control	0.000	< LOD	-
	0.019	0.0068	0.0072	105.9
	0.060	0.021	0.020	95.2
	0.19	0.068	0.069	101.5
	0.61	0.217	0.192	88.5
	1.95	0.693	0.640	92.4
	6.25	2.222	2.325	104.6
	20	7.110	6.895	97.0
Day 7 07.09.2021	control	0.000	< LOD	-
	0.019	0.0068	< LOD	-
	20	7.110	< LOD	-
Day 14 14.09.2021	control	0.000	< LOD	-
	0.019	0.0068	< LOD	-
	0.060	0.021	< LOD	-
	0.19	0.068	< LOD	-
	0.61	0.217	< LOD	-
	1.95	0.693	< LOD	-
	6.25	2.222	< LOD	-
	20	7.110	< LOD	-

LOQ = 0.001 mg/L; LOD = 0.00015 mg/L;
- not calculated;

Results from analysis of iodosulfuron methyl sodium (aqueous phase), definitive test

Date of sampling	Nominal test item concentration [mg/L]	Nominal concentration of iodosulfuron methyl sodium [µg/L]	Average determined concentration of iodosulfuron methyl sodium (n=3) in samples collected [µg/L]	Recovery [%]
Day 0 31.08.2021	control	0.0000	< LOD	-
	0.019	0.1843	0.1937	105.1
	0.060	0.582	0.639	109.8
	0.19	1.843	1.930	104.7
	0.61	5.917	6.378	107.8
	1.95	18.915	20.326	107.5
	6.25	60.625	64.628	106.6
	20	194.000	198.267	102.2
Day 7 07.09.2021	control	0.0000	< LOD	-
	0.019	0.1843	0.1492	81.0
	20	194.000	190.472	98.2
Day 14 14.09.2021	control	0.0000	< LOD	-
	0.019	0.1843	0.1588	86.2
	0.060	0.582	0.496	85.2
	0.19	1.843	1.536	83.3
	0.61	5.917	5.374	90.8
	1.95	18.915	16.451	87.0
	6.25	60.625	57.408	94.7
	20	194.000	174.831	90.1

LOQ = 0.01 µg/L; LOD = 0.005 µg/L;

- not calculated;

Agreed endpoints based on nominal test concentrations:

Endpoint values for growth rate based on the nominal concentration of 2,4-D 2-EHE, definitive test

Endpoint value [mg/L]	Total shoot length		Fresh weight	Dry weight
	day 7	day 14	day 14	day 14
E_rC_{50}	0.1701 (0.1152 – 0.2502)	0.0496 (0.0385 – 0.0638)	1.7697 (1.0238 – 3.6370)	3.9072 (1.9040 – 13.2875)
E_rC_{20}	0.0169 (0.0078 – 0.0292)	0.0135 (0.0083 – 0.0189)	0.1000 (0.0331 – 0.1978)	0.1905 (0.0458 – 0.4127)
E_rC_{10}	0.0051 (0.0017 – 0.0104)	0.0068 (0.0035 – 0.0106)	0.0223 (0.0041 – 0.0581)	0.0393 (0.0037 – 0.1185)
LOEC	0.068	0.021	0.217	0.217
NOEC	0.021	0.0068	0.068	0.068

(-) - 95% confidence limits

n.d. – not determined

Calculations were made according to [6], [SOP/W/68]

Endpoint values for yield based on the nominal concentration of 2,4-D 2-EHE, definitive test

Endpoint value [mg/L]	Total shoot length		Fresh weight	Dry weight
	day 7	day 14	day 14	day 14
E_yC_{50}	0.1820 (0.1045 – 0.3149)	0.0354 (0.0264 – 0.0474)	0.2449 (0.1258 – 0.4813)	0.6703 (0.3294 – 1.5684)
E_yC_{20}	0.0181 (0.0056 – 0.0371)	0.0126 (0.0070 – 0.0180)	0.0174 (0.0038 – 0.0412)	0.0350 (0.0063 – 0.0875)
E_yC_{10}	0.0054 (0.0010 – 0.0139)	0.0074 (0.0033 – 0.0116)	< 0.0068 *0.0044 (0.0005 – 0.0138)*	0.0075 (0.0006 – 0.0261)
LOEC	0.217	0.068	0.217	0.217
NOEC	0.068	0.021	0.068	0.068

(-) - 95% confidence limits
n.d. – not determined
Calculations were made according to [6], [SOP/W/68]

However, the chemical analysis for the product Jockey 387 OD revealed, that the concentration of 2,4-D 2-EHE was below LOQ at the end of the test concentrations. Hence, it is concluded the toxicity endpoints from this studies may be questionable due to cannot be determined as exposure of the test compound was not maintained throughout the study. On the other hand, the combined risk assessment confirmed that it is clear that the calculated MDR value was 0.11 indicating antagonism effect hence the risk assessment for all scenarios was performed in Step 8 on the basis of RQ_{mix}. RQ_{mix} values were below the relevant trigger indicating acceptable risk for most scenarios in Step 3 or Step 4. For the other scenarios further risk mitigations are needed at national level.

The risk assessment for 2,4-D and iodosulfuron-methyl-sodium alone and combined risk assessment is considered sufficient to cover the risk of exposure to the product based on step 4 and the iodosulfuron-methyl-sodium concentration were properly maintained throughout the studies for Myriophyllum. All validity criteria in the study was met. However, the reliable endpoint for the study and risk assessment for plant product protection Jockey 387 OD and Myriophylum should be considered at MSs level.

Reference:	KCP 10.2.1.4/02
Report	JMD-HER 387 OD Water-sediment *Myriophyllum spicatum* toxicity test; Turek-Lipka T.; 2021; Study Code: W-05-21
Guideline(s):	Yes, OECD 239
Deviations:	In the definitive test, the temperature during the rooting phase was in the range of 19.9 – 23.6ºC (not within the range of 20 ± 2°C). Therefore, range of the temperature was greater than stated in the OECD No. 239 (2014), SOP/W/87 and the study plan. However, the growth of plants in the control was sufficient and the validity criteria were met. Therefore, the impact of the higher temperature on the generated results is assumed not significant (negligible).
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023
Stability of test compound:	The concentrations of iodosulfuron-methyl-sodium were determined with a validated high performance liquid chromatographic method with MS detection in aqueous phase and with a validated high performance liquid chromatographic method with DAD detection in sediment. The concentrations of 2,4-D 2-EHE were determined with a validated gas chromatography method with ECD detection in aqueous phase and sediment.
2. Vehicle and/or positive control:	vehicle: Smart & Barko medium positive control: 3,5-dichlorophenol

3. Test organism

Species:	watermilfoil *Myriophyllum spicatum*
Source:	standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology
Test units:	glass beakers of 11 cm diameter and 24 cm height

4. Environmental conditions:

Medium:	aerated test medium Smart and Barko and a conditioned sediment 281 - 294 µS/cm conductivity
pH:	pH in control: 7.45 – 9.09
Dissolved oxygen:	92.1 – 136.0 %
Lighting:	11.05 – 11.24 klux in a daily cycle of 16 h day and 8 h night
Temperature:	19.9 – 23.6 °C

STUDY DESIGN AND METHOD

The growth of watermilfoil *Myriophyllum spicatum* exposed to the test item, JMD-HER 387 OD for 14 days was studied in a water-sediment system, in static test design, in conditions required for the vegetative

growth. The toxicity test consisted of a rooting phase (7 days) and an exposure phase (14 days). The plants (representative group) were exposed in a set of nominal test item concentrations and control. The test item was applied into aqueous phase of water-sediment system. For each nominal test item concentration four replicates (i.e. 12 plants) and for the control six replicates (i.e. 18 plants) were used for exposure.. The impact of the test item on the plants growth was assessed based on total shoot length, fresh weight and dry weight of plants.

Test design:	rooting phase: five plants per replicate exposure phase: four replicates for each test item concentration and six replicates for the control
Test type:	exposure with application of the test item into aqueous phase of water-sediment system
Type of the exposure:	static
Exposure time:	7 days rooting phase, 14 days exposure phase
Tested concentrations, definitive test:	20, 6.25, 1.95, 0.61, 0.19, 0.060, 0.019 mg/L
Dates:	start of the study 08.06.2021 start of the experimental part: 24.08.2021 end of the experimental part: 18.09.2021 end of the study: 29.11.2021
Statistic:	Probit method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, Multiple Sequentially-rejective Welsh-t-test After Bonferroni-Holm, Multiple Sequentially-rejective U-test After Bonferroni-Holm.

RESULTS

In the tested range of the test item concentrations the inhibition of growth rate for total shoot length ranged from -7.3 to 85.2%, for fresh weight ranged from 3.1 to 63.6%, for dry weight ranged from 1.8 to 59.3% in comparison with plants in the control. The inhibition of yield for total shoot length ranged from -40.4 to 96.1%, for fresh weight ranged from 5.5 to 84.0%, for dry weight ranged from 4.1 to 76.5% in comparison with plants in the control.

At exposure termination in the control the plants were healthy, with green leaves and stems, without discolorations with very good developed roots, anchored in sediment. In the test item concentrations of 0.019 and 0.060 mg/L no visible changes were observed in comparison with plants in the control. In the test item concentration of 0.19 mg/L distorted shoots and leaves, and moderate root development were observed. In the test item concentration of 0.61 mg/L chlorosis, loss of turgor, distorted shoots and leaves, and moderate root development were observed. In the test item concentration of 1.95 mg/L necrosis, stem fragmentation, loss of turgor, distorted shoots and leaves, and moderate root development were observed. In the test item concentrations of 6.25 and 20 mg/L necrosis, stem fragmentation, loss of turgor, distorted shoots and leaves, and very few roots were observed.

The concentrations of 2,4-D 2-EHE in aqueous phase and sediment were determined in the collected samples of water-sediment system using a gas chromatography method with ECD detection. The concentrations of iodosulfuron-methyl-sodium in aqueous phase were chemically analyzed using a validated high performance liquid chromatographic method with MS/MS detection. The concentrations of iodosulfuron-methyl-sodium in sediment were chemically analyzed using a validated high performance liquid chromatographic method with DAD detection.

In samples collected from all test item concentrations at exposure initiation, the determined concentration of 2,4-D 2-EHE in aqueous phase was in the range of 92.4 – 105.9% of nominal concentration and the determined concentration of iodosulfuronmethyl-sodium in aqueous phase was in the range of 102.2 – 109.8% of nominal concentration. The results confirm that the test item concentrations were prepared correctly.

In the sample collected from the test item concentration of 20 mg/L at exposure initiation, the analysed concentration of 2,4-D 2-EHE and iodosulfuron-methyl-sodium in sediment was below LoD.

In samples collected from the test item concentrations of 0.019 and 20 mg/L after 7 days of exposure, the analysed concentration of 2,4-D 2-EHE in aqueous phase was below LOD and the determined concentration of iodosulfuron-methyl-sodium in aqueous phase was 81.0 and 98.2% of nominal concentration, respectively.

In samples collected from the test item concentrations of 0.019 and 20 mg/L after 7 days of exposure, the analysed concentration of iodosulfuron-methyl-sodium in sediment was below LOD and the analysed concentration of 2,4-D 2-EHE in sediment was below LOD and LOQ, respectively.

In samples collected from all test item concentrations at exposure termination, the analysed concentration of 2,4-D 2-EHE in aqueous phase was below LOD and the determined concentration of iodosulfuron-methyl-sodium in aqueous phase was in the range of 83.3 – 94.7% of nominal concentration, respectively.

In samples collected from all test item concentrations at exposure termination, the analysed concentration of 2,4-D 2-EHE in sediment was below LOD for the test item concentrations of 0.019 and 0.060 mg/L and below LOQ for the test item concentrations in the range of 0.19 – 20 mg/L.

The analysed concentration of iodosulfuron-methyl-sodium in sediment was below LOD for the test item concentrations of in the range of 0.019 – 6.25 mg/L and below LOQ for the test item concentration of 20 mg/L.

CONCLUSION

The results confirm, that the concentrations of iodosulfuron-methyl-sodium in aqueous phase were stable under test conditions, whereas the concentrations of 2,4-D 2-EHE in aqueous phase were not stable. Endpoint values were determined based on nominal test item concentrations, nominal concentrations of iodosulfuron-methyl-sodium and 2,4-D 2-EHE.

Table KCP 10.2.1.4-4: *Myriophyllum spicatum* toxicity test -final results, endpoint values for growth rate based on the nominal concentration of iodosulfuron-methyl-sodium, definitive test

Endpoint value [µg/L]	Total shoot length		Fresh weight	Dry weight
	day 7	day 14	day 14	day 14
E_rC_{50}	4.6446 (3.1417 – 6.8377)	1.3530 (1.0504 – 1.7396)	48.2674 (27.9296 – 99.1498)	106.5812 (51.9434 – 362.2527)
E_rC_{20}	0.4626 (0.2123 – 0.7984)	0.3706 (0.2288 – 0.5173)	2.7288 (0.9039 – 5.3962)	5.1965 (1.2509 – 11.2556)
E_rC_{10}	0.1386 (0.0472 – 0.2856)	0.1883 (0.0973 – 0.2910)	0.6078 (0.1118 – 1.5850)	1.0713 (0.1012 – 3.2325)

LOEC	1.843	0.582	5.917	5.917
NOEC	0.582	0.1843	1.843	1.843

(-) - 95% confidence limits n.d. – not determined

Table KCP 10.2.1.4-5: *Myriophyllum spicatum* toxicity test -final results, endpoint values for yield based on the nominal concentration of iodosulfuron-methyl-sodium, definitive test

Endpoint value [µg/L]	**Total shoot length**		**Fresh weight**	**Dry weight**
	day 7	**day 14**	**day 14**	**day 14**
E_yC_{50}	4.9675 (2.8530 – 8.5985)	0.9673 (0.7236 – 1.2921)	6.6821 (3.4348 – 13.1273)	18.2837 (8.9880 – 42.7623)
E_yC_{20}	0.4950 (0.1516 – 1.0140)	0.3482 (0.1928 – 0.4944)	0.4756 (0.1028 – 1.1265)	0.9544 (0.1726 – 2.3878)
E_yC_{10}	0.1483 (0.0285 – 0.3807)	0.2041 (0.0901 – 0.3206)	< 0.1843 *0.1195 (0.0136 – 0.3762)*	0.2039 (0.0162 – 0.7127)
LOEC	5.917	1.843	5.917	5.917
NOEC	1.843	0.582	1.843	1.843

(-) - 95% confidence limits n.d. – not determined

Table KCP 10.2.1.4-6: *Myriophyllum spicatum* toxicity test -final results, endpoint values for growth rate based on the nominal concentration of 2,4-D 2-EHE, definitive test

Endpoint value [mg/L]	**Total shoot length**		**Fresh weight**	**Dry weight**
	day 7	**day 14**	**day 14**	**day 14**
E_rC_{50}	0.1701 (0.1152 – 0.2502)	0.0496 (0.0385 – 0.0638)	1.7697 (1.0238 – 3.6370)	3.9072 (1.9040 – 13.2875)
E_rC_{20}	0.0169 (0.0078 – 0.0292)	0.0135 (0.0083 – 0.0189)	0.1000 (0.0331 – 0.1978)	0.1905 (0.0458 – 0.4127)
E_rC_{10}	0.0051 (0.0017 – 0.0104)	0.0068 (0.0035 – 0.0106)	0.0223 (0.0041 – 0.0581)	0.0393 (0.0037 – 0.1185)
LOEC	0.068	0.021	0.217	0.217
NOEC	0.021	0.0068	0.068	0.068

(-) - 95% confidence limits n.d. – not determined

Table KCP 10.2.1.4-7: *Myriophyllum spicatum* toxicity test -final results, endpoint values yield based on the nominal concentration of 2,4-D 2-EHE, definitive test

	Total shoot length	**Fresh weight**	**Dry weight**

Endpoint value [mg/L]	day 7	day 14	day 14	day 14
E_yC_{50}	0.1820 (0.1045 – 0.3149)	0.0354 (0.0264 – 0.0474)	0.2449 (0.1258 – 0.4813)	0.6703 (0.3294 – 1.5684)
E_yC_{20}	0.0181 (0.0056 – 0.0371)	0.0126 (0.0070 – 0.0180)	0.0174 (0.0038 – 0.0412)	0.0350 (0.0063 – 0.0875)
E_yC_{10}	0.0054 (0.0010 – 0.0139)	0.0074 (0.0033 – 0.0116)	< 0.0068 *0.0044 (0.0005 – 0.0138)*	0.0075 (0.0006 – 0.0261)
LOEC	0.217	0.068	0.217	0.217
NOEC	0.068	0.021	0.068	0.068

(-) - 95% confidence limits n.d. – not determined

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

Not relevant. No studies submitted.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not relevant. No studies submitted.

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 was accepted by RMS. The validity criteria was met. The test met the validity criteria for an experiment in accordance with OECD 213 Guideline: ➢ bee mortality in control group was 0% (required: ≤10%); ➢ LD_{50} value for reference item after 24 hours was 0.168 µg of the reference item/bee (required: 0.10-0.35 µg/bee). Deviation of the study: According to the OECD Guideline 213, the test should be carried out at air humidity of 60±10%. During the range-finding test, the humidity decreased to 47.4% and increased to 76.1%. During the definitive test, the humidity decreased to 45.3%. **Agreed toxicity endpoints:**

Final results

Final results calculated by ToxRat Professional		
Parameter	Time of observation	
	24 h	48 h
LD_{10} [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD_{20} [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD_{50} [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*

LD_{10} test item dose causing mortality in 10% of individuals
LD_{20} test item dose causing mortality in 20% of individuals
LD_{50} test item dose causing mortality in 50% of individuals
*) the lower and upper 95% confidence limits are given in brackets
) **based on the analysis of the results, the value was defined as >100 µg of the test item/bee
n.d. impossible to determine due to mathematical reasons

The test item in the course of this experiment did not affect the survival of adult honey bee workers *(Apis mellifera carnica*). The test item is nontoxic at a dose of 100 µg of the test item/bee, used in the definitive test. Based on the analysis of results, the LD_{10} LD_{20} and LD_{50} values were defined as >100 µg Jockey 387 OD/bee.

Reference:	KCP 10.3.1.1.1/01
Report	Honeybees, Acute Oral Toxicity Test of the test item JMD-HER 387 OD according to OECD Guideline 213; Meler, A.; 2021; Study Code: 0005/0097/E
Guideline(s):	Yes, OECD 213
Deviations:	According to the OECD Guideline 213, the test should be carried out at air humidity of 60±10%. During the range-finding test, the humidity decreased to 47.4% and increased to 76.1%. During the definitive test, the humidity decreased to 45.3%. These deviations were short-term and had no effect on the results of the test. The test met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020

Production date:	02.2021
Expiration date:	02.2023
2. Vehicle and/or positive control:	vehicle: 50% sucrose solution positive control: dimethoate
3. Test organism	
Species:	honeybee *Apis mellifera*
Source:	registered breeding of Mr. Wiesław Londzinin Poznań, entered in the register under veterinary number 30 21 71 1077
Age:	about 3 weeks after pupation
Acclimation period:	the quarantine was not carried out because insects were not treated with any chemical compounds within a month before the start of the study
Diet:	50% sucrose solution
Test units:	well ventilated cages of 18 cm x 12 cm x 7.5 cm in dimension
4. Environmental conditions:	
Temperature:	average temperature 24.620°C (minimal temperature 23.1°C. maximal temperature 26.5°C)
Relative humidity:	average humidity: 52.198% (minimal humidity 45.3%. maximal humidity 63.1%)
Photoperiod:	darkness (excluding observations)

STUDY DESIGN AND METHOD

The aim of the study was to determine the dose that would cause mortality of 50% of the population after 24 and 48 hours. The experiment was carried out in accordance with OECD Guideline No 213. The study was conducted on honeybee, *Apis mellifera*. Quarantine of the bees was not carried out, because within a month before the beginning of the study, insects were not treated with chemicals compounds. The tested bees were collected at the start day, in order to compensate for the condition of the bees. The bees were then provided with 50% sucrose solution and appropriate environmental conditions. The study employed adult honeybees workers at a similar age (about 3 weeks after pupation) from a healthy, well-maintained family with a fertile mother. During the test following data and actions were registered: mortality and signs of intoxication after 4 hours from the start of exposure and after 24 and 48 hours from changing the solution with the test item to the sucrose solution, the amount of consumed sucrose solution containing the test item and the amount of sucrose solution without the test item consumed by control group during exposure period (2 h) and the temperature and the air humidity during the test were continuously measured with a temperature recorder at 1 hour intervals.

Test design:	tested dose and control in three repetitions, 10 bees per repeat
Exposure time:	2 hours exposition and 48 hours from the moment of changing the solution with the test item to the sucrose solution
Tested concentrations, definitive test:	100 µg/bee (10g/L) (limit test)
Dates:	start of the study 27.04.2021 start of the experimental part: 13.05.2021 end of the experimental part: 15.05.2021 end of the study: 05.07.2021
Statistic:	ToxRat Professional statistical program

CONCLUSION

The test item in the course of this experiment did not affect the survival of adult honey bee workers *(Apis mellifera carnica*). The test item is nontoxic at a dose of 100 µg of the test item/bee, used in the definitive test. Based on the analysis of results, the LD10 LD20 and LD50 values were defined as >100 µg of the test item/bee.

Table KCP 10.3.1.1.1-1: *Apis mellifera* acute oral toxicity test -final results

Parameter	Exposure time 24h	Exposure time 48h
LD_{10} [µg/bee]	n.d.**	n.d.**
LD_{20} [µg/bee]	(n.d. – n.d.)*	(n.d. – n.d.)*
LD_{50} [µg/bee]	n.d.**	n.d.**

*) the lower and upper 95% confidence limits are given in brackets
**) based on the analysis of the results, the value was defined as >100 µg of the test item/bee
n.d. impossible to determine due to mathematical reasons

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. The test met the validity criteria determined in OECD 247 guideline: ➢ bumblebee mortality in control after 48 h was 0.0% (required: ≤ 10%), ➢ bumblebee mortality in reference test after 48 h was 80.0% (required: ≥50%). Deviation of the study: According to the OECD guideline 247, the test should be carried out at the temperature fitting the range of 25±2°C.During the definitive test, the temperature decreased to 22.9°C. The deviation was brief and had no effect on the results of the test. The test met the validity criteria. **Agreed toxicity endpoints:**

Final results

Time of reading	Bumblebee mortality [pcs.]		
	Control	1000 µg of test item/bumblebee	Statistical significance*)
4 hours	0	0	-
24 hours	0	0	-
48 hours	0	0	-

Parameter	Value
LD_{50}	>1000 µg of test item/bumblebee
NOED	>1000 µg of test item/bumblebee

- statistically insignificant
*) values calculated using ToxRat Professional software
LD_{50} test item dose causing reduction of individuals by 50%
NOED the highest test item dose which does not cause statistically significant differences in relations to the control

Reference:	KCP 10.3.1.1.1/02
Report	Bumblebee, Acute Oral Toxicity Test of the test item JMD-HER 387 OD according to OECD guideline 247; Orzechowska U; 2021; Study Code: 0005/0101/E
Guideline(s):	Yes, OECD 247
Deviations:	According to the OECD guideline 247, the test should be carried out at the temperature fitting the range of 25±2°C.During the definitive test, the temperature decreased to 22.9°C. The deviation was brief and had no effect on the results of the test. The test met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: 50% sucrose solution

positive control: dimethoat

3. Test organism

Species:	bumbleebee (*Bombus* spp.)
Source:	commercial supplier
Age:	adult worker bumblebees
Acclimation period:	acclimatized to the test conditions for about 24 hours before starting the experiment
Diet:	50% sucrose solution
Test units:	well-ventilated cages of 55 cm3 volume

4. Environmental conditions:

Temperature:	average temperature 24.382°C (minimal temperature 22.9°C, maximal temperature 25.6°C)
Relative humidity:	humidity: 59.990% (minimal humidity 52.5%, maximal humidity 73.3%)
Photoperiod:	darkness

STUDY DESIGN AND METHOD

An acute oral toxicity test of the test item JMD-HER 387 OD was performed on adult bumblebee workers (*Bombus* spp.). The aim of the test was to determine the dose causing mortality of 50% of the population in the experiment (LD50 value) and NOED after 24 and 48 h. One dose of the test item, i.e. 1000 µg test item/bumblebee, plus the control and one dose of the reference item were used. The design of the definitive test was selected on the basis of the non-GLP preliminary test results. The test consisted of single administration of the test item in a 50% (m/v) sucrose solution in proper concentration in a volume of 40 µL/bumblebee with glass micropipettes. After 4 hours from the start of the test and every 24 hours throughout the test, mortality observations and behavioral changes were performed.

Test design:	tested dose and control in 50 replicates, 1 insect per replicates; reference item in 30 replicates, 1 insect per replicates
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	1000 µg/bumblebee (20325.2 mg of the test item/kg of food) (limit test)
Dates:	start of the study 18.05.2021 start of the experimental part: 28.05.2021 end of the experimental part: 30.05.2021 end of the study: 16.07.2021
Statistic:	ToxRat Professional statistical software

CONCLUSION

In the course of the study, the test item did not shown apitoxic effects on adult bumblebee workers (*Bombus spp*.). The test item is do not cause mortality at a dose of 1000 µg of the test item/bumblebee, used in the definitive test. On the basis of data analysis, the values LD_{50} and NOED were determined at the level of >1000 µg of test item/bumblebee.

Table KCP 10.3.1.1.1-2: *Bombus* spp. acute oral toxicity test -final results

Time of reading	**Bumblebee mortality [pcs.]**		
	Control	**1000 µg of test item/bumblebee**	**Statistical significance**
4 hours	0	0	-
24 hours	0	0	-
48 hours	0	0	-
Parameter	**Value**		
LD_{50}	>1000 µg of test item/bumblebee		
NOED	>1000 µg of test item/bumblebee		

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.
The test met the validity criteria for an experiment in accordance with OECD 214 Guideline:

- bee mortality in control group was 0% (required: ≤10%).

Deviation of the study: According to the OECD Guideline 214, the test should be carried out at air humidity of 60±10%. The humidity range during the range-finding test was 47.4% to 76.1%. The humidity range during the definitive test was 45.3% to 63.1%, These deviations were short-term and had no effect on the results of the test.

Agreed toxicity endpoints:

Final results

Final results calculated by ToxRat Professional		
Parameter	**Time of observation**	
	24 h	**48 h**
LD_{10} [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD_{20} [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*
LD_{50} [µg of the test item/bee]	n.d.** (n.d. – n.d.)*	n.d.** (n.d. – n.d.)*

LD_{10} test item dose causing mortality in 10% of individuals
LD_{20} test item dose causing mortality in 20% of individuals
LD_{50} test item dose causing mortality in 50% of individuals
*) the lower and upper 95% confidence limits are given in brackets
) **based on the analysis of the results, the value was defined as >100 µg of the test item/bee
n.d. impossible to determine due to mathematical reasons

The test item in the course of this experiment did not affect the survival of adult honey bee workers (*Apis mellifera carnica*). The test item is nontoxic at a dose of 100 µg of the test item/bee, corresponding to concentration 100 g of the test item/L.

	Based on the analysis of results, the $LD_{10,}$ LD_{20} and LD_{50} values were defined as > 100 µg of the test item/bee.

Reference:	KCP 10.3.1.1.2/01
Report	Honeybees, Acute Contact Toxicity Test of the test item JMD-HER 387 OD according to OECD Guideline 214; Meler A.; 2021; Study Code: 0005/0098/E
Guideline(s):	Yes, OECD 214
Deviations:	According to the OECD Guideline 214, the test should be carried out at air humidity of 60±10%. The humidity range during the range-finding test was 47.4% to 76.1%. The humidity range during the definitive test was 45.3% to 63.1%, These deviations were short-term and had no effect on the results of the test. The test met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: water
positive control: dimethoate

3. Test organism

Species:	honeybee *Apis mellifera*
Source:	registered breeding of Mr. Wiesław Londzin in Poznań, entered in the register under veterinary number 30 21 71 1077
Age:	about 3 weeks
Acclimation period:	the quarantine was not carried out because insects were not treated with any chemical compounds within a month before the start of the study
Diet:	50% sucrose solution

Test units:	well ventilated cages of 18 cm x 12 cm x 7.5 cm in dimension

4. Environmental conditions:

Temperature:	average temperature 24.690°C (minimal temperature 23.4°C, maximal temperature 26.6°C)
Relative humidity:	average humidity: 52.268% (minimal humidity 45.3%, maximal humidity 63.1%)
Photoperiod:	darkness (excluding observations)

STUDY DESIGN AND METHOD

The aim of the study was to determine the dose that would cause mortality of the population after 424 and 48 hours. The study was carried out in accordance with OECD Guideline No 214. The study was conducted on honeybee, *Apis mellifera*. Quarantine of the bees was not carried out, because within a month before the beginning of the study, insects were not treated with chemicals compounds. The tested bees were collected at the start day of the test in the morning, in order to compensate for the condition of the bees. The bees were then provided with 50% sucrose solution and appropriate environmental conditions. The study employed adult honeybees workers at a similar age from a healthy, well-maintained family with a fertile mother. During the test following data and actions were registered: bees mortality and signs of intoxication in each cages after 4, 24 and 48 hours from the beginning of the test, the temperature and the air humidity during the test were continuously measured with a temperature recorder at 1-hour intervals.

Test design:	tested dose and control in five replicates, 10 bees per replicate
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	100 µg/bee (100 g/L) (limit test)
Dates:	start of the study 27.04.2021 start of the experimental part: 13.05.2021 end of the experimental part: 15.05.2021 end of the study: 07.07.2021
Statistic:	ToxRat Professional statistical program

CONCLUSION

The test item in the course of this experiment did not affect the survival of adult honey bee workers (*Apis mellifera carnica*). The test item is nontoxic at a dose of 100 µg of the test item/bee, corresponding to concentration 100 g of the test item/L. Based on the analysis of results, the $LD_{10,}$ LD_{20} and LD_{50} values were defined as > 100 µg of the test item/bee.

Table KCP 10.3.1.1.2-1: *Apis mellifera* acute contact toxicity test - final results

Parameter	Exposure time 24h	Exposure time 48h
LD_{10} [µg/bee]	n.d.**	n.d.**
LD_{20} [µg/bee]	(n.d. – n.d.)*	(n.d. – n.d.)*
LD_{50} [µg/bee]	n.d.**	n.d.**

*) the lower and upper 95% confidence limits are given in brackets
**) based on the analysis of the results, the value was defined as >100 µg of the test item/bee
n.d. impossible to determine due to mathematical reasons

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.
The test met the validity criteria determined in OECD 246 Guideline:

- bumblebee mortality in control after 48 h was 0.0% (required: ≤ 10%),

Deviation of the study:
According to the OECD guideline 246, the test should be carried out at the temperature fitting the range of 25±2°C. During the definitive test, the temperature decreased to 22.9°C. The deviation was brief and had no effect on the results of the test. The test met the validity criteria.

Agreed toxicity endpoints:

Final results

Time of reading	Bumblebee mortality [pcs.]		
	Control	1000 µg of test item/bumblebee	Statistical significance*)
4 hours	0	0	-
24 hours	0	0	-
48 hours	0	0	-

Parameter	Value
LD_{50}	>1000 µg of test item/bumblebee
NOED	>1000 µg of test item/bumblebee

- statistically insignificant
*) values calculated using ToxRat Professional software
LD_{50} test item dose causing 50% mortality of individuals
NOED the highest test item dose not causing statistically significant differences in relations to the control

Reference:	KCP 10.3.1.1.2/02
Report	Bumblebee, Acute Contact Toxicity Test of the test item JMD-HER 387 OD according to OECD guideline 246; Orzechowska U; 2021; Study Code: 0005/0104/E
Guideline(s):	Yes, OECD 246

Deviations:	According to the OECD guideline 246, the test should be carried out at the temperature fitting the range of 25±2°C. During the definitive test, the temperature decreased to 22.9°C. The deviation was brief and had no effect on the results of the test. The test met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle water
positive control: dimethoate

3. Test organism

Species:	bumbleebee (*Bombus* spp.)
Source:	commercial supplier
Age:	adult worker bumblebees
Acclimation period:	acclimatized to the test conditions for about 24 hours before starting the experiment
Diet:	50% sucrose solution
Test units:	well-ventilated cages of 55 cm3 volume

4. Environmental conditions:

Temperature:	average temperature 24.382°C (minimal temperature 22.9°C, maximal temperature 25.6°C)
Relative humidity:	average humidity: 59.990% (minimal humidity 52.5%, maximal humidity 73.3%)
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The study was conducted to determine the acute contact toxicity of JMD-HER 387 OD to bumblebees (*Bombus* spp.) with a laboratory method and to demonstrate, that the median lethal dose, i.e. the LD_{50} at the end of exposure, is higher than the dose used in the test (limit test). One dose of the test item, i.e. 1000 µg test item/bumblebee, plus the controls and one dose of the reference item were used. The design of the definitive test was selected on the basis of the non-GLP preliminary range - finding test results. The test consisted of single administration of the test item in aqueous solution in proper concentration in a volume of 2 µL directly at central, dorsal thorax. After 4 hours from the start of the test and every 24 hours throughout the test, mortality observations and behavioral changes were performed. During the test, following measurements and observations were performed: bumblebee mortality after 4, 24, 48 h, intoxication signs, temperature and humidity during definitive test were recorded in continuous way using temperature and humidity recorder with the record at 1-hour intervals, weight of bumblebees recorded directly before the beginning of the test.

Test design:	tested dose and controls in 50 replicates, 1 insect per replicates; reference item in 30 replicates, 1 insect per replicates
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	000 µg of the test item/bumblebee (500 g of the test item/L of solution) (limit test)
Dates:	start of the study 18.05.2021 start of the experimental part: 28.05.2021 end of the experimental part: 30.05.2021 end of the study: 16.07.2021
Statistic:	ToxRat Professional statistical software

CONCLUSION

In the course of the study, the test item did not shown apitoxic effects on adult bumblebee workers (*Bombus* spp.). The test item is do not cause mortality at a dose of 1000 µg of the test item/bumblebee, used in the definitive test. On the basis of data analysis, the values LD_{50} and NOED after 48 h were determined at the level of >1000 µg of test item/bumblebee.

Table KCP 10.3.1.1.2-2: *Bombuss spp.* acute contact toxicity test - final results

Time of reading	**Bumblebee mortality [pcs.]**		
	Control	**1000 µg of test item/bumblebee**	**Statistical significance**
4 hours	0	0	-
24 hours	0	0	-
48 hours	0	0	-
Parameter	**Value**		
LD_{50}	>1000 µg of test item/bumblebee		
NOED	>1000 µg of test item/bumblebee		

A 2.3.1.2 KCP 10.3.1.2 Chronic toxicity to bees

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. The test met the validity criteria of the experiment according to OECD 245 guideline: ➢ bee mortality in control after 10 days was 0.0% (required: ≤15%);

- bee mortality in the reference test after 10 days was 66.7% (required: ≥50%).

Deviation of the study: During the stability, range-finding and definitive tests, changes in temperature and humidity took place. They resulted from everyday activities and observations and were recorded and corrected on an ongoing basis. These were short-term declines which did not affect the condition of the research system. The above deviations did not affect the test result. The study met the validity criteria.

Agreed toxicity endpoints:

Final results of the study

Final results calculated using ToxRat Professional on the basis of the nominal concentrations of the tested item and nominal concentrations of active substances				
Parameter	**Concentration [mg of the test item/kg of food]**	**Concentration [mg 2,4-D/kg of food]**	**Concentration [mg 2,4-D 2EHE /kg of food]**	**Concentration [mg iodosulfuron methylsodium/kg of food]**
LC_{10}	n.d.[1] (n.d. – n.d.)*	n.d.[2] (n.d. – n.d.)*	n.d.[3] (n.d. – n.d.)*	n.d.[4] (n.d. – n.d.)*
LC_{20}	n.d.[1] (n.d. – n.d.)*	n.d.[2] (n.d. – n.d.)*	n.d.[3] (n.d. – n.d.)*	n.d.[4] (n.d. – n.d.)*
LC_{50}	n.d.[1] (n.d. – n.d.)*	n.d.[2] (n.d. – n.d.)*	n.d.[3] (n.d. – n.d.)*	n.d.[4] (n.d. – n.d.)*
NOEC	>2500	>591.5	>888.75	>24.25
LOEC	≥2500	≥591.5	≥888.75	≥24.25
Final results calculated using ToxRat Professional on the basis of the dose of the tested item or active substances consumed by bees				
Parameter	**Dose [µg of the test item/bee/day]**	**Dose [µg 2,4-D /bee/day]**	**Dose [µg 2,4-D 2EHE /bee/day]**	**Dose [µg iodosulfuron methylsodium /bee/day]**
LDD_{10}	n.d.[5] (n.d. – n.d.)*	n.d.[6] (n.d. – n.d.)*	n.d.[7] (n.d. – n.d.)*	n.d.[8] (n.d. – n.d.)*
LDD_{20}	n.d.[5] (n.d. – n.d.)*	n.d.[6] (n.d. – n.d.)*	n.d.[7] (n.d. – n.d.)*	n.d.[8] (n.d. – n.d.)*
LDD_{50}	n.d.[5] (n.d. – n.d.)*	n.d.[6] (n.d. – n.d.)*	n.d.[7] (n.d. – n.d.)*	n.d.[8] (n.d. – n.d.)*
NOEDD	>89.53	>21.18	>31.83	>0.87
LOEDD	≥89.53	≥21.18	≥31.83	≥0.87

n.d.	impossible to determine for mathematical reasons
LC_{10}	concentration causing mortality in 10% of individuals
LC_{20}	concentration causing mortality in 20% of individuals
LC_{50}	concentration causing mortality in 50% of individuals
NOEC	the highest concentration that did not cause statistically significant differences compared to the control
LOEC	the lowest concentration causing statistically significant differences from the control
LDD_{10}	the daily dose causing mortality in 10% of individuals
LDD_{20}	the daily dose causing mortality in 20% of individuals
LDD_{50}	the daily dose causing mortality in 50% of individuals
NOEDD	the highest daily dose, showing no statistically significant differences compared to the control
LOEDD	the lowest daily dose inducing statistically significant differences compared to the control
*	lower and upper 95% confidence interval
1)	based on the analysis of the results, the values were determined as >2500 mg of the test item/kg of food
2)	based on the analysis of the results, the values were determined as >591.5 mg 2,4-D/kg of food
3)	based on the analysis of the results, the values were determined as >888.75 mg 2,4-D 2EHE/kg of food
4)	based on the analysis of the results, the values were determined as >24.25 mg iodosulfuron methylsodium/kg of food
5)	based on the analysis of the results, the values were determined as >89.53 µg of the test item/bee/day
6)	based on the analysis of the results, the values were determined as >21.18 µg 2,4-D/bee/day
7)	based on the analysis of the results, the values were determined as >31.83 µg 2,4-D 2EHE/bee/day
8)	based on the analysis of the results, the values were determined as >0.87 µg iodosulfuron methylsodium /bee/day

Reference: KCP 10.3.1.2/01

Report	Honey bee, chronic oral toxicity test of the test item JMD-HER 387 OD according to OECD 245 Guideline; Orzechowska U.; 2021; Study Code: 0005/0100/E
Guideline(s):	Yes, OECD 245
Deviations:	During the stability, range-finding and definitive tests, changes in temperature and humidity took place. They resulted from everyday activities and observations and were recorded and corrected on an ongoing basis. These were short-term declines which did not affect the condition of the research system. The above deviations did not affect the test result. The study met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: 50% sucrose solution
positive control: dimethoate

3. Test organism

Species:	honeybee *Apis mellifera*
Source:	registered breeding of Mr. Wiesław Londzin in Poznań, entered into the register under veterinary number 3021711077
Age:	2-day old
Acclimation period:	the quarantine was not carried out because insects were not treated with any chemical compounds within a month before the start of the study
Diet:	50% sucrose solution
Test units:	plastic cages, size 18 cm × 12 cm × 7.5 cm with food dispensers

4. Environmental conditions:

Temperature:	average temperature 33.046°C (minimal temperature 31.0°C; maximal temperature 35.9°C)
Relative humidity:	average humidity: 64.183% (minimal humidity 47.4%; maximal humidity 97.0%)
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The aim of the study was to determine the concentration (value LC_{50}) and the dose (value LDD_{50}) that would cause mortality of 50% of the population after 10 days. The study was carried out in accordance with OECD Guideline No 245. The study was conducted on honeybee, *Apis mellifera L*. Quarantine of the bees was not carried out, because within a month before the beginning of the study, insects were not treated with chemicals compounds including antibiotics or anti-varroa treatment. In the study, young bees being in the similar age (approx. 2 days old) were used, originating from a healthy and well maintained breeding. Bees were placed in a test room in experiment conditions one day before the beginning of the experiment. The following measurements and observations were made during the experiment: bee mortality every 24±2 hours, starting 24±2 hours from the start of exposure, symptoms of intoxication, temperature and humidity during acclimatization were read with thermohygrometer and during the test it was recorded continuously with a recorder.

Test design:	tested dose and control in five replicates, 10 bees per replicate
Exposure time:	chronic test, 10 days
Tested concentrations, definitive test:	2500 mg/kg of food (89.53 µg/bee/day) (limit test)
Dates:	start of the study 14.05.2021 start of the experimental part: 16.06.2021 end of the experimental part: 26.06.2021 end of the study: 19.08.2021
Statistic:	ToxRat Professional (Version 3.3.0)

CONCLUSION

The tested item in the course of this test did not show any apitoxic effect on the mortality of bees after 10 days of the experiment. Based on the analysis of the results, the LC_{50} and NOEC values were determined at >2500 mg of the test item/kg food, the LDD_{50} and NOEDD values were determined as >89.53 µg of the test item/bee/day.

Table KCP 10.3.1.2-1: Honeybees, Chronic Oral Toxicity Test – final results

Parameter	Concentration [mg of the test item/kg of food]	Parameter	Dose [µg of the test item/bee/day]
LC_{10}	n.d.**	**LDD_{10}**	n.d.***
LC_{20}	(n.d. – n.d.)*	**LDD_{20}**	(n.d. – n.d.)*
LC_{50}	n.d.**	**LDD_{50}**	n.d.***
NOEC	>2500	**NOEDD**	>89.53

LOEC	≥2500	**LOEDD**	≥89.53

n.d. impossible to determine for mathematical reasons
* lower and upper 95% confidence interval
** based on the analysis of the results, the values were determined as >2500 mg of the test item/kg of food
*** based on the analysis of the results, the values were determined as >89.53 µg of the test item/bee/day

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

Not relevant. No studies submitted.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.

- in control cumulative larval mortality from D3 to D8 was 0.0% (required: ≤15%),
- in control the adults emergence rate on D22 was 94.4% (required: ≥70%),

Deviation of the study:
The following concentrations of the test item were used in the stability study: 50 g of the test item/L and 0.05 g of the test item/L (in the Study plan stated incorrectly: 50 g of the test item/L and 0.5 g of the test item/L). In course of the range-finding and definitive test, periodic decreases of temperature (required: 34-35°C) and humidity (required: 50-100%) occurred. It resulted from daily feedings and observations. These drops were short-termed, did not affect the condition of the test system. The deviations had no effect of the test results. The test met the validity criteria.

Agreed toxicity endpoints:

Final results of the study

Parameter	Concentration [mg of test item/kg of food]	Parameter	Dose [µg of test item/larva]
LC_{10}	44.291 (19.871 – 98.720)*	LD_{10}	6.809 (3.054 – 15.182)*
LC_{20}	141.131 (76.522 – 260.291)*	LD_{20}	21.704 (11.766 – 40.038)*
LC_{50}	1295.640 (408.279 – 4111.613)*	LD_{50}	199.398 (62.812 – 632.994)*
NOEC	72.22	NOED	11.11

* upper and lower confidence limits (95%) given in the brackets
LC_{10} test item concentration causing mortality of 10% population
LC_{20} test item concentration causing mortality of 20% population
LC_{50} test item concentration causing mortality of 50% population
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LD_{10} test item dose causing mortality of 10% population
LD_{20} test item dose causing mortality of 20% population
LD_{50} test item dose causing mortality of 50% population
NOED the highest test item dose not causing statistically significant differences in relations to the control

Reference: KCP 10.3.1.4/01

Report	Honey Bee Larval Toxicity Test following Repeated Exposure to the test item JMD-HER 387 OD according to OECD GD 239 ENV/JM/MONO(2016)34; Orzechowska U.; 2021; Study Code: 0005/0103/E
Guideline(s):	Yes, OECD GD 239
Deviations:	The following concentrations of the test item were used in the stability study: 50 g of the test item/L and 0.05 g of the test item/L (in the Study plan stated incorrectly: 50 g of the test item/L and 0.5 g of the test item/L). In course of the range-finding and definitive test, periodic decreases of temperature (required: 34-35°C) and humidity (required: 50-100%) occurred. It resulted from daily feedings and observations. These drops were short-termed, did not affect the condition of the test system. The deviations had no effect of the test results. The test met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: 50% sucrose solution
positive control: fenoxycarb

3. Test organism

Species:	honeybee *Apis mellifera*
Source:	registered breeding of Mr. Wiesław Londzin in Poznań, entered into the register under veterinary number 3021711077
Age:	1-day old larvae of honey bee originated from 3 different, healthy, well-maintained breeding
Acclimation period:	the quarantine was not carried out because insects were not treated with any chemical compounds within a month before the start of the study

Diet:	Larval diets were adjusted depending on the developmental stage (all solutions were prepared in weight percentage): Food A: 50% fresh royal jelly + 50% aqueous solution containing 2% yeast extract/ 12% glucose/12% fructose; Food B: 50% fresh royal jelly + 50% aqueous solution containing 3% yeast extract / 15% glucose /15% fructose; Food C: 50% fresh royal jelly + 50% aqueous solution containing 4% yeast extract / 18% glucose /18% fructose. Following the above, prepared food should have density around 1.1 mg/µL (20 µL of food corresponds to 22 mg of food). Before administration, food was warmed to 34.5°C. It was provided using automatic pipette, with caution to avoid touching a larva or drowning it in food liquid. From the emergence phase (D15 - D22) as food was used: 50% aqueous solution of sucrose, pine pollen.
Test units:	48-well breeding plates with queen-cell cups placed in the dissector and placed in incubator; since day 15 of the test – transparent plastic boxes placed in test room

4. Environmental conditions:

Temperature:	average temperature 34.497°C (minimal temperature 33.5°C; maximal temperature 34.7°C)
Relative humidity:	average humidity: 83.706% (minimal humidity 58.4%; maximal humidity 99.9%)
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The aim of the study was determination of the concentration causing 50% mortality of population (LC50 value) and the dose of the test item causing mortality of 50% of the population after 22 days (LD50 value). Values NOEC and NOED were determined for each following developmental stages for honey bee. The study was carried out in accordance with OECD GD 239. The study was conducted on honeybee, *Apis mellifera L*. Quarantine of the bees was not carried out, because within a month before the beginning of the study, insects were not treated with chemicals compounds including antibiotics or anti-mite agents. The study used 1-day larvae of honey bee originated from 3 different, healthy, well-maintained breeding.
3 days before the beginning of the test (D-3), in each family, queen bee was isolated using one-frame isolator. After max. 30 hours (D-2), queens were released from the isolator (after conforming the presence of freshly laid eggs). The frame containing the eggs remains in the isolator, placed next to the frame containing brood, for 3 days, until the hatching (D1). At day 1 (D1), the frames with freshly brooded larvae are transferred from the hive to laboratory in the temperature optimal for larvae (above 20°C). Frames are placed under the inactive laminar-flow hood. For the study are chosen larvae, which has not yet formed C-shape or the ones laying on the top of royal jelly. The larvae were carefully placed in the same position at the bottom of queen-cell cup filled with diet A placed in breeding plate's well. Plates were placed in desiccators, in which, during 1-8 days, humidity was maintained on level of 95±5% using saturated solution of K2SO4 placed in the dish at the bottom of desiccator. On day 8 (D8), larvae were transferred to the fresh plates with pieces of absorption paper placed at the bottom of each well. Plates with larvae were placed in the desiccator, in which humidity was maintained at the level of 80±5% with saturated solution of NaCl placed ate the bottom of desiccator. Desiccators were placed in test room. On day 15 (D15), plated were

transferred to plastic cages with *ad libitum* access to 50% (w/v) aqueous sucrose solution pine pollen. Cages were placed in test room of humidity at the humidity of 50-80% maintained with humidifier.

During the test, the following data and activities are recorded:
- larval mortality from D4 to D8, observations were made during feeding; immobile or an unresponsive larva was noted as dead; dead individuals were removed during feedings for sanitary reasons
- pre-pupal mortality on D15; individuals that do not pupate were noted as dead.
- on D22 the number of emerged or non-emerged pupae
- on D22 adult insects
- alive or dead
- at the end of the test, the emergence rate was calculated (by comparing the number of emerged individuals on D22 with the number of larvae on D3), pupal mortality (percentage calculated by comparing the number of non-emerged pupae and dead pre-pupa from D8 to D22 with the number of larvae on D8) and larval mortality (percentage calculated by comparing the number of dead larvae from D4 to D8 with the number of larvae on day D3)
- on day D8 the presence of food that has not been consumed
- temperature and humidity during the definitive test was recorded continuously by a temperature and humidity recorder
- all other observations (for larvae, pre-pupae, pupae and imago: appearance, size, behavior, morphological differences).

Test design:	tested concentrations and control in one replicate; 36 larvae per replicate
Exposure time:	chronic test, exposition: 4 days (from D3 to D6)
Tested concentrations, definitive test:	control (0 mg of test item/kg of food), 8.02, 24.07, 72.22, 216.67 and 650 mg of test item/kg of food corresponding to 1.23, 3.70, 11.11, 33.33 and 100 µg of test item/larva
Dates:	start of the study 10.05.2021 start of the experimental part: 07.06.2021 end of the experimental part: 28.06.2021 end of the study: 19.08.2021
Statistic:	ToxRat Professional statistical program

CONCLUSION

During definitive test, no statistically significant larval mortality was observed in all tested concentrations. In all concentrations, larvae shown slight signs of intoxication, represented by stunted development, i.e. inhibited food intake, smaller size, decreased mobility. For pupal mortality, statistically significant effect was observed on day 22 in three highest concentrations. Statistically significant influence on emergence rate was observed in two highest concentrations. At the end of the study, the concentration and the dose causing 50% mortality of the population in the test (LC_{50} and LD_{50} values) were determined, as well as LC_{10}, LC_{20}, LD_{10}, LD_{20}, NOEC and NOED values were determined at 22 day.

Table KCP 10.3.1.4-1: Honeybees, Chronic Oral Toxicity Test – final results

Parameter	Concentration [mg/kg of food]	Parameter	Dose [µg/larva]

LC_{10}	44.291 (19.871 – 98.720)*	LD_{10}	6.809 (3.054 – 15.182)*
LC_{20}	141.131 (76.522 – 260.291)*	LD_{20}	21.704 (11.766 – 40.038)*
LC_{50}	1295.640 (408.279 – 4111.613)*	LD_{50}	199.398 (62.812 – 632.994)*
NOEC	72.22	NOED	11.11

* upper and lower confidence limits (95%) given in the brackets

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

Not relevant. No studies submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Not relevant. No studies submitted.

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

No new studies provided.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. The following validity criteria were met during the study: – after 48 hours, mortality of the control group was 0.0% (criterion: a maximum of 10.0%), – after 48 hours, mortality of the group treated with the reference item at the rate of 4.0 g/ha was 66.7% (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 22.1 (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). **Deviation of the study:** none **Agreed toxicity endpoints:**

Parametr (endpoint)						
Mortality			Fecundity			
Test item [L/ha]	Total [%]	LR_{50} [L/ha]	Test item [L/ha]	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50} [L/ha]
Control	0.0	> 1.0	Control	22.1	–	> 1.0
0.11	0.0		0.11	21.4	3.3	
0.33	0.0		0.33+	15.5	29.8	
1.0	0.0		1.0+	14.4	34.9	
$NOER_{mortality}$ ≥ 1.0 [L/ha]			$NOER_{fecundity}$ 0.11 [L/ha]			
Reference item: dimethoate						
Reference item [g/ha]	4.0					
Mortality (after 48 h)						
Total [%]	66.7					

+: statistically significant differences

Reference:	KCP 10.3.2.2/01
Report	An extended laboratory test for evaluating the effects of JMD-HER 387 OD on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez)*;* Knapik M.; 2021; Study Code: B-41-21
Guideline(s):	Yes, SETAC; ESCORT I, ESCORT II; IOBC/BART/EPPO
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: distilled water
positive control: dimetholate

3. Test organism

Species:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: *Braconidae, Aphiidinae*
Source:	the culture was obtained from a commercial breeder (Katz Biotech AG)
Age:	adult females (24 – 48 hours after emerging from mummies)
Acclimation period:	no data
Diet:	cotton wool bung soaked with a 10% solution of fructose in water
Test units:	a test unit consisted of a transparent PMMA cylinder (isolator) with a diameter of 11 cm and a height of 20 cm, put on a plastic pot with a diameter of 12 cm, to assess mortality, the pots contained 7-day-old barley seedlings (8 seedlings per pot), to assess fecundity, the pots contained approximately 20 seedlings of 7-day-old barley infested with the bird cherry-oat aphid, *Rhopalosiphum padi* (> 100 aphids per pot), to provide good ventilation, the apex of each cylinder and two longitudinal openings on its two sides are covered with fine metal netting, there was a hole in the cylinder to introduce the wasps to the test unit

4. Environmental conditions:

Temperature:	1-22°C
Relative humidity:	64-67%
Photoperiod:	16 hours light : 8 hours dark, light intensity: mortality and oviposition assessment: 2513 lx, fecundity phase: 5409 lx

STUDY DESIGN AND METHOD

The extended laboratory test involved the evaluation of the effects of the test item, JMD-HER 387 OD on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. On the basis of the results of the preliminary test, it was decided to use three rates of the test item in the definitive test. These were 0.11, 0.33 and 1.0 L/ha.
Adult wasps were exposed to the test item applied to barley plants. Observations of settling behavior were made during the initial 3 hours of exposure. The aims were to determine repellent effects of JMD-HER 387 OD and to check if the test insects had contact with barley plants sprayed with the test item. Settling behavior of wasps from each replicate was observed five times. Mortality was determined 2, 24 and 48 hours after the introduction of the wasps to the test arenas.
Females which survived the 48-hour exposure to JMD-HER 387 OD and the ones from the control group were subjected to fecundity assessments. Fifteen female wasps from the four group treated with the test item and the control were individually introduced into the fecundity units containing 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 wasp pupae were developing) was recorded.
Mortality after 48 hours of exposure and the percentage of fecundity reduction (Pr) 12 days after the oviposition were the endpoints.

To verify the sensitivity of the biological test system and the precision of the test procedure, dimethoate, which is an insecticide, was used as a reference item. The rate of the reference item was 4.0 g dimethoate/ha. The control group was treated with distilled water.

Test design:	mortality assessment: 6 replicates/group; 5 females/replicate, fecundity assessment: 15 replicates/group; 1 females/replicate
Exposure time:	mortality phase: 48 hours + fecundity phase : 12 days
Tested concentrations, definitive test:	0.11, 0.33 and 1 L/ha, 400 L water/ha
Dates:	start of the study: 30.03.2021 start of the experimental part: 30.03.2021 end of the experimental part: 14.04.2021 end of the study: 02.07.2021
Statistic:	Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity, Williams Multiple Sequential t-test Procedure

RESULTS

In the definitive test, after 48 hours mortality of the control wasps was 0.0%. The mortality, in the groups treated with JMD-HER 387 OD at the rates of 0.11, 0.33 and 1.0 L/ha were 0.0%. Based on the obtained results the LR50 value could not be estimated. It could be assumed that LR50 is higher than 1.0 L/ha. The NOERmortality is higher than or equal to 1.0 L/ha. The mortality of the wasps exposed to dimethoate at the rate of 4.0 g/ha was 66.7% after 48 hours. Therefore, the validity criterion specified in the Method description was met. The results showed that the test organisms were sensitive to dimethoate.

The fecundity assessment showed that the mean number of mummies per female in the control group was 22.1 (after 12 days after oviposition). As for the wasps treated with JMD-HER 387 OD at the rates of 0.11, 0.33 and 1.0 L/ha the mean number of mummies per female were 21.4, 15.5 and 14.4, respectively. Fecundity reduction (Pr) in the group treated with the test item at the rates of 0.11, 0.33 and 1.0 L/ha were 3.3, 29.8 and 34.9%, 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 rate of 0.11 L/ha and the control group (Williams Multiple Sequential t-test Procedure, $p>0.05$). At the significance level of 0.05, there were statistically significant differences in fecundity between the wasps exposed to the test item at the rates of 0.33 and 1.0 L/ha and the control group (Williams Multiple Sequential t-test Procedure, $p>0.05$). Based on the obtained fecundity results it could be assumed that the ER_{50} value is above 1.0 L/ha and the $NOER_{fecundity}$ is equal to 0.11 L/ha of the test item.

Table KCP 10.3.2.2-1: The effects of JMD-HER 387 OD on mortality and fecundity of *Aphidius rhopalosiphi* in the extended laboratory test

Test item rate [L/ha]	Mortality		Reproduction			
	Total [%]	LR_{50} [L/ha]	Test item rate [L/ha]	Mean number of eggs/ female (Rr) [no.]	Reproduction reduction Pr [%]	ER_{50} [L/ha]
Control	0.0	>1.0	Control	22.1	-	>1.0

0.11	0.0		0.11	21.4	3.3	
0.33	0.0		0.33	15.5	29.8	
1.0	0.0		1.0	14.4	34.9	
$NOER_{mortality} \geq 0.1$ [L/ha]			**$NOER_{reproduction} = 0.11$ [L/ha]**			

CONCLUSION

On the basis of the obtained mortality results it can be concluded that JMD-HER 387 OD at the rates of 0.11, 0.33 and 1.0 L/ha has no adverse effect on the mortality of the wasps. On the basis of the obtained fecundity results it can be concluded that JMD-HER 387 OD at the rates of 0.33 and 1.0 L/ha has an adverse effect on the fecundity of the wasps.

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.
The following validity criteria were met during the study:

- mortality of the control group was 3.3% on day 7 of exposure (criterion: a maximum of 20%),
- mortality of the mites exposed to the reference item at the rate of 4.0 g/ha was 89.7% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 6.4 (required: ≥ 4 eggs per female).

Deviation of the study: In the experiment additional food in the form of the two-spotted spider mite (*T. urticae*) eggs, was used. Another food source prevents the mites from escaping from discs.

Agreed toxicity endpoints:

Test item rate [L/ha]	Parameter (endpoint)						
	Mortality			Reproduction			
	Total [%]	Total [%]ª	LR_{50} [L/ha]	Test item rate [L/ha]	Mean number of eggs/ female (Rr) [no.]	Repro-duction reduction Pr [%]	ER_{50} [L/ha]
Control (0.0)	3.3	-	> 1.0	Control (0.0)	6.4	–	> 1.0
0.03	0.0	-3.5		0.03⁺	5.6	12.6	
0.1	5.0	1.7		0.1⁺	5.2	19.0	
0.3⁺	8.3	5.2		0.3⁺	5.1	19.6	
1.0⁺	16.7	13.8		1.0⁺	3.8	40.6	
$NOER_{mortality}$ 0.1 [L/ha]				$NOER_{reproduction}$ < 0.03 [L/ha]			
Reference item: dimethoate							
Reference item [g/ha]				4.0			
Mortality							
Total [%]				90.0			
Total [%]ª				89.6			

⁺: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [12], [SOP/B/67]
ª: mortality was corrected according Abbott's equation [1]

Reference:	KCP 10.3.2.2/02
Report	An extended laboratory test for evaluating the effects of JMD-HER 387 OD on the predatory mite, *Typhlodromus pyri* (Sch.);

Knapik M.; 2021; Study Code: B-40-21

Guideline(s):	Yes, IOBC, BART, EPPO
Deviations:	In the experiment additional food in the form of the two-spotted spider mite (*T. urticae*) eggs, was used. Another food source prevents the mites from escaping from discs.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: distilled water
positive control: dimetholate

3. Test organism

Species:	the predatory mite, *Typhlodromus pyri* (Sch.) (*Acari*: *Phytoseiidae*)
Source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder
Age:	24-hour-old protonymphs
Acclimation period:	no data
Diet:	pine pollen (*Pinus sp.*) and *T. urticae* eggs
Test units:	each test set consisted of a glass tray filled with water and a glass bench containing 6 test units, leaf discs (Ø 45 mm) were floating on the water surface in glass Petri dishes ('island dishes', Ø 54 mm) with central holes at the bottom (Ø 6 mm), water in the test units prevented the mites from escaping

4. Environmental conditions:

Temperature:	23-26°C

Relative humidity:	60-73%
Photoperiod:	16 h light : 8 h dark; light intensity: 813 lux

STUDY DESIGN AND METHOD

The aim of the extended laboratory test was to evaluate the effects of the test item, JMD-HER 387 OD on mortality and reproduction of the predatory mite, T. pyri (Sch.). On the basis of the preliminary test results, it was decided to use four rates of the test item in the definitive test. These were 0.03, 0.1, 0.3 and 1.0 L/ha. The mites, T. pyri at the protonymphal stage (24 hours old) were exposed to the test item applied to leaf discs. The mites were fed with pine pollen (Pinus sp.) and T. urticae eggs. Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and groups treated with the test item at rates 0.03, 0.1, 0.3 and 1.0 L/ha were made after 8, 11 and 14 days of the treatment. Mortality of T. pyri after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints. To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 4.0 g/ha. The control group was treated with distilled water.

Test design:	tested concentrations, reference item and control in 3 replications, number of mites: 20 mites/replicate
Exposure time:	14 days (7 days of mortality phase + 7 days of fecundity test)
Tested concentrations, definitive test:	0,03, 0,1, 0.3 and 1 L/ha, 200 L water /ha
Dates:	start of the study: 23.03.2021 start of the experimental part: 25.03.2021 end of the experimental part: 08.04.2021 end of the study: 13.08.2021
Statistic:	Logit analysis using linear max. likelihood regression, Tarone's Test Procedure, Step-down Cochran-Armitage Test Procedure, Probit analysis using linear weighted regression, Shapiro Wilk's Test on Normal Distribution, Levene's Test on Variance Homogenity (with Residuals), Williams Multiple Sequential t-test Procedure, Chi2 2x2 Table Test with Bonferroni Correction

RESULTS

In the definitive test, mortality of the control group after 7 days of exposure was 3.3%. After 7 days of exposure to JMD-HER 387 OD at rates of 0.03, 0.1, 0.3 and 1.0 L/ha, the corrected percentages of *T. pyri*, mortality were -3.5, 1.7, 5.2 and 13.8%, respectively. There were no statistically significant differences in mortality between group treated with the test item at the rates of 0.03 and 0.1 L/ha and the control group. There were statistically significant differences in mortality between group treated with the test item at the rates of 0.3 and 1.0 L/ha (Step-down Cochran-Armitage Test Procedure, $p(trend)>\alpha$).

Reproduction of the surviving mites from the control group and the groups treated with JMD-HER 387 OD at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha, was assessed since mortality of these groups was < 50.0%. The

mean reproduction rate (Rr) in the control group was 6.4 eggs/female. The mean Rr after 14 days of exposure to JMD-HER 387 OD at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha were 5.6, 5.2, 5.1 and 3.8 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha were 12.6, 19.0, 19.6 and 40.6%, respectively. There were statistically significant differences in reproduction between group treated with the test item at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha and the control group (Williams Multiple Sequential t-test Procedure,|t|>|t*|).

Table KCP 10.3.2.2-2: The effects of JMD-HER 387 OD on mortality and reproduction of *Typhlodromus pyri* in in the extended laboratory test

Test item rate [L/ha]	Mortality			Reproduction			
	Total [%]	Total [%]a	LR_{50} [L/ha]	Test item rate [L/ha]	Mean number of eggs/ female (Rr) [no.]	Reproduction reduction Pr [%]	ER_{50} [L/ha]
Control	3.3	-	>1.0	Control	6.4	-	>1.0
0.03	0.0	-3.5		0.03	5.6	12.6	
0.1	5.0	1.7		0.1	5.2	19.0	
0.3	8.3	5.2		0.3	5.1	19.6	
1.0	16.7	13.8		1.0	3.8	40.6	
$NOER_{mortality}$ = 0.1 [L/ha]				**$NOER_{reproduction}$ < 0.03 [L/ha]**			

CONCLUSION

Based on the obtained results the LR_{50} value could not be estimated. The LR_{50} value is higher than 1.0 L/ha of JMD-HER 387 OD. $NOER_{mortality}$ is 0.1 L/ha of JMD-HER 387 OD. It could be assumend that the ER50 value is higher than 1.0 L/ha of JMD-HER 387 OD. $NOER_{reproduction}$ is below 0.03 L/ha of JMD-HER 387 OD.

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. The following validity criteria were met during the study: ➢ pre-imaginal mortality of the control group was 0.0% (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 4.6 (criterion: ≥ 2 fertile eggs/female). **Deviation of the study:** 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. **Agreed toxicity endpoints:**

Study group	Parameters (endpoints)				
	Mortality		Reproduction		
Test item [L/ha]	[%]	LR_{50} [L/ha]	Mean no. of eggs/female/day	Mean no. of fertile eggs/female/day	Reproduction reduction Pr [%]*
Control (0.0)	0.0	> 1.0	6.2	4.6	–
0.03	5.0		5.5	4.1	10.9
0.1	5.0		7.9	5.1	-10.9
0.3	0.0		5.2	3.6	21.7
1.0	0.0		6.3	4.5	2.2
$NOER_{mortality}$	≥ 1.0 [L/ha]				
dimethoate					
Reference item [g/ha]	100.0	–			
3.2					

* - The negative values means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group

Reference:	KCP 10.3.2.2/03
Report	An extended laboratory test for evaluating effects of JMD-HER 387 OD on the ladybird beetle, *Coccinella septempunctata* (L.); Knapik M.; 2021; Study Code: B-39-21
Guideline(s):	Yes, IOBC, BART, EPPO
Deviations:	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.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2020
Production date:	02.2021

Expiration date:	02.2023
2. Vehicle and/or positive control:	vehicle: distilled water positive control: dimetholate
3. Test organism	
Species:	the ladybird beetle, *C. septempunctata L. (Arthropoda: Coccinellidae)*
Source:	Beetles was obtained from commercial breeder (Katz Biotech AG, Germany)
Age:	4-day-old larvae
Acclimation period:	no data
Diet:	fresh aphids, *Acyrthosiphon pisum ad libitum* every day except for the weekends
Test units:	discs cut out of leaves of rose (*Rosa* L.) with diameter of 5.2 cm, for treatment, the leaf discs were individually placed on wet cotton pads in Petri dishes, leaves were surrounded by a transparent PMMA cylinder (ext. diameter: 5 cm; height: 4 cm), the inner walls of the cylinders were coated with talcum in order to prevent both ladybird larvae and aphids (ladybirds' food) from climbing up the walls. To assess reproductive performance of the ladybird beetles, glass terrariums (dimensions: 20 x 20 x 30 cm) were used as reproduction units
4. Environmental conditions:	
Temperature:	23.2 – 27.0 °C
Relative humidity:	60.4 − 81.8 %
Photoperiod:	16 hours light : 8 hours dark, light intensity 3132 lx

STUDY DESIGN AND METHOD

The extended laboratory test involved the evaluation of the effects of the test item, JMD-HER 387 OD on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata*. In a definitive test, four test item application rates of 0.03, 0.1, 0.3 and 1.0 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 0.03, 0.1, 0.3 and 1.0 L/ha were subjected to evaluate the reproductive performance. 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 14 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.

Test design:	tested 4 concentrations, reference item and control in 40 replicates per group, 1 larva per replicate
Tested concentrations, definitive test:	0.03, 0.1, 0.3 and 1.0 L/ha, 200 L water/ha
Dates:	start of the study: 28.04.2021 start of the experimental phase: 07.07.2021 end of the experimental phase: 16.08.2021 end of the study: 12.10.2021
Statistic:	Probit analysis using linear max. likelihood regression, Step-down Cochran-Armitage Test Procedure

RESULTS

In the definitive test mortality in the control group was 0.0%. The mortality of *Coccinella septempunctata* exposed to the test item at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha, were 5.0, 5.0, 0.0 and 0.0%, respectively. Based on the obtained mortality results, it could be assumed that the LR50 value (the application rate at which 50% mortality of the test system is observed) is higher than 1.0 L/ha of JMD-HER 387 OD. The NOERmortality is higher or equal to 1.0 L/ha of JMD-HER 387 OD. In the definitive test reproduction of the ladybird beetles from the control group and the groups treated with the test item at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha were assessed, since the mortality were < 50%. The mean number of fertile eggs/female/day in the control group was 4.6 (criterion: ≥ 2 eggs/female/day) The mean numbers of fertile eggs/female/day in the groups treated with the JMD-HER 387 OD at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha were equal to 4.1, 5.1, 3.6 and 4.5 and it refers to 10.9, -10.9, 21.7 and 2.2% reproduction reduction, respectively. The mean number of fertile eggs per viable female per day were above 2 in the groups treated with the test item at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha, therefore there is no treatment related effect on the reproductive performance in mentioned rates. It can be concluded that JMD-HER 387 OD at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha has no adverse effect on the reproduction capacity of the ladybird beetle.

Table KCP 10.3.2.2-3: The effects of JMD-HER 387 OD on mortality and fecundity efficiency of *Coccinella septempunctata* in in the extended laboratory test

Study group	**Mortality**		**Reproduction**		
Test item [L/ha]	**(%)**	**LR_{50} [L/ha]**	**Mean no. of eggs/female/day**	**Mean no. of fertile eggs/female/day**	**Reproduction reduction Pr [%]***
Control (0.0)	0.0	>1.0	6.2	4.6	-
0.03	5.0		5.5	4.1	10.9
0.1	5.0		7.9	5.1	-10.9
0.3	0.0		5.2	3.6	21.7
1.0	0.0		6.3	4.5	2.2
NOERmortality		≥ 1.0 [L/ha]			

* - The negative values means that in the tested rates there were higher mean numbers of fertile eggs per viable female per day than in the control group

CONCLUSION

It can be concluded that JMD-HER 387 OD at the rates of 0.03, 0.1, 0.3 and 1.0 L/ha had no adverse effect on the reproduction capacity of the ladybird beetle. The LR_{50} value is above 1.0 L/ha of JMD-HER 387 OD. The $NOER_{mortality}$ is higher or equal to 1.0 L/ha of JMD-HER 387 OD.

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.
The following validity criteria were met during the study:

Emerged beetles in control group	Mean number of emerged beetles to be > 400 per replicate (the mean was 697.25, so the validity criteria was met).
Reduction in the reference item compared to the control group	Effect on reproduction to be ≥ 50% (the effect on reproduction was 91.04%, so the validity criteria was met).

Deviation of the study: none

Agreed toxicity endpoints:

Survival and reproduction of *Aleochara bilineata*

Treatment	JMD-HER 387 OD						ROGOR L40 ST
	T1 Control	T2 37.04 mL test item/ha	T3 111.11 mL test item/ha	T4 333.33 mL test item/ha	T5 1000 mL test item/ha	T6 3000 mL test item/ha	T7 2200 mL reference item/ha
	Deionised water	13.96 + 0.37 g a.i./ha	41.89 + 1.11 g a.i./ha	125.67 + 3.33 g a.i./ha	377 + 10 g a.i./ha	1131 + 30 g a.i./ha	880 g a.i./ha
Mean of alive adults at the end of the exposure period	18.50	18.25	18.00	18.00	17.75	18.25	5.25
Mean adult emergence	697.28	684.00	676.25	675.50	673.25	670.25	62.50
Significance [a b]	-	n.s.	n.s.	n.s.	n.s.	n.s.	***
Effect on reproduction [%]	-	1.90	3.01	3.12	3.44	3.87	91.04
Endpoints	**mL test item/ha**		**g 2,4-D-2EH /ha***		**g iodosulfuronmethylsodium /ha****		
ER_{50} [95% confidence intervals] (Reproduction)	>3000 [95%-CLs n.d.]		>1131 [95%-CLs n.d.]		>30 [95%-CLs n.d.]		
NOEC (Reproduction)	≥3000		≥1131 [95%-CLs n.d.]		≥30 [95%-CLs n.d.]		
LOEC (Reproduction)	>3000		>1131 [95%-CLs n.d.]		>30 [95%-CLs n.d.]		

a.i. = 2,4-D-2EH + iodosulfuronmethylsodium (from treatments T2 to T6); dimethoate (treatment T7)
a, William's t-test, α=0.05
b, Student-t test, α≤0.05
-, not applicable
n.s., not significantly different compared to the control
95%-CLs, Confidence Limits
n.d.: not determined due to mathematical reasons
*The active ingredient content was calculate based on the nominal test item content of 377 g/L
**The active ingredient content was calculate based on the nominal test item content of 10 g/L

Reference:	KCP 10.3.2.2/04
Report	Effects of JMD-HER 387 OD (2,4-D-2EH + iodosulfuronmethylsodium) on the rove beetle *Aleochara bilineata* – extended laboratory test; Mautino G.; 2023; Study Code: 1185.H.SAG22/r
Guideline(s):	Yes, IOBC, BART, EPPO
Deviations:	No
GLP:	Yes

Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2021
Production date:	02.2021
Expiration date:	02.2024

2. Vehicle and/or positive control: vehicle: distilled water
positive control: dimetholate

3. Test organism

Species:	Staphylinid beetle (*Aleochara bilineata*)
Source:	De Groene Vlieg Bio Control, Dronten, Netherlands
Age:	adult
Acclimation period:	3 days
Diet:	During the acclimation period and after the introduction of the test organisms to the test units (day 0) and 3 times a week, midge larvae (*Chironomus* sp.) were provided as food for the adults. During the test 7, 14 and 21 days after application approximately 500 onion fly pupae (*Delia antiqua*) were provided as host for the larvae.
Test units:	Mortality assessment: Inert, transparent container 13.5 × 13.5 cm with a ground surface > 150 cm^2 with Perforated lid with an insect-proof net. 1100 g/test unit (>600 mL) of soil with a depth > 4 cm. Reproduction assessment: Buchner funnel with 2 mm sieve with a vial at the base for collecting the emerged adult beetles with Insect-proof net held by a rubber band.

4. Environmental conditions:

Temperature:	20.10 ± 0.646 °C (18.55 – 21.46 °C)
Relative humidity:	74.1 ± 5.1% (66.7 – 86.2%)
Photoperiod:	16 hours light : 8 hours dark, light intensity 1000 – 1100 lux
Soil:	Standard soil LUFA 2.1.
Max. Water Holding Capacity:	29.5 %

STUDY DESIGN AND METHOD

The extended laboratory test involved the evaluation of the effects of the test item, JMD-HER 387 OD on mortality and reproduction of staphylinid beetle *Aleochara bilineata*. In a definitive test, five test item application rates of 37.04, 111.11, 333.33, 1000 and 3000 mL/ha were used.
The study encompassed 7 treatments (5 rates of the test item, control, reference item) with 4 replicates each containing 10 adult males + 10 adult females of the beetle. Application was performed in a spray chamber, with a spaying surface of 2 m2 (plot length: 2 m, plot width: 1 m) and the application was carried out by simulating the good agricultural practices. The beetles were exposed to residues on LUFA 2.1 soil. Adult beetles were kept in the test units for 28 days. Approximately 500 Delia pupae were placed in the soil of each test unit after 7, 14 and 21 days. Remaining adult beetles were removed on Day 28 and the soil was allowed to dry for a week. The soil was then sieved to remove the Delia pupae and these were placed in emergence units. The emergence was assessed over approximately 5 weeks, until very few adult beetles were still emerging each day in the controls.
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.

Test design:	tested 5 concentrations, reference item and control in 4 replicates per group, 10 adult males + 10 adult females per replicate
Tested concentrations, definitive test:	37.04, 111.11, 333.33, 1000, 3000 mL/ha + 400 L water/ha
Dates:	start of the study: 23.11.2022 start of the experimental phase: 25.01.2023 end of the experimental phase: 14.04.2023 end of the study: 13.09.2023
Statistic:	Softwares used for statistical analysis were “ToxRatPro” Solutions GmbH, version 3.3.0 Reproduction data were analysed by using the William's t-test, α=0.05 and at least the EC_{50} determined using a 3-parameters non-linear regression. The No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOER) values for mortality and reproduction were calculated, where possible.

RESULTS

The mean percentage of dead beetles on the treated ranged from 8.75% in treatment T2 (37.04 mL test item/ha) and T6 (3000 mL test item/ha) to 11.25% on T5 (1000 mL test item/ha). Control and reference item ROGOR L40 ST showed a percentage of 7.50% and 73.75%, respectively.
In the control group, the number of beetles emerge per replicate ranged from 664 to 712. The mean number of beetles emerge was 697.25 in the control group and in the treated groups ranged from 670.25 in T6 (3000 mL test item/ha) to 684.00 in T2 (37.04 mL test item/ha).
No significant difference in terms of reproduction was observed in comparison to the control group.
The NOEC (reproduction) and LOEC (reproduction) values were estimated to be ≥3000 mL test item/ha (≥1131 g 2,4-D-2EH/ha + ≥30 g iodosulfuronmethylsodium/ha) and > 3000 mL test item/ha (>1131 g 2,4-D-2EH/ha + >30 g iodosulfuronmethylsodium/ha) respectively.
The EC_{50} value could not be determined, but was estimated to be >3000 mL test item/ha (95% confident limit not determined) corresponding to > 1131 g 2,4-D-2EH/ha + >30 g iodosulfuronmethylsodium/ha.

Table KCP 10.3.2.2-4: The effects of JMD-HER 387 OD on survival and reproduction of *Aleochara bilineata* in in the extended laboratory test

Treatment	JMD-HER 387 OD						ROGOR L40 ST
	T1 Control	T2 37.04 mL test item/ha	T3 111.11 mL test item/ha	T4 333.33 mL test item/ha	T5 1000 mL test item/ha	T6 3000 mL test item/ha	T7 2200 mL reference item/ha
	Deionised water	13.96 + 0.37 g a.i./ha	41.89 + 1.11 g a.i./ha	125.67 + 3.33 g a.i./ha	377 + 10 g a.i./ha	1131 + 30 g a.i./ha	880 g a.i./ha
Mean of alive adults at the end of the exposure period	18.50	18.25	18.00	18.00	17.75	18.25	5.25
Mean adult emergence	697.28	684.00	676.25	675.50	673.25	670.25	62.50
Significance [a b]	-	n.s.	n.s.	n.s.	n.s.	n.s.	***
Effect on reproduction [%]	-	1.90	3.01	3.12	3.44	3.87	91.04
Endpoints	**mL test item/ha**		**g 2,4-D-2EH /ha***		**g iodosulfuronmethylsodium /ha****		
ER_{50} [95% confidence intervals] (Reproduction)	>3000 [95%-CLs n.d.]		>1131 [95%-CLs n.d.]		>30 [95%-CLs n.d.]		
NOEC (Reproduction)	≥3000		≥1131 [95%-CLs n.d.]		≥30 [95%-CLs n.d.]		
LOEC (Reproduction)	>3000		>1131 [95%-CLs n.d.]		>30 [95%-CLs n.d.]		

a.i. = 2,4-D-2EH + iodosulfuronmethylsodium (from treatments T2 to T6); dimethoate (treatment T7)
a, William's t-test, α=0.05
b , Student-t test, α≤0.05
-, not applicable
n.s., not significantly different compared to the control
95%-CLs, Confidence Limits
n.d.: not determined due to mathematical reasons
*The active ingredient content was calculate based on the nominal test item content of 377 g/L
**The active ingredient content was calculate based on the nominal test item content of 10 g/L

CONCLUSION

All study validity criteria were met.
The NOEC (reproduction) and LOEC (reproduction) values were estimated to be ≥3000 mL test item/ha (≥1131 g 2,4-D-2EH/ha + ≥30 g iodosulfuronmethylsodium/ha) and > 3000 mL test item/ha (>1131 g 2,4-D-2EH/ha + >30 g iodosulfuronmethylsodium/ha) respectively.
The EC50 value could not be determined, but was estimated to be >3000 mL test item/ha (95% confident limit not determined) corresponding to > 1131 g 2,4-D-2EH/ha + >30 g iodosulfuronmethylsodium/ha.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.
The following validity criteria were met during the study:

- each replicate produced from 166 to 203 juveniles (176.1 mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 10.7% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 2.5% (criterion: ≤ 10%).

Deviation of the study: none

Agreed toxicity endpoints:

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of 2,4-D-2EHE/kg dry weight of artificial soil]	Value [mg of 2,4-D/kg dry weight of artificial soil]	Value [mg of iodosulfuron methyl sodium/kg dry weight of artificial soil]
EC_{10}	>1000.0	> 361.11	> 239.52	> 9.58
EC_{20}	>1000.0	> 361.11	> 239.52	> 9.58
EC_{50}	>1000.0	> 361.11	> 239.52	> 9.58
NOEC (reproduction)	≥ 1000.0	≥ 361.11	≥ 239.52	≥ 9.58
LOEC (reproduction)	>1000.0	> 361.11	> 239.52	> 9.58
LC_{50}	>1000.0	> 361.11	> 239.52	> 9.58
NOEC (survival)	≥ 1000.0	> 361.11	> 239.52	> 9.58
LOEC (survival)	> 1000.0	≥ 361.11	≥ 239.52	≥ 9.58

Reference:	KCP 10.4.1.1/01
Report	JMD-HER 387 OD Earthworm reproduction test (*Eisenia andrei*); Arendarczyk A.; 2021; Study Code: G-03-21
Guideline(s):	Yes, OECD 222
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2021
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: deionized water
positive control: carbendazim

3. Test organism

Species:	earthworm *Eisenia andrei*
Source:	culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology
Age:	about 4 months old
Acclimation period:	24 hours
Diet:	airdried finely ground cow manure
Test units:	plastic containers (204 cm2) with a capacity of about 1.4 L, covered with perforated transparent foil in order to prevent the earthworms from escaping, to allow gaseous exchange, and to provide access to light

4. Environmental conditions:

Temperature:	19.6 – 22.0°C
pH:	pH at the beginning of the experiment: 6.13 – 6.23 pH at the end of the experiment: 5.78 – 5.93
Soil:	artificial soil: 10% sphagnum peat, 20% kaolin clay, 70% air-dried quartz sand
Soil moisture:	soil moisture content at the beginning of the experiment: 20.3 – 21.9% (49.0 – 52.9% of the maximum water holding capacity); soil moisture content at the end of the experiment: 18.5 – 23.4% (44.7 – 56.5% of the maximum water holding capacity);

Photoperiod:	light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 585 – 674 lx light intensity at the end of the experiment: 580 – 625 lx

STUDY DESIGN AND METHOD

The aims of the study were to assess the impact of JMD-HER 387 OD on reproduction of the earthworm, *Eisenia andrei* and to determine EC10, EC20, EC50 and NOEC. The test item in the form of an aqueous suspension was mixed with a suitable amount of the artificial soil. The concentrations of the test item were: 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 was also one untreated control group with the deionised water only. Control group was divided into eight replicates. The exposure period lasted 8 weeks. After 4 weeks, all of 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 the additional 4 week period on the basis of the number of juveniles hatched from cocoons during the exposure period.

Test design:	number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
Exposure time:	8 weeks
Tested concentrations, definitive test:	control, 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
Dates:	start of the study: 20.05.2021 start of the experimental part: 25.05.2021 end of the experimental part: 22.07.2021 end of the study: 23.08.2021
Statistic:	ToxRat Professional 2.10

CONCLUSION

After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 163.0 and 188.8 per replicate. The mean number of juveniles in the control group was equal to 176.1 per replicate. After 8 weeks of the experiment, it was concluded that JMD-HER 387 OD had no statistically significant impact on reproduction of the earthworms at the concentrations ranging from 5.6 to 1000.0 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.

Table KCP 10.4.1.1-1: Earthworm reproduction test – final results

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of 2,4-D-2EHE/kg dry weight of artificial soil]	Value [mg of 2,4-D/kg dry weight of artificial soil]	Value [mg of iodosulfuron methyl sodium/kg dry weight of artificial soil]
EC_{10}	>1000.0	> 361.11	> 239.52	> 9.58

EC_{20}	>1000.0	> 361.11	> 239.52	> 9.58
EC_{50}	>1000.0	> 361.11	> 239.52	> 9.58
NOEC reproduction	≥1000.0	≥ 361.11	≥ 239.52	≥9.58
LOEC reproduction	>1000.0	> 361.11	> 239.52	> 9.58
LC_{50}	>1000.0	> 361.11	> 239.52	> 9.58
NOEC survival	≥1000.0	≥ 361.11	> 239.52	> 9.58
LOEC survival	>1000.0	> 361.11	≥ 239.52	≥ 9.58

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant. No studies submitted.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. The results are considered valid because the following criteria were satisfied in the controls: ➢ mean adult mortality: 7.5% (criterion: ≤ 20%), ➢ the mean number of juveniles per vessel at the end of the test: 602.0 (criterion: ≥100 juveniles at the end of the test), ➢ the coefficient of variation calculated for the number of juveniles: 12.9% (criterion: ≤ 30%). **Deviation of the study:** - 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), - 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). **Agreed toxicity endpoints:**

Mortality:

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of 2.4-D-2EHE/kg dry weight of the artificial soil]	Value [mg of 2.4-D/kg dry weight of the artificial soil]	Value [mg of iodosulfuron methyl sodium /kg dry weight of the artificial soil]
LC_{10}	**19.489** (9.264 – 28.285)	**6.928** (3.293 – 10.054)	**4.595** (2.184 – 6.669)	**0.189** (0.090 – 0.274)
LC_{20}	**26.544** (15.112 – 36.717)	**9.435** (5.372 – 13.051)	**6.258** (3.563 – 8.657)	**0.257** (0.146 – 0.355)
LC_{50}	**47.934** (34.320 – 67.915)	**17.039** (12.199 – 24.141)	**11.302** (8.091 – 16.012)	**0.464** (0.332 – 0.657)
NOEC	**18.000**	**6.398**	**4.244**	**0.174**

Reproduction:

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of 2.4-D-2EHE/kg dry weight of the artificial soil]	Value [mg of 2.4-D/kg dry weight of the artificial soil]	Value [mg of iodosulfuron methyl sodium /kg dry weight of the artificial soil]
EC_{10}	**4.394** (2.522 – 6.285)	**1.562** (0.896 – 2.234)	**1.036** (0.594 – 1.482)	**0.043** (0.024 – 0.061)
EC_{20}	**7.483** (4.990 – 9.859)	**2.660** (1.774 – 3.504)	**1.764** (1.177 – 2.324)	**0.072** (0.048 – 0.095)
EC_{50}	**20.722** (16.728 – 25.675)	**7.366** (5.946 – 9.126)	**4.886** (3.944 – 6.053)	**0.200** (0.162 – 0.248)
NOEC	**1.800**	**0.640**	**0.425**	**0.017**

Reference:	KCP 10.4.2.1/01
Report	JMD-HER 387 OD Collembolan (*Folsomia candida*) Reproduction Test; Gierbuszewska A.; 2021; Study Code: G-04-21
Guideline(s):	Yes, OECD 232
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): JMD-HER 387 OD

Formulation: OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)

Description (physical state):	brown liquid
Batch no.:	JMD/01/2021
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: deionized water
positive control: boric acid

3. Test organism

Species:	Collembolan *Folsomia candida*
Source:	culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Laboratory of Soil Organisms Toxicology
Age:	between 9 to 11 days old
Acclimation period:	no data
Diet:	small amount of granulated dried baker's yeast
Test units:	plastic containers to form a 1-cm layer

4. Environmental conditions:

Temperature:	20.6 – 22.0°C
pH:	pH at the beginning of the test: 5.60 – 5.86 pH at the end of the test: 5.50 – 5.57
Soil:	artificial soil: 5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Soil moisture:	soil moisture content at the beginning of the test: 18.6 – 19.2% (45.7 – 47.2% of the maximum water holding capacity) soil moisture content at the end of the test: 17.9 – 19.1% (46.5 – 47.0% of the maximum water holding capacity)
Photoperiod:	light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 582.0 – 756.4 lux; light intensity at the end of the experiment: 596.0 – 682.0 lux

STUDY DESIGN AND METHOD

The aims of the study were to assess the impact of JMD-HER 387 OD on reproduction of the collembolans, Folsomia candida and to determine the EC10, EC20, EC50, and NOEC. Twelve concentrations of the test item were used. These were 0.32, 0.56, 1.00, 1.80, 3.20, 5.60, 10.00, 18.00, 32.00, 56.00, 100.00, and 180.00 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized

water alone. The exposure period lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Test design:	number of replicates: 4 replicates / concentration + 8 replicates / control; number of collembolans: 10 / replicate
Exposure time:	28 days
Tested concentrations, definitive test:	a control, 0.32, 0.56, 1.00, 1.80, 3.20, 5.60, 10.00, 18.00, 32.00, 56.00, 100.00, and 180.00 mg of the test item/kg of dry weight of the artificial soil
Dates:	start of the study: 20.05.2021 start of the experimental part: 24.05.2021 end of the experimental part: 23.06.2021 end of the study: 09.07.2021
Statistic:	EC_{10}, EC_{20}, EC_{50}, LC_{10}, LC_{20} and LC_{50} – probit analysis using linear max. likelihood regression NOEC (number of juveniles): Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure NOEC (survival): Fisher's Exact Binomial Test with Bonferroni Correction.

CONCLUSION

At the concentrations ranging from 0.32 to 180.00 mg/kg dry weight of the artificial soil, the mortality of adults ranged from 0 to 100%. As for the control group, it was equal to 7.5%.
The concentration of the test item causing a 50% mortality of adults within the exposure period (LC_{50}) is equal to 47.934 mg/kg dry weight of the artificial soil (17.039 mg of 2,4-D-2EH + 0.464 mg of iodosulfuronmethylsodium/kg dry weight of the artificial soil).

Table KCP 10.4.2.1-1: Collembolan *Folsomia candida* survival test – final results

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of 2,4-D-2EHE/kg dry weight of artificial soil]	Value [mg of 2,4-D/kg dry weight of artificial soil]	Value [mg of iodosulfuron methyl sodium/kg dry weight of artificial soil]
LC_{10}	19.489	6.928	4.595	0.189
LC_{20}	26.544	9.435	6.258	0.257
LC_{50}	47.934	17.039	11.302	0.464
NOEC	18.000	6.398	4.244	0.174

After the exposure of collembolans to the test item at the concentrations ranging from 0.32 to 180.00 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 2.3 – 656.5 per replicate. As for the control group, the number of juveniles was equal to 602.0 per replicate.

The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the table given below.

Table KCP 10.4.2.1-2: Collembolan *Folsomia candida* reproduction test – final results

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of 2,4-D-2EHE/kg dry weight of artificial soil]	Value [mg of 2,4-D/kg dry weight of artificial soil]	Value [mg of iodosulfuron methyl sodium/kg dry weight of artificial soil]
LC_{10}	4.394	1.562	1.036	0.043
LC_{20}	7.483	2.660	1.764	0.072
LC_{50}	20.722	7.366	4.886	0.200
NOEC	1.800	0.640	0.425	0.017

Comments of zRMS:

The study was accepted by RMS.
The validity criteria was met.
The results are considered valid because the following criteria were satisfied in the control:

- mean adult mortality: 7.5% (criterion: ≤ 20%),
- the mean number of juveniles per vessel at the end of the test: 100.5 (criterion: ≥ 50 juveniles at the end of the test),
- the coefficient of variation for the number of juveniles: 11.9% (criterion: ≤ 30%).

Deviation of the study: According to the OECD Guideline No. 226 (2016) the water content of the soil substrate should be maintained throughout the test by weighing and if needed re-watering the vessels periodically. In the study to maintain proper moisture content, a small sample of soil was drying at 105°C and re-weighing at the beginning, after 7 days of the test and at the end of the test. Due to the use of the temperature extraction method, there was no need for euthanasia of the extracted organisms since the mites are fixed in a 70% ethanol solution. Due to the use of the temperature extraction method, it was not possible to record the symptoms with behavioral and morphology changes of the extracted predatory mites.

Agreed toxicity endpoints:

Concentration [mg/kg dry weight of the artificial soil]	Adult mites			Number of juveniles (mean)
	Number of tested mites	Dead mites after 14 days		
		No.	%	
control	80	6	7.5	100.5
5.6	40	0	0.0	103.5
10.0	40	0	0.0	94.3
18.0	40	3	7.5	95.3
32.0	40	1	2.5	128.0
56.0	40	2	5.0	95.0
100.0	40	0	0.0	94.3
180.0	40	1	2.5	117.3
320.0	40	0	0.0	126.8
560.0	40	1	2.5	105.8
1000.0	40	0	0.0	119.5

Endpoint values – the impact of the test item on reproduction and on mortality of the predatory mites *(Hypoaspis aculeifer)*.

Endpoint	Value [mg/kg dry weight of the artificial soil]	Value [mg of 2,4-D-2EHE/kg dry weight of the artificial soil]	Value [mg of 2,4-D/kg dry weight of the artificial soil]	Value [mg of iodosulfuron methyl sodium /kg dry weight of the artificial soil]
EC_{10}	> 1000	> 355.5	> 235.8	> 9.7
EC_{20}	> 1000	> 355.5	> 235.8	> 9.7
EC_{50}	> 1000	> 355.5	> 235.8	> 9.7
NOEC (reproduction)	≥ 1000	≥ 355.5	≥ 235.8	≥ 9.7
LC_{10}	> 1000	> 355.5	> 235.8	> 9.7
LC_{20}	> 1000	> 355.5	> 235.8	> 9.7
LC_{50}	> 1000	> 355.5	> 235.8	> 9.7
NOEC (survival)	≥ 1000	≥ 355.5	≥ 235.8	≥ 9.7

Reference:	KCP 10.4.2.1/02
Report	Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil; Gierbuszewska A.; 2021; Study Code: G-05-21
Guideline(s):	Yes, OECD 226
Deviations:	According to the OECD Guideline No. 226 (2016) the water content of the soil substrate should be maintained throughout the test by weighing and if needed re-watering the vessels periodically. In the study to maintain proper moisture content, a small sample of soil was drying at 105°C and re-weighing at the beginning, after 7 days of the test and at the end of the test. Due to the use of the temperature extraction method, there was no need for euthanasia of the extracted organisms since the mites are fixed in a 70% ethanol solution. Due to the use of the temperature extraction method, it was not possible to record the symptoms with behavioral and morphology changes of the extracted predatory mites.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)

Description (physical state):	brown liquid
Batch no.:	JMD/01/2021
Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: deionized water
positive control: boric acid

3. Test organism

Species:	the predatory mites, *Hypoaspis (Geolaelaps) aculeifer*
Source:	culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology
Age:	7 – 14 days after becoming adult
Acclimation period:	not relevant
Diet:	cheese mite *Tyrophagus putrescentiae*
Test units:	glass vessels with a capacity of 50 mL (diameter: 3.5 cm; height of soil: about 2 cm) with covers were used

4. Environmental conditions:

Temperature:	20.8 – 22.0°C
pH:	pH at the beginning of the test: 5.58 – 6.07 pH at the end of the test: 5.52 – 5.97
Soil:	artificial soil: 5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Soil moisture:	soil moisture content at the beginning of the test: 18.5 – 20.0% (45.5 – 49.2% of the maximum water holding capacity) soil moisture content in the middle of the test: 17.7 – 20.6% (43.5 – 50.7% of the maximum water holding capacity) soil moisture content at the end of the test: 17.6 – 20.6% (43.3 – 50.7% of the maximum water holding capacity)
Photoperiod:	light-dark cycle: 16h : 8h; light intensity at the beginning of the test: 643.9 – 788.4 lux light intensity at end of the test: 674.7 – 728.7 lux

STUDY DESIGN AND METHOD

The aims of the study were to assess the impact of JMD-HER 387 OD on reproduction of the predatory mite, *Hypoaspis (Geolaelaps) aculeifer* and to determine the EC10, EC20, EC50, and NOEC.
Ten concentrations of the test item were used. These included: 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 concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in the form

of oil dispersion was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The experiment lasted 14 days. After that, the mites were extracted from the artificial soil (48-hour extraction). The numbers of adults and juveniles were determined separately.

Test design:	4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate
Exposure time:	14 days
Tested concentrations, definitive test:	a control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg test item/kg dry weight of the artificial soil
Dates:	start of the study: 20.05.2021 start of the experimental part: 24.05.2021 end of the experimental part: 09.06.2021 end of the study: 09.07.2021
Statistic:	EC_{10}, EC_{20}, EC_{50} – probit analysis using linear max. likelihood regression LC_{10}, LC_{20}, LC_{50} – probit analysis using linear max. likelihood regression NOEC: offspring number – Shapiro-Wilk's Test on Normal Distribution, Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure, survival – Fisher's Exact Binomial Test with Bonferroni Correction

RESULTS

Mortality of the predatory mites exposed to the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil was between 0.0% and 7.5%. Mortality of the control group was equal to 7.5%.
After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil the mean number of juveniles was between 94.3 – 128.0 per replicate. The mean number of juveniles in the control group was equal to 100.5 per replicate.

Table KCP 10.4.1.1-1: Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) mortality test – final results

Concentration [mg/kg dry weight of the artificial soil]	Adult mites			Number of juveniles (mean)
	Number of tested mites	Dead mites after 14 days		
		No.	%	
control	80	6	7.5	100.5
5.6	40	0	0.0	103.5
10.0	40	0	0.0	94.3
18.0	40	3	7.5	95.3
32.0	40	1	2.5	128.0
56.0	40	2	5.0	95.0
100.0	40	0	0.0	94.3
180.0	40	1	2.5	117.3
320.0	40	0	0.0	126.8
560.0	40	1	2.5	105.8
1000.0	40	0	0.0	119.5

CONCLUSION

Endpoint values the impact of the test item on reproduction and on mortality of the predatory mites (Hypoaspis aculeifer).

Table KCP 10.4.1.1-1: *Hypoaspis aculeifer* – the impact of the test item on reproduction and on mortality

Endpoint	mg/kg dry weight of the artificial soil	mg of 2,4-D-2EHE/kg dry weight of the artificial soil	mg of 2,4-D/kg dry weight of the artificial soil	mg of iodosulfuron methyl sodium /kg dry weight of the artificial soil
EC_{10}	> 1000	> 355.5	> 235.8	> 9.7
EC_{20}	> 1000	> 355.5	> 235.8	> 9.7
EC_{50}	> 1000	> 355.5	> 235.8	> 9.7
NOEC (reproduction)	≥ 1000	≥ 355.5	≥ 235.8	≥ 9.7
LC_{10}	> 1000	> 355.5	> 235.8	> 9.7
LC_{20}	> 1000	> 355.5	> 235.8	> 9.7
LC_{50}	> 1000	> 355.5	> 235.8	> 9.7
NOEC (survival)	≥ 1000	≥ 355.5	≥ 235.8	≥ 9.7

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Not relevant. No studies submitted.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. The coefficients of variation (CV) in the control group were 7.0, 6.8, 11.2 and 0.8%,

after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than 15%.

Deviation of the study:

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 deviation did not affect the results of the study.

Agreed toxicity endpoints:

Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control						PEC						5 x PEC					
	Replicate			Mean	±	SD	Replicate			Mean	±	SD	Replicate			Mean	±	SD
	I	II	III				I	II	III				I	II	III			
0 – 7	23.496	19.668	22.475	21.880	±	1.98	29.038	24.510	23.631	25.726	±	2.90	23.215	24.993	24.122	24.110	±	0.89
0 – 14	8.968	7.022	6.647	7.545	±	1.25	10.614	10.050	9.989	10.218+	±	0.34	9.120	8.384	8.188	8.564+	±	0.49
0 – 28	6.903	6.770	6.858	6.844	±	0.07	8.161	7.690	7.877	7.910+	±	0.24	8.255	8.571	8.191	8.339+	±	0.20

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14, 28 and 42 day

\+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, two sided)

Reference:	KCP 10.5/01
Report	JMD-HER 387 OD Soil Microorganisms: Nitrogen Transformation Test; Pieczka P.; 2022; Study Code: G-09-21
Guideline(s):	Yes, OECD 216
Deviations:	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 deviation did not affect the results of the study.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2021

Production date:	02.2021
Expiration date:	02.2023

2. Vehicle and/or positive control: vehicle: deionized water
positive control: not relevant

3. Test organism

Soil:	Agricultural soil collected from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna
Source:	Agricultural soil collected from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna
Soil preparation:	the collected soil was manually cleared of large objects, sieved to a particle size equal to 2 mm and thus the laboratory soil sample was obtained, the soil, prepared in that way, was thoroughly mixed and divided into three equal portions, the test item at two concentrations: PEC and 5 x PEC was added into two portions of the soil, the test item in the form of aqueous suspensions was introduced to the soil, the control artificial soil was mixed with deionized water alone, at the beginning of the experiment, the soil moisture content was adjusted with deionized water to obtain value between 40 – 60% (about 50%) of the maximum water holding capacity
Test units:	plastic containers covered with perforated aluminium foil

4. Environmental conditions:

Temperature:	19.6 – 22.0°C
Soil moisture:	45.9 – 49.3% of the maximum water holding capacity
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The aim of the study was to detect long-term adverse effects of JMD-HER 387 ODon the processes of nitrogen transformation in aerobic surface soils. The freshly collected agricultural soil was used in the experiment. It was manually cleared of large objects and sieved to a particle size of 2 mm. Two concentrations of the test item were used, i.e.: PEC and 5 x PEC. The treated and the control soils were divided into three replicates. On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrate. The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using deionised water. The nitrate formation rate in each treated group was compared with that in the control, and the percent deviation of the treated from the control was calculated.

Test design:	concentrations and control in 3 replicates
Exposure time:	28 days

Tested concentrations, definitive test:	PEC: 0.696 mg test item/kg dry weight of soil (i.e. 0.249 mg of 2,4-D-2EH + 0.007 mg of iodosulfuron-methylsodium/kg dry weight of soil); 5 x PEC: 3.480 mg test item/kg dry weight of soil (i.e. 1.244 mg of 2,4-D-2EH + 0.033 mg of iodosulfuron-methylsodium/kg dry weight of soil)
Dates:	start of the study 06.04.2021 start of the experimental part: 08.04.2021 end of the experimental part: 07.05.2021 end of the study: 15.06.2021
Statistic:	Shapiro-Wilk's test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure, ToxRat 2.10. computer software

CONCLUSION

The difference in the nitrate formation rate between the control soil and the ones treated with the test item at the concentrations corresponding to the PEC: 0.696 mg test item/kg dry weight of soil (i.e. 0.249 mg of 2,4-D-2EH + 0.007 mg of iodosulfuronmethylsodium/kg dry weight of soil) and 5xPEC: 3.480 mg test item/kg dry weight of soil (i.e. 1.244 mg of 2,4-D-2EH + 0.033 mg of iodosulfuronmethylsodium/kg dry weight of soil) did not exceed 25% on 28 day of analysis.

On the basis of the results, it was concluded that JMD-HER 387 OD at the concentrations corresponding to the PEC: 0.696 mg test item/kg dry weight of soil (i.e. 0.249 mg of 2,4-D-2EH + 0.007 mg of iodosulfuronmethylsodium/kg dry weight of soil) and 5 x PEC: 3.480 mg test item/kg dry weight of soil (i.e. 1.244 mg of 2,4-D-2EH + 0.033 mg of iodosulfuronmethylsodium/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Table KCP 10.5.-1: Nitrogen transformation (deviation from the control) – final results

Time interval [d]	1PEC	5PEC
0-7	-17.6	-10.2
0-14	-35.4	-13.5
0-28	-15.6	-21.9

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of **Jockey 387 OD** on seedling emergence and seedling growth of terrestrial plants were met:

- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100.0% – pea,
100.0% – cabbage,
85.0% – red clover,
100.0% – carrot,
100.0% – onion,
100.0% – corn,
- the mean survival of the emerged control seedlings was 100% for pea, cabbage, red clover, carrot, onion and corn (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

Deviation of the study:

Deviation 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 69.80 and 174.3 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 on July 20, 2021 and not in June 2021 as it had been planned in the study plan.
The deviations did not affect results of the experiment.

Agreed toxicity endpoints:

expressed as mL product Jockey 387 OD/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>1000.0	>1000.0	>1000.0	174.6	745.5	>1000.0
NOER	>1000.0	>1000.0	333.3	111.1	111.1	≥1000.0
Shoot length (plants without roots)						
ER_{50}	>1000.0	359.9	97.0	114.8	175.3	>1000.0
NOER	111.1	12.3	12.3	12.3	37.0	333.3
Plant dry weight (plants without roots)						
ER_{50}	880.0	244.0	164.5	104.8	226.0	>1000.0
NOER	333.3	111.1	37.0	37.0	37.0	333.3

expressed as g 2,4-D 2-EHE/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>377.000	>377.000	>377.000	65.824	281.054	>377.000
NOER	>377.000	>377.000	125.654	41.885	41.885	>377.000
Shoot length (plants without roots)						
ER_{50}	>377.000	135.682	36.569	43.280	66.088	>377.000
NOER	41.885	4.637	4.637	4.637	13.949	125.654
Plant dry weight (plants without roots)						
ER_{50}	331.760	91.988	62.017	39.510	85.202	>377.000
NOER	125.654	41.885	13.949	13.949	13.949	125.654

expressed as g 2,4-D acid/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>250.059	>250.059	>250.059	43.660	186.419	>250.059
NOER	>250.059	>250.059	83.345	27.782	27.782	>250.059
Shoot length (plants without roots)						
ER_{50}	>250.059	89.996	24.256	28.707	43.835	>250.059
NOER	27.782	3.076	3.076	3.076	9.252	83.345
Plant dry weight (plants without roots)						
ER_{50}	220.052	61.014	41.135	26.206	56.513	>250.059
NOER	83.345	27.782	9.252	9.252	9.252	83.345

expressed as g iodosulfuronmethylsodium/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>10.000	>10.000	>10.000	1.746	7.455	>10.000
NOER	>10.000	>10.000	3.333	1.111	1.111	>10.000
Shoot length (plants without roots)						
ER_{50}	>10.000	3.599	0.970	1.148	1.753	>10.000
NOER	1.111	0.123	0.123	0.123	0.370	3.333
Plant dry weight (plants without roots)						
ER_{50}	8.800	2.440	1.645	1.048	2.260	>10.000
NOER	3.333	1.111	0.370	0.370	0.370	3.333

Phytotoxicity parameter:
The phytotoxicity parameter was assessment by RMS based on data in the study report without statistical analysis:
Pea ER_{50} > 333.3 mL formulation Jockey 387 OD/ha
Cabbage ER_{50} > 333.3 mL formulation Jockey 387 OD/ha
Red clover ER_{50} > 37.0 mL formulation Jockey 387 OD/ha
Carrot ER_{50} > 111.1 mL formulation Jockey 387 OD/ha
Onion ER_{50} > 37.0 mL formulation Jockey 387 OD/ha
Corn = no phytotoxicity effect was observed

Reference:	KCP 10.6.2/01
Report	JMD-HER 387 OD Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test; Pieczka P.; 2021; Study Code: G-08-21
Guideline(s):	Yes, OECD 208
Deviations:	Deviation from OECD Guideline No. 208: 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 69.80 and 174.3 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 on July 20, 2021 and not in June 2021 as it had been planned in the study plan. The deviations did not affect the results of the experiment.

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

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2021
Production date:	02.2021
Expiration date:	02.2023
Stability of test compound:	not relevant
2. Vehicle and/or positive control:	vehicle control: water positive control: not relevant
3. Test plants:	pea (Pisum sativum), cabbage (Br*assica oleracea var. capitata*), red clover (*Trifolium pratense*), carrot (*Daucus carota*), onion (*Allium cepa*), corn (*Zea mays*)
Soil:	sandy loam
Test containers:	plastic pots, each pot contained about 719 g of the soil (i.e. 600 g dry weight)
4. Environmental conditions:	
Temperature:	18.4 – 24.8°C
Relative humidity:	45.5 – 82.7%
Photoperiod:	lighting: 16 h light : 8 h dark; light intensity: 69.80 – 174.3 µE/m2/s
CO_2 concentration:	341 – 382 ppm

STUDY DESIGN AND METHODS

The study, aimed at evaluating the effect of JMD-HER 387 OD 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, eight application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 3 (pea, cabbage) or 5 (carrot, red clover, onion) or 2 (corn) 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 until the emergence of 50% of the control seedlings and then every 1 – 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_{25}, ER_{50}, and NOER.

Test design:	number of rates: 8 + control; number of replicates/rate: 4 (carrot, red clover, onion) or 7 (pea, cabbage) or 10 (corn). The total number of seeds per application rate – 20 (carrot, red clover, onion, corn) or 21 (pea, cabbage)
Exposure time:	14 days since emergence of 50% seeds in control
Tested concentrations, definitive test:	control, 0.5, 1.4, 4.1, 12.3, 37.0, 111.1, 333.3 and 1000.0 mL of the test item / ha, dilution in 200 L water/ha, dilution in 200 L water/ha
Dates:	start of the study 29.04.2021 start of the experimental part: 30.04.2021 end of the experimental part: 21.05.2021 end of the study: 20.06.2021
Statistic:	ER_{25}, ER_{50} – probit analysis, 3-param. Normal CDF or 4 param. Normal CDF NOER: In order to determine the NOER values, the following tests were used: - for the emergence of plants: 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, Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Chi2 2x2 Table Test with Bonferroni Correction, Tarone's Test Procedure, Multiple Sequentially Rejective Fisher Test After Bonferroni-Holm, - for the shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, - for the plant weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Multiple Sequentially-rejective Median (2x2 Table) Test After Bonferroni-Holm, Step-down Jonckheere-Terpstra Test Procedure.

CONCLUSION

The ER_{50} and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ha for all test species are given below.

Table KCP 10.6.2-1: Seedling emergence and seedling growth test – final results expressed as ml of test item/ha

	Pea *Pisum sativum*	**Cabbage**	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*

		Brassica oleracea var. capitata				
Plant number at the end of the experiment						
ER_{50}	>1000.0	>1000.0	>1000.0	174.6	745.5	>1000.0
NOER	>1000.0	>1000.0	333.3	111.1	111.1	≥1000.0
Shoot length						
ER_{50}	>1000.0	359.9	97.0	114.8	175.3	>1000.0
NOER	111.1	12.3	12.3	12.3	37.0	333.3
Plant dry weight						
ER_{50}	880.0	244.0	164.5	104.8	226.0	>1000.0
NOER	333.3	111.1	37.0	37.0	37.0	333.3

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of 2,4-D 2-EHE/ha for all test species are given below.

Table KCP 10.6.2-2: Seedling emergence and seedling growth test – final results stoichiometrically recalculated from 2,4-D 2-EHE and expressed as g of 2,4-D acid/ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>377.000	>377.000	>377.000	65.824	281.054	>377.000
NOER	>377.000	>377.000	125.654	41.885	41.885	>377.000
Shoot length						
ER_{50}	>377.000	135.682	36.569	43.280	66.088	>377.000
NOER	41.885	4.637	4.637	4.637	13.949	125.654
Plant dry weight						
ER_{50}	331.760	91.988	62.017	39.510	85.202	>377.000
NOER	125.654	41.885	13.949	13.949	13.949	125.654

The table given below presents the ER_{50} and NOER values stoichiometrically recalculated from 2,4-D 2-EHE and expressed as g of 2,4-D acid/ha.

Table KCP 10.6.2-3: Seedling emergence and seedling growth test – final results stoichiometrically recalculated from 2,4-D 2-EHE and expressed as g of 2,4-D acid/ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>250.059	>250.059	>250.059	43.660	186.419	>250.059
NOER	>250.059	>250.059	83.345	27.782	27.782	>250.059
Shoot length						
ER_{50}	>250.059	89.996	24.256	28.707	43.835	>250.059
NOER	27.782	3.076	3.076	3.076	9.252	83.345
Plant dry weight						
ER_{50}	220.052	61.014	41.135	26.206	56.513	>250.059
NOER	83.345	27.782	9.252	9.252	9.252	83.345

The ER_{50} and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of iodosulfuronmethylsodium/ha for all test species are given below.

Table KCP 10.6.2-4: Seedling emergence and seedling growth test – final results expressed as g of iodosulfuronmethylsodium/ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	>10.000	>10.000	>10.000	1.746	7.455	>10.000
NOER	>10.000	>10.000	3.333	1.111	1.111	>10.000
Shoot length						
ER_{50}	>10.000	3.599	0.970	1.148	1.753	>10.000
NOER	1.111	0.123	0.123	0.123	0.370	3.333
Plant dry weight						
ER_{50}	8.800	2.440	1.645	1.048	2.260	>10.000
NOER	3.333	1.111	0.370	0.370	0.370	3.333

On the basis of the obtained results it was proved that the test item i.e. JMD-HER 387 OD had an impact on the process of growth of pea, cabbage, red clover, carrot and onion. In cultivation of corn the slight impact on the process of growth was observed.

Comments of zRMS:	The study was accepted by RMS. The validity criteria was met. On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of **Jockey 387 OD** on vegetative vigour of terrestrial plants were met: - the seedling emergence of plants (validity criterion: at least 70%) was as follows: 83.3 – 90.5% – pea, 85.7 – 92.9% – cabbage, 82.5 – 95.0% – red clover, 82.5 – 97.5% – carrot, 90.0 – 97.5% – onion, 82.5 – 90.0% – corn, - 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 identical. **Deviation of the study:** *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 93.4 and 170.2 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 deviations from the study plan occurred. The volume of samples subjected to the chemical analysis was 120 mL (each test suspension) instead of 150 mL, as it was mentioned in the study plan. The transferred volumes of suspensions, i.e. 120 mL, were suitable for conducting the chemical analysis. The study was finished in July 2021, not as it was planned in the study plan in June 2021. The deviations did not affect the results of the experiment. **Agreed toxicity endpoints:** ***expressed as mL product Jockey 387 OD/ha:***

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 1000.0	> 1000.0	> 1000.0	> 1000.0	> 1000.0	> 1000.0
NOER	≥ 1000.0	≥ 1000.0	≥ 1000.0	≥ 1000.0	111.1	≥ 1000.0
Shoot length (plants without roots)						
ER_{50}	210.3	> 1000.0	72.1	396.9	61.0	> 1000.0
NOER	4.1	333.3	1.4	4.1	1.4	37.0
Plant dry weight (plants without roots)						
ER_{50}	143.2	622.7	18.7	26.4	78.9	487.6
NOER	12.3	4.1	4.1	4.1	12.3	37.0

The ER_{10}, ER_{25}, ER_{50} and NOER values were calculated using the ToxRat Professional 3.3.0 computer software.

expressed as g 2,4-D-2EH/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 377.000	> 377.000	> 377.000	> 377.000	> 377.0	> 377.000
NOER	≥ 377.000	≥ 377.000	≥ 377.000	≥ 377.000	41.885	≥ 377.000
Shoot length (plants without roots)						
ER_{50}	79.292	> 377.000	27.172	149.635	23.015	> 377.000
NOER	1.546	125.654	0.528	1.546	0.528	13.949
Plant dry weight (plants without roots)						
ER_{50}	53.980	234.755	7.039	9.952	29.746	183.842
NOER	4.637	1.546	1.546	1.546	4.637	13.949

expressed as g 2,4-D acid/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 250.059	> 250.059	> 250.059	> 250.059	> 250.059	> 250.059
NOER	≥ 250.059	≥ 250.059	≥ 250.059	≥ 250.059	27.782	≥ 250.059
Shoot length (plants without roots)						
ER_{50}	52.593	> 250.059	18.023	99.251	15.266	> 250.059
NOER	1.025	83.345	0.350	1.025	0.350	9.252
Plant dry weight (plants without roots)						
ER_{50}	35.804	155.709	4.669	6.601	19.730	121.940
NOER	3.076	1.025	1.025	1.025	3.076	9.252

expressed as g iodosulfuronmethylsodium/ha:

	Pea *Pisum sativum*	Cabbage *Brassica oleracea var. capitata*	Red clover *Trifolium pratense*	Carrot *Daucus carota*	Onion *Allium cepa*	Corn *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 10.000	> 10.000	> 10.000	> 10.000	> 10.000	> 10.000
NOER	≥ 10.000	≥ 10.000	≥ 10.000	≥ 10.000	1.111	≥ 10.000
Shoot length (plants without roots)						
ER_{50}	2.103	> 10.000	0.721	3.969	0.610	> 10.000
NOER	0.041	3.333	0.014	0.041	0.014	0.370
Plant dry weight (plants without roots)						
ER_{50}	1.432	6.227	0.187	0.264	0.789	4.876
NOER	0.123	0.041	0.041	0.041	0.123	0.370

Some phytotoxic symptoms as stunted growth, deformations, wilting, chlorosis and necrosis were observed. In case of onion mortality of plants at the rates 333.3 and 1000 mL/ha was also observed.

Phytotoxicity parameter:

The phytotoxicity parameter was assessment by RMS based on data in the study report without statistical analysis:

Pea ER_{50} > 111.1 mL formulation Jockey 387 OD/ha
Cabbage ER_{50} > 111.1 mL formulation Jockey 387 OD/ha
Red clover ER_{50} > 12.3 mL formulation Jockey 387 OD/ha
Carrot ER_{50} > 12.3 mL formulation Jockey 387 OD/ha
Onion ER_{50} > 37.0 mL formulation Jockey 387 OD/ha
Corn ER_{50} > 1000 mL formulation Jockey 387 OD/ha

Reference:	KCP 10.6.2/02
Report	JMD-HER 387 OD Terrestrial Plant Test: Vegetative Vigour Test; Arendarczyk A.; 2021; Study Code: G-07-21
Guideline(s):	Yes, OECD 227
Deviations:	Deviation from OECD Guideline No. 227: 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 93.4 and 170.2 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviations from the study plan occurred: the volume of samples subjected to the chemical analysis was 120 mL (each test suspension) instead of 150 mL, as it was mentioned in the study plan. The trans-ferred volumes of suspensions, i.e. 120 mL, were suitable for conduct-ing the chemical analysis. The study was finished in July 2021, not as it was planned in the study plan in June 2021. The deviations did not affect the results of the experiment
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	JMD-HER 387 OD
Formulation:	OD (iodosulfuron-methyl-sodium 10 g/L + 2,4-D 377 g/L)
Description (physical state):	brown liquid
Batch no.:	JMD/01/2021
Production date:	02.2021
Expiration date:	02.2023
Stability of test compound:	not relevant
2. Vehicle and/or positive control:	vehicle control: water positive control: not relevant
3. Test plants:	pea (Pisum sativum), cabbage (Br*assica oleracea var. capitata*), red clover (*Trifolium pratense*), carrot (*Daucus carota*), onion (*Allium cepa*), corn (*Zea mays*)
Soil:	sandy loam
Test containers:	plastic pots (pot's diameter – 15 cm, pot's surface area – about 177 cm^2)
4. Environmental conditions:	
Temperature:	17.9 – 25.1°C
Relative humidity:	46.1 – 79.8%
Photoperiod:	16h light and 8h dark, light intensity: 93.4 – 170.2 µE/m2/s
CO_2 concentration:	356 – 387 ppm

STUDY DESIGN AND METHODS

The study, aimed at evaluating the effect of JMD-HER 387 OD on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. Seeds of the test plant species were sown in plastic pots (6 seeds/pot for pea and cabbage; 10 seeds/pot for red clover, carrot, onion and 4 seeds/pot for corn). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per application rate were:
- pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- cabbage: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- red clover: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- corn: 2 plants/pot – 20 plants/ application rate (10 pots/ application rate).

The pot is defined as a replicate. The test item was sprayed onto the plants. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The experiment finished 21 days after the spraying. At the end of the experiment, the number

of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.
The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER25, ER50 and NOER.

Test design:	number of rates: 8 + control; number of replicates/rate: 7 (pea, cabbage), 4 (carrot, onion) or 10 (corn). The total number of plants per application rate – 21 (pea, cabbage) or 20 (red clover, carrot, onion, corn)
Exposure time:	21 days after the spraying
Tested concentrations, definitive test:	control, 0.5, 1.4, 4.1, 12.3, 37.0, 111.1, 333.3 and 1000.0 mL of the test item / ha, dilution in 200 L water/ha
Dates:	start of the study 29.04.2021 start of the experimental part: 30.04.2021 end of the experimental part: 24.05.2021 end of the study: 20.07.2021
Statistic:	Trend analysis by contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure.

CONCLUSION

The ER_{50} and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements and ER_{50} values for plant damages at the end of the exposure period expressed as mL of the test item/ha for all test species are given below.

Table KCP 10.6.2-5: Vegetative Vigour Test – final results expressed as mL of the test item/ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 1000.0	> 1000.0	> 1000.0	> 1000.0	> 1000.0	> 1000.0
NOEC	≥1000.0	≥1000.0	≥1000.0	≥1000.0	111.1	≥1000.0
Shoot length (plants without roots)						
ER_{50}	210.3	> 1000.0	72.1	396.9	61.0	> 1000.0
NOEC	4.1	333.3	1.4	4.1	1.4	37.0
Plant dry weight (plants without roots)						
ER_{50}	143.2	622.7	18.7	26.4	78.9	487.6
NOEC	12.3	4.1	4.1	4.1	12.3	37.0

The ER_{50} and NOER values, determined on the basis of plants number, shoot length and shoot dry weight measurements at the end of the experiment, expressed as g of 2,4-D-2EH/ha for all test species are given below.

Table KCP 10.6.2-6: Vegetative Vigour Test – final results expressed as g of 2,4-D-2EH/ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 377.000	> 377.000	> 377.000	> 377.000	> 377.000	> 377.000

NOEC	≥ 377.000	≥ 377.000	≥ 377.000	≥ 377.000	41.885	≥ 377.000
Shoot length (plants without roots)						
ER_{50}	79.292	> 377.000	27.172	149.635	23.015	> 377.000
NOEC	1.546	125.654	0.528	1.546	0.528	13.949
Plant dry weight (plants without roots)						
ER_{50}	53.980	234.755	7.039	9.952	29.746	183.842
NOEC	4.637	1.546	1.546	1.546	4.637	13.949

The table given below presents the ER_{50} and NOER values stoichiometrically recalculated from 2,4-D 2-EHE and expressed as g of 2,4-D acid/ha.

Table KCP 10.6.2-7: Vegetative Vigour Test – final results stoichiometrically recalculated from 2,4-D 2-EHE and expressed as g of 2,4-D acid/ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 250.059	> 250.059	> 250.059	> 250.059	> 250.059	> 250.059
NOEC	≥ 250.059	≥ 250.059	≥ 250.059	≥ 250.059	27.782	≥ 250.059
Shoot length (plants without roots)						
ER_{50}	52.593	> 250.059	18.023	99.251	15.266	> 250.059
NOEC	1.025	83.345	0.350	1.025	0.350	9.252
Plant dry weight (plants without roots)						
ER_{50}	35.804	155.709	4.669	6.601	19.730	121.940
NOEC	3.076	1.025	1.025	1.025	3.076	9.252

The ER50 and NOER values, determined on the basis of plants number, shoot length and shoot dry weight measurements at the end of the experiment, expressed as g of iodosulfuronmethylsodium /ha for all test species are given below.

Table KCP 10.6.2-8: Vegetative Vigour Test – final results expressed as g of iodosulfuronmethylsodium /ha

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Red clover** *Trifolium pratense*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 10.000	> 10.000	> 10.000	> 10.000	> 10.000	> 10.000
NOEC	≥ 10.000	≥ 10.000	≥ 10.000	≥ 10.000	1.111	≥ 10.000
Shoot length (plants without roots)						
ER_{50}	2.103	> 10.000	0.721	3.969	0.610	> 10.000
NOEC	0.041	3.333	0.014	0.041	0.014	0.370
Plant dry weight (plants without roots)						
ER_{50}	1.432	6.227	0.187	0.264	0.789	4.876
NOEC	0.123	0.041	0.041	0.041	0.123	0.370

The lowest ER_{50} value determined on the basis of the plant shoot length at the end of the experiment, was observed for onion and it was equal to 61.0 mL of the test item/ha. The lowest ER_{50} value determined on the basis of the plant shoot weight at the end of the experiment, was observed for red clover and it was equal to 18.7 mL of the test item/ha. Some phytotoxic symptoms as stunted growth, deformations, wilting, chlorosis and necrosis were observed. In case of onion mortality of plants at the rates 333.3 and 1000 mL/ha was also observed.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant. No studies submitted.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant. No studies submitted.

A 2.8 KCP 10.8 Monitoring data

Not relevant. No studies submitted.