REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: CHR/H MEZO 30 OD

Product name(s): Vidal 30 OD, Pacyfik 30 OD

Chemical active substance:

Mesosulfuron-methyl, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Innvigo Sp. z o.o

Submission date: December 2023

zRMS Assessment: 26/07/2024

MS Finalisation date: 19/11/2024

Version history

When	What
July 2024	zRMS Assessment
November 2024	Following commenting period

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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 arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	Winter wheat *Triticum aestivum* (TRZAW)	F	*Apera spica-venti* *Alopecurus myosuroides* *Poa annua* *Bromus hordeaceus* *Lolium perennium* *Viola arvensis* *Brassica napus* *Anthemis arvensis* *Papaver rhoeas* *Sinapsis arvensis* *Capsella brusa-pastoris* *Stellaria media* *Veronica herderifolia*	Spray, medium sprayer	BBCH 21-32	a) 1 b) 1	n/a	a) 0,5 l/ha b) 0,5 l/ha	a) 0,015 kg a.s./ha b) 0,015 kg a.s./ha	100-400					R3 scenario				
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (field uses)																				

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 (interzonal uses)																				
2	PL	Spelt *Triticum spelta* (3SPWC) Emmer wheat *Triticum dicoccum* (TRZDI) Einkorn wheat *Triticum monococcum* (TRZMO) Durum wheat *Triticum durum* (TRZDW) Spring Rye *Secale cereale* (SECCS)	F	*Apera spica-venti* *Alopecurus myosuroides* *Poa annua* *Bromus hordeaceus* *Lolium perennium* *Viola arvensis* *Brassica napus* *Anthemis arvensis* *Papaver rhoeas* *Sinapsis arvensis* *Capsella brusa-pastoris* *Stellaria media* *Veronica herderifolia*	Spray, medium sprayer	BBCH 21-32	a) 1 b) 1	n/a	a) 0,5 l/ha b) 0,5 l/ha	a) 0,015 kg a.s./ha b) 0,015 kg a.s./ha	100-400					R3 scenario				

* 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

9.1.1 Overall conclusion

9.1.1.1 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)

CHR/H/MEZO 30 OD no pose any unacceptable risk for birds and mammals according to label.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

For the protection of aquatic organisms in both intended uses of product CHR/H/MEZO 30 OD in Austria, Hungary and Republic of Ireland, are necessary to maintain the 20 meters of vegetative buffer zone and 5 meters no-spray buffer zone. For the rest of the countries from central zone (including: Belgium, Czech Republic, Poland, Romania, Slovakia, Slovenia) these limitations are not necessary.

9.1.1.3 Effects on bees (KCP 10.3.1)

CHR/H/MEZO 30 OD no pose any unacceptable risk for bees according to label.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Risk assessment for in-field and off-field exposure for non-target arthropods is acceptable because in all checked cases results were in necessary criteria. Intended use of CHR/H/MEZO 30 OD is safe for these organisms.

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

CHR/H/MEZO 30 OD no pose any unacceptable risk for non-target soil meso- and macrofauna according to label.

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

CHR/H/MEZO 30 OD pose a unacceptable risk for non-target terrestrial plants according to label. This product can be used on non-target terrestrial plants only with 5m no-spray buffer zone or with 1m no-spray buffer zone and 50% nozzle reduction.

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

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).

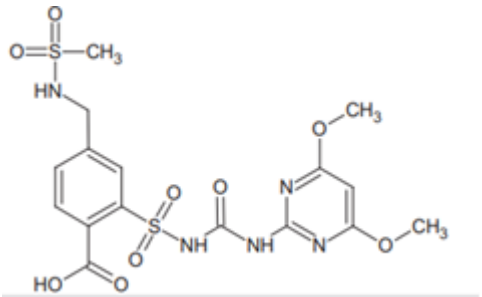
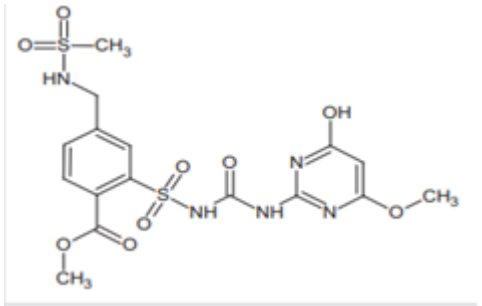
Table 9.1-2: Critical use pattern of CHR/H/MEZO 30 OD grouped according to environmental risk assessment section

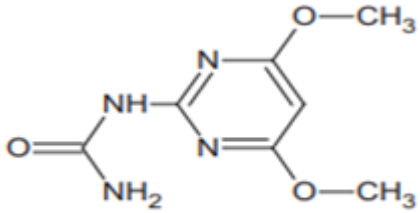
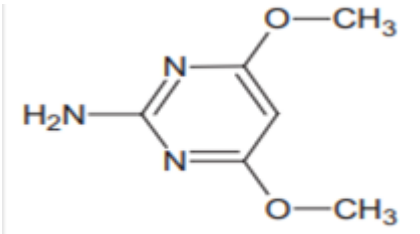
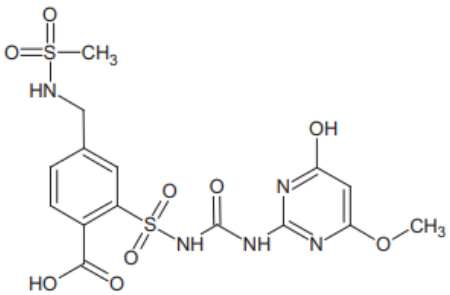
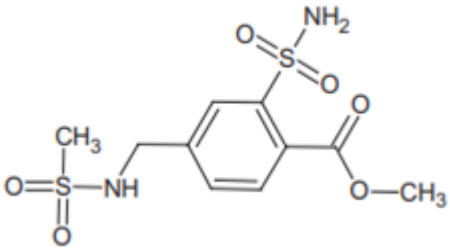
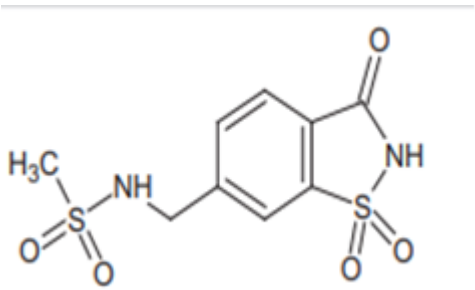
Grouping according to environmental risk assessment			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
1	Winter Cereals	BBCH, application rate, number of application	BBCH, application rate, number of application
2	Spring cereals	BBCH, application rate, number of application	BBCH, application rate, number of application

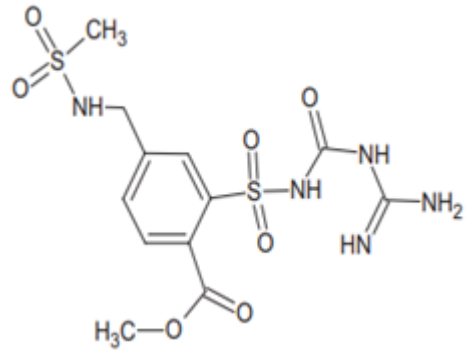
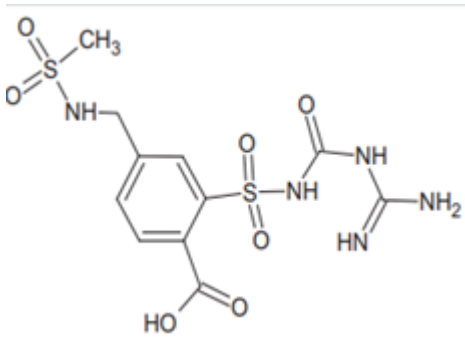
9.1.3 Consideration of metabolites

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 CHR/H/MEZO 30 OD is indicated in the table.

Table 9.1-3 Metabolites of Mesosulfuron-methyl

Metabolite	Chemical structure	Molar mass [g/mol]	Maximum occurrence in compartments	Risk assessment required?
Mesosulfuron		489.5	Soil:16.2% Total Water and Sediment:4.9%	Yes for aquatic organisms, non-target terrestrial plants, soil microbial activity, earthworms and other non-target
AE F160459		489.5	Soil: 8.9% Total Water/Sediment: 21.6%	Yes for aquatic organisms, non-target terrestrial plants, soil microbial activity, earthworms and other non-target

Metabolite	Chemical structure	Molar mass [g/mol]	Maximum occurrence in compartments	Risk assessment required?
AE F099095		198.2	Soil: 29.2% Total Water and Sediment:0.9%	Yes for aquatic organisms, non-target terrestrial plants, soil microbial activity, earthworms and other non-target soil organisms
AE F092944		155.2	Soil: 10.1% Total Water and Sediment:3.2%	Yes for aquatic organisms, non-target terrestrial plants, soil microbial activity, earthworms and other non-target soil organisms
AE F160460		475.5	Soil: 8.6% Total Water and Sediment:8.4%	Yes for aquatic organisms, non-target terrestrial plants, earthworms and other non-target soil organisms
AE F140584		322.4	Soil:7.1 % Total Water and Sediment:1.9 %	Yes for aquatic organisms, non-target terrestrial plants, earthworms and other non-target soil organisms
AE F147447		290.3	Soil:0.001% Total Water and Sediment:10.9%	Yes for aquatic organisms, non-target terrestrial plants, soil microbial activity, earthworms and other non-target soil organisms

Metabolite	Chemical structure	Molar mass [g/mol]	Maximum occurrence in compartments	Risk assessment required?
BCS-CO60720		407.4	Soil:0.001% Total Water and Sediment1%	Yes for aquatic organisms
BCS-CV14885		393.4	Soil:5% Total Water and Sediment:22%	Yes for non-target terrestrial plants

9.2 Effects on birds (KCP 10.1.1)

Available data

According to RAR Mesosulfuron-methyl 2016 data with the following studies: C000232, (1998); A67403, (1998); C009084, (2000); C005103 (1999) were not claimed a protection They can be used in this documentation

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on birds of CHR/H/MEZO 30 OD were not evaluated as part of the EU assessment of Mesosulfuron-methyl.

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

Species	Substance	Exposure System	Results	Reference
bobwhite quail	Mesosulfuron-methyl	Acute	LD_{50} >2000 mg/kg bw/d	EFSA Journal 2016;14(10):4584
mallard duck	Mesosulfuron-methyl	Acute	LD_{50} >2000 mg/kg bw/d	EFSA Journal 2016;14(10):4584

Species	Substance	Exposure System	Results	Reference
mallard duck	Mesosulfuron-methyl	Long-term	LD_{50} /10 >200 mg/kg bw/d (estimating endpoint for accute study divide by 10 (assesment factor))	n/a
~~mallard duck~~	~~Metabolite~~	~~Acute~~	~~LD_{50} = ( )~~	~~EFSA Journal 2016;14(10):4584~~
bobwhite quail	Mesosulfuron-methyl	Long-term	NOEL=93	EFSA Journal 2016;14(10):4584
mallard duck	Mesosulfuron-methyl	Long-term	NOEL=126	EFSA Journal 2016;14(10):4584

9.2.1.1 Justification for new endpoints

No new endpoints. All endpoints were assessment on EU level. Only estimating endpoints were checked on worst case system.

9.2.2 Risk assessment for spray application

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 1 also covers the risk for birds from all other intended uses in group 2 (see 9.1.2).

9.2.2.1 Screening step of acute and reproductive risk assessment for birds (indicator species)

The results of the acute and reproductive risk assessments on the screening step are summarised in the following tables.

Table 9.2-2: Screening step of acute and reproductive risk assessment for birds due to the use of CHR/H/MEZO 30 OD in Cereals.

Acute Dietary Risk Assessment for Birds - Mesosulfuron-methyl					
Screening step					
Intended use			cereals		
Active substance/product			Mesosulfuron-methyl		
Application rate (g/ha)			15 (g/ha)		
Acute toxicity (mg/kg bw)			2000		
TER criterion			10		
Indicator species	**Short cut value**	**Daily Dietary Dose (single)**	**MAF (90)**	**Daily Dietary Dose (Multi-ple)**	**TER**
Small omnivorous bird	158.8	2.38	1.0	2.38	839.6
Reproductive Risk Assessment for Birds- Mesosulfuron methyl					
Intended use		cereals			
Active substance/product		Mesosulfuron-methyl			
Application rate (g/ha)		15 (g/ha)			
Reproductive toxicity (mg/kg bw)		~~2000~~ 93			
TER criterion		5			
Screening step					
Indicator species	**Short cut value**	**Daily Dietary Dose (single)**	**MAF mean**	**Daily Dietary Dose (Multi-ple)**	**TER**
Small omnivorous bird	64.8	0.97	1.0	0.52	180.5

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.

9.2.2.2 Higher-tier risk assessment

Not necessary

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 CHR/H/MEZO 30 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 does not have to be considered.

Puddle scenario

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

With a K(f)oc of 64 mL/g, Mesosulfuron- methyl belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for birds from all other intended uses in groups 2 (see 9.1.2).

Effective application rate (g/ha)	=	~~476.3~~ 15			
Acute toxicity (mg/kg bw)	=	2000	quotient	=	~~0.24~~ 0.0075
Reprod. toxicity (mg/kg bw/d)	=	93	quotient	=	~~5.12~~ 0.0075

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Mesosulfuron- methyl amounts to ~~0.48~~ ranges between 1.90 at pH 4 and -2.10 at pH 10 (25°C; EFSA Journal 2016;14(10):4584) (-0.48) is below the trigger value of 3, indicating a negligible risk of secondary poisoning. In addition, the log P_{OW} values of the potentially relevant metabolites of mesosulfuron-methyl are all below the trigger of 3 (EFSA Conclusion, 2016). and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not relevant

Risk assessment for fish-eating birds via secondary poisoning

Not relevant

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

Mesosulfuron-methyl has no potential acute and chronic risk on birds because in both cases TER values are above required values (TER>10 for acute risk assessment; TER > 5 for chronic risk assessment). Intended use of CHR/H/MEZO 30 OD are safe for birds.

zRMS comments:

The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for birds resulting from acute and long-term exposure to active substance following use of CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) in compliance with proposed GAP.

A quantitative drinking water risk assessment is not triggered for the proposed use pattern of CHR/H MEZO 30 OD according to EFSA/2009/1438 criteria and therefore the risk to birds via drinking water is acceptable.

No unacceptable effects to fish-eating and earthworm-eating birds are expected following application of CHR/H MEZO 30 OD according to the proposed use pattern..

No risk mitigation measures are required.

Conclusion
According to the performed risk assessment there is no potential of risk to birds resulting from exposure to active substance following use of CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) in compliance with proposed GAP.

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 Mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of CHR/H/MEZO 30 OD were not evaluated as part of the EU assessment of Mesosulfuron-methyl

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

Species	Substance	Exposure System	Results	Reference
Rat	Mesosulfuron-methyl	Acute	LD_{50} > 5000 mg/kg bw	EFSA Journal 2016;14(10):4584
Rat	Mesosulfuron-methyl	Long-term Two-generation study	NOEL = 840 mg/kg bw/d	EFSA Journal 2016;14(10):4584
Rat	Mesosulfuron-methyl	Long-term	NOEL = 500mg/kg bw/d (estimating endpoint for accute study divide by 10 (assesment factor))	n/a
~~Rat~~	~~Metabolite~~	~~Acute~~	~~LD50 =( ) mg/kg bw~~	~~EFSA Journal 2016;14(10):4584~~

9.3.1.1 Justification for new endpoints

No new endpoints. All endpoints were assessment on EU level. Only estimating endpoints were checked on worst case system.

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 1 also covers the risk for mammals from all other intended uses in groups 2 (see 9.1.2).

9.3.2.1 Screening step of risk 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: Screening step of the acute and long-term/reproductive risk for mammals due to the use of CHR/H/MEZO 30 OD in Cereals

Acute Dietary Risk Assessment for Mammals- Mesosulfuron-methyl	
Intended use	**cereals**
Active substance	Mesosulfuron-methyl
Application rate (g/ha)	15 (g/ha)
Acute toxicity (mg/kg bw)	> 5000
TER criterion	10
Screening step:	

Indicator species	Short cut value	Daily Dietary Dose (single)	MAF (90)	Daily Dietary dose (Multiple)	TER
Small herbivo-rous mammal	118.4	1.78	1.0	1.78	> 2815.3

Reproductive Risk Assessment for Mammals- Mesosulfuron-methyl	
Intended use	**Cereals**
Active substance	Mesosulfuron-methyl
Application rate (g/ha)	15 (g/ha)
Reproductive toxicity (mg/kg bw)	500~~0~~
TER criterion	5

Screening step					
Indicator species	**Short cut value**	**Daily Dietary Dose (single)**	**MAF mean**	**Daily Dietary Dose (Multiple)**	**TER**
Small herbivorous mammal	48.3	0.72	1.0	0.38	1302.13

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.

9.3.2.2 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 64, Mesosulfuron-methyl belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for mammals from all other intended uses in groups 2 (see 9.1.2).

Effective application rate (g/ha) = ~~476.3~~ 15

Acute toxicity (mg/kg bw)	= 5000	quotient	=	~~0.09526~~ 0.003
Reprod. toxicity (mg/kg bw/d)	= 500	quotient	=	~~0.9526~~ 0.03

9.3.2.3 Effects of secondary poisoning

The log P_{ow} of Mesosulfuron-methyl amounts to ~~0.48~~ ranges between 1.90 at pH 4 and -2.10 at pH 10 (25°C; EFSA Journal 2016;14(10):4584) and thus does not exceed the trigger value of 3. A risk assessment

for effects due to secondary poisoning is not required.

9.3.2.4 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

Mesosulfuron-methyl has no potential acute and chronic risk on mammals because in both cases TER values are above required values (TER>10 for acute risk assessment; TER> 5 for chronic risk assessment).
CHR/H/MEZO 30 OD will be used on cereals so checking leaf scenario is not relevant.
Assessment of effects of secondary poisoning is not required for this situation: log Pow is below trigger value.

zRMS comments:

The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).
The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for mammals resulting from acute and long-term exposure to active substance following use of CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) in compliance with proposed GAP.

No unacceptable effects to mammals through drinking water are expected following application of CHR/H MEZO 30 OD according to the proposed use pattern.

No unacceptable effects to fish-eating and earthworm-eating birds are expected following application of CHR/H MEZO 30 OD according to the proposed use pattern..

No risk mitigation measures are required.

Conclusion
According to the performed risk assessment there is no potential of risk to mammals resulting from exposure to active substance following use of CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) in compliance with proposed GAP.

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

Not required.

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 Mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Available data

According to RAR Mesosulfuron-methyl 2016 data with the following studies: C003718, (1999); C003682, (1999); C004237 (2000); Sowig P., Weller O., Gosch H., (1999); Heusel R.; Weller O.; Gosch H., (1998); Sowig P.; Gosch H.; Weller O. (2000); Sowig P.,Gosch H., Weller O., (2000); were not claimed a protection They can be used in this documentation.

The following studies: Abedi J., Stachura B., Young B., (2001); Sousa J. V., (2003); Heusel R., (1993); Dionne, E (2000); Dorgerloh M. (2005); Dorgerloh M. (2005); Bruns E., (2011); Bruns E., (2011); Abedi J., Christ M., Young B., (2001); Young B. M.; Abedi J., (2001); Sowig P., Gosch H., (2002); Abedi J., Christ M., Young B., (2001); Young B. M.; Abedi J., (2001); Sowig P., Gosch H., (2002); Dorgerloh M. (2005); Dorgerloh M. (2005); Sowig P., Weller O., (1999); Bruns E., (2013); Bruns E., (2013); were presented in core assessment and latest supplements of registration report Part B, Section 9: Ecotoxicology of Atlantis 12 OD revised in 03/2020.We are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal. According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided.

Effects on aquatic organisms of CHR/H/MEZO 30 OD were not evaluated as part of the EU assessment of Mesosulfuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms –Mesosulfuron-methyl and relevant metabolites

Species	Substance	Exposure System	Results	Reference
FISH				
Oncorhynchus mykiss	Mesosulfuron-methyl	Acute 96 h, s	LC_{50} > 100 mg a.s./L mm $_{(nom)}$	EFSA Journal 2016;14(10):4584
Lepomis macrochirus	Mesosulfuron-methyl	Acute 96 h, s	LC_{50} > 100	EFSA Journal

Species	Substance	Exposure System	Results	Reference
			mg a.s./L mm (nom)	2016;14(10):4584
Cyprinodon variegates	Mesosulfuron-methyl	Acute 96 h, s	LC_{50} > 100 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Oncorhynchus mykiss	Mesosulfuron-methyl	Chronic 28d, ss	NOEC= 32 mg a.s./L mm (nom) (juvenie fish)	EFSA Journal 2016;14(10):4584
Pimephales promelas	Mesosulfuron-methyl	Chronic 32 d, f	ELS NOEC = 95 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Oncorhynchus mykiss	AE F092944	Acute 96 h, s	LC_{50} > 97 mg/L mm*	EFSA Journal 2016;14(10):4584
Oncorhynchus mykiss	AE F099095	Acute 96 h, s	LC_{50} > 70.7 mg/L mm*	EFSA Journal 2016;14(10):4584
AQUATIC INVERTEBRATES				
Daphnia magna	Mesosulfuron-methyl	48 h, s	EC_{50} >100 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Mysidopsis bahia	Mesosulfuron-methyl	48 h, s	EC_{50} >100 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Daphnia magna	Mesosulfuron-methyl	21 d, ss	NOEC =1.8 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Daphnia magna	AE F092944	48 h, s	EC_{50} =223 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Daphnia magna	AE F092944	48 h, s	EC_{50} > 100 mg/L mm*	EFSA Journal 2016;14(10):4584
Daphnia magna	AE F099095	48 h, s	EC_{50} > 100 mg/L nom**	EFSA Journal 2016;14(10):4584
Daphnia magna	AE F092944	21 d, ss	NOEC = 24.9 mg/L mm*	EFSA Journal 2016;14(10):4584
Crassostrea virginica	Mesosulfuron-methyl	96 h, f	EC_{50} > 100 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
ALGAE				
Pseudokirchneriella subcapitata	Mesosulfuron-methyl	72 h, s	E_rC_{50} > 0.29 mg a.s./L mm (nom) E_bC_{50} = 0.18 mg a.s./L mm (nom) NOErC = 0.018 mg a.s./L (nom)	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	Mesosulfuron-methyl	72 h, s	$E_rC_{50=}$ 3.99 mg a.s./L mm (nom) NOErC = 0.143 mg a.s./L (nom)	EFSA Journal 2016;14(10):4584
Navicula pelliculosa	Mesosulfuron-methyl	72 h, s	E_rC_{50} > 74.9	EFSA Journal

Species	Substance	Exposure System	Results	Reference
			mg a.s./L mm (nom) E_bC_{50} > 74.9 mg a.s./L mm (nom) NOErC = 74.9 mg a.s./L (nom)	2016;14(10):4584
Anabaena flos-aquae	Mesosulfuron-methyl	96h, s	E_rC_{50} = 4.1 mg a.s./L mm (nom) E_bC_{50} = 2.4 mg a.s./L mm (nom) NOErC = 1 mg a.s./L (nom)	EFSA Journal 2016;14(10):4584
Skeletonema costatum	Mesosulfuron-methyl	72h, s	E_rC_{50} >100 mg a.s./L mm (nom) E_bC_{50} = 82 mg a.s./L mm (nom) NOErC = 60 mg a.s./L (nom)	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	Mesosulfuron	72 h, s	E_rC_{50} =38 mg/ L(mm)	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	AE F160459	72 h, s	E_rC_{50} > 100 mg a.s./L mm (nom) E_bC_{50} = 92 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	AE F099095	72 h, s	E_rC_{50} > 100 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	AE F099095	72 h, s	E_rC50 = 99.1 mg/L*** E_bC50 = 41.1 mg/Lc	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	AE F092944	72 h, s	E_rC_{50} > 120 mg/L nom* E_bC_{50} > 120 mg/L nom* NOE_rC = 7.5 mg/L nom*	EFSA Journal 2016;14(10):4584
Desmodesmus sub-spicatus	AE F092944	72 h, s	E_rC_{50} > 100 mg/L**** E_bC_{50} > 100 mg/L**** NOEC = 100 mg/L nom****	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	AE F147447	72 h, s	E_rC_{50} > 100 mg a.s./L mm (nom) E_bC_{50}> 100 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584

Species	Substance	Exposure System	Results	Reference
Pseudokirchneriella subcapitata	BCS-CO60720	72 h, s	E_rC_{50} > 10 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
Pseudokirchneriella subcapitata	BCS-CO60721	72 h, s	E_rC_{50} > 10 mg a.s./L mm (nom)	EFSA Journal 2016;14(10):4584
HIGHER PLANTS				
Lemma gibba	Mesosulfuron-methyl	7d, ss	E_rC_{50} = 0.001717 mg a.s./$L_{(twa)}$ E_bC_{50}= 0.001863 mg a.s./$L_{(twa)}$ NOEC < 0.00077 mg a.s./$L_{(twa)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	Mesosulfuron	7d, s	E_rC_{50} = 0.11 mg a.s./$L_{(nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	AE F160459	7d, s	E_rC_{50} = 2.6 mg a.s./$L_{(nom)}$ E_bC_{50}= 1.7mg a.s./$L_{(nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	AE F099095	7d, s	E_rC_{50} >100 mg a.s./$L_{nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	AE F092944	7d, ss	E_rC_{50} >100 mg a.s./$L_{nom)}$ E_bC_{50} > 100 mg a.s./$L_{(nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	AE F160460	7d, ss	E_rC_{50} >100 mg a.s./$L_{nom)}$ E_bC_{50} > 100 mg a.s./$L_{(nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	AE F140584	7d, ss	E_rC_{50} >10 mg a.s./$L_{nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	AE F147447	7d, ss	E_rC_{50} >100 mg a.s./$L_{(nom)}$	EFSA Journal 2016;14(10):4584
Lemma gibba	BCS-CO60720	7d, s	E_rC_{50} >11.8 mg a.s./L (nom)	EFSA Journal 2016;14(10):4584
Lemma gibba	BCS-CO60721	7d, s	E_rC_{50} > 10 mg	EFSA Journal

Species	Substance	Exposure System	Results	Reference
			a.s./$L_{(nom)}$	2016;14(10):4584
Higher-tier studies				
Aquatic macrophytes (9 species) Elodea canadensis Potamogeton pectinatus Pontederia cordata Nymphaea odorata Cabomba caroliniana Cerat. demersum Glyceria maxima Mentha aquatica Myrio-phyll.heterophyllum	Mesosulfuron-methyl	Outdoor growth inhibi-tion, static, 8 weeks	Lowest NOAEC = 0.00057 mg a.s./L mm	EFSA Journal 2016;14(10):4584
Lemna gibba	Mesosulfuron-methyl	Growth inhibi-tion, mimick-ing exposure of outdoor study 8 weeks	7 d endpoint E_rC_{50} (frond number) 0.00161 mg a.s./L nom E_rC_{50} (frond area) **0.00129** mg a.s./L nom NOE_rC 0.00039 mg a.s./L nom 8-week endpoint NOE_rC (frond number & frond area) 0.000388 mg a.s./L nom 0.00026 mg a.s./L mm	EFSA Journal 2016;14(10):4584

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, (nom)- nominal concentration, ; (mm) mean measured concentration, (twa)- time-weighted average

* Refer to the EFSA conclusion on the peer review of the active substance flupyrsulfuron-methyl, EFSA (2014a)
** Refer to the EFSA conclusion on the peer review of the active substance orthosulfamuron, EFSA (2014b)
*** Refer to the EFSA conclusion on the peer review of the active substance bensulfuron, EFSA (2009)
**** Refer to the EFSA conclusion on the peer review of the active substance flazasulfuron, EFSA (2016c)

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CHR/H/MEZO 30 OD.

Species	Substance	Exposure System	Results*	Reference
Daphnia magna	CHR/H/MEZO 30 OD	48 h, acute	EC_{50} = 142.09 mg test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-61-20
Lemma gibba	CHR/H/MEZO 30 OD	7d	ErC_{50} = 0.109 mg test item/$L_{(nom)}$ EyC50 = 0.054 mg test item/$L_{(nom)}$ E_rC_{50} = 2.695 µg a. s./$L_{(geom\ m)}$	Brzozowska-Wojoczek K., 2023, Study code: W-62-20
Raphidocelis subcapitata formerly (*Pseudokirchneriella subcapitata)*	CHR/H/MEZO 30 OD	72 h	ErC_{50} = 1.109 mg a.s./$L_{(geom.\ m)}$ E_yC_{50} = 0.439 mg a.s./$L_{(geom.\ m)}$ E_rC_{50} = 40.55 mg test item/$L_{(nom)}$ E_yC_{50} = 15.72 mg test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-63-20
Anabaena flos-aquae UTEX B 1444	CHR/H/MEZO 30 OD	72 h	ErC_{50} = 24.97 mg test item/$L_{(nom)}$ EyC50 = 5.60 mg test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-64-20

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations
*Corrected according to studies results

9.5.1.1 Justification for new endpoints

Not required.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum 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.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for aquatic organisms from all other intended uses in group 2 (see **Table 9.5-3.**).

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 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesosulfuron-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use CHR/H/MEZO 30 OD in Winter cereals.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba.***
Endpoint (~~µg/L~~ mg/L)		LC_{50} > 100 mg a.s./L mm (nom)	NOEC= 32 mg a.s./L mm (nom) (juvenie fish)	EC_{50} >100 mg a.s./L mm (nom)	NOEC =1.8 mg a.s./L mm (nom)	E_bC_{50} = 0.18 mg a.s./L mm (nom) / E_rC_{50} = 0.29 mg a.s./L mm (nom)	ErC_{50} = 0.001717 mg a.s./$L_{(twa)}$/ E_rC_{50} = 0.00129 mg a.s./L(nom)
AF		100	10	100	10	10	10
RAC (µg/L)		1000	320	1000	180	18/29	0.1717/0.129
FOCUS Scenario	**PEC gl-max (µg/L)**						
Step 1							
	4.74	0.00474	0.015	0.00474	0.026	0.263/0.163	27.6/36.74
Step 2							
N-Europe	0.82	0.00082	0.0025625	0.00082	0.00456	0.04/0.028	4.776/6.36
Step 3							
D3/ditch	0.1001	0.0001001	0.000313	0.0001001	0.000556	0.005561/0.0035	0.582994/0.776
D4/pond	0.04573	0.00004573	0.00014	0.00004573	0.000254	0.002541/0.0016	0.266337/0.354

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba.***
Endpoint (~~µg/L~~ mg/L)		LC_{50} > 100 mg a.s./L mm (nom)	NOEC= 32 mg a.s./L mm (nom) (juvenie fish)	EC_{50} >100 mg a.s./L mm (nom)	NOEC =1.8 mg a.s./L mm (nom)	E_bC_{50} = 0.18 mg a.s./L mm (nom) / E_rC_{50} = 0.29 mg a.s./L mm (nom)	ErC_{50} = 0.001717 mg a.s./$L_{(twa)}$/ E_rC_{50} = 0.00129 mg a.s./L(nom)
AF		100	10	100	10	10	10
RAC (µg/L)		1000	320	1000	180	18/29	0.1717/0.129
D4/stream	0.07589	0.00007589	0.0002372	0.00007589	0.000422	0.004216/0.0026	0.441992/0.588
D5/pond	0.02100	0.000021	0.000066	0.000021	0.000117	0.001167/0.00072	0.122306/0.163
D5/stream	0.08323	0.0000832	0.0002601	0.0000832	0.0004624	0.004624/0.0029	0.484741/0.645
R1/pond	0.006176	0.000006176	0.0000193	~~0.0001025~~ 0.000006176	3.43111E-05	0.000343/0.00021	0.035970/0.048
R1/stream	0.1025	0.0001025	0.0003201~~3~~	~~0.0002571~~ 0.0001025	0.000569	0.005694/0.0035	0.596971/0.795
R3/stream	0.2571	0.0002571	0.0008034	~~0.0000832~~ 0.0002571	0.001428	0.014283/0.0089	**1.497379/1.993**
R4/stream	0.06192	0.00006192	0.0001935	~~0.000006176~~ 0.00006192	0.000344	0.00344/0.0021	0.360629/0.480
Step 4- 20 meters vegetative buffer zone and 5 meters no-spray buffer zone							
D3/ditch	0.03073	3.07E-05	9.603E-05	3.07E-05	0.000171	0.001707/0.001	0.178975/0.238
D4/pond	0.04571	4.57E-05	0.000143	4.57E-05	0.000254	0.002539/0.0016	0.266220/0.354

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba.***
Endpoint (~~µg/L~~ mg/L)		LC_{50} > 100 mg a.s./L mm (nom)	NOEC= 32 mg a.s./L mm (nom) (juvenie fish)	EC_{50} >100 mg a.s./L mm (nom)	NOEC =1.8 mg a.s./L mm (nom)	E_bC_{50} = 0.18 mg a.s./L mm (nom) / E_rC_{50} = 0.29 mg a.s./L mm (nom)	ErC_{50} = 0.001717 mg a.s./$L_{(twa)}$/ E_rC_{50} = 0.00129 mg a.s./L(nom)
AF		100	10	100	10	10	10
RAC (µg/L)		1000	320	1000	180	18/29	0.1717/0.129
D4/stream	0.04028	4.03E-05	0.000126	4.03E-05	0.000224	0.002238/0.0014	0.234595/0.312
D5/pond	0.02050	2.05E-05	6.406E-05	2.05E-05	0.000114	0.001139/00071	0.119394/0.159
D5/stream	0.03568	3.57E-05	0.000112	3.57E-05	0.000198	0.001982/0.0012	0.207804/0.277
R1/pond	0.002794	2.79E-06	8.731E-06	2.79E-06	0.000016	0.000155/0.000096	0.016273/0.022
R1/stream	0.02287	2.29E-05	7.147E-05	2.29E-05	0.000127	0.001271/0.00079	0.133197/0.177
R3/stream	0.06058	6.06E-05	0.000189	6.06E-05	0.000337	0.003366/0.0021	0.352825/0.470
R4/stream	0.02265	2.27E-05	7.078E-05	2.27E-05	0.000126	0.001258/0.00078	0.131916/0.176

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

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesosulfuron-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use CHR/H/MEZO 30 OD in Spring cereals

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba.***
Endpoint (~~µ~~mg/L)		LC_{50} > 100 mg a.s./L mm $_{(nom)}$	NOEC= 32 mg a.s./L mm $_{(nom)}$ (juvenie fish)	EC_{50} >100 mg a.s./L mm $_{(nom)}$	NOEC =1.8 mg a.s./L mm $_{(nom)}$	E_bC_{50} = 0.18 mg a.s./L mm $_{(nom)}$/E_rC_{50} = 0.29 mg a.s./$L_{(nom)}$	ErC_{50} = 0.001717 mg a.s./$L_{(twa)}$/E_rC_{50} = 0.00129 mg a.s./$L_{(nom)}$
AF		100	10	100	10	10	10
RAC (µg/L)		1000	320	1000	180	18/29	0.1717/0.129
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**						
Step 1							
	4.74	0.00474	0.015	0.00474	0.026	0.263/0.163	27.61/**36.74**
Step 2							
N-Europe	0.82	0.00082	0.0025625	0.00082	0.00456	0.046/0.028	4.776/6.36
Step 3							
D3/ditch	0.1008	0.000101	0.000315	0.000101	0.000560	0.005600/0.0035	0.58707/0.7814
D4/pond	0.04931	0.000049	0.000154	0.000049	0.000274	0.002739/0.0017	0.287187/0.3822

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro-longed	Algae	Higher plants
D4/stream	0.08283	0.000083	0.000259	0.000083	0.000460	0.004602/0.0029	0.482411/0.6421
D5/pond	0.01915	0.000019	0.000060	0.000019	0.000106	0.001064/0.0007	0.111532/0.1484
D5/stream	0.08138	0.000081	0.000254	0.000081	0.000452	0.004521/0.0028	0.473966/0.6309
R1/pond*	0.006176	0.000006	0.000019	0.000006	0.000034	0.000343/0.0002	0.03597/0.0479
R1/stream*	0.1025	0.000103	0.000320	0.000103	0.000569	0.005694/0.0035	0.596971/0.7946
R3/stream*	0.2571	0.000257	0.000803	0.000257	0.001428	0.014283/0.0089	**1.497379/1.9930**
R4/stream	0.1135	0.000114	0.000355	0.000114	0.000631	0.006306/0.0039	0.661037/0.8800
Step 4- 20 meters vegetative buffer zone and 5 meters no-spray buffer zone							
D3/ditch	0.03140	0.000031	0.000098	0.000031	0.000174	0.001744/0.0011	0.182877/0.2434
D4/pond	0.04928	0.000049	0.000154	0.000049	0.000274	0.002738/0.0017	0.287012/0.3820
D4/stream	0.04349	0.000043	0.000136	0.000043	0.000242	0.002416/0.0015	0.253291/0.3371
D5/pond	0.01914	0.000019	0.000060	0.000019	0.000106	0.001063/0.0007	0.111474/0.1484
D5/stream	0.03356	0.000033	0.000105	0.000033	0.000186	0.001864/0.0012	0.195457/0.2602
R1/pond	0.002794	0.000003	0.000009	0.000003	0.000016	0.000155/0.0001	0.016273/0.0217
R1/stream	0.02287	0.000023	0.000071	0.000023	0.000127	0.001271/0.0008	0.133197/0.1773
R3/stream	0.06058	0.000061	0.000189	0.000061	0.000337	0.003366/0.0021	0.352825/0.4700
R4/stream	0.02674	0.000027	0.000084	0.000027	0.000149	0.001486/0.0009	0.155737/0.2073

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

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AE F092944 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Invertebr. Prolong.**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} = 97000	EC_{50} ~~=223000~~ 100000	NOEC = 24900	ErC50 = 100000	E_rC_{50}>100 000
AF		100	100	10	10	10
RAC(µg/L)		970	~~2230~~ 1000	2490	10000	10000
FOCUS scenario	**PEC gl-max (µg/L)**					
Step 1	0.09	0.00009	~~4.44E 5~~ 0.00009	0.00004	9E-6	9E-6
Step 2 N-Europe	0.01	0.00001	~~4.48E-6~~ 0.00001	4.02E-6	1E-6	1E-6

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

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AEF099095 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} = 70700	EC_{50} = 100000	~~ErC_{50}>100 000~~ 99100	E_rC_{50}>100 000
AF		100	100	10	10
RAC(µg/L)		707	1000	~~10000~~ 9910	10000
FOCUS scenario	**PEC gl-max (µg/L)**				
Step 1	0.31	0.0004	0.0003	3.1E-5	3.1E-5
Step 2 N-Europe	0.05	0.00007	0.00005	5E-6	5E-6

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

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AEF099095 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**

Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} = 70700	EC_{50} = 100000	~~ErC_{50}>100 000~~ 99100	E_rC_{50}>100 000
AF		100	100	10	10
RAC(µg/L)		707	1000	~~10000~~ 9910	10000
FOCUS scenario	**PEC $_{gl-max}$ (µg/L)**				
Step 1	0.32	0.0005	0.00032	3.2E-5	3.2E-5
Step 2 N-Europe	0.06	0.00008	0.00006	6.1E-6	5E-6

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 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AEF160459 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss****	***Daphnia magna****	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 100000	EC_{50} > 100000	~~EC_{50}= 92 000~~ ErC50 > 100000	E_bC_{50} =1700/ E_rC_{50} = 2600
AF		100	100	10	10
RAC(µg/L)		1000	1000	~~9200~~ 10000	170/ 260
FOCUS scenario	**PEC $_{gl-max}$ (µg/L)**				
Step 1	1.47	0.0015	0.0015	~~1.6E-4~~ 1.5E-4	8.65E-3/ 0.006
Step 2 N-Europe	0.25	0.0003	0.0003	~~2.72E-5~~ 2.5E-5	1.47E-3/ 0.0001

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

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AEF160459 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss****	***Daphnia magna****	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 100000	EC_{50} > 100000	~~EC_{50}= 92 000~~	E_bC_{50} =1700/

				E_rC_{50} > 100000	E_rC_{50} = 2600
AF		100	100	10	10
RAC(µg/L)		1000	1000	~~9200~~ 10000	170/ 260
FOCUS scenario	**PEC gl-max (µg/L)**				
Step 1	1.46	0.0015	0.0015	~~1.59E-4~~ 1.5E-4	8.59E-3/ 0.006
Step 2 N-Europe	0.25	0.0003	0.0003	~~2.72E-5~~ 2.5E-5	1.47E-3/ 0.001

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AEF160460 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss****	***Daphnia magna****	***Pseudokirch-nella. Subcapi-tata****	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50} > 29	E_rC_{50} >100000
AF		100	100	10	10
RAC(µg/L)		100	100	2.9	10000
FOCUS sce-nario	**PEC gl-max (µg/L)**				
Step 1	0.80	0.008	0.008	0.276	8E-5
Step 2 N-Europe	0.13	0.0013	0.0013	0.045	1.3E-5

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

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AE F147447 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss****	***Daphnia magna****	***Raphidocelis sub-capitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50}>100 000	E_rC_{50}>100 000
AF		100	100	10	10
RAC(µg/L)		100	100	10000	10000
FOCUS sce-nario	**PEC gl-max (µg/L)**				
Step 1	0.49	0.0049	0.0049	4.9E-5	4.9E-5
Step 2 N-Europe	0.08	0.0008	0.0008	8E-6	8E-6

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

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AE F140584 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals~~, Spring cereals~~.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhyn-chus mykiss****	***Daphnia magna****	***Pseudokirch-nella. Subcap-itata****	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50} > 29	ErC_{50}>10000
AF		100	100	10	10
RAC(µg/L)		100	100	2.9	1000
FOCUS scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1	0.29	0.0029	0.0029	0.1	2.9E-4
Step 2 N-Europe	0.03	0.0003	0.0003	0.01	3E-5

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

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for AE F140584 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss****	***Daphnia magna****	***Pseudokirch-nella. Subcapi-tata****	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50} > 29	ErC_{50}>10000
AF		100	100	10	10
RAC(µg/L)		100	100	2.9	1000
FOCUS scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1	0.25	0.0025	0.0025	0.0862	2.5E-4
Step 2 N-Europe	0.04	0.0004	0.0004	0.0138	4E-5

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

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BCS-CO60720 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss****	***Daphnia magna****	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50}>10000	E_rC_{50}>11800
AF		100	100	10	10
RAC(µg/L)		100	100	1000	1180
FOCUS scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1	0.54	0.0054	0.0054	5.4E-4	4.58E-4
Step 2 N-Europe	0.09	0.0009	0.0009	9E-5	9E-5

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

*In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BCS-CO60721 for each organism group based on FOCUS Steps 1, 2 calculations for the use CHR/H/MEZO 30 OD in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss*****	***Daphnia magna*****	***Raphidocelis subcapitata* formerly *Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50}>10000	E_rC_{50}>10000
AF		100	100	10	10
RAC(µg/L)		100	100	1000	1000
FOCUS scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Step 1	4.74*	0.0474	0.0474	0.00474	0.00474
Step 2 N-Europe	0.99*	0.0099	0.0099	0.00099	0.00099

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

* worst case- PEC $_{sw}$ for active substance

**In the absence of a toxicity endpoint for the metabolite 10 times higher toxicity than the parent is assumed, in line with the EFSA Conclusion (2016)

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CHR/H/MEZO 30 OD on each organism group based on FOCUS Steps 1 calculations for the use of CHR/H/MEZO 30 OD in Winter cereals, Spring cereals.

Group	**Inverteb. acute**	**Algae**	**Algae**	**Higher plants**
Test species	***Daphnia magna***	***Raphidocelis sub-capitata formerly Pseudokirchnella. subcapitata***	***Anabaena flos-aquae UTEX B 1444***	***Lemma gibba***
Endpoint (µg/L)	EC_{50} 142090	E_yC_{50}/E_rC_{50} ~~367*~~ 15720/40550	E_yC_{50} 5600 / E_rC_{50} 24970	E_yC_{50}/ErC_{50} ~~43~~ * 54/109
AF	100	10	10	10
RAC (µg/L)	1420.9	~~36.7~~ 1572/4055	560/2497	~~4.3~~ 5.4/10.9
$PEC_{sw/sed}$ of CHR/H/MEZO 30 OD	3.0601			
FOCUS Scenario				
	0.002154	~~0.083381~~ 0.002/0.0008	0.005376/0.0012	~~0.7116512~~ 0.6/0.3

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

For the intended uses , calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Mesosulfuron-methyl as characterised by an E_rC_{50} for *Lemma gibba* of Higher plants in connection with an assessment factor of 10) in one FOCUS Steps 1-3 scenario. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

9.5.3 Overall conclusions

For the protection of aquatic organisms in both intended uses of product CHR/H/MEZO 30 OD in Austria, Hungary and Republic of Ireland, are necessary to maintain the 20 meters of vegetative buffer zone and 5 meters no-spray buffer zone. For the rest of the countries from central zone (including: Belgium, Czech Republic, Poland, Romania, Slovakia, Slovenia) these limitations are not necessary.

zRMS comments:

According to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290) growth rate is the preferred endpoint to be used in the risk assessment for algae and aquatic plants. Therefore the PEC/RAC calculations with E_rC_{50} were added.

For the risk assessment for aquatic plants the E_rC_{50} based on twa concentrations listed in the Table of Endpoint in the EFSA Conclusion (2016) was used by the Applicant. However it is inconsistent with what was applied to the risk assessment in the EFSA Conclusion. Therefore the PEC/RAC calculations with E_rC_{50} at 0.00129 mg/L for *Lemna gibba* were added in the tables 9.5-3 and 9.5-4.

Calculations of PEC/RAC ratios for the metabolites Mesosulfuron and BCS-CV14885 were omitted by the Applicant. These calculations are presented below.

PEC/RAC for Mesosulfuron in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss*****	***Daphnia magna*****	***Pseudokirchnella. subcapitata***	***Lemma gibba***
Endpoint (µg/L)		LC_{50} > 10000	EC_{50} > 10000	E_rC_{50} = 38000	E_rC_{50} = 110
AF		100	100	10	10
RAC(µg/L)		100	100	3800	11
FOCUS scenario	**PEC gl-max (µg/L)**				
Step 1	0.95	0.0095	0.0095	0.00025	0.086
Step 2 N-Europe	0.15	0.0015	0.0015	0.00004	0.014

** Since no toxicity endpoint for the metabolite is available, the toxicity endpoint for the parent divided by 10 was used in line to EFSA Journal 2016

PEC/RAC for BCS-CV14885 in Winter cereals, Spring cereals.

Group		**Fish**	**Inverteb. acute**	**Algae**	**Higher plants**
Test species		***Oncorhynchus mykiss*****	***Daphnia magna*****	***Pseudokirchnella. Subcapitata*****	***Lemma gibba****
Endpoint (µg/L)		LC_{50} > 100000	EC_{50} > 100000	E_rC_{50} = 290	E_rC_{50} = 1.29
AF		100	100	10	10
RAC(µg/L)		1000	1000	29	0.129
FOCUS scenario	**PEC gl-max (µg/L)**				

Step 1	1.05*	0.00105	0.00105	0.036	**8.14**
Step 2 N-Europe	0.18*	0.00018	0.00018	0.006	**1.40**
Step 3 winter cereals (BBCH 21-32)*					
D3 ditch	0.04284	-	-	-	0.33209
D4 pond	0.09712	-	-	-	0.75287
D4 stream	0.04057	-	-	-	0.31450
D5 pond	0.05570	-	-	-	0.43178
D5 stream	0.01958	-	-	-	0.15178
R1 pond	0.002039	-	-	-	0.01581
R1 stream	0.005320	-	-	-	0.04124
R3 stream	0.01531	-	-	-	0.11868
R4 stream	0.000363	-	-	-	0.00281
Step 3 winter cereals (BBCH 21-32)*					
D3 ditch	0.04355	-	-	-	0.33760
D4 pond	0.09355	-	-	-	0.72519
D4 stream	0.03615	-	-	-	0.28302
D5 pond	0.05379	-	-	-	0.41698
D5 stream	0.01874	-	-	-	0.14527
R1 pond	0.002039	-	-	-	0.01581
R1 stream	0.005320	-	-	-	0.04124
R3 stream	0.01531	-	-	-	0,11868
R4 stream	0.006509	-	-	-	0.05046

*PECsw values according to Part B8
** According to the EFSA Journal 2016 “In the absence of a toxicity endpoint for the metabolite the available toxicity endpoint of the parent compound was used since from the available information the toxophore appear to be lost.”

Mesosulfuro-methyl
Winter cereals
Using FOCUS Step 3 PECsw values the PEC/RAC ratios are below the trigger value of 1 for all scenarios except R3 stream.
Using FOCUS Step 4 PECsw values (with 20 m buffer zone and 5 m non-spray buffer zone) the PEC/RAC ratios are below the trigger value of 1 for all scenarios.

Spring cereals
Using FOCUS Step 3 PECsw values the PEC/RAC ratios are below the trigger value of 1 for all scenarios except R3 stream.
Using FOCUS Step 4 PECsw values (with 20 m buffer zone and 5 m non-spray buffer zone) the PEC/RAC ratios are below the trigger value of 1 for all scenarios.

Metabolites of masosulfuron-methyl
For metabolites AE F092944, AE F099095, AE F160459, AE F160460, AE F14447, AE F140584, BCS-CO60720 BCS-CO60721 and Mesosulfuron the PEC/RAC ratios are below the trigger value of 1 with FOCUS Step 1 PECsw values.

For metabolite BCS-CV14885 the PEC/RAC ratios are below the trigger value of 1 with FOCUS Step 3 PECsw values.

Formulation
For the risk assessment the results of studies with formulation were used.
For *Daphnia manga* and *Anabaena flos-aquae* the results expressed as the nominal concentration of test item can be used for the risk assessment since measured concentrations were within 80 to 120% of nominal values.
For *Pseudokirchnella. Subcapitata* and *Lamna Gibba* the results expressed as geometric mean concentrations should be used for the risk assessment, instead of the nominal, since measured concentrations were not within 80 to 120% of nominal. However, the comparison of the toxicity values for the active substance and the formulation (expressed as mg a.s./L) indicates that the risk assessment for the active substance covers the risk for the formulation.

Conclusion
According to the performed risk assessment there in no potential of risk for aquatic organisms resulting from the acute and long-term exposure to active substance and metabolites following use of CHR/H/MEZO 30 OD in compliance with proposed GAP without the risk mitigation measures except R3 stream scenario.

For R3 stream scenario 20 meters of vegetative buffer zone and 5 meters no-spray buffer zone is required. The relevance of R3 scenario should be considered at the national level.

9.6 Effects on bees (KCP 10.3.1)

Available data

The following study: Schmitzer S. (2012) was presented in core assessment and latest supplements of registration report Part B, Section 9: Ecotoxicology of Atlantis 12 OD revised in 03/2020.We are obliged to relied upon following study taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal. According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided.

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Mesosulfuron-methyl. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of formulation were not evaluated as part of the EU assessment of Mesosulfuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Mesosulfuron-methyl	Acute Oral	LD_{50} >105.6 µg/bee	EFSA Journal 2016;14(10):4584
Apis mellifera	Mesosulfuron-methyl	Acute	LD_{50} >100 µg/bee	EFSA Journal

Species	Substance	Exposure System	Results	Reference
		Contact		2016;14(10):4584
Apis mellifera	Mesosulfuron-methyl	Chronic, 10 d	LC50 > 120 mg a.s./kg food LDD50 > 4.85 µg a.s./bee/da	EFSA Journal 2016;14(10):4584
Apis mellifera	Mesosulfuron-methyl a	Bee brood development	NOEClarvae > 37.5 mg a.s./L c	EFSA Journal 2016;14(10):4584
Apis melifera	CHR/H/MEZO 30 OD	Acute Oral	LD_{50}>200.0 µg/bee	Fulczyk A,2023, B-72-20
Apis melifera	CHR/H/MEZO 30 OD	Acute Contsct	LD_{50}>200.0 µg/bee	Fulczyk A,2023, B-73-20
Apis mellifera	CHR/H/MEZO 30 OD	Chronic Oral	LDD_{50} >15.1 µg/bee/day LC_{50}> 667000 µg/kg NOEC > 667000 µg/kg NOED ≥ 15.1 µg/bee/day	Fulczyk A,2023, B-71-20
Apis mellifera	CHR/H/MEZO 30 OD	Honey bee larval toxicity test	LD_{50} >100* [µg of test item/larva] NOED ≥ 100* [µg of test item/larva] LOED>100* [µg of test item/larva]	Woźniak A, 2023 0038/0104/E
Bumblebee	CHR/H/MEZO 30 OD	Acute Oral	LD_{50} > 20 µg/bumblebee	Extrapolated from bee study and divide by factor 10 as a worst case
Bumblebee	CHR/H/MEZO 30 OD	Acute Contact	LD_{50} > 20 µg/bumblebee	Extrapolated from bee study and divide by factor 10 as a worst case

***** values determined based on the analysis of the results

9.6.1.1 Justification for new endpoints

Not required

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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for birds from all other intended uses in group 2 (see 9.1.2).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of CHR/H/MEZO 30 OD in Cereals

Intended use	Cereals		
Active substance	Mesosulfuron-methyl		
Application rate (g as/ha)	15 g as /ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>105.6 µg/bee	15 g as/ha	0.14
Contact toxicity	>100 µg/bee		0.15
Product	CHR/H/MEZO 30 OD		
Application rate (g/ha)	1x476.3 g/ha		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	>200 µg/bee	476.3 (g/ha)	2.38
Contact toxicity	>200 µg/bee		2.38

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

~~**Table 9.6-3: First-tier assessment of the chronic risk for bees due to the use of CHR/H/MEZO 30 OD in winter cereals**~~

~~Type of assessment~~	~~Step~~	~~Formula~~	~~Endpoint~~	~~Application rate AR (kg prod/ha)~~	~~Shortcut value SV~~		~~ETR calculations~~		~~Trigger value~~
					~~Downward~~	~~Sideward~~			
~~Chronic oral exposure adult bees Honeybees~~	~~Screening~~	~~ETRchronic adult oral = AR * SV/10 d LDD50~~	~~LD50>15.1 µg/bee/Day~~	~~0.4763~~	~~7.6~~	~~10.6~~	~~0.24~~	~~0.334~~	~~<0.03~~
~~Chronic oral exposure adult bees Honeybees~~	~~1st tier~~	~~ETRchronic adult oral = AR * Ef * SV * twa/10 d LDD50~~	~~LDD50>15.1 µg/bee/Day~~	~~0.4763~~	~~7.6~~	~~10.6~~	~~0.0016~~	~~0.002~~	~~<0.03~~
~~Repeated larval Exposure~~	~~Screening~~	~~ETRlarvae = AR * SV/NOEDlarvae~~	~~NOED= 100 µg of test item/larva~~	~~0.4763~~	~~4.4~~	~~6.1~~	~~0.02~~	~~0.03~~	~~<0.2~~

~~*Ef- exposure factor. According to the EFSA GD 2013, for field crops Ef= 0.0092 and twa =0.72. The twa value of 0.72 is based on a default DT50 of 10 days and a 10-day time window.~~
~~The protection goal is met if the calculated value is smaller or equal to the trigger. If the calculated value is greater than the trigger value then proceed with the 1st tier risk assessement~~

Screening step and first-tier assessment of the chronic risk for bees and assessment for honey bees larvae due to the use of CHR/H/MEZO 30 OD

This assessment was done by Bee Tool v.3.

a) Screening step

Table 9.6-3: Screening step assessment of the chronic risk for bees and assessment for honey bees larvae due to the use of CHR/H/MEZO 30 OD in all intended uses.

Intended uses	Cereals			
Product	CHR/H/MEZO 30 OD			
Application rate (g product/ha)	1 × 476.3 g/ha			
Test design	**Endpoints (µg/bee/d or µg/larva)**	**Ef x SV**	**ETR**	**Trigger**
Chronic oral toxicity	LDD50 > 15.1 µg/bee/day	7.6	**0.24**	0.03
Larvae toxicity	NOED ≥ 100 µg ai/larva	4.4	0.02	0.2
Intended use	Downward spray			
Active substance	Mesosulfuron-methyl			
Application rate (g a.s./ha)	1 × 15 g as /ha			
Test design	**Endpoint (lab.)**	**Single application rate**	**Shortcut value (downward spray)**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	> 4.85 µg a.s./bee/day	0.0144 kg a.s./ha	7.6	< 0.023	0.03

The calculated ETR values of honey bees larvae is lower than the trigger values of 0.2, therefore Tier 1 assessment is not required.

The calculated ETR values of chronic oral toxicity for adult bees is higher than the trigger values of 0.03,therefore Tier 1 assessment is required and provided below

b) First Tier assessment

Table 9.6-4: First Tier assessment of the chronic oral risk for bees due to the use of CHR/H/MEZO 30 OD in cereals.

Intended use	Cereals					
Product	CHR/H/MEZO 30 OD					
Application rate (g product/ha)	1 × 476.3					
Test design	**Scenario/BBCH**	**Shortcut Value (downward spray)**	**TWA**	**fDep/ Ef**	**ETR**	**Trigger**
Chronic oral toxicity LDD_{50} > 15.1 µg/bee/day	treated crop/BBCH 10-29	0.92	0.72	1	0.021	<0.03
	treated crop/BBCH 30-39	0.92		1	0.021	

	weeds/10-29	2.9		1	**0.066**	
	weeds/30-39	2.9		0.5	**0.033**	
	field margin/10-29	2.9		0.0092	0.001	
	field margin/30-39	2.9		0.0092	0.001	
	adjacent crop/10-29	5.8		0.0033	0.000	
	adjacent crop/30-39	5.8		0.0033	0.000	
	next crop/10-29	0.54		1	0.012	
	next crop/30-39	0.54		1	0.012	

The calculated ETR value of chronic oral toxicity for adult bees for treated crop, field margin, adjacent crop, next crops scenario are lower than the trigger value of 0.03, so it pose acceptable risk to bees following application of CHR/H/MEZO 30 OD at the proposed label rate.

The calculated ETR value of chronic oral toxicity for adult bees for weeds scenario are higher than the trigger values of 0.03, so it pose unacceptable risk to bees following application of CHR/H/MEZO 30 OD at the proposed label rate.

Table 9.6-5: Uses not passing the 1st oral tier risk assessment of CHR/H/MEZO 30 OD.

Crop group	Scenario/BBCH	Max. single application rate [kg prod/ha]	ETR values	Trigger value
Cereals	weeds/10-29	476.3	**0.066**	<0.03
Cereals	weeds/30-39	476.3	**0.033**	

* value in bold give the ratio the ETR is above the EFSA trigger value

c) Risk refinements

Considering that MEZO 30 OD is intended to be used tillering phase to the second branch phase is acceptable chronic risk to bees, because MEZO 30 OD has herbicidal properties and it eliminate weeds before flowering period.

According to Guidance Document on risk assessment on bees –(EFSA Journal 2013;11(7):3295):

- To improve the chronic risk assessment for weed-foraging bees, all weeds should be removed from a crop field before use of MEZO 30 OD.

9.6.3 Effects on solitary bees

Not available.

9.6.4 Overall conclusions

CHR/H/MEZO 30 OD no pose any unacceptable risk for bees according to label.

zRMS Comments:

The submitted risk assessment is based on the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) and new EU guidance (2013).

The EU agreed endpoints for active substance were used in risk assessment.
In addition to that, the Applicant submitted studies on chronic toxicity of formulation MEZO 100 SC to adult bees and larvae. New studies were accepted. Therefore, the requirements set out in Regulation 284/2013 are considered fulfilled.

The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted.

There is currently no EU agreed chronic risk assessment scheme for bees. However, as agreed in the Central Zone a risk assessment based on the EFSA bee GD is presented below for illustrative purposes.

The ETR value is less than the Tier 1 trigger value for downward sprays indicating that the chronic risk to honeybee larvae is acceptable following use of CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) according to the proposed use pattern.
An exception is the weeds scenario, where the ETR value is slightly higher than the trigger. The refined risk assessment is thus left to the national level of the concerned Member States.

However, considering the available data on chronic toxicity (adult) with the active substance mesosulfuron -methyl and that NOEDD value is higher than or equal 15.1 µg/bee/day an acceptable chronic risk to adult honeybees might be concluded (even on the screening step).

Effects on bumblebees and solitary bees.
No data with the active substances or the formulated product is available.

An acceptable risk to bees of the formulation CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) can be concluded, based on the risk assessment scheme of the Guidance Document on Terrestrial Eco-toxicology (SANCO/10329/2002 rev 2).

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

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

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	CHR/H/MEZO 30 OD	Extended laboratory test	ER_{50} >0.5 L/ha, which is equivalent to 476.3 g/ha	Fulczyk A, 2023, B-69-20
Aphidius rhopalosiphi (imago)	CHR/H/MEZO 30 OD	Extended laboratory test	ER_{50} >0.5 L/ha, which is equivalent to 476.3 g/ha	Fulczyk A, 2023 B 70-20
Coccinella septempunctata	CHR/H/MEZO 30 OD	Extended laboratory test	ER_{50}< 0.125 L/ha, which is equivalent to 119.075 g/ha LR_{50} >0.5 L/ha, which is equivalent to 476.3 g/ha	Fulczyk A, 2023, B-45-21
Chrysoperla carnea	CHR/H/MEZO 30 OD	Extended laboratory test	ER_{50} >0.5 L/ha, which is equivalent to 476.3 g/ha	Fulczyk A, 2023 B 46-21

9.7.1.1 Justification for new endpoints

Not required.

9.7.2 Risk assessment

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

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for non-target arthropods from all other intended uses in groups 2 (see 9.1.2).

Table 9.7-2: Higher-tier assessment of the in-field risk for non-target arthropods due to the use of CHR/H/MEZO 30 OD in Cereals

Intended use	Cereals
Active substance/product	CHR/H/MEZO 30 OD
Application rate (g/ha)	1 x 476.3 g/ha
MAF	1

Test species **Higher tier**	**ER_{50} (lab.)** **(g/ha) or LR_{50}**	**$PER_{in\text{-}field}$** **(g/ha)**	**$HQ_{in\text{-}field}$** **criterion: HQ ≤ 1**
Typhlodromus pyri (protonymphs)	>476.3	476.3	1
Aphidius rhopalosiphi (imago)	>476.3	476.3	1
Coccinella septempunctata	<119.075 >476.3	476.3	**4** **1**
Chrysoperla carnea	>476.3	476.3	1

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

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

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 1 also covers the risk for non-target arthropods from all other intended uses in group 2(see 9.1.2).

Table 9.7-3: Higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/H/MEZO 30 OD in Cereals

Intended use	cereals
Active substance/product	CHR/H/MEZO 30 OD
Application rate (g/ha)	1x476.3 g/ha
MAF	1
vdf	1 (higher tier)

Test species **Higher tier**	**ER_{50} (lab.)** **(g/ha) or LR_{50}**	**Drift rate**	**$PER_{off\text{-}field}$** **(g/ha)**	**CF**	**$HQ_{off\text{-}field}$** **criterion: HQ ≤ 1**
Coccinella septempunctata	<119.075 >476.3	0.0277	13.19	5	0.55 0.14
Chrysoperla carnea	>476.3		13.19		0.14
Typhlodromus pyri	~~<119.075~~ >476.3		13.19		0.14
Aphidius rhopalosiphi	>476.3		13.19		0.14

MAF: Multiple application factor; vdf: Vegetation distribution factor; PER: 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.

9.7.2.3 Additional higher-tier risk assessment

The in-field HQ values for exposure to maximum residues on leaves for *Coccinella septempunctata* L. falls above the trigger value, and, therefore triggers further assessment. Such assessment was made for CHR/H/MEZO 30 OD with aged residues study.

Results proves that after 14 days after treatment is possible to regrowth the arthropods colony.

Detailed results are presented below:

The results of the mortality assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	% pre-imaginal mortality [a)]	Corrected % pre-imaginal mortality [b)]
0 DAT	Control	-	5.0	-
	CHR/H/MEZO 30 OD	0.5	7.5	2.6
	Toxic reference	-	92.5*	92.1
14 DAT	Control	-	10.0	-
	CHR/H/MEZO 30 OD	0.5	5.0	-5.6

a) For each bioassay, pre-imaginal mortality in the test item treatment, and the toxic reference treatment in the 0 DAT bioassay, was compared to the respective control using Fisher's exact binomial test (one sided, > control, $\alpha = 0.05$). An asterisk (*) indicates where differences were significant.

b) Corrected mortalities were calculated using Abbott's formula. A positive value indicates an increase in mortality, a negative value indicates a decrease in mortality, relative to the respective control.

The results of the reproduction assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Mean no. eggs/♀/ day	Mean % egg viability	Mean no. viable eggs/♀/ day
0 DAT	Control	-	11.8	34.1	4.0
	CHR/H/MEZO 30 OD	0.5	9.6	36.6	3.5
14 DAT	Control	-	20.5	46.0	9.5
	CHR/H/MEZO 30 OD	0.5	22.8	50.1	11.4

In the 0 and 14 DAT bioassays, the mean numbers of viable eggs produced in all the treatments evaluated was ≥ 2.0 eggs/female/day. This threshold is currently viewed as being indicative of no harmful treatment effects.

Conclusions

The effect of both fresh and aged foliar residues of CHR/H/MEZO 30 OD on ladybird beetle *Coccinella septempunctata* were evaluated under extended laboratory conditions. When applied at rate equivalent to 0.5L test item/ha, freshly-dried (0-days- old) residues and 14-old field-aged residues of CHR/H/MEZO 30 OD showed no unacceptable effects on either the survival, or subsequent reproductive capacity, of the ladybirds.

9.7.2.4 Risk mitigation measures

No risk mitigation is needed.

9.7.3 Overall conclusions

The in-field HQ values for exposure to maximum residues on leaves for *Coccinella septempunctata* L. falls above the trigger value, and, therefore triggers further assessment. Such assessment was made for CHR/H/MEZO 30 OD with aged residues study.
CHR/H/MEZO 30 DO applied at the maximum use rates poses no risk to non-target arthropods.

No risk mitigation are needed.

zRMS Comments:
The submitted risk assessment based on the "Guidance Document on Terrestrial Ecotoxicology" (2002) was accepted.

Based on calculations performed with consideration of the Tier I and Tier II data acceptable in-field risk to non-target arthropods from CHR/H MEZO 30 OD for all intended uses of may be concluded with the exception of Coccinella septempunctata L. falls above the trigger value.
However, considering in the higher tier the LR50 value instead of the ER50 (10% of mortality at 0.125 l/ha) value for Coccinella septempunctata from the extended laboratory test, an acceptable risk can be concluded in the field. This is also supported by the results of studies on the effects of both fresh and aged foliar residues of CHR/H/MEZO 30 OD on the ladybird beetle Coccinella septempunctata, presented by the applicant, showing no unacceptable effects on the survival or subsequent reproductive capacity of ladybirds.

Acceptable risk may be concluded for in-field and off-field populations of non-target arthropods from the intended uses of CHR/H MEZO 30 OD.

Conclusion
The risk to arthropods other than bees is acceptable if the CHR/H MEZO 30 OD (Vidal 30 OD, Pacyfik 30 OD) is applied in accordance with proposed use pattern.

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

Available data
The following studies: Moser T., Scheffczyk, A. (2010); Moser, T.; Scheffczyk, A. (2012); Kratz, M. A. (2013), Kratz, M. A., (2013); Kratz M. A., (2013); Moser, T.; Scheffczyk A., (2012); Moser, T.; Scheffczyk A., (2012); Frommholz U., (2012); Friedrich S., (2013); Friedrich S., (2013); Friedrich S., (2013); Friedrich S., (2013); Kratz M.A, (2012) Schulz L., (2013); were presented in core assessment and latest supplements of registration report Part B, Section 9: Ecotoxicology of Atlantis 12 OD revised in 03/2020.We are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months if study was necessary for the renewal or review of an authorisation. Product Atlantis 12 OD was renewed in 24.08.2020 under MRiRW decision R – 555/2020d and data presented was necessary for authorisation renewal. According to Official Journal of the European Union C 229/2 Period of protection is 30 months from date of first renewal of authorisation of product containing that active substance in each Member State where the data is necessary for the renewal of authorisation, therefore no new study was provided.

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 Mesosulfuron-methyl and its 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 CHR/H/MEZO 30 OD were not evaluated as part of the EU assessment of Mesosulfuron-methyl . New data submitted with

this application are listed in Appendix 1 and summarised in Appendix 2.

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
EARTHWORMS				
Eisenia fetida	Mesosulfuron-methyl	Growth, reproduction, behaviour Chronic 56 d	NOEC = 125 mg a.s./kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia fetida	AE F160459	Growth, reproduction, behaviour Chronic 56 d	NOEC = 90 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia fetida	AE F099095	Growth, reproduction, behaviour Chronic 56 d	NOEC= 100 mg/kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia fetida	AE F092944	Growth, reproduction, behaviour Chronic 56 d	NOEC = 10 mg/kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia fetida	AE F160460	Growth, reproduction, behaviour Chronic 56 d	NOEC= 100 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia fetida	AE F140584	Growth, reproduction, behaviour Chronic 56 d	NOEC= 117 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia fetida	AE F147447	Growth, reproduction, behaviour Chronic 56 d	NOEC= 90 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Eisenia andrei	CHR/H/MEZO 30 OD	Reproduction test	NOEC >1000.0 mg/kg dw NOECcorr >500 mg/kg dw*	Wróbel A.,2023,G-45-20
OTHER SOIL MACROORGANISMS				
Folsomia candida	Mesosulfuron-methyl	Mortality, Reproduction Chronic, 28 d	NOEC =1000 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Folsomia candida	Mesosulfuron	Mortality, Reproduction Chronic, 28 d	NOEC =100 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Folsomia candida	AE F160459	Mortality, Reproduction	NOEC = 100 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584

Species	Substance	Exposure System	Results	Reference
		Chronic, 28 d		
Folsomia candida	AE F092944	Mortality, Reproduction Chronic, 28 d	NOEC = ~~100~~ 50** mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Folsomia candida	AE F147447	Mortality, Reproduction Chronic, 28 d	NOEC = 100 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Folsomia candida	CHR/H/MEZO 30 OD	Reproduction test	NOEC = 560 mg/kg dw $NOEC_{corr}$ = 280 mg/kg dw*	Pieczka P., 2023, G-46-20
Hypoaspis (Geolaelaps) aculeifer)	Mesosulfuron-methyl	Mortality, Reproduction Chronic, 14 d	NOEC = 1000 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Hypoaspis (Geolaelaps) aculeifer)	AE F092944	Mortality, Reproduction Chronic, 14 d	NOEC = 100 mg /kg d.w.soil	EFSA Journal 2016;14(10):4584
Hypoaspis (Geolaelaps) aculeifer)	CHR/H/MEZO 30 OD	Reproduction test	NOEC >1000.0 mg/kg dw $NOEC_{corr}$ > 500 mg/kg dw*	Wróbel A.,2023,G-47-20

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.
**Refer to the EFSA conclusion on the peer review of the active substance flupyrsulfuron-methyl, EFSA (2014a)

9.8.1.1 Justification for new endpoints

Not required.

9.8.2 Risk assessment

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

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Mesosulfuron-methyl.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 1 also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in group 2 (see Table 9.8-2.).

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 CHR/H/MEZO 30 OD in Cereals

Intended use	Cereals		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Mesosulfuron-methyl	Not required		
CHR/H/MEZO 30 OD	Not required		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Mesosulfuron-methyl	~~10~~ 125*	~~0.0199~~ 0.0168**	~~502.25~~ 7440
AE F160459	90	~~0.0010~~ 0.0014**	~~90000~~ 64286
AE F099095	100	~~0.0199 (worst case PEC$_{soil}$ for active substance)~~ 0.0021**	~~5025,13~~ 47619
AE F092944	10	~~0.0007~~ 0.0005**	~~14285.71~~ 20000
AE F160460	100	~~0.0034~~ 0.0013**	~~29411.76~~ 76923
AE F140584	117	~~0.0002~~ 0.0007**	~~585000~~ ~~167143~~
AE F147447	90	~~0.0028~~ 0.0006**	~~32142.86~~ 150000
Mesosulfuron	12.5*	0.0028**	4464
CHR/H/MEZO 30 OD	500	0.508	984.25
Chronic effects on other soil macro- and mesofauna **Test species: *Folsomia candida***			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Mesosulfuron-methyl	1000	~~0.0199~~ 0.0168**	~~50251,26~~ 59524
Mesosulfuron	100	~~0.0029~~ 0.0028**	~~34482.76~~ 35714
AE F160459	100	~~0.0010~~ 0.0014**	~~100000~~ 71429
AE F092944	~~100~~ 50***	~~0.0007~~ 0.0005**	~~142857.14~~ 100000
AE F147447	100	~~0.0028~~ 0.0006**	~~35714.29~~ 166667
AE F099095	100*	0.0021**	47619

AE F160460	100*	0.0013**	76923
AE F140584	100*	0.0007**	142857
CHR/H/MEZO 30 OD	280	0.508	511.18
Chronic effects on other soil macro- and mesofauna Test species: *Hypoaspis* (Geolaelaps) *aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Mesosulfuron-methyl	1000	~~0.0199~~ 0.0168**	~~50251,26~~ 59524
AE F092944	100	~~0.0007~~ 0.0005**	~~142857.14~~ 200000
Mesosulfuron	100*	0.0028**	35714
AE F160459	100*	0.0014**	71429
AE F99095	100*	0.0021**	47619
AE F160460	100*	0.0013**	76923
AE F140584	100*	0.0007**	142857
AE F147447	100*	0.0006**	166667
CHR/H/MEZO 30 OD Test species: *Hypoaspis* (Geolaelaps) *aculeifer*	500	0.508	984.25

TER values shown in bold fall below the relevant trigger.
*According to the EFSA Journal 2016;14(10):4585: assuming it is 10 times more toxic than the parent
**According to Part B8
*** According to the EFSA Journal 2016;14(10):4585

9.8.2.2 Higher-tier risk assessment

Not relevant.0.000000

9.8.3 Overall conclusions

In all evaluated substances (Mesosulfuron- methyl and his metabolites, CHR/H/MEZO 30 OD) TER values were above required criterion (TER ≥ 5) so risk assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) is acceptable. Intended use of tested product are safe for these organisms.

zRMS comments:

The worst-case predicted environmental concentrations in soil for the use in cereals were used in the risk assessment.

For the active substance and its metabolite the EU agreed endpoints were used. Because toxicity end-points are not available for some metabolites, the parent substance toxicity endpoint divided by 10 was used, which is consistent with risk assessment presented in EFSA Journal 2016;14(10):4585.

All TER_{LT} values for active substance, metabolites and formulation are above trigger value of 5.

The formulation contains a safener mefenpyr-diethyl. The applicant did not provide any information on the chronic toxicity of mefenpyr diethyl to soil organisms. However, mefenpyr-diethyl as a safener is not considered an active substance and has not been subject to review at EU level for inclusion in Annex I to Directive 91/414/EEC or Regulation (EC) No 1107/2009.

Conclusion:
According to the performed risk assessment there is low chronic risk to earthworms and other non-target soil organisms resulting from long-term exposure to active substances and its metabolites following use of CHR/H/MEZO 30 OD in compliance with proposed GAP.

9.9 Effects on soil microbial activity (KCP 10.5)

Available data
According to RAR Mesosulfuron-methyl 2016 data with the following studies: Heusel R., (1998); Schaefer E. C., Siddiqui A. I., (2002); Heusel R., (1998); Schaefer E. C., Siddiqui A. I., (2002); were not claimed a protection They can be used in this documentation.

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on soil microorganisms of CHR/H/MEZO 30 OD were not evaluated as part of the EU assessment Mesosulfuron-methyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Conclusion of the study Wróbel A, 2023, B-48-20
On the basis of the results, it was concluded that CHR/H/MEZO 30 OD at the concentrations corresponding to the PEC: 0.63 mg test item/kg dry weight of soil (i.e. 0.02 mg of mesosulfuron-methyl + 0.06 mg of mefenpyr-diethyl) and 5 x PEC: 3.15 mg test item/kg dry weight of soil (i.e. 0.10 mg of mesosulfuron-methyl + 0.30 mg of mefenpyr-diethyl) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
Mesosulfuron-methyl				
N-mineralisation	Mesosulfuron-methyl	28 d, aerobic soil type	**< 25% effect at day 28 at 0.1 mg a.s./kg dw**	EFSA Conclusion 4584/2016
N-mineralisation	Mesosulfuron	28 d, aerobic soil type	**< 25% effect at day 28 at 0.1 mg/kg dw**	EFSA Conclusion 4584/2016
N-mineralisation	AE F160459	28 d, aerobic soil type	**< 25% effect at day 42 at 0.1 mg/kg dw**	EFSA Conclusion 4584/2016
N-mineralisation	AE F099095	28 d, aerobic soil type	**< 25% effect at day 28 at 0.1 mg/kg dw**	EFSA Conclusion 4584/2016
N-mineralisation	AE F092944*	28 d, aerobic	< 25% effect at day 28	EFSA Conclusion

Endpoint	Substance	Exposure System	Results	Reference
		soil type	at 0.06 mg/kg dw[a]	4584/2016
N-mineralisation	AE F092944	28 d, aerobic soil type	**< 25% effect at day 28 at 0.137 mg/kg dw**	EFSA Conclusion 4584/2016
N-mineralisation	AE F147447	28 d, aerobic soil type	**< 25% effect at day 28 at 0.057 mg/kg dw**	EFSA Conclusion 4584/2016

* Refer to the EFSA conclusion on the peer review of the active substance flazasulfuron (EFSA, 2016c)

9.9.1.1 Justification for new endpoints

Not required

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 1 also covers the risk for the soil microorganisms from all other intended uses in group 2(see **Table 9.9-1.**).

Table 9.9-1: Assessment of the risk for effects on soil micro-organisms due to the use of CHR/H/MEZO 30 OD in Cereals

Intended use	Cereals		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Mesosulfuron-methyl	0.1 mg a.s/kg d.w. soil (at 28 day)	~~0.0199~~ 0.0168*	yes
Mesosulfuron	0.1 mg/kg d.w.soil (at 28 day)	~~0.0029~~ 0.0028*	yes
AE F160459	0.1 mg/kg d.w.soil (at 42 day)	~~0.0010~~ 0.0014*	yes
AE F099095	0.1 mg/kg d.w.soil (at 28 day)	~~0.0199 (worst case PEC soil for active substance)~~ 0.0021*	yes
AE F092944	~~0.1 mg/kg d.w.soil (at 28 day)~~ < 25% effect at day 28 at 0.137 mg/kg dw	~~0.0007~~ 0.0005*	yes

AE F147447	~~0.137 mg/kg d.w.soil (at 28 day)~~ < 25% effect at day 28 at 0.057 mg/kg dw	~~0.0028~~ 0.0006*	yes
AE F160460	< 25% effect at day 28 at 0.01 mg a.s./kg dw**	0.0013	yes
AE F140584	< 25% effect at day 28 at 0.01 mg a.s./kg dw**	0.0007	
CHR/H/MEZO 30 OD	0.63 mg test item/kg dry weight of soil (i.e. 0.02 mg of mesosulfuron-methyl + 0.06 mg of mefenpyr-diethyl) and 5 x PEC: 3.15 mg test item/kg dry weight of soil (i.e. 0.10 mg of mesosulfu-ron-methyl + 0.30 mg of mefenpyr-diethyl)	0.508	yes
*Corrected according to Part B8 ** Since no toxicity endpoint for the metabolite is available, the toxicity endpoint for the parent divided by 10 was used			

9.9.3 Overall conclusions

Risk assessments for effect on soil micro-organisms due to the use of CHR/H/MEZO 30 OD in Cereals is acceptable for active substance, almost all metabolites and product, because PEC soil values are below max concentration with effects. ~~For metabolite AE F099095 there is no available PEC soil value~~.

zRMS comments:

The worst-case predicted environmental concentrations in soil for the use in cereals were used in the risk assessment.

For the active substance and its metabolite the EU agreed endpoints were used. Because toxicity endpoints are not available for some metabolites, the parent substance toxicity endpoint divided by 10 was used, which is consistent with risk assessment presented in EFSA Journal 2016;14(10):4585.

Conclusion:
Since no effects (> 25%) were seen at application rates far higher than the values of PECsoil for active substance, metabolites and formulation it can be concluded that application of CHR/H/MEZO 30 OD, according to the GAP, will not cause any detrimental effect to soil microorganisms.

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

9.10.1 Toxicity data

Effects on non-target terrestrial plants of CHR/H/MEZO 30 OD were not evaluated as part of the EU assessment Mesosulfuron-methyl. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

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

Species	Substance	Exposure System	Results (mL test item/ha)	Reference
Pea *Pisum sativum*	CHR/H/MEZO 30 OD	Vegetative vigour	ER_{50} (Plant number at the end of the experiment)> 500.00 ER_{50} (Shoot length)= 131.12 ER_{50} (Plant dry weight)= 259.33 ER_{50} (Plant damage)= 47.63	Gierbuszewska A.,2023, G-49-20
Pea *Pisum sativum*	CHR/H/MEZO 30 OD	Seedling Emergence and Seedling Growth Test	ER_{50} (Plant number at the end of the experiment)> 500.00 ER_{50} (Shoot length)> 500.00 ER_{50} (Plant dry weight) > 500.0 ER_{50} (Plant damage) > 500.0	Gierbuszewska A.,2023, G-50-20
Flax *Linum usitatissimum*	CHR/H/MEZO 30 OD	Vegetative vigour	ER_{50} (Plant number at the end of the experiment)> 500.00 ER_{50} (Shoot length)>500.00 ER_{50} (Plant dry weight)>500.00 ER_{50} (Plant damage)>500.00	Gierbuszewska A.,2023, G-49-20
Flax *Linum usitatissimum*	CHR/H/MEZO 30 OD	Seedling Emergence and Seedling Growth Test	ER_{50} (Plant number at the end of the experiment)> 500.00 ER_{50} (Shoot length) > 500.00 ER_{50} (Plant dry weight)>500.00 ER_{50} (Plant damage)>500.00	Gierbuszewska A.,2023, G-50-20

Species	Substance	Exposure System	Results (mL test item/ha)	Reference
Cabbage *Brassica oleracea var. capitata*	CHR/H/MEZO 30 OD	Vegetative vigour	ER_{50} (Plant number at the end of the experiment)> 500.00 ER_{50} (Shoot length)=389.00 ER_{50} (Plant dry weight)=72.32 ER_{50} (Plant damage)=68.17	Gierbuszewska A.,2023, G-49-20
Cabbage *Brassica oleracea var. capitata*	CHR/H/MEZO 30 OD	Seedling Emergence and Seedling Growth Test	ER_{50} (Plant number at the end of the experiment)> 500.00 ER_{50} (Shoot length) > 500.0 ER_{50} (Plant dry weight)= 461.31 ER_{50} (Plant damage)>500	Gierbuszewska A.,2023, G-50-20
Carrot *Daucus carota*	CHR/H/MEZO 30 OD	Vegetative vigour	ER_{50} (Plant number at the end of the experiment)> 500.0 ER_{50} (Shoot length)=284.89 ER_{50} (Plant dry weight)=217.43 ER_{50} (Plant damage)=169.99	Gierbuszewska A.,2023, G-49-20
Carrot *Daucus carota*	CHR/H/MEZO 30 OD	Seedling Emergence and Seedling Growth Test	ER_{50} (Plant number at the end of the experiment)> 500.0 ER_{50} (Shoot length) > 500.0 ER_{50} (Plant dry weight)= 293.84 ER_{50} (Plant damage) > 500.0	Gierbuszewska A.,2023, G-50-20
Onion *Allium cepa*	CHR/H/MEZO 30 OD	Vegetative vigour	ER_{50} (Plant number at the end of the experiment)> 500.0	Gierbuszewska A.,2023, G-49-20

Species	Substance	Exposure System	Results (mL test item/ha)	Reference
			ER_{50} (Shoot length)=175.09 ER_{50} (Plant dry weight)=630.18 ER_{50} (Plant damage)=195.01	
Onion *Allium cepa*	CHR/H/MEZO 30 OD	Seedling Emergence and Seedling Growth Tes	ER_{50} (Plant number at the end of the experiment) > 500.0 ER_{50} (Shoot length) >500.0 ER_{50} (Plant dry weight) > 500.0 ER_{50} (Plant damage) >500.0	Gierbuszewska A.,2023, G-50-20
Corn *Zea mays*	CHR/H/MEZO 30 OD	Vegetative vigour	ER_{50} (Plant number at the end of the experiment)> 500.0 ER_{50} (Shoot length=426.80 ER_{50} (Plant dry weight)=322.46 ER_{50} (Plant damage)=261.09	Gierbuszewska A.,2023, G-49-20
Corn *Zea mays*	CHR/H/MEZO 30 OD	Seedling Emergence and Seedling Growth Test	ER_{50} (Plant number at the end of the experiment)> 500.0 ER_{50} (Shoot length) >500.0 ER_{50} (Plant dry weight)>500.0 ER_{50} (Plant damage)>500.0	Gierbuszewska A.,2023, G-50-20

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not required.

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 1 also covers the risk for non-target terrestrial plants from all other intended uses in groups 2 (see **Błąd! Nie można odnaleźć źródła odwołania.**).

Table 9.10-2: Assessment of the risk for non-target plants due to the use of CHR/H/MEZO 30 OD in Cereals, based on study: Terrestrial Plant Test: Vegetative vigour test

Intended use	cereals
Product	CHR/H/MEZO 30 OD
Application rate (g/ha)	476.3 g/ha
MAF	1

Test species	ER_{50} (ml test item/ha)	Drift rate	$PER_{off\text{-}field}$ (g/ha)	TER criterion: TER ≥ 5
Pea *Pisum sativum*	47.63 which is equivalent to 45.37 g test item/ha	0.0277	13.19	3.44
Flax *Linum usitatissimum*	500.0 which is equivalent to 476.3 g test item /ha	0.0277	13.19	36.11
Cabbage *Brassica oleracea var. capitata*	68.17 which is equivalent to 64.94 g test item/ha	0.0277	13.19	4.92
Carrot *Daucus carota*	169.99 which is equivalent to 161.93 g test item/ha	0.0277	13.19	12.28
Onion *Allium cepa*	~~500.0 which is equivalent to 476.3 g test item/ha~~ 175.09 which is equivalent to 166.79 g test item/ha*	0.0277	13.19	~~36.11~~ 12.65
Corn *Zea mays*	261.09 which is equivalent to 248.71g test item/ha	0.0277	13.19	18.86

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

*worst-case endpoint based on the shoot lenght

Table 9.10-3: Assessment of the risk for non-target plants due to the use of CHR/H/MEZO 30 OD in Cereals, based on study: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test

Intended use	cereals
Product	CHR/H/MEZO 30 OD
Application rate (g/ha)	476.3 g/ha
MAF	1

Test species	**ER_{50} (mLtest item /ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
Pea *Pisum sativum*	500.0 which is equivalent to 476.3 g test item/ha	0.0277	13.19	36.11
Flax *Linum usitatissimum*	500.0 which is equivalent to 476.3 g test item/ha	0.0277	13.19	36.11
Cabbage *Brassica oleracea var. capitata*	461.31 which is equivalent to 439.44	0.0277	13.19	33.32
Carrot *Daucus carota*	293.84 which is equivalent to 279.91g test item/ha	0.0277	13.19	21.22
Onion *Allium cepa*	500.0 which is equivalent to 476.3g test item /ha	0.0277	13.19	36.11
Corn *Zea mays*	500.0 which is equivalent to 476.3g test item /ha	0.0277	13.19	36.11

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 9.10-4: Risk assessment for non-target terrestrial plants due to the use of CHR/H/MEZO 30 OD in Cereals considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Cereals			
Product		CHR/H/MEZO 30 OD			
Application rate (g/ha)		1x476.3 (g/ha)			
MAF		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	0.0277	13.19	6.595	3.2975	1.319
5	0.0057	2.71	1.355	0.6775	0.271
10	0.0029	1.38	0.69	0.345	0.138
Toxicity value **Test species** **ER_{50}** **Criterion:**		TER=3.44 Pea *Pisum sativum* 45.37 g test item/ha TER ≥ 5			
Buffer strip (m)	**Drift rate**	**TER**	**TER 50 % drift red.**	**TER 75% drift red.**	**TER 90 % drift red.**
1	0.0277	3.44	6.88	13.76	34.40
5	0.0057	16.74	33.48	66.97	167.42
10	0.0029	32.88	65.75	131.5	328.77

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

CHR/H/MEZO 30 OD pose a unacceptable risk for non-target terrestrial plants according to label. This product can be used on non-target terrestrial plants only with 5m no-spray buffer zone or with 1m no-spray buffer zone and 50% nozzle reduction.

zRMS comments

The risk assessment was performed based on the endpoints for formulation CHR/H/MEZO 30 OD and the maximum application rate in cereals.

All TER value are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011 with 5 m buffer zone or 50% nozzle reduction.

Conclusion
No unacceptable risk to non-target terrestrial plants is expected following the application of CHR/H/MEZO 30 OD according to the proposed use pattern when 5 m buffer zone or 50% nozzle reduction is applied.

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

Not relevant

9.11 Monitoring data (KCP 10.8)

Not relevant

9.12 Classification and Labelling

CHR/H/MEZO 30 OD was classified and labelled according to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Classification according ~~to~~ CLP Regulation:
Aquatic Acute 1, H400
Aquatic Chronic 1, H410

Hazard statement:
H400 – Very toxic to aquatic life.
H410 – Very toxic to aquatic life with long lasting effects.

Labelling:
Aquatic Chronic 1, H410
H410 – Very toxic to aquatic life with long lasting effects.

Pictogram:

GHS09

Signal word:
WARNING

Precautionary statement:
P273: Avoid release to the environment.
P391: Collect spillage.
P501: Dispose of contents, container in accordance with local regulation.

EUH401: To avoid risks to man and the environment, comply with the instructions for use.

zRMS comments

Endpoints and effect values relevant for aquatic organisms – CHR/H/MEZO 30 OD.

Species	Substance	Exposure System	Results	Reference
Daphnia magna	CHR/H/MEZO 30 OD	48 h, acute	EC_{50} = 142.09 mg test item/$L_{(nom)}$ NOEC = 1.76 test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-61-20

Species	Substance	Exposure System	Results	Reference
Lemma gibba	CHR/H/MEZO 30 OD	7d	**$ErC_{50\ front\ number}$ = 0.109 mg test item/$L_{(nom)}$** $E_rC_{20\ front\ number}$ = 0.036 mg test item/$L_{(nom)}$ $ErC_{10\ front\ number}$ = 0.020 mg test item/$L_{(nom)}$ $EyC_{50\ front\ number}$ = 0.054 mg test item/$L_{(nom)}$ $EyC_{20\ front\ number}$ = 0.030 mg test item/$L_{(nom)}$ $EyC_{10\ front\ number}$ =0.022 mg test item/$L_{(nom)}$ $NOEC_{front\ number}$= 0.03 mg test item/$L_{(nom)}$ $ErC_{50\ dry\ weight}$ = 0.185 mg test item/$L_{(nom)}$ $E_rC_{20\ dry\ weight}$ = 0.006 mg test item/$L_{(nom)}$ **$ErC_{10\ dry\ weight}$ = 0.001 mg test item/$L_{(nom)}$** $EyC_{50\ dry\ weight}$ = 0.051 mg test item/$L_{(nom)}$ $EyC_{20\ front\ number}$ = 0.009 mg test item/$L_{(nom)}$ $EyC_{10\ front\ number}$ =0.004 mg test item/$L_{(nom)}$ $NOEC_{growth\ rate\ and\ yield}$ = 0.03 mg test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-62-20
Raphidocelis subcapitata formerly (*Pseudokirchneriella subcapitata)*	CHR/H/MEZO 30 OD	72 h	E_rC_{50} = 40.55 mg test item/$L_{(nom)}$ E_yC_{50} = 15.72 mg test item/$L_{(nom)}$ NOEC = 3.7 mg test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-63-20
Anabaena flos-aquae UTEX B 1444	CHR/H/MEZO 30 OD	72 h	ErC_{50} = 24.97 mg test item/$L_{(nom)}$ EyC50 = 5.60 mg test item/$L_{(nom)}$ NOEC = 0.95 mg test item/$L_{(nom)}$	Brzozowska-Wojoczek K., 2023, Study code: W-64-20

For formulation CHR/H/MEZO 30 OD the valid toxicity data is available for *Daphnia magna*, *Pseudokirchneriella subcapitata, Anabaena flos-aquae* and *Lemma gibba*. No data is available for fish.

According to the Guidance on the Application of the CLP Criteria, Version 5.0, July 2017: *Where a classification is made based on the test data, valid data should be normally be available on each of fish, crustacea and algae or other aquatic plants, unless a decision to classify in the most stringent category(ies) (Acute 1 and Chronic 1) can be made without a full dataset.*

Because the formulation can be classified into the most stringent categories based on available data, this approach is used for classification.

Based on the *Lemna gibba* E_rC_{50} equal to 0.109 mg/L and in accordance with CLP Regulation the following classification for formulation is proposed:
Aquatic acute toxicity Category 1, H 400 Very toxic to aquatic life.

Based on the *Lemna gibba* E_rC_{10} equal to 0.0.001 mg/L and in accordance with CLP Regulation the following classification for formula-tion is proposed:
Aquatic chronic toxicity Category 1, H 410 Very toxic to aquatic life with long lasting effects.

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	Brzozowska-Wojoczek K.	2023	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] Daphnia *magna*, Acute Immobilisation Test Study code: W-61-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.2	Brzozowska-Wojoczek K.	2023	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] *Lemna gibba* CPCC 310, Growth inhibition test Study code: W-62-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yess unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.2	Brzozowska-Wojoczek K.	2023	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test Study code: W-63-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group	N	PUH „Chemirol” Sp. z o. o.

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
			GLP: yes unpublished		
KCP 10.2	Brzozowska-Wojoczek K.	2023	*Anabaena flos-aquae* UTEX B 1444 Growth inhibition test Study code W-64-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.1	Fulczyk A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Study code: B-72-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.1.	Fulczyk A.	2023	Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Study code: B-73-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.1	Fulczyk A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test Study code: B-71-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.1	Woźniak A.	2023	Honey bee larval toxicity test following repeated exposure of the test item Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)	N	PUH „Chemirol”

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**
			Study code 0038/0104/E SORBOLAB Research Laboratory LLC GLP: yes unpublished		Sp. z o. o.
KCP 10.3.2	Fulczyk A.	2023	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the ladybird beetle, *Coccinella septempunctata L*. Study code: B-45-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.2	Fulczyk A.	2023	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the green lacewing, *Chrysoperla carnea* Study code B-46-21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.2	Fulczyk A.	2023	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the predatory mite, *Typhlodromus pyri* (Sch.). Study code B-69-20 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.3.2	Fulczyk A.	2023	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) Study code B-70-20	N	PUH „Chemirol” Sp. z o. o.

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**
			Łukasiewicz Research Network –Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished		
KCP 10.3.2	Staden V. C	2023	CHR/H/MEZO 30 OD- A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beeetle, Coccinella septempunctata (Coleoptera: Coccinellidae) Study code: CHR-23-02 Mambo-Tox GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.4	Wróbel A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Earthworm reproduction test (*Eisenia andrei*) Study code: G-45-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.4	Pieczka P.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Collembolan (*Folsomia candida*) Reproduction Test Study code: G-46-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.4	Wróbel A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil Study code: G-47-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes	N	PUH „Chemirol” Sp. z o. o.

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
			unpublished		
KCP 10.5	Wróbel A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Soil Microorganisms: Nitrogen Transformation Test Study code: G-48-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.6	Gierbuszewska A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Terrestial Plant Test: Vegetative Vigour Test Study code: G-49-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.
KCP 10.6	Wróbel A.	2023	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-50-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group GLP: yes unpublished	N	PUH „Chemirol” Sp. z o. o.

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
KCP 10.1.1		1998	Bobwhite quail acute oral toxicity test AE F130060 substance, technical Code: AE F130060 00 1C95 0001 [redacted], GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1		1998	Mallard duck acute oral toxicity study AE F130060 substance, technical Code: AE F130060 00 1C95 0001 [redacted], GLP: yes unpublished	Y	Bayer CropScience
KCP 10.1.1		2000	Bobwhite quail dietary reproduction study AE F130060 substance technical Code: AE F130060 00 1C95 0001 [redacted], Date: 2000-07-18 GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.1.1		1999	Mallard duck dietary reproduction toxicity study AE F130060 substance technical Code: AE F130060 00 1C95 0001 [redacted], GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.2		1999	Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) AE F130060 substance, technical Code: AE F130060 00 1C95 0001	Y	Bayer CropScience

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**
			[redacted] unpublished		
KCP 10.2		1999	Acute toxicity to bluegill sunfish (*Lepomis macrochirus*) AE F130060 substance, technical Code: AE F130060 00 1C95 0001 [redacted] GLP: yes unpublished	Y	Bayer CropScience
KCP 10.2	[redacted]	2001	96 Hour acute toxicity to the sheepshead minnow, *Cyprinodon variegatus*, in a static system AE F130060 technical 95.7 percent w/w [redacted] GLP: yes unpublished	Y	Bayer Crop-Science
KCP 10.2		2000	Effects on juvenile growth of rainbow trout (*Oncorhynchus mykiss*) in a 28 days static renewal system AEF130060 substance, technical Code: AE F130060 00 1C95 0001 [redacted] GLP: yes unpublished	Y	Bayer CropScience
KCP 10.2	Sousa, J. V.	2003	Mesosulfuron - The Toxicity to Fathead Minnow (*Pimephales promela*s) During an Early Life-Stage Exposure [redacted] GLP: yes, unpublished	Y	Bayer CropScience
KCP 10.2	Sowig P.; Weller O.; Gosch H.	1999	Acute toxicity to waterflea (*Daphnia magna*) AE F130060 substance, technical Code: AE F130060 00 1C95 0001 Report No: C003741	N	Bayer CropScience

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**
			Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, GLP: yes, unpublished		
KCP 10.2	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Daphnia magna* (waterflea) in a Static -Acute Toxicity Test (method OECD) Report No.: A50353, Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, GLP: yes, unpublished	N	Bayer Crop-Science
KCP 10.2	Dionne, E.	2000	AE F130060 00 1C96 0004 - Acute Toxicity to Eastern Oysters (*Crassostrea virginica*) Under Flow-Through Conditions Springborn Laboratories, Inc. (SLS), USA Bayer CropScience, Report No.: B003104 Date: 2000-11-30 **...Amended: 2000-12-07** GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Heusel, R.; Weller, O.; Gosch, H.	1998	Algal growth inhibition (*Pseudokirchneriella subcapitata*) AE F130060 substance, technical 94.6 percent Code: AE F130060 00 1C95 0001 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A59843, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Dorgerloh, M.	2005	*Pseudokirchneriella subcapitata* - growth inhibition test with AE F154851 00 1B96 0001 Bayer CropScience, Report No.: EBMMX093, GLP: yes, unpublished	N	Bayer CropScience

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	Sowig, P.; Gosch, H.; Weller, O.	2000	Algal growth inhibition - *Pseudokirchneriella subcapitata* AE F160459 (metabolite of AE F130060) substance, pure Code: AE F160459 00 1B97 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Report No.: C010060, GLP: yes unpublished	N	Bayer CropScience
KCP 10.2	Sowig, P.; Gosch, H.; Weller, O.	2000	Algal growth inhibition - *Pseudokirchneriella subcapitata* AE F147447 (metabolite of AE F130060) substance, technical Code: AE F147447 00 1C93 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Report No.: C009927, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Dorgerloh, M.	2005	*Pseudokirchneriella subcapitata* - growth inhibition test with AE F099095 00 1B99 0001 Bayer CropScience, Report No.: EBMMX092, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Bruns, E.	2011	*Pseudokirchneriella subcapitata* growth inhibition test with BCS-CO60720 - limit test Bayer CropScience, Report No.: EBMML012, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Bruns, E.	2011	*Pseudokirchneriella subcapitata* growth inhibition test with BCS-CO60721 - limit test Bayer CropScience, Report No.: EBMML013, GLP: yes	N	Bayer CropScience

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**
			unpublished		
KCP 10.2	Abedi, J.; Christ, M.; Young, B.	2001	Effect to *Anabaena flos-aquae* (Blue-Green Alga) in a Growth Inhibition Test, AE F130060 Technical, 95.7% w/w Aventis CropScience USA LP, RTP, NC, USA Bayer CropScience, Report No.: B003222, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Young, B. M.; Abedi, J.	2001	Effect to *Skeletonema costatum* (Marine Diatom) in a Growth Inhibition Test AE F130060 Technical 95.7% w/w Aventis CropScience USA LP, RTP, NC, USA Bayer CropScience, Report No.: B003156, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Sowig, P.; Gosch, H.	2002	Duckweed (*Lemna gibba* G3) - Growth inhibition test with recovery phase AE F130060 substance, pure Code: AE F130060 00 1B98 0002 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C018852, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Dorgerloh, M.	2005	*Lemna gibba* G3, growth inhibition test with AE F154851 under static conditions, (code: AE F154851 00 1B96 0001) Bayer CropScience, Report No.: EBMMX090, GLP: yes, unpublished	N	Bayer CropScience

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	Dorgerloh, M.	2005	*Lemna gibba* G3 - growth inhibition test with AE F099095 under static conditions (Code: AE F099095 00 1B99 0001) Bayer CropScience, Report No.: EBMMX091, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.2	Sowig, P.; Weller, O.	2000	Duckweed (*Lemna gibba* G3) growth inhibition test AE F092944 (metabolite of ethoxysulfuron and amidosulfuron) substance technical Code: AE F092944 00 1C99 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C003865, GLP: yes, unpublished	N	Bayer Crop-Science
KCP 10.2	Bruns, E.	2013	*Lemna gibba* G3 - Growth inhibition test with BCS-CO60720 under static conditions Bayer CropScience, Report No.: EBMML010, GLP: yes, unpublished	N	Bayer Crop-Science
KCP 10.2	Bruns, E.	2013	*Lemna gibba* G3 - Growth inhibition test with BCS-CO60721 under static conditions Bayer CropScience, Report No.: EBMML011, GLP: yes, unpublished	N	Bayer Crop-Science
KCP 10.3.1	Schmitzer, S.	2012	Effects of mesosulfuron-methyl tech. (Acute contact and oral) on honey bees *(Apis mellifera* L.) in the laboratory Report No.: 72941035, IBACON GmbH, Rossdorf, Germany Bayer CropScience,	N	Bayer CropScience

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**
			GLP: yes, unpublished		
KCP 10.4	Moser, T.; Scheffczyk, A.	2010	Mesosulfuron-methyl - Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: 10P30RR, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Moser, T.; Scheffczyk, A.	2012	AE F160459: Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: 11P32RR, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Kratz, M. A.	2013	AE F099095 (BCS-AB40283): Effects on survival, growth and reproduction of the earthworm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-158/13, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Kratz, M. A.	2013	AE F092944 (BCS-AA25052): Effects on survival, growth and reproduction of the earthworm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-147/13, GLP: yes, unpublished	N	Bayer CropScience

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 10.4	Kratz, M. A.	2013	Mesosulfuron-methyl-AE F140584 (BCS-AU66443): Effects on survival, growth and reproduction of the earthworm *Eisenia fetida* tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-155/13, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Moser, T.; Scheffczyk, A.	2012	AE F147447: Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: 11P34RR, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Frommholz, U.	2012	Mesosulfuron-methyl (AE F130060) a.s.: Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-138/12, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Friedrich, S.	2013	Mesosulfuron-methyl-AE F154851 (BCS-AU80405): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 104 S, GLP: yes, unpublished	N	Bayer CropScience

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 10.4	Friedrich, S.	2013	Mesosulfuron-methyl-AE F160459 (BCS-AU84907): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 103 S, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Friedrich, S.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 045 S, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Friedrich, S.	2013	Mesosulfuron-methyl-AE F147447 (BCS-AU73625): Effects on the reproduction of the collembolan *Folsomia candida* BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 105 S, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.4	Kratz M.A	2012	Mesosulfuron-methyl (AE F130060): Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil Bayer CropScience, Report No.: KRA-HR-67/12, GLP: yes, unpublished	N	Bayer CropScience

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 10.4	Schulz L.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 044 S, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.5	Heusel R.	1998	AE F130060; substance, technical; Code: AE F130060 00 1C96 0002 - Effects on soil microbial activity (nitrogen turn-over) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: A59696, GLP: yes, unpublished	N	Bayer CropScience
KCP 10.5	Schaefer E. C.; Siddiqui A. I.	2002	Soil microorganisms: Nitrogen transformation test Code: AE F154851 00 1B96 0001 Wildlife International, Ltd., Easton, MD, USA Bayer CropScience, Report No.: C027822, GLP: yes unpublished	N	Bayer CropScience
KCP 10.5	Schaefer E. C.; Siddiqui A. I.	2002	Soil microorganisms: Nitrogen transformation test Code: AE F099095 00 1B99 0001 Wildlife International, Ltd., Easton, MD, USA Report No.: C027821, Bayer CropScience, GLP: yes, unpublished	N	Bayer CropScience

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 10.5	Heusel, R.	1998	AE F130060; substance, technical; Code: AE F130060 00 1C96 0002 - Effects on soil microbial activity (short-term respiration) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: A59695, Bayer CropScience, GLP: yes, unpublished	N	Bayer CropScience

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	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

Not required.

A 2.1.1 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

Not required

A 2.1.2 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

Not required

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 2.2.1.1.1 Study 1

Comments of zRMS:	The study was performed according to OECD TG 202 and principles of GLP. The validity criteria were met. No deviations to the study plan were recorded. All results refer to nominal concentrations since the measured concentrations were within 80 to 120 of nominal. The study is considered acceptable and suitable for the risk assessment. 48h EC_{50} = 142.09 $mg/L_{(nom)}$

Reference:	KCP 10.2.1
Report	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] *Daphnia magna*, Acute Immobilisation Test. Brzozowska-Wojoczek K., 2023, Study code W-61-20
Guideline(s):	OECD Guideline No. 202 (2004)/EU method C.2.
Deviations:	No
GLP:	Yes
Acceptability:	

Duplication (if vertebrate study)	No
Validity criteria	In the definitive test, the validity criteria were met according to the OECD Guideline No. 202 (2004) and EU Method C.2.: - the percentage of immobilisation of Daphnia magna in the control was 0% (criterion: not more than 10%), - the dissolved oxygen concentrations in the test vessels were within the range of 8.4 –8.8 mg/L (criterion: not less than 3 mg/L).

SUMMARY

Immobilisation of *Daphnia magna* exposed to the test item, Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] was investigated during a 48-hour static test. The definitive test was performed with a test item concentrations of 200, 90.9, 41.3, 18.8, 8.54, 3.88, 1.76 and 0.80 mg/L plus the control. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentrations or the control per replicate. Four replicates were used for the test item concentrations and the control, each with five *Daphnia magna*.

The *Daphnia magna* were observed for immobilisation and any abnormal behavior or appearance after 24 and 48 h of exposure. The *Daphnia magna* were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel.

In the control and in the test item concentrations of 0.80 mg/L, no immobilisation of *Daphnia magna* was observed during exposure. At exposure termination in the test item concentrations of 200, 90.9, 41.3, 18.8, 8.54, 3.88, 1.76 mg/L, the immobilisation of *Daphnia magna* was 65, 35, 20, 25, 25, 15 and 5%, respectively. In the range of the test item concentrations of 0.80 – 18.8 mg/L, daphnides were entrapped on the water surface.

The concentrations of mesosulfuron-methyl and mefenphyr-dietyl were chemically analyzed using the validated liquid chromatographic method with Diode Array Detection.

The concentrations of active substances were chemically analyzed in samples of all test item concentrations and the control collected at exposure initiation and exposure termination.

In fresh samples at exposure initiation, the determined concentrations of Mesosulfuron-methyl were in the range of 82.5 – 90.4% and the concentrations of mefenphyr-dietyl were in the range of 95.2 – 102.1% of the nominal concentration. The results confirm that the test item concentration was prepared correctly.

In spent samples exposure termination, the determined concentrations of Mesosulfuron-methyl were in the range of 87.5 – 96.0% and the concentrations of mefenphyr-dietyl were in the range of 81.4 – 94.8% of the nominal concentration. Therefore, the concentrations of mesosulfuron-methyl and mefenphyr-dietyl were

stable under test conditions.

The endpoint value was determined based on the nominal test item concentration.

Material and methods:

Test item:	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD]; batch no. 040322; content of mesosulfuron-methyl 30.53 g/L, content of mefenpyr-diethyl: 90.67 g/L; density at 20°C: 0.95 g/cm3; manufacturing date: March 04, 2022; expiry date: March 22, 2024.
Test system:	*Daphnia magna* Straus (< 24 h old at exposure initiation); not first brood progeny; neonates collected from a laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna.
Test design:	Static test (48 h of exposure); 4 replicates per each test item concentration and the control; 5 Daphnia magna in each replicate.
Nominal test item concentration:	200, 90.9, 41.3, 18.8, 8.54, 3.88, 1.76 and 0.80 mg/L plus the control.
Test conditions:	Temperature: 19.0 - 20.9 °C; pH of the control: 7.35 – 7.38; dissolved oxygen concentration in the control: 8.5 – 8.6 mg/L; daily cycle 16 h light : 8 h dark; fluorescent light source; no feeding; no aeration; medium: Elendt M7.
Chemical determinations:	The concentrations of mesosulfuron-methyl and mefenphyr-dietyl were chemically analyzed using validated liquid chromatographic method with Diode Array Detection.
Statistics:	Probit method calculations and analyses by Step-down Cochran-Armitage Test Procedure.
Endpoint value:	EC50/48 h, NOEC/48 h, and LOEC/48 h.

Results:

The endpoint value based on nominal test item concentration:
The EC50/48 h value is 142.09 mg/L (95%-confidence limits: 66.18 mg/L – 599.50 mg/L)
The LOEC is 3.88 mg/L
The NOEC is 1.76 mg/L

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

A 2.2.2.1.1 Study 2

Comments of zRMS:	The study was performed according to OECD TG 221 and GLP. Validity criteria were met. No deviations to the study plan were recorded. The measured concentrations were not within 80 to 120% of nominal values. In the study report the endpoint values were determined on the basis of the nominal test item concentrations, geometric mean of determined mesosulfuron-methyl and mefenpyr-diethyl concentrations. The study is considered acceptable. The results based on the geometric means of determined concentrations of mesosulfuron-methyl should be considered for the risk assessment. 7d ErC50 $_{\text{frond number}}$ = 0.109 mg test item/L(nom) 7d h EyC50 $_{\text{frond number}}$ = 0.054 mg test item/L(nom) 7d ErC50 $_{\text{dry weight}}$ = 0.185 mg test item/L(nom) 7d h EyC50 $_{\text{dry weight}}$ = 0.051 mg test item/L(nom) 7d ErC50 $_{\text{frond number}}$ = 2.695 µg a.s./L(geom m) 7d EyC50 $_{\text{frond number}}$ = 1.318 µg a.s./L(geom m) 7d ErC50 $_{\text{dry weight}}$ = 8.247 µg a.s./L(geom m) 7d EyC50 $_{\text{dry weight}}$ = 1.349 µg a.s./L(geom m)

Reference:	KCP 10.2.2
Report	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] *Lemna gibba* CPCC 310, Growth inhibition test. Brzozowska-Wojoczek K., 2023, Study code W-62-20
Guideline(s):	OECD Guideline No. 221 (2006)/ EU Method C.26.
Deviations:	No
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
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 1.9 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7

day was 13.0),
- the average specific growth rate in the control between day 0 and day 7 was 0.366 d-1 (minimum requirement: higher than 0.275 d-1).

SUMMARY

The growth of *Lemma gibba* exposed to the test item, Mesosulfuron 30 OD [CHR/H/MEZO 30 OD], was investigated in a 7 day semi-static test. The test was performed in glass crystallizers with a depth of 4 cm and a diameter of 9 cm containing 150 mL of either 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: 0.03, 0.095, 0.31, 0.98, 3.13, 10 mg/L plus the control.

The total number of fronds in each test vessel was counted twice during exposure (day 2 and 5) 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.

At exposure termination, in the test item concentration of ~~3.13~~ 0.095 mg/L, deformed young fronds were observed. In the remaining test item concentrations no distinctive changes from the normal development of plants in the control were observed.

The concentrations of Mesosulfuron-methyl and mefenpyr-diethyl were chemically determined. The concentrations of active substances were chemically analysed using the validated liquid chromatographic method with Diode Array Detection.

The concentrations of active substances were chemically analysed in samples of all fresh test item concentrations and the control collected at exposure initiation and in samples of all spent test item concentrations and the control collected at the first renewal. Moreover, fresh and spent samples of the test item concentration of 10 mg/L, the lowest test item concentration of 0.03 mg/L and the control at renewals and at exposure termination were chemically determined.

In fresh samples at exposure initiation and at the renewal, the determined concentrations of mesosulfuron-methyl were in the range of 80.1 – 86.2%, and the concentrations of mefenpyr-diethyl were in the range of 93.4 – 111.8% 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 mesosulfuron-methyl were in the range of 44.9 – ~~87.2~~ 85.0%, and the determined concentrations of mefenpyr-diethyl were in the range of 10.8 – 64.3% of the nominal concentration. Therefore, the concentrations of mesosulfuron-methyl and mefenpyr-diethyl were not stable during 24 h under test conditions.

The endpoint value was determined based on the nominal test item concentration, geometric mean of determined concentrations of mesosulfuron-methyl and geometric mean of determined concentrations of mefenpyr-diethyl.

Material and methods

Test item: Mesosulfuron 30 OD [CHR/H/MEZO 30 OD];
batch no. 040322;
content of mesosulfuron-methyl 30.53 g/L,

	content of mefenpyr-diethyl: 90.67 g/L; density at 20°C: 0.95 g/cm3 manufacturing date: March 04, 2022; expiry date: March 22, 2024.
Test system:	Freshwater aquatic plant *Lemna gibba* L. specification CPCC 310, cultured in the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology, stock G3 from Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada.
Test design:	Semi-static system (7 days of exposure with renewal every 24 h); three replicates for each test item concentration and six replicates for the control.
Nominal test item concentrations:	10, 3.13, 0.98, 0.31, 0.095, 0.03 mg/L plus control
Geometric means of determined concentrations of mesosulfuron-methyl:	266.5, 81.6, 24.2, 7.7, 2.4 and 0.7 µg/L plus the control
Geometric means of determined concentrations of mefenpyr-diethyl:	754.6, 224.9, 66.7, 21.4, 6.5 and 2.2 µg/L plus the control
Test conditions:	Temperature: 22.7 – 23.4ºC; pH of the control: 7.40 – 8.68; light intensity mean: 7266 – 7322 lux; constant illumination; test vessels: glass crystallizers with a depth of 4 cm and a diameter of 9 cm containing 150 mL of each treatment; initial frond number: 9, i.e. 3 plants per 3 fronds; medium: 20X AAP.
Endpoint value:	ErC_{50}, ErC_{20}, ErC_{10}, EyC_{50}, EyC_{20}, EyC_{10}, LOEC and NOEC, based on frond number and dry weight

The endpoint values based on the nominal test item concentrations:
Endpoints based on the frond number:
The ErC_{50}/7 d value is 0.109 mg/L (95% confidence interval 0.061 – 0.195)
The ErC_{20}/7 d value is 0.036 mg/L (95% confidence interval 0.022 – 0.057).

The ErC_{10}/7 d value is 0.020 mg/L (95% confidence interval 0.012 – 0.033).
The EyC_{50}/7 d value is 0.054 mg/L (95% confidence interval 0.043 – 0.069).
The EyC_{20}/7 d value is 0.030 mg/L (95% confidence interval 0.025 – 0.037).
The EyC_{10}/7 d value is 0.022 mg/L (95% confidence interval 0.018 – 0.027).
For growth rate and yield, the LOEC/7 d value is lower than or equal to 0.03 mg/L, whereas NOEC/7 d value is lower than 0.03 mg/L.

Endpoints based on the dry weight:
The ErC_{50}/7 d value is 0.185 mg/L (95% confidence interval 0.016 – 2.439).
The ErC_{20}/7 d value is 0.006 mg/L (95% confidence interval: 0.001 – 0.052).
The ErC_{10}/7 d value is 0.001 mg/L (95% confidence interval: n.d – 0.010).
The EyC_{50}/7 d value is 0.051 mg/L (95% confidence interval: 0.014 – 0.199).
The EyC_{20}/7 d value is 0.009 mg/L (95% confidence interval: 0.003 – 0.028).
The EyC_{10}/7 d value is 0.004 mg/L (95% confidence interval: 0.001 – 0.012)
For growth rate and yield, the LOEC/7 d value is lower than or equal to 0.03 mg/L, whereas NOEC/7 d value is lower than 0.03 mg/L.
The endpoint values based on the geometric means of determined concentrations of mesosulfuron-methyl:
Endpoints based on the frond number:
The ErC50/7 d value is 2.695 µg/L (95% confidence interval 1.528 – 4.735).
The ErC20/7 d value is 0.864 µg/L (95% confidence interval 0.546 – 1.380).
The ErC10/7 d value is 0.476 µg/L (95% confidence interval 0.291 – 0.780).
The EyC50/7 d value is 1.318 µg/L (95% confidence interval 1.023 – 1.699).
The EyC20/7 d value is 0.702 µg/L (95% confidence interval 0.572 – 0.868).
The EyC10/7 d value is 0.505 µg/L (95% confidence interval 0.404 – 0.631).
For growth rate and yield, the LOEC/7 d value is lower than or equal to 0.7 µg/L, whereas NOEC/7 d value is lower than 0.7 µg/L.

Endpoints based on the dry weight:
The ErC_{50}/7 d value is 8.247 µg/L (95% confidence interval 1.616 – 41.582).
The ErC_{20}/7 d value is 0.353 µg/L (95% confidence interval: 0.095 – 1.358).
The ErC_{10}/7 d value is 0.068 µg/L (95% confidence interval: 0.017 – 0.281).
The EyC_{50}/7 d value is 1.349 µg/L (95% confidence interval: 0.488 – 3.799).
The EyC_{20}/7 d value is 0.253 µg/L (95% confidence interval: 0.109 – 0.601).
The EyC_{10}/7 d value is 0.105 µg/L (95% confidence interval: 0.042 – 0.262).
For growth rate and yield, the LOEC/7 d value is lower than or equal to 0.7 µg/L, whereas NOEC/7 d value is lower than 0.7 µg/L.

The endpoint values based on the geometric means of determined concentrations of mefenpyr-diethyl:
Endpoints based on the frond number:
The ErC_{50}/7 d value is 7.569 µg/L (95% confidence interval 4.264 – 13.543).
The ErC_{20}/7 d value is 2.541 µg/L (95% confidence interval 1.594 – 4.101).
The ErC_{10}/7 d value is 1.436 µg/L (95% confidence interval 0.871 – 2.369).
The EyC_{50}/7 d value is 3.833 µg/L (95% confidence interval 3.068 – 4.815).
The EyC_{20}/7 d value is 2.218 µg/L (95% confidence interval 1.847 – 2.678).
The EyC_{10}/7 d value is 1.667 µg/L (95% confidence interval 1.367 – 2.033).
For growth rate and yield, the LOEC/7 d value is lower than or equal to 2.2 µg/L,

whereas NOEC/7 d value is lower than 2.2 µg/L.

Endpoints based on the dry weight:
The ErC_{50}/7 d value is 23.979 µg/L (95% confidence interval 4.786 – 116.621).
The ErC_{20}/7 d value is 1.075 µg/L (95% confidence interval: 0.296 – 4.006).
The ErC_{10}/7 d value is 0.212 µg/L (95% confidence interval: 0.053 – 0.843).
The EyC_{50}/7 d value is 3.941 µg/L (95% confidence interval: 1.384 – 11.502).
The EyC_{20}/7 d value is 0.794 µg/L (95% confidence interval: 0.336 – 1.929).
The EyC_{10}/7 d value is 0.344 µg/L (95% confidence interval: 0.136 – 0.873).
For growth rate and yield, the LOEC/7 d value is lower than or equal to 2.2 µg/L, whereas NOEC/7 d value is lower than 2.2 µg/L.

A 2.2.2.1.2 Study 3

Comments of zRMS:	The study was performed according to OECD TG 201 and principles of GLP. The validity criteria were met. No deviations to the study plan were recorded. The measured concentrations were not within 80 to 120 of nominal values. In the study report the endpoint values were determined on the basis of the nominal test item concentrations, geometric mean of determined mesosulfuron-methyl and mefenpyr-diethyl concentrations. The study is considered acceptable. The results based on the geometric means of determined concentrations of mesosulfuron-methyl should be considered for the risk assessment. 72h E_rC_{50} = 40.55 mg test item/$L_{(nom)}$ 72 h E_yC_{50} = 15.72 mg test item/$L_{(nom)}$ 72h E_rC_{50} = 1.109 mg a.s./$L_{(geom\ m)}$ 72h E_yC_{50} = 0.439 mg a.s./$L_{(geom\ m)}$

Reference:	KCP 10.2.2
Report	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test. Brzozowska-Wojoczek K., 2023, Study code W-63-20
Guideline(s):	OECD Guideline No. 201 (2006)/EU method C.3.
Deviations:	No
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
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 100.4 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 2.5% (criterion: it must not exceed 7%),
-the mean coefficient of variation for the section-by-section growth rate in the control culture was 22.4% (criterion: it must not exceed 35.0%).

SUMMARY

The growth of the green algae *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) exposed to the test item, Mesosulfuron 30 OD [CHR/H/MEZO 30 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 10^4 cells/mL. The definitive test was performed with the following test item concentrations: 100, 33.3, 11.1, 3.7, 1.23 mg/L plus the control.

The number of algal cells was determined with direct method, which involves counting the number of cells in the Bürker chamber under a microscope. In case of each replicate, the number of cells was determined after 24, 48, and 72 h of exposure. Morphology observations of the algae cells were performed at exposure termination.

Calculated inhibition of growth rate for the test item concentrations in the range of 11.1 – 100 mg/L after 72 h of exposure was in the range of 6.8 – 80.5% when compared to the control. Inhibition of yield for the test item concentrations in the range of 11.1 – 100 mg/L after 72 h of exposure was in the range of 27.0 – 98.5% when compared to the control. In the test item concentrations of 3.7 and 1.23 mg/L no yield and growth rate inhibition was observed.

In the test item concentrations in the range of 1.23 – 33.3 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 100 mg/L, opalescent algae cells were observed.

The concentrations of mesosulfuron-methyl and mefenpyr-diethyl were chemically determined using validated high performance liquid chromatographic method with DAD detection. Samples of all test item concentrations and the control collected at exposure initiation and at exposure termination were chemically determined. At exposure initiation, the determined concentrations of mesosulfuron-methyl were in the range of 82.5 – 93.2% of the nominal concentration. The determined concentrations of mefenpyr-diethyl were in the range of 90.7 – 99.5% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly.

At exposure termination, the determined concentrations of mesosulfuron-methyl were in the range of 79.8 – 87.7% of the nominal concentration. The determined concentrations of mefenpyr-diethyl were in the range of 37.2 – 70.7% of the nominal concentration. The results confirm, that the concentrations of mesosulfuron-methyl and mefenpyr-diethyl were not stable under test conditions.

The endpoint values were determined based on the nominal test item concentrations, geometric means of determined concentrations of mesosulfuron-methyl and and geometric means of determined concentrations of mefenpyr-diethyl.

Material and methods:

Test item:	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD]; batch no. 040322, the content of mesosulfuron-methyl: 30.53 g/L, mefenpyr-diethyl 90.67 g/L, density at 20°C: 0.95 g/cm3; manufacturing date: March 04, 2022, expiry date: March 04, 2024.
Test system:	The unicellular freshwater green algae, *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata* (Korshikov) Hindák, Selenastrum capricornutum Prinz) SAG 61.81 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.
Test design:	72 hours of exposure; three replicates per each test item concentration; six replicates per control; initial algal cell density: 1 x 104 cells/mL.
Nominal test item concentrations:	100, 33.3, 11.1, 3.7 and 1.23 mg/L plus the control.
Geometric means of determined concentrations of Mesosulfuron-methyl:	2.821, 0.891, 0.316, 0.102 and 0.033 mg/L plus the control.
Geometric means of determined concentrations of control .	mefenpyr-diethyl:7.054, 2.567, 0.800, 0.228 and 0.071mg/L plus the con-
Test conditions:	Temperature: 22.5 – 22.8°C; pH of the control: 7.62 – 7.98; mean light intensity: 5998 - 6124 lux; constant illumination and shaking; medium: AAP.
Statistics:	3-param. normal CDF method calculations and analyses by: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Wiliams Multiple Sequential t-test Procedure

Endpoint values: ErC_{50}/72 h, EyC_{50}/72 h, NOEC/72 h, LOEC/72 h.

Results:

The endpoint values based on nominal test item concentrations are given below:

The ErC50/72 h value is 40.55 mg/L (95% confidence interval: 31.34 – 52.12).
The LOEC/72 h value for growth rate is 11.1 mg/L.
The NOEC/72 h value for growth rate is 3.7 mg/L. The EyC_{50}/72 h value is 15.72 mg/L (95% confidence interval: 9.99 – 24.43).
The LOEC/72 h value for yield is 11.1 mg/L.
The NOEC/72 h value for yield is 3.7 mg/L.
The endpoint values based on the geometric means of determined concentrations of mesosulfuron-methyl are given below:

The ErC_{50}/72 h value is 1.109 mg/L (95% confidence interval: 0.850 – 1.444).
The LOEC/72 h value for growth rate is 0.316 mg/L.
The NOEC/72 h value for growth rate is 0.102 mg/L.
The EyC_{50}/72 h value is 0.439 mg/L (95% confidence interval: 0.286 – 0.667).
The LOEC/72 h value for yield is 0.316 mg/L.
The NOEC/72 h value for yield is 0.102 mg/L.

The endpoint values based on the geometric means of determined concentrations of mefenpyr-diethyl are given below:

The ErC_{50}/72 h value is 3.035 mg/L (95% confidence interval: 2.369 – 3.866).
The LOEC/72 h value for growth rate is 0.800 mg/L.
The NOEC/72 h value for growth rate is 0.228 mg/L.
The EyC_{50}/72 h value is 1.158 mg/L (95% confidence interval: 0.717 – 1.849).
The LOEC/72 h value for yield is 0.800 mg/L. The NOEC/72 h value for yield is 0.228 mg/L.

A 2.2.2.1.3 Study 4

Comments of zRMS:	The study was performed according to OECD TG 201 and principles of GLP. The validity criteria were met. No deviations to the study plan were recorded. The measured concentrations were within 80 to 120% of nominal values for mesosulfuron-methyl. In the study report the endpoint values were determined on the basis of the nominal test item concentrations. The study is considered acceptable and suitable for the risk assessment. 72h E_rC_{50} = 24.97 mg test item/$L_{(nom)}$ 72 h E_yC_{50} = 5.60 mg test item/$L_{(nom)}$

Reference:	KCP 10.2.2
Report	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD] *Anabaena flos-aquae* UTEX

	B 1444 Growth inhibition test. Brzozowska-Wojoczek K., 2023, Study code W-64-20
Guideline(s):	OECD Guideline No. 201 (2006)/EU method C.3.
Deviations:	No
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria:	In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) were met: - the biomass in the control increased by a factor of 26.0 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 4.1% (criterion: it must not exceed 10%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 13.9% (criterion: it must not exceed 35%).

SUMMARY

The growth of the cyanobacteria *Anabaena flos-aquae* exposed to the test item, Mesosulfuron 30 OD [CHR/H/MEZO 30 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 cyanobacteria was 1 x 104 cells/mL. The definitive test was performed using the following test item concentrations: 100, 31.3, 9.77, 3.05 and 0.95 mg/L (with a spacing factor of 3.2) plus the control.

The number of cyanobacterial cells was determined with a direct method, which involves counting the number of cells in the Bürker chamber under a microscope. In case of each replicate, the number of cells was determined after 24, 48, and 72 h of exposure.

Morphology observations of the cyanobacteria cells were performed at exposure termination.

In the test item concentrations in the range of 0.95 – 31.3 mg/L, no differences in shape, size and colour of cyanobacterial cells were reported as compared to the cyanobacteria cells in the control. In the test item concentration of 100 mg/L no morphological observations were performed due to lack of the cyanobacteria cells.

The concentrations of mesosulfuron-methyl and mefenpyr-diethyl were chemically analyzed using the validated liquid chromatographic method with Diode Array Detection. The concentrations of active substances were chemically analysed in samples of all test item concentrations and the control collected at exposure initiation and exposure termination.

In fresh samples at exposure initiation, the determined concentrations of Mesosulfuron-methyl were in the range of 82.2 – 93.5% and the concentrations of mefenphyr-dietyl were in the range of 92.5 – 106.3% of the nominal concentration. The results confirm that the test item concentration was prepared correctly.

In spent samples at exposure termination, the determined concentrations of mesosulfuron-methyl were in the range of 82.5 – 99.0% and the concentrations of mefenphyr-dietyl were in the range of 62.6 – 98.2% of the nominal concentration.

Therefore, the concentrations of mesosulfuron-methyl were stable under test conditions and concentrations of mefenphyr-dietyl were not stable under test conditions.

The endpoint value was determined based on the nominal test item concentration and geometric mean of determined mefenpyr-diethyl concentrations.

Materials and methods:

Test item:	Mesosulfuron 30 OD [CHR/H/MEZO 30 OD]; batch no. 040322; content of mesosulfuron-methyl 30.53 g/L, content of mefenpyr-diethyl: 90.67 g/L; density at 20°C: 0.95 g/cm3; manufacturing date: March 04, 2022; expiry date: March 22, 2024.
Test system:	The freshwater cyanobacteria, Anabaena flos-aquae (Lyng.) Bréb UTEX B 1444 cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Aquatic Organisms Toxicology. The culture was obtained from the Culture Collection of Algae at the University of Texas at Austin, USA.
Test design:	72 hours of exposure; three replicates per each test item concentration; six replicates per the control; initial cyanobacterial cell density: 1 x 104 cells/mL.
Nominal test item concentrations::	100, 31,3, 9.77, 3.05 and 0.95 mg/L plus the control.
Geometric mean of determined	mefenpyr-diethyl concentrations: 7.274, 2.472, 0.827, 0.273 and 0.093 mg/L plus the control
Test conditions:	Temperature: 22.3 – 23.1°C; pH of the control: 7.63 – 7.94; mean light intensity: 4044 - 4134 lux; constant illumination and shaking; medium: AAP.
Chemical determinations:	The concentrations of mesosulfuron-methyl and mefenphyr-dietyl

	were chemically analyzed using validated liquid chromatographic method with Diode Array Detection.
Statistics:	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.
Endpoint values:	ErC50/72 h, EyC50/72 h, NOEC/72 h, LOEC/72 h.

Results:

The endpoint values based on the nominal test item concentrations:

The ErC_{50}/72 h value is 24.97 mg/L (95% confidence interval: 15.50 – 41.55)
The EyC_{50}/72 h value is 5.60 mg/L (95% confidence interval: 4.06 – 7.64)
The LOEC/72 h value for growth rate and yield is 3.05 mg/L.
The NOEC/72 h value for growth rate and yield is 0.95 mg/L.

The endpoint values based on the geometric mean od determined mefenpyr-diethyl concentrations:

The ErC50/72 h value is 1.991 mg/L (95% confidence interval: 1.266 – 3.219).
The EyC50/72 h value is 0.488 mg/L (95% confidence interval: 0.360 – 0.655).
The LOEC/72 h value for growth rate and yield is 0.273 mg/L.
The NOEC/72 h value for growth rate and yield is 0.093 mg/L

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1.1.1 Study 5

Comments of zRMS:	The study was conducted according to the method IOBC Schmuck V. et al., 2000. Validity criteria were met: • pre-imaginal mortality of the control group was 0.0% (criterion: a maximum of 30.0%), • 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 6.0 • (criterion: ≥ 2 fertile eggs/female).

	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. The study is acceptable and suitable for the use in the risk assessment. LR50>0.5 l product/ha $NOER_{mortality}$<0.125 l product/ha

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the ladybird beetle, *Coccinella septempunctata L*. Fulczyk .A, 2023, Study code: B-45-21
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Schmuck et al., 2000)
Deviations:	Yes The experimental part of the study was conducted according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART and EPPO Joint Initiative (Schmuck V. et al., 2000), SOP/B/63 and other procedures related with the study and the Study Plan. 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. This method was described in the Study Plan and the SOP/B/63. The deviations is due to the type of study ordered by the Sponsor.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	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%), -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 6.0 (criterion: ≥ 2 fertile eggs/female).

SUMMARY

The extended laboratory test involved the evaluation of the effects of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata L.* In a definitive test, three test item application rates of 0.125, 0.25 and 0.5 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 application rates of 0.125, 0.25 and 0.5 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 9 days.

To check the relative susceptibility of the test system and the sensitivity of the test method, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 3.2 g/ha. Control beetles had contact with leaf discs sprayed with distilled water.

Materials and methods

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) content: 30.53 g/L of mesosulfuron-methyl (CAS No. 208465-21-8) 90.67 g/L of mefenpyr diethyl (CAS No. 135590-91-9) batch no.: 040322 production date: 04.03.2022 expiry date: 22.03.2024
Biological test system:	the ladybird beetle, *C. septempunctata* L. (Arthropoda: Coccinellidae)
– age:	4-day-old larvae
– source:	ladybird beetles were obtained from commercial breeder (Katz Biotech AG, Germany)
Experimental design:	5 study groups: - a control group (0.0 L/ha) -Test item at the rates of: - 0.125 L/ha - 0.25 L/ha - 0.5 L/ha -dimethoate at the rate of 3.2 g/ha
number of replicates:	40 replicates/group
number of larvae:	1 larva of *Coccinella septempunctata* /replicate
Test conditions:	– temperature: 23.1 – 27.0°C – relative air humidity: 60.0- 89.9% – photoperiod: 16 hours light : 8 hours dark – light intensity 2073 lx
Statistical analysis:	Probit analysis using linear max. likelihood regression, Chi2 2x2 Table Test with Bonferroni Correction
Endpoints:	– preimaginal mortality of the ladybird beetles – LR_{50}

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

Results and discussions

The effects of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on mortality and reproductive capacity of the ladybird beetle, *Coccinella septempunctata* L. in the laboratory test are summarized below.

Study group	Parameters (endpoints)				
	Mortality		Reproduction		
Test item [L/ha]	[%]	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	> 0.5	6.4	6.0	–
0.125+	10.0		5.4	5.1	14.2
0.25+	17.5		6.9	6.7	-10.8*
0.5+	12.5		4.4	4.2	30.5
$NOER_{mortality}$	< 0.125 [L/ha]				
Reference item: dimethoate					
Reference item [g/ha]	100.0	–			
3.2					

+: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [9], [SOP/B/67]

*: the negative value means that in the tested rate there was higher mean number of fertile eggs per viable female per day than in the control group

Conclusion

The validity criterion concerning mortality was met, because mortality of the ladybird beetle, *Coccinella septempunctata* L. in the control group was equal to 0.0% (≤ 30.0%). The mortality of the ladybird beetles exposed to the test item at the rates of 0.125, 0.25 and 0.5 L/ha was 10.0, 17.5 and 12.5%, respectively.

At the significance level of 0.05, there were statistically significant differences in mortality between the ladybirds exposed to the test item at the rates of 0.125, 0.25 and 0.5 L/ha and the control group (Chi2 2x2 Table Test with Bonferroni Correction, (Alpha = 0.05, p(z) < Alpha*)).

Based on the obtained mortality results, it can be concluded that the LR50 value is higher than 0.5 L/ha of test item and the NOER mortality value is lower than 0.125 L/ha of test item.

The mortality of the ladybird beetles exposed to the reference item at the rate of 3.2 g of dimethoate/ha was equal to 100.0%. Therefore, the validity criterion was met. The results showed that the insects were sensitive to dimethoate. The mean number of fertile eggs/female/day in the control group was 6.0 (criterion: ≥ 2 eggs/female/day).

The mean numbers of fertile eggs/female/day in the group treated with the Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha were equal to 5.1, 6.7 and 4.2, and it refers to 14.2, -10.8 and 30.5% reproduction reduction, respectively. The negative value means that in the tested rate there was higher mean numbers of fertile eggs per viable female per day than in the control group.

It can be concluded that Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha had no adverse effect on the reproduction capacity of the ladybird beetle.

A 2.3.1.1.2 Study 6

Comments of zRMS:	The study was carried out according to current guidelines. The study is considered acceptable, validity criteria were met. • Pre-imaginal mortality within the control treatment was 0% (should not exceed 20.0%, i.e. 8 lacewings from 40). • Corrected pre-imaginal mortality within the toxic-reference treatment was 100% (should exceed 50%). • Mean egg production per female per day in the control treatment was 17.2 (should be ≥ 15.0 per female per day). • Mean egg viability in the control treatment was 86.0% (should be ≥ 70%). In the experimental part of the study a deviation from the guidelines developed by the IOBC, BART and EPPO Joint initiative (Vogt H. et al., 2000) occurred. This deviation is to use leaf discs as a surface instead of plastic discs Agreed endpoint: LR50 > 0.5 L prod./ha ER50 > 0.5 L prod./ha

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the green lacewing, *Chrysoperla carnea*, Fulczyk A. Study code: B-46-21
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Vogt H. et al., 2000)
Deviations:	Yes The study was conducted according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART and EPPO Joint Initiative (Vogt H. et al., 2000), SOP/B/62 and other procedures related to the study and the Study Plan. In the experimental part of the study a deviation from the guidelines developed by the IOBC, BART and EPPO Joint initiative (Vogt H. et al., 2000) occurred. This deviation is to use leaf discs as a surface instead

	of plastic discs. The deviations is due to the type of study ordered by the Sponsor.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	The following validity criteria were met during the study: – pre-imaginal mortality of the control group was 0.0% (criterion: a maximum of 20.0%), – mortality of the reference item group was 100.0% (criterion: a minimum of 50%), – the mean number of eggs per female per day in the control group (fecundity) was 17.2 (criterion: ≥ 15.0), – the mean hatching rate in the control group (fertility) was 86.0 (criterion: ≥ 70%).

SUMMARY

The extended laboratory test involved the evaluation of the effects of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on mortality and reproductive capacity of the green lacewing, *Chrysoperla carnea*. In a definitive test, three test item application rates were used. These were 0.125, 0.25 and 0.5 L/ha.
To assess mortality, 3-day-old larvae of *Chrysoperla carnea* were exposed to dry residues of the test item on leaf discs. Eggs of the mill moth *Ephestia kuehniella* were offered as food. After emergence of adults, total mortality was calculated on the basis of the numbers of dead larvae, pupae, and adults which died during emergence. There were 30 replicates of each treated group. Each of them contained 1 larva of *Chrysoperla carnea*.
To determine possible adverse effects of the test item on fecundity and fertility of the lacewings, reproductive performance was conducted. Total mortality of the lacewings, the mean number of eggs laid per female lacewing per day, and the mean hatching rate were the endpoints.
To control the sensitivity of the biological test system, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 15.0 g/ha. Control lacewings had contact with leaf discs sprayed with distilled water.

Material and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Content: 30.53 g/L of mesosulfuron-methyl (CAS No. 208465-21-8) 90.67 g/L of mefenpyr diethyl (CAS No. 135590-91-9) Batch number: 040322 Manufacturing date: 04.03.2022 Expiry date: 22.03.2024
Biological test system:	the green lacewing, *Chrysoperla carnea* (Steph.), Neuroptera: Chrysopidae

– age:	first instars' larvae (3 days old)
– source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from a commercial breeder (Katz Biotech AG, Germany),
Experimental design:	5 study groups: – a control group (0.0 L/ha) – Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of: – 0.125 L/ha – 0.25 L/ha – 0.5 L/ha – dimethoate at the rate of 15.0 g/ha number of replicates: 30 replicates/group number of larvae: 1 larva of *Chrysoperla carnea* /replicate
Test conditions:	– temperature: 23.2 – 27.0°C – relative air humidity: 60.0 – 89.9% – photoperiod: 16 hours light : 8 hours dark – light intensity 1743 lux
Statistical analysis:	Probit analysis using linear max. likelihood regression, Chi2 2x2 Table Test with Bonferroni Correction
Endpoints:	– cumulative mortality of larvae, pupae, and adults after emergence – LR_{50} value – reproduction of the lacewings: – fecundity (mean number of eggs/female/day) – fertility (mean hatching rate)

Results:

The effects of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on mortality and reproductive capacity the green lacewings, *Chrysoperla carnea* (Steph.) in the laboratory test are summarized below.

Study group [application rate]	Parameter (endpoints)				
	Mortality		Reproduction		
Test item: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)					
[L/ha]	[%]	LR_{50} [L/ha]	Mean number of eggs/ female/day [no.]	Mean hatching rate [%]	Reduction [%]
Control (0.0)	0.0	**> 0.5**	17.2	86.0	–
0.125	3.3		16.3	82.2	4.4
0.25	0.0		16.7	84.4	1.9
0.5	0.0		16.8	81.7	5.0
$NOER_{mortality}$	**≥ 0.5 [L/ha]**				
Reference item: Dimethoate					
[g/ha]	[%]	Reproduction			
15.0	100.0	not assessed			

Conclusions:

The validity criterion concerning mortality was met, because mortality of the green lacewings, *Chrysoperla carnea* (Steph.) in the control group was 0.0%. The percentages of mortality of the green lacewings exposed to the test item at the rates of 0.125, 0.25 and 0.5 L/ha of the test item were 3.3, 0.0 and 0.0%, respectively.

There were no statistically significant differences in mortality of the green lacewings in the groups treated with the test item at the rates of 0.125, 0.25 and 0.5 L/ha in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > Alpha*, (Alpha=0.05)).

On the basis of the obtained results it can be concluded that the LR50 value is higher than 0.5 L/ha. The $NOER_{mortality}$ value is higher than or equal to 0.5 L/ha. The percentage of mortality of *Chrysoperla carnea* (Steph.) exposed to dimethoate at rate of 15.0 g/ha was 100.0%. The results obtained in the reference item group indicated that the biological test system was sensitive to dimethoate.

The mean number of eggs/female/day in the control group was equal to 17.2 (criterion: ≥ 15.0). The mean numbers of eggs/female/day in the groups treated with the test item at the rates of 0.125, 0.25 and 0.5 L/ha were equal to 16.3, 16.7 and 16.8, respectively. The mean hatching rate in the control group was 86.0% (criterion: ≥ 70%). The mean hatching rate in the groups treated with the test item at the rates of 0.125, 0.25 and 0.5 L/ha were 82.2, 84.4 and 81.7%, respectively. Fecundity reduction (Pr) in the group treated with

the test item at the rates 0.125, 0.25 and 0.5 L/ha were 4.4, 1.9 and 5.0%, respectively.

Based on the results it can be stated that Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha has no adverse effect on mortality of the tested organisms. The test item at the rates of 0.125, 0.25 and 0.5 L/ha has no adverse effect on the mean number of layed eggs by green lacewings and no adverse effect on mean hatching rate at all tested rates, i.e. 0.125, 0.25 and 0.5 L/ha.

A 2.3.1.1.3 Study 7

Comments of zRMS:	The study was conducted according to the method IOBC Blümel et al. (2000). Validity criteria were met: - mortality in the control treatment over the initial 7 days did not exceed 20% (actual: 0%). - mortality in the toxic reference was 50-100 % (91 %). - the mean cumulative number of eggs produced between 7 and 14 days ex-ceeded 4.0 per female in the control treatment (actual 8.7 eggs/female) The study is acceptable and suitable for the use in the risk assessment. Deviation occurred in the experimental part of the study; in the definitive test there was a short term deviation (<2 h) from the recommended range of humidity. However it had no influence on the final results of the study. LR50> 0.5 l product/ha ER50> 0.5 l product/ha NOERmortality ≥ 0.5 L/ha NOERreproduction > 0.125 L/ha

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the predatory mite, *Typhlodromus pyri* (Sch.). Fulczyk A., 2023, Study code: B-69-20
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M. P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000))
Deviations:	Yes The experiment was performed according to the ESCORT 1 and the ESCORT 2 guidance documents, the guidelines developed by the IOBC, BART, and EPPO Joint Initiative, the Standard Operating Procedure SOP/B/36: ‘An extended laboratory test for evaluating the effects of plant protection products on the predatory mite, *Typhlodromus pyri* (Sch.)..

	According to the guideline developed by the IOBC, BART, EPPO Joint Initiative, as a food source only pollen was used. However, 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. There was a deviation occurred in the experimental part of the study; in the definitive test there was a short term deviation (<2 h) from the recommended range of humidity. However it had no influence on the final results of the study.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Test validity criteria:	The following validity criteria were met during the study: - mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%), -mortality of the mites exposed to the reference item at the rate of 4.0 g/ha, was 91.7% on day 7 of exposure (criterion: from 50 to 100%), -the cumulative mean number of eggs per female in the control group was 8.7 (required: ≥ 4 eggs per female).

SUMMARY

The aim of the extended laboratory test was to evaluate the effects of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 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 three rates of the test item in the definitive test. These were 0.125, 0.25 and 0.5 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 0.125, 0.25 and 0.5 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

Material and methods

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)
Content:	30.53 g/L of Mesosulfuron-methyl (CAS number: 208465-21-8) 90.67 g/L of Mefenpyr diethyl (CAS number: 135590-91-9) Batch number: 040322

	Manufacturing date: 04.03.2022 Expiry date: 22.03.2024
Biological test system:	the predatory mite, *Typhlodromus pyri* (Sch.) (Acari: Phytoseiidae)
– age:	24-hour-old protonymphs
– source:	a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented from a commercial breeder
Experimental design:	4 study groups: – a control group (0.0 L/ha) – the test item at the rate of 0.125 L/ha – the test item at the rate of 0.25 L/ha – the test item at the rate of 0.5 L/ha – reference item: dimethoate at the rate of 4.0 g/ha number of replicates: 3/group number of mites in each replicate: 20
Test conditions:	– temperature: 24.5 – 26.0°C – relative air humidity: 60.0 – 97.0% – photoperiod: 16 h light : 8 h dark – light intensity: 787 lx
Statistical analysis:	Probit analysis using linear max. likelihood regression Chi2 2x2 Table Test with Bonferroni Correction Shapiro Wilk's Test on Normal Distribution Levene's Test on Variance Homogenity (with Residuals) Williams Multiple Sequential t-test Procedure.
Endpoints:	– mite mortality after 7 days of the treatment – LR_{50} and $NOER_{mortality}$ – reproduction reduction (Pr) after 14 days of the treatment – ER_{50} and $NOER_{reproduction}$

Results:

In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at rates of 0.125, 0.25 and 0.5 L/ha, the percentages of mortality, were 1.7, 0.0 and 3.3%, respectively. There were no statistically significant difference in mortality of groups treated with the test item at all rates in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > Alpha*).

The LR_{50} value is higher than 0.5 L/ha. $NOER_{mortality}$ is higher than or equal to 0.5 L/ha. After 7 days of exposure to dimethoate at the rate of 4.0 g/ha, mortality was 91.7%. Therefore, the validity criterion specified in the method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

Reproduction of the surviving mites from the control group and all groups treated with test item was assessed since mortality of these groups was < 50.0%.

The mean reproduction rate (Rr) in the control group was 8.7 eggs/female. The mean Rr after 14 days of exposure to test item at the rates of 0.125, 0.25 and 0.5 L/ha were 8.2, 6.1 and 5.5 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.125, 0.25 and 0.5 L/ha were 6.0, 30.3 and 37.5%, respectively.

There were no statistically significant difference in reproduction between group treated with the test item at the rate of 0.125 L/ha and the control group (Williams Multiple Sequential t-test Procedure, |t||t*|). The calculated ER_{50} value is higher than 0.5 L/ha and $NOER_{reproduction}$ is 0.125 L/ha.

The effects of test item on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized in the table.

Parameter (endpoint)				
Mortality		**Reproduction**		
Test item rate [L/ha]	**Total [%]**	**Test item rate [L/ha]**	**Mean number of eggs/ female (Rr) [no.]**	**Repro-duction reduction Pr [%]**
control	0.0	**control**	8.7	–
0.125	1.7	**0.125**	8.2	6.0
0.25	0.0	**0.25⁺**	6.1	30.3
0.5	3.3	**0.5⁺**	5.5	37.5
LR_{50}	**> 0.5 L/ha**	**ER_{50}**	**> 0.5 L/ha**	
$NOER_{mortality}$	**≥ 0.5 L/ha**	**$NOER_{reproduction}$**	**0.125 L/ha**	
Reference item: dimethoate				
Rate [g/ha]	**Total [%]**	**Reproduction**		
4.0	91.7	not assessed		

⁺: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [12], [SOP/B/67]

A 2.3.1.1.4 Study 8

Comments of zRMS:	The study was conducted according to the method Mead-Briggs et al., 2000 and Mead-Briggs et al., 2010 Validity criteria were met: -mortality in the control treatment at 48 h did not exceed 10 % (actual: 0%). -mortality in the toxic reference treatment ≥50 % at 48 h (actual: 90 %). - all wasps survived the 24-hour oviposition period, -the mean number of mummies in the control treatment was >5.0 per per female

	(actual: 47) and no more than two females should fail to produce mummies (actual: no zero values). There were no deviations. The study is acceptable and suitable for the use in the risk assessment. 48h LR50> 0.5 l product/ha ER50> 0.5 l product/ha NOERmortality ≥ 0.5 L/ha NOERreproduction < 0.125 L/ha

Reference:	KCP 10.3.2
Report	An extended laboratory test for evaluating the effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez), Fulczyk A., 2023, Study code: B-70-20
Guideline(s):	according to the ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2010
Deviations:	Yes The experiment was performed according to the ESCORT 1 [1] and the ESCORT 2 guidance documents, the guidelines developed by the IOBC, BART, and EPPO Joint Initiative, the Standard Operating Procedure SOP/B/28: 'An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez.).. There were no deviations from mentioned documents.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Test validity criteria:	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 20.0 g/ha was 90.0% (criterion: a minimum of 50%), – all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity), – the mean number of mummies per female in the control group was 47.0 (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).

SUMMARY

The extended laboratory test involved the evaluation of the effects of the test item, Mesosulfuron 30 OD

(CHR/H/MEZO 30 OD) on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. On the basis of the results of the preliminary range-finding non-GLP test it was decided to use three rates of the test item in the definitive test. These were 0.125, 0.25 and 0.5 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 Mesosulfuron 30 OD (CHR/H/MEZO 30 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 from all the groups treated with the test item which survived the 48-hour exposure to test item and the ones from the control group were subjected to fecundity assessments. Fifteen female wasps from the four groups 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 20.0 g/ha. The control group was treated with distilled water.

Materials and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)	
	Batch number:	040322
	Production date:	04.03.2022
	Expiry date:	22.03.2024
	Active substance:	30.53 g/L of Mesosulfuron-methyl (CAS number: 208465-21-8) 90.67 g/L of Mefenpyr diethyl (CAS number: 135590-91-9)
Biological test system:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae	
– age:	imago (24 – 48 hours after emerging from mummies)	
– source:	breeding of the parasitic wasps at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from a commercial breeder (Katz Biotech AG)	
Experimental design:	5 study groups: – a control group (0.0 L/ha) – test item at the rate of 0.125 L/ha – test item at the rate of 0.25 L/ha – test item at the rate of 0.5 L/ha – reference item: dimethoate at the rate of 20.0 g/ha mortality assessment: 6 replicates/group, 5 females/replicate fecundity assessment: 15 replicates/group, 1 female/replicate	
Test conditions:	– temperature: 18.5 – 20.5°C	

– relative air humidity: 65.0 – 89.0%
– photoperiod: 16 hours light : 8 hours dark
– light intensity: mortality and oviposition assessment: 2053 lx fecundity phase: 4903 lx
Statistical analyses:
– Probit analysis using linear max. likelihood regression
– Shapiro-Wilk's Test on Normal Distribution
– Levene's Test on Variance Homogeneity
– Williams Multiple Sequential t-test Procedure
– One-way Analysis of Variance
– Multiple sequentially-rejective t-test after Bonferroni-Holm

Endpoints:
– wasp mortality after 48 hours of exposure
– LR_{50} and the $NOER_{mortality}$
– ER_{50} and the $NOER_{fecundity}$
– reduction in fecundity (Pr) of the surviving female wasps exposed to test item, 12 days after the oviposition period

Results:

In the definitive test, after 48 hours, mortality of the control wasps was 0.0%. After 48 hours of the exposure to Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha, the percentages mortality of *A. rhopalosiphi*, were 0.0% for each group.

Based on the obtained mortality results it could be assumed that the LR_{50} is higher than 0.5 L/ha and the $NOER_{mortality}$ is higher than or equal to 0.5 L/ha.

The mortality of the wasps exposed to dimethoate at the rate of 20.0 g/ha was 90.0% after 48 hours. Therefore, the validity criterion specified in the method description was met [6]. The results showed that the test organisms were sensitive to dimethoate.

At the significance level of 0.05, there were no statistically significant differences in the mean percentages of wasps settled on the plants between the test item groups at the rates of 0.125, 0.25 and 0.5 L/ha and the control group (Multiple sequentially-rejective t-test after Bonferroni-Holm, p(t) > alpha(i)). The NOER is higher than or equal to 0.5 L/ha.

The fecundity assessment showed that the mean number of mummies per female in the control group was 47.0 (after 12 days after oviposition). As for the wasps treated with test item at the rates of 0.125, 0.25 and 0.5 L/ha the mean number of mummies per female were 38.8, 33.0 and 30.5, respectively.

Fecundity reduction (Pr) in the group treated with the test item at the rates of 0.125, 0.25 and 0.5 L/ha were 17.4, 29.8 and 35.2%, respectively.

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 0.125, 0.25 and 0.5 L/ha and the control group (Williams Multiple Sequential t-test Procedure, $|t| > |t^*|$).

Based on the obtained fecundity results it could be assumed that the ER_{50} value is higher than 0.5 L/ha and the $NOER_{fecundity}$ is lower than 0.125 L/ha.

The effects of the test item, test item on mortality and fecundity of Aphidius rhopalosiphi in the extended

laboratory test are summarized below.

Parametr (endpoint)						
Mortality after 48 hours			**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	–	**Control**	47.0	–	–
0.125	0.0	**> 0.5**	**0.125⁺**	38.8	17.4	**> 0.5**
0.25	0.0		**0.25⁺**	33.0	29.8	
0.5	0.0		**0.5⁺**	30.5	35.2	
$NOER_{mortality}$	**≥ 0.5 L/ha**		**$NOER_{fecundity}$**	**< 0.125 L/ha**		
Reference item: dimethoate						
Rate [g/ha]	**Total mortality [%]**		**Fecundity**			
20.0	90.0		not assessed			

⁺: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [3], [SOP/B/67]

Conclusions:

On the basis of the obtained repellency results it can be concluded that Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha has no repellent properties.

On the basis of the obtained mortality results it can be concluded that Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha has no adverse effect on the mortality of the wasps, *A. rhopalosiphi*.

On the basis of the obtained fecundity results it can be concluded that Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the rates of 0.125, 0.25 and 0.5 L/ha has an adverse effect on the fecundity of the wasps, *A. rhopalosiphi*.

A 2.3.1.1.5 Study 9

Comments of zRMS:	The study was conducted according to the method Schmuck et al., 2000 Validity criteria were met:

	- Pre-imaginal mortality (this includes dead larvae, pupae and adults dying during emergence from their pupae) in the control treatment should not exceed 30% (actual 10%), - The level of mortality in the toxic reference treatment should be ≥ 50% (actual 92.%). - Mean egg production should be > 2 viable eggs/female/day in the control treatment (4 at 0 DAT and 9.5 at 14 DAT). There were no deviations. The study is acceptable and suitable for the use in the risk assessment.

Reference:	KCP 10.3.2
Report	CHR/H/MEZO 30 OD- A Series of Aged-Residue Extended Laboratory Tests to Determine Effects on the Ladybird Beeetle, Coccinella septempunctata (Coleoptera: Coccinellidae), Staden V.C., 2023, Study code: CHR-23-02
Guideline(s):	Schmuck et al. (2000) A laboratory test system for assessing effects of plant protection products on the plant-dwelling insect Coccinella septempunctata L. (coleoptera: Coccinellidae).
Deviations:	No
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Test validity criteria:	According to the guideline of Schmuck *et al.* (2000), for the test to be considered valid: a) Pre-imaginal mortality (this includes dead larvae, pupae and adults dying during emergence from their pupae) in the control treatment should not exceed 30%. b) The level of mortality in the toxic reference treatment should be 2: 50%. c) Mean egg production should be > 2 viable eggs/female/day in the control treatment. All of these criteria were met throughout the study, where applicable.

1. SUMMARY

Aims

The test item in this study was CHR/H/MEZO 30 OD, an oil dispersion formulation containing mesosulfuron-methyl (nominally 30 g/L) and the safener mefenpyr-diethyl (nominally 90 g/L). The aim of this study was to evaluate the effects of both freshly dried and field-aged foliar residues of the test item on the ladybird beetle, *Coccinella septempunctata* L. (Coleoptera: Coccinellidae), under

extended laboratory test conditions.

Methods

CHR/H/MEZO 30 OD was evaluated at a single application rate, equivalent to 0.5 L test item/ha. The bioassay programme commenced on the day of treatment application, with the test item being compared to a water-treated control. A toxic reference treatment of dimethoate (an EC formulation of nominally 400 g a.s./L, applied at a rate of 75 mL in 400 L water/ha) was also included in the initial bioassay only.

Treatments were applied to plants of the dwarf French bean, *Phaseolus vulgaris* L., var. The Prince). Applications were made using a hand-held small-plot sprayer fitted with a 2-m-wide spray boom. This was calibrated so that when the boom was moved over the tops of the plants it delivered a volume rate equivalent to 400 L spray solution/ha. Following treatment applications, the plants were maintained outdoors, but their foliage was protected from rainfall by suspending a sheet of polythene permeable to UV light above them.

Extended laboratory bioassays were carried out using leaves collected from the treated plants. The first bioassay commenced shmily after residues had dried following the treatment applications, hereafter referred to as O days after treatment (0 DAT), and a subsequent bioassay commenced at 14 DAT. Excised leaves were used to line the floor of the test arenas (n = 40 per treatment) into which individual larvae of
C. *septempunctata* (3-4 days old) were introduced. The larvae were fed with pea aphids *(Acyrthosiphon pisum* (Harris)) and any pre imaginal mortality of the ladybirds was recorded. A check was then made for sub-lethal effects on the reproductive performance of the adults surviving in the control and the test-item treatment rate in the 0 and 14 DAT bioassays, since the test item resulted in S 50% corrected pre-imaginal mortality in each bioassay. For this assessment, the number of eggs produced by the beetles (i.e., a measure of fecundity) was recorded for a 14-day period and the number that hatched (i.e., a measure of fertility) was also assessed.

The intention of the bioassay programme was to demonstrate that residues of the test item did not result in unacceptable effects in two consecutive bioassays (i.e., demonstrating that corrected pre-imaginal mortality was :S 50% and that certain fecundity and fertility criteria were met).

Results

The results of the mortality assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	% pre-imaginal mortality [a)]	Corrected % pre-imaginal mortality [b)]
0 DAT	Control	-	5.0	-
	CHR/H/MEZO 30 OD	0.5	7.5	2.6
	Toxic reference	-	92.5*	92.1
14 DAT	Control	-	10.0	-
	CHR/H/MEZO 30 OD	0.5	5.0	-5.6

a) For each bioassay, pre-imaginal mortality in the test item treatment, and the toxic reference treatment in the 0 DAT bioassay, was compared to the respective control using Fisher's exact binomial test (one sided, > control, $\alpha = 0.05$). An asterisk (*) indicates where differences were significant.

b) Corrected mortalities were calculated using Abbott's formula. A positive value indicates an increase in mortality, a negative value indicates a decrease in mortality, relative to the respective control.

The results of the reproduction assessments are summarised below.

Bioassay initiated	Treatment	Test-item rate (L/ha)	Mean no. eggs/♀/day	Mean % egg viability	Mean no. viable eggs/♀/day
0 DAT	Control	-	11.8	34.1	4.0
	CHR/H/MEZO 30 OD	0.5	9.6	36.6	3.5
14 DAT	Control	-	20.5	46.0	9.5
	CHR/H/MEZO 30 OD	0.5	22.8	50.1	11.4

In the 0 and 14 DAT bioassays, the mean numbers of viable eggs produced in all the treatments evaluated was ≥ 2.0 eggs/female/day. This threshold is currently viewed as being indicative of no harmful treatment effects.

Conclusions

The effects of both fresh and aged foliar residues of CHR/H/MEZO 30 OD on the ladybird beetle, *Coccinella septempunctata,* were evaluated under extended laboratory conditions. When applied at a rate equivalent to 0.5 L test item/ha, freshly-dried (0-day-old) residues and 14-day-old field-aged residues of CHR/H/MEZO 30 OD showed no unacceptable effects on either the survival, or the subsequent reproductive capacity, of the ladybirds.

A 2.3.2 KCP 10.3.1 Effects on bees

A 2.3.2.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.2.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

A 2.3.2.1.2 Study 10

Comments of zRMS:	The study is acceptable. The validity criteria were met. The study was conducted according to OECD guidance 213. The following endpoint was accepted: Oral LD50 > 200 µg product/bee

Reference:	KCP 10.3.1.1.1
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test. Fulczyk A., 2023, Study code: B-72-20
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	Yes The test was performed according to the OECD Guideline for the Testing of Chemicals No. 213 (1998): 'Honeybees, acute oral toxicity test', the EU Method C.16 (2008): 'Honeybees, acute oral toxicity test' and other references.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	The following validity criteria were met during the test: - the mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%). - the LD_{50}/24 h of the reference item (dimethoate) was 0.15 µg a.i./bee (criterion:0.10 – 0.35 µg a.i./bee).

The acute oral toxicity study of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) was conducted to determine the LD_{50}. Five doses of the test item were used. These included: 12.5, 25.0, 50.0, 100.0 and 200.0 µg/honeybee. The range of doses was selected on the basis of the preliminary non-GLP range-finding test results.

Each group of 10 bees (3 replicates containing 10 bees each) was fed with 100 µL of 50% sucrose solution, containing the test item at the doses mentioned above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.

The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.

After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute oral toxicity test finished after the 48-hour observation.

Material and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) content: 30.53 g/L of mesosulfuron-methyl (CAS No. 208465-21-8) 90.67 g/L of mefenpyr diethyl (CAS No. 135590-91-9) batch no.: 040322 production date: 04.03.2022 expiry date: 22.03.2024
Biological test system: – age: – source:	the honeybee, *Apis mellifera* L., strain: carnica approximately 3 weeks an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna
Test design:	the test item: -exposure duration: 48 hours -number of doses: 5 doses and a control -number of replicates: 3 replicates -number of bees: 10 bees/replicate
Test item doses:	12.5, 25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses:	0.1, 0.2 and 0.4 µg a.i./bee
Test conditions:	– temperature: 24.0 – 25.0°C – relative air humidity: 62.5 – 64.5%
Place:	dark room
Statistical analysis:	Probit analysis using linear max. likelihood regression
Endpoints:	– honeybee mortality after 24 and 48 hours of the test item exposure, – the oral LD_{50}/24 h of the reference item (dimethoate).

Results:

The acute oral toxicity study of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on honeybees (*Apis mellifera* L.) in the laboratory test are summarized below.

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment		LD_{50} [µg/bee]
		Total		
		[no.]	[%]	
0.0 (Control)	30	0	**0.0**	**> 200.0**
12.5	30	0	**0.0**	
25.0	30	0	**0.0**	
50.0	30	1	**3.3**	
100.0	30	1	**3.3**	
200.0	30	1	**3.3**	

A 2.3.2.1.3 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.2.1.4 Study 11

Comments of zRMS:	The study is acceptable. The validity criteria were met. The study was conducted according to OECD guidance 214 with minor deviations - anesthesia recommended by the OECD Guideline No. 214 / EU Method C.17. was replaced with immobilization. The mentioned deviation had not effect on the results of the study. The following endpoint was accepted:: Contact LD50 > 200 µg product/bee

Reference:	KCP 10.3.1.1.2
Report	Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008). Fulczyk A., 2023, Study code B-73-20
Deviations:	Yes The study was performed according to the the OECD Guideline No. 214/EU Method C.17., references given in section 9, SOP's listed in section 10 of the report, and the study plan. However, According to the Guideline No. 214/ EU Method C.17., the honeybees may be anesthetized with carbon dioxide for application of the test item. Anesthesia was replaced with mechanical immo-bilisation.
GLP:	Yes
Acceptability:	

Duplication (if vertebrate study)	No
Validity criteria	The following validity criteria were met during the test: -the mortality for the control was 0.0% after 48 h (criterion: it must not exceed 10.0%), -the LD_{50}/24 h of the reference item (dimethoate) was 0.27 µg a.i./bee (criterion: 0.10 – 0.30 µg a.i./bee).

SUMMARY

Mortality of honeybees, *Apis mellifera*, exposed to Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) was investigated during 48-hour test. Five doses of the test item were used. These included: 12.5, 25.0, 50.0, 100.0 and 200.0 µg/honeybee. The range of doses was selected on the basis of the preliminary non-GLP range-finding test results. A microapplicator was used to apply the test item. The volume was 1 µL/bee. During the experiment, the insects were caged in groups of 10. The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure. After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

Material and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) content: 30.53 g/L of mesosulfuron-methyl (CAS No. 208465-21-8) 90.67 g/L of mefenpyr diethyl (CAS No. 135590-91-9) batch no.: 040322 production date: 04.03.2022 expiry date: 22.03.2024
Biological test system: – age: – source:	the honeybee, *Apis mellifera* L., strain: carnica approximately 3 weeks an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna
Test design:	the test item: – exposure duration: 48 hours – number of doses: 5 doses with surfactant and two controls: water control and control with surfactant (1% Triton) – number of replicates: 3 replicates – number of bees: 10 bees/replicate
Test design:	the reference item: – exposure duration: 24 hours – number of doses: 3 doses with surfactant – number of replicates: 3 replicates

Test item doses:	– number of bees: 10 bees/replicate 12.5, 25.0, 50.0, 100.0 and 200.0 µg test item/bee and water control (0.0 µg/bee), 1% Triton control (0.0 µg/bee)
Reference item doses:	0.1, 0.2 and 0.4 µg a.i./bee
Test conditions:	– temperature: 24.5 – 25.5°C – relative air humidity: 62.0 – 64.0%
Place:	dark room
Statistical analysis:	Probit analysis using linear max. likelihood regression
Endpoints:	– honeybee mortality after 24 and 48 hours of the exposure, – the contact LD_{50}/24 h of the reference item (dimethoate).

Results:
The acute contact toxicity study of the test item, Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on honeybees (*Apis mellifera* L.) in the laboratory test are summarized below.

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h of exposure		LD_{50} [µg/bee]
		Total		
		[no.]	[%]	
0.0 (water control)	30	0	0.0	> 200.0
0.0 (1% Triton control)	30	0	0.0	
12.5	30	0	0.0	
25.0	30	0	0.0	
50.0	30	0	0.0	
100.0	30	0	0.0	
200.0	30	0	0.0	

Conclusions:
The median lethal doses LD_{50}/24 h and LD_{50}/48 h are higher than the highest dose used in the test, i.e. 200.0 µg/honeybee.

A 2.3.2.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.2.2.1 Study 12

Comments of zRMS:	The study was conducted in accordance with OECD 245.

	All validity criteria for the study were met. After 10 days of continuous exposure, mortality in the control was 8 % and thus below the threshold of 15 %. Mortality in the reference treatment group was 100 % and thus above the threshold of 50 %. Study is acceptable. Following endpoint are accepted: LDD50 > 15.1 µg/bee/day NOEC ≥ 666.7 mg/kg, the NOEDD ≥ 15.1 µg/bee/day

Reference:	KCP 10.3.1.2.
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Honeybees (*Apis mellifera* L.), Chronic Oral Toxicity Test, Fulczyk A., 2023, Study code B-71-20
Guideline(s):	OECD Guideline No. 245 (2017)
Deviations:	Yes
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	The following validity criteria were met during the test: -At the end of the experiment average mortality of the control groups was 8.0% (criterion: it must not exceed 15%), . -After 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.8 mg/kg (dietary dose: 0.011 µg/bee/day) was 100.0% (criterion: it must be ≥ 50% on day 10 of exposure).

SUMMARY

The mortality of honeybees exposed to Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) was investigated during 10-days chronic oral toxicity test.

The design of the definitive test was selected on the basis of the preliminary range-finding non-GLP test results. One dose of the test item was used (limit test). The nominal concentration was 666.7 mg/kg of diet (corresponding to the nominal dose of 20.0 µg/30 mg/day).

Daily dose, consumed by the bees in the group treated with the test item at the nominal concentration of 666.7 mg/kg (20 µg/30 mg/day) was 15.1 µg/bee/day (dietary dose). Daily dose was calculated on the basis of average consumption of a treated 50% sucrose solution and the nominal dose used for the treatment.

Each group of bees (5 replicates/group; 10 bees/replicate) was fed with 2 mL of a 50% sucrose solution containing the test item at the concentration of 666.7 mg/kg or 50% sucrose solution alone (control group) for 10 days.

Dimethoate, which is a recommended reference item, was used to verify the sensitivity of the bees and the precision of the test procedure. The group treated with the reference item (3 replicates per 10 bees) was fed the with 2 mL of a 50% sucrose solution containing reference item at the nominal concentration of 0.8 mg/kg (corresponding to the nominal dose of 0.024 µg/30 mg). Daily weighed feeders were used. During the experiment, the insects were caged in groups of 10. Daily dose, consumed by the bees in the group treated with the reference item at the nominal concentration of 0.8 mg/kg (0.024 µg/30 mg/day) was 0.011 µg/bee/day (dietary dose).

The insects were observed for mortality and behavioral abnormalities (signs of intoxication) at daily intervals up to 10 days of exposure.

Average consumption of a 50% sucrose solution in the control group was 21.72 mg/bee/day. Average consumption in the group treated with the test item at the concentration of 666.7 mg/kg was 22.62 mg/bee/day. Average consumption of a 50% sucrose solution containing the reference item at the concentration of 0.8 mg/kg was 13.68 mg/bee/day.

The concentrations of mesosulfuron-methyl and mefenpyr diethyl were chemically determined using the validated high performance liquid chromatographic method with DAD detection. Fresh samples of the test item concentration and the control were chemically analyzed at test initiation and at the end of the maximum storage period (i.e. after 4 days). At exposure initiation, in the fresh sample of the test item of 666.7 mg/kg, the determined concentration of mesosulfuron-methyl was 88.2% of nominal concentration and the concentration of mefenpyr diethyl was 95.2% of nominal concentration. The results confirm that the test item concentration was prepared correctly.

After 4 days of the storage period, in the sample of the test item of 666.7 mg/kg, the determined concentration of mesosulfuron-methyl was 88.3% of nominal concentration and the concentration of mefenpyr diethyl was 92.9% of nominal concentration. Based on the results of chemical analyses, the concentrations of mesosulfuron-methyl and mefenpyr diethyl were stable under storage conditions.

Material and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) content: 30.53 g/L of mesosulfuron-methyl (CAS No. 208465-21-8) 90.67 g/L of mefenpyr diethyl (CAS No. 135590-91-9) batch no.: 040322 production date: 04.03.2022 expiry date: 22.03.2024
Biological test system:	species: the honeybee, *Apis mellifera* L.; strain: carnica, source:an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; age: freshly emerged worker honeybees (max. 2 days old) from the same queen-right colony
Experimental design:	-the test item: number of concentrations: 1 and the control number of replicates: 5

	number of insects: 10 bees/replicate - the reference item: number of concentrations: 1 number of replicates: 3 number of insects: 10 bees/replicate exposure duration: 10 days
Nominal concentration of the test item:	666.7 mg/kg
Nominal dose of the test item:	20.0 µg/bee/day
Test item dietary dose:	15.1 µg/bee/day
Nominal concentration of the reference item (dimethoate):	0.8 mg/kg
Nominal dose of the reference item (dimethoate):	0.024 µg/bee/day
Reference item dietary dose:	0.011 µg/bee/day
Test conditions:	temperature: 32.7 – 34.5°C; relative humidity: 50.0 – 64.4%;
Statistical method:	Levene's Test on Variance Homogeneity (with Residuals), Multiple Sequentially-rejective t-test After Bonferroni-Holm
Endpoints:	honeybee mortality after 10 days of exposure

Results:

The validity criterion concerning mortality was met, because mortality in the control was 8.0% after 10 days of exposure (criterion: it must not exceed 15%). The percentage of mortality of the honeybees exposed to the test item, at the concentration of 666.7 mg/kg (dietary dose 15.1 µg/bee/day) at exposure termination (after 10 days), was 2.2%, after Abbott's correction. On the basis of the obtained mortality results, it can be concluded that the LC50 is higher than 666.7 mg/kg, and the LDD50 value is higher than 15.1 µg/bee/day. There is no statistically significant differences in mortality between group treated with the test item at the dose of 666.7 mg/kg (dietary dose 15.1 µg/bee/day) and the control group (Multiple Sequentially-rejective t-test After Bonferroni-Holm, Alpha = 0.05, p(t) > Alpha(i)). The NOEC value is higher than or equal 666.7 mg/kg, the NOEDD value is higher than or equal 15.1 µg/bee/day. The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because mortality was equal to 100.0% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate.

The effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on mortality of honeybees are summarized below:

Nominal test item concentration/ dose		Ingested[a] dose [µg/bee/day]	Number of tested bees [no]	Total mortality		LC_{50} [mg/kg]	LDD_{50} [µg/bee/day]
[µg/30 mg/day] [µg/bee/day]	[mg/kg]			No.	[%]		
Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)							
0.0 (Control)			50	4	**8.0**	**> 666.7**	**> 15.1**
20.0	**666.7**	**15.1**	50	5	**2.2***		
NOEC			**≥ 666.7 mg/kg**				
NOEDD			**≥ 15.1 µg/bee/day**				
Dimethoate (reference item)							
0.024	**0.8**	**0.019**	30	30	**100.0**	not determined	

[a]: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item / reference item and average sucrose solution consumption
*: corrected according Abbott's formula [7]

A 2.3.2.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A 2.3.2.3.1 Study 13

Comments of zRMS:	The study was conducted in accordance with OECD 239. The validity criteria with regards to control larval mortality on D8, control adult emergence on D22 and toxicity of the reference item were met. Study is acceptable. There were deviations from guideline, temperature as well as humidity deviated from the range of values specified in the guidelines. Temperature and humidity: - for larval stage (day 1-8): average temperature 34.112°C (min 32.8°C; max 34.4°C); average relative humidity 88.846% (min 58.6%; max 91.3%), - for pre-pupal stage (day 8-15): average temperature 34.236°C (min 34.2°C; max 34.3°C); average relative humidity 72.246% (min 71.2%; max 76.7%), - for pupal/imago stage (day 15-22): average temperature 33.732°C (min 32.3°C; max 36.5°C); average relative humidity 62.383% (min 56.2%; max 72.7%). According to study director deviations did not affect the course of the study and the reliability of the study.

	Study is acceptable.

Reference:	KCP 10.3.1.3
Report	Honey bee larval toxicity test following repeated exposure of the test item Mesosulfuron 30 OD (CHR/H/MEZO 30 OD), Woźniak A., 2023, Study code: 0038/0104/E
Guideline(s):	OECD GD 239 ENV/JM/MONO(2016)34
Deviations:	Yes *Deviations from Guideline / Standard Experimental Procedure / Study plan* During the, range-finding, definitive and reference test 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 changes which did not affect the condition of the test system. The above deviations did not affect the test result. The study met the validity criteria.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria:	The test met the validity criteria (acc. to OECD GD 239 OECD GD 239 ENV/JM/MONO(2016)34): -in control group cumulative larval mortality from day 3 to day 8 was 11.110% (required: ≤15%), - in control group the adults emergence rate on day 22 was 77.780% (required: ≥70%), -for dimethoate as reference item, the larval mortality on day 8 was 100.00% (required: ≥50%).

SUMMARY

The assessment test of the test item Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) toxicity on honey bee larvae (*Apis mellifera* L.) was conducted in accordance with the OECD GD 239 ENV/JM/MONO(2016)34 Guideline.

During the test, the impact on the successive stages of development of the honey bee, resulting from the repeated exposure of the larval stage to the test item, were determined. The aim of the study was to determine the concentration of the test item causing the mortality of 50% of the population in the test (LC_{50} value) and the dose of the test item causing the mortality of 50% of the population after 22 days (LD_{50} value). The values of NOEC and NOED, LC_{10}/LD_{10} and LC_{20}/LD_{20} were determined for emerged adults (survival) on the 22nd day of the study

Test design	stability test: tested concentrations and control in one replicate range-finding, definitive test: tested concentrations and control in one replicate; 36 larvae per replicate, 12 larvae from 3 different breeding reference test: tested concentration and control in one replicate; 36 larvae per replicate, 12 larvae from 3 different breeding
Test cages	stability test: volumetric flask of 100 mL volume range-finding, definitive, reference test: 48-well breeding plates with queen-cell cups placed in the dissector and placed in incubator; from day 15 of the test – transparent plastic boxes placed in test room
Exposition time	4 days (from day 3 to day 6)
Duration of the test	stability test: 72 hours Range-finding, definitive, reference test: 22 days
Tested concentrations (doses)	stability test: control (0 g of test item/L of solution) 0.05 g of test item/L of solution, corresponding to 0.65 mg of test item/kg of food 50 g of test item/L of solution, corresponding to 650 mg of test range-finding test: control (0 mg of test item/kg of food), corresponding to 0 µg of test item/larva (0 g of test item/L of solution) 0.65 mg of test item/kg of food, corresponding to 0.1 µg of test item/larva (0.05 g of test item/L of solution) 6.5 mg of test item/kg of food, corresponding to 1 µg of test item /larva (0.50 g of test item/L of solution) 65 mg of test item/kg of food, corresponding to 10 µg of test item /larva (5.0 g of test item/L of solution) 650 mg of test item/kg of food, corresponding to 100 µg of test item /larva (50.0 g of test item/L of solution) definitive test (limit test): control (0 mg of test item/kg of food)), corresponding to 0 µg of test item/larva (0 g of test item/L of solution)

	650.00 mg of test item/kg of food, corresponding to 100.00 µg of test item/larva (50.0 g of test item/L of solution) reference test: control - 0 mg of reference item/kg of food dimethoate: 48 mg of reference item/kg of food i.e. 0.053 µg of reference item/µL, corresponding to 7.39 µg of reference item/larva (0.528 g of reference item/L of solution)
Test conditions	stability test: average temperature 5.707°C (min 4.9°C; max 8.0°C); darkness range-finding test: - for larval stage (day 1-8): average temperature 34.740°C (min 33.8°C; max 34.9°C); average relative humidity 95.039% (min 83.8%; max 97.0%), darkness* - for pre-pupal stage (day 8-15): average temperature 34.546°C (min 33.3°C; max 34.7°C); average relative humidity 78.318% (min 73.5%; max 86.5%), darkness* -for pupal/imago stage (day 15-22): average temperature 34.442°C (min 32.9°C; max 34.9°C); average relative humidity 74.902% (min 73.4%; max 75.6%), darkness* definitive test and reference test: -for larval stage (day 1-8): average temperature 34.112°C (min 32.8°C; max 34.4°C); average relative humidity 88.846% (min 58.6%; max 91.3%), darkness* -for pre-pupal stage (day 8-15): average temperature 34.236°C (min 34.2°C; max 34.3°C); average relative humidity 72.246% (min 71.2%; max 76.7%), darkness -for pupal/imago stage (day 15-22): average temperature 33.732°C (min 32.3°C; max 36.5°C); average relative humidity 62.383% (min 56.2%; max 72.7%), darkness*

* *Deviations from the Study plan were found concerning changes in temperature and humidity during larval, pre-pupal and pupal/imago stage during the range-finding, definitive and reference test. The above deviations did not affect the test result. The study met the validity criteria. Deviations from the Study plan are described in details in point 6.*

Final results

In course of the experiment, the test item has shown no apitoxic effect in mortality of following developmental stages of bees after 22 days of the test. At the end of the study, the concentration and the dose causing 10%, 20% and 50% mortality of the population in the test (LC_{10}, LC_{20}, LC_{50} and LD_{10}, LD_{20}, LD_{50} values) were determined, as well as NOEC and NOED values were determined at 22nd day.
The final results of the experiment are presented in Table 1.

Table 1. Final results of the study

Parameter	Concentration [mg of test item/kg of food]	Parameter	Dose [µg of test item/larva]
LC_{10}	> 650*	LD_{10}	> 100*
LC_{20}	> 650*	LD_{20}	> 100*
LC_{50}	> 650*	LD_{50}	> 100*
NOEC	≥ 650*	NOED	≥ 100*
LOEC	> 650*	LOED	> 100*

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
LOEC the lowest test item concentration 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

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

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1.1 Study 13

Comments of zRMS:	The study was performed according to OECD TG 222 and principles of GLP. The validity criteria are met. For the control group: - Adult mortality: ≤ 10 % (being 3.8%) - Number of juveniles per replicate: ≥ 30 (being 86 to 149) - Coefficient of variation of reproduction: ≤ 30 % (being 17.8 %). One deviation was recorded. The amount of calcium carbonate to adjust the pH should be in the range from 0.04 to 0.055%. In the study, the needed amount of calcium carbonate was equal to 0.15%, therefore it is a deviation from the SOP/G/122. According to the OECD Guideline the amount of $CaCO_3$ should be less than 1.0%. The applied quantity of the calcium carbonate in the study was in line with OECD assumptions. The deviation did not affect the results of the study. The study is considered acceptable and suitable for the risk assessment. NOEC > 1000 mg test item/kg soil dry weight (equivalent to 32.1 mg of

	mesosulfuron-methyl + 95.4 mg of mefenpyr-diethyl/kg dry weight of the artificial soil)

Reference:	KCP 10.4.1
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Earthworm reproduction test (*Eisenia andrei*), Wróbel A., 2023, Study code: G-45-20
Guideline(s):	OECD Guideline No. 222 (2016)
Deviations:	Yes *The deviation from the SOP/G/122*: As it is indicated in the SOP/G/122, the amount of calcium carbonate to adjust the pH should be in the range from 0.04 to 0.055%. In the study, the needed amount of calcium carbonate was equal to 0.15%, therefore it is a deviation from the SOP/G/122. According to the OECD Guideline the amount of $CaCO_3$ should be less than 1.0%. The applied quantity of the calcium carbonate in the study was in line with OECD assumptions. The deviation did not affect the results of the study
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	

SUMMARY

The aims of the study were to assess the impact of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on reproduction of the earthworm, *Eisenia andrei* and to determine EC_{10}, EC_{20}, EC_{50} and NOEC. The test item in the form of an aqueous suspension was mixed with a suitable amount of the artificial soil. Ten 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 experiment 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 experiment.

Materials and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) batch no.: 040322
Active substance:	Mesosulfuron-methyl – 30.53 g/L
Safener:	mefenpyr-diethyl – 90.67 g/L
Artificial soil:	10% sphagnum peat, 20% kaolin clay, 69.85% air-dried quartz sand,

	0.15% calcium carbonate;
Test organism:	the earthworm, *Eisenia andrei* obtained from a standard laboratory culture cultivated at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology
Test design:	test duration: 8 weeks; number of replicates: 4 replicates/concentration + 8 replicates/control; number of earthworms: 10 earthworms/replicate
Concentrations of the test item:	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
Test conditions:	temperature: 20.1 – 22.0°C; pH at the beginning of the experiment: 5.55 – 5.63; pH at the end of the experiment: 5.55 – 5.63; soil moisture content at the beginning of the experiment: 19.2 – 20.6% (43.4 – 46.6% of the maximum water holding capacity); soil moisture content at the end of the experiment: 18.1 – 19.6% (40.9 – 44.3% of the maximum water holding capacity); light-dark cycle: 16h : 8h; light intensity at the beginning of the experiment: 647.2 – 708.3 lux light intensity at the end of the experiment: 648.3 to 652.1 lux
Statistical analysis:	EC_{10}, EC_{20}, EC_{50} – probit analysis using linear max. likelihood regression LC_{50} – probit analysis using linear max. likelihood regression NOEC (reproduction): - Shapiro-Wilk's Test on Normal Distribution, - Bartlett's Test Procedure on Variance Homogeneity, - Williams Multiple Sequential t-test Procedure, NOEC (survival): - Fisher's Exact Binomial Test with Bonferroni Correction LOEC: a values suggested by the ToxRat Professional 2.10 statistical computer software
Endpoint:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC (reproduction) LC_{50}, NOEC, LOEC (survival)

Results:

At concentrations ranging from 5.6 to 1000.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was between 0.0 and 2.5%. As for the control group, mortality of the adult earthworms was equal to 3.8%. The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is above 1000.0 mg/kg dry weight of the artificial soil (i.e. 32.1 mg of mesosulfuron-methyl + 95.4 mg of mefenpyr-diethyl/kg dry weight of the artificial soil). No changes in the appearance (morphology) and behaviour of the living adult earthworms were noticed.

After 4 weeks of the exposure period of the test item at the concentrations ranging from 5.6 to 1000.0

mg/kg dry weight of artificial soil, the body weight increase was between 36.6 and 45.7%. As for the control group, the body weight increase was equal to 39.2%.

After 8 weeks of the experiment, the obtained results led to the following conclusions:

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 104.0 and 124.0 per replicate. The mean number of juveniles in the control group was equal to 111.8 per replicate.

After 8 weeks of the experiment, it was concluded that Mesosulfuron methyl 30 OD (CHR/H/MEZO 30 OD) had no a 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

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of mesosulfuron-methyl/kg dry weight of artificial soil]	Value [mg of mefenpyr-diethyl/kg dry weight of artificial soil]
EC_{10}	> 1000.0	> 32.1	> 95.4
EC_{20}	> 1000.0	> 32.1	> 95.4
EC_{50}	> 1000.0	> 32.1	> 95.4
NOEC (reproduction)	≥ 1000.0	≥ 32.1	≥ 95.4
LOEC (reproduction)	> 1000.0	> 32.1	> 95.4
LC_{50}	> 1000.0	> 32.1	> 95.4
NOEC (survival)	≥ 1000.0	≥ 32.1	≥ 95.4
LOEC (survival)	> 1000.0	> 32.1	> 95.4

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

A 2.4.2.1.1 Study 14

Comments of zRMS:	The study was performed according to OECD TG 232 and principles of GLP. The validity criteria were met. For the control group: - Mean adult mortality: ≤ 20 % (observed: 7.5%) - Mean number of juveniles per test vessel: ≥100 (observed at the end of the test 497.1) - Coefficient of variation for the mean number of juveniles: < 30 % (observed: 22.1%) The following deviations were recorded:

	Deviations from the OECD Guideline No. 232 (2016): - culturing of collembolans takes place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232 (2016) (3.3), - 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) (3.6.6). Deviation from the SOP/G/122: As it is indicated in the SOP/G/122, the amount of calcium carbonate to adjust the pH should be in the range from 0.02 to 0.04%. In the study, the needed amount of calcium carbonate was equal to 0.12%, therefore it is a deviation from the SOP/G/122. According to the OECD Guideline the amount of CaCO3 should be less than 1.0%. The applied quantity of the calcium carbonate in the study was in line with OECD assumptions. The deviations did not affect the results of the study. The study is considered acceptable and suitable for the risk assessment. $NOEC_{repr.}$ = 560 mg test item/kg soil dry weight (equivalent to 18.0 mg of mesosulfuron-methyl + 53.45 mg of mefenpyr-diethyl/kg dry weight of the artificial soil).

Reference: KCP 10.4.2

Report: Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Collembolan (*Folsomia candida*) Reproduction Test. Pieczka P., 2023, Study code G-46-20

Guideline(s): OECD Guideline No. 232 (2016)

Deviations: Yes

Deviations from the OECD Guideline No. 232 (2016):

- culturing of collembolans takes place in plastic containers containing an artificial substrate consisting of plaster and charcoal in ratio 9:1 and not 10:1 or 8:1 as is mentioned in OECD Guideline No. 232 (2016) (3.3),

- 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) (3.6.6).

Deviation from the SOP/G/122:

As it is indicated in the SOP/G/122, the amount of calcium carbonate to adjust the pH should be in the range from 0.02 to 0.04%. In the study, the needed amount of calcium carbonate was equal to 0.12%, therefore it is a deviation from the SOP/G/122. According to the OECD Guideline the amount of CaCO3 should be less than 1.0%. The applied quantity of the calcium carbonate in the study was in line with OECD assumptions. The deviations did not affect the results of the study

GLP: Yes

Acceptability:

Duplication (if vertebrate study)	No
Validity criteria:	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: 497.1 (criterion: ≥100 juveniles at the end of the test), • the coefficient of variation calculated for the number of juveniles: 22.1% (criterion: ≤ 30%).

SUMMARY:

The aims of the study were to assess the impact of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on reproduction of the collembolans, *Folsomia candida* and to determine the EC_{10}, EC_{20}, EC_{50}, and NOEC. Ten concentrations of the test item were used. These were 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 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.

Materials and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) batch no.: SCL – 040322
Active substance:	mesosulfuron-methyl – 30.53 g/L
Safener:	mefenpyr diethyl – 90.67 g/L
Artificial soil:	5% sphagnum peat, 20% kaolin clay, 74.88% airdried industrial sand and 0.12% calcium carbonate,
Test organism:	the collembolan, *Folsomia candida* obtained from a standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Laboratory of Soil Organisms Toxicology. The collembolans used in the study were between 9 and 12 days old.
Test design:	test duration: 28 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of collembolans: 10 / replicate

Concentrations of the test item: a control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg of the test item/kg of dry weight of the artificial soil

Test conditions:	temperature: 20.5 – 22.0°C; pH at the beginning of the test: 5.89 – 5.93; pH at the end of the test: 5.83 – 5.92;

soil moisture content at the beginning of the test: 15.1 – 16.1% (43.1 – 45.9% of the maximum water holding capacity);
soil moisture content at the end of the test: 14.9 – 16.2% (42.5 – 46.2% of the maximum water holding capacity);
lighting: 16 h light and 8h dark;
light intensity at the beginning of the experiment: 607.2 – 668.5 lux;
light intensity at the end of the experiment: 694.5 – 724.3 lux;

Statistical analysis: EC_{10}, EC_{20}, EC_{50} – 4-param. Normal CDF
LC_{10}, LC_{20}, LC_{50} – logit 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),
- Trend analysis by Contrasts (Monotonicity of Concentration/Response),
- Dunnett's Multiple t-test Procedure NOEC (survival):
- Qualitative Trend Analysis by Contrasts (Monotonicity of Concentration/Response)
- Chi2 2x2 Table Test with Bonferroni Correction Endpoints: EC_{10}, EC_{20}, EC_{50}, NOEC LC_{10}, LC_{20}, LC_{50}, NOEC.

Results:

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 mortality of adults ranged from 7.5 to 50.0%. As for the control group, it was equal to 7.5%.
The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the Table given below.

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of mesosulfuron-methyl /kg dry weight of the artificial soil]	Value [mg of mefenpyr diethyl/kg dry weight of the artificial soil]
LC_{10}	287.2 (6.5 – 823.7)	9.23 (0.21 – 26.47)	27.41 (0.62 – 78.62)
LC_{20}	614.3 (216.0 - >1000.0)	19.74 (6.94 - >32.14)	58.63 (20.62 - >95.44)
LC_{50}	>1000.0	>32.14	>95.44
NOEC	560.0	18.00	53.45

After the exposure of collembolans to 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 264.3 – 565.8 per replicate. As for the control group, the number of juveniles was equal 497.1 per replicate. The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in the Table given below.

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of mesosulfuron-methyl /kg dry weight of the artificial soil]	Value [mg of mefenpyr diethyl/kg dry weight of the artificial soil]
EC_{10}	601.3 (305.7 - >1000.0)	19.32 (9.82 - >32.14)	57.39 (29.18 - >95.44)
EC_{20}	746.6 (364.8 - >1000.0)	23.99 (11.72 - >32.14)	71.26 (34.82 - >95.44)
EC_{50}	>1000.0 (387.5 - >1000.0)	>32.14 (12.45 - >32.14)	>95.44 (36.98 - >95.44)
NOEC	560.0	18.0	53.45

A 2.4.2.1.2 Study 15

Comments of zRMS:	The study was performed according to OECD TG 226 and principles of GLP. The validity criteria were met. For the control group: - Mean mortality of adult females: ≤ 20 % (observed: 0.0 %) - Mean number of juveniles per replicate: ≥ 50 (observed: 99.8) - Coefficient of variation (mean number of juveniles per replicate): ≤ 30 % (observed: 20.0 %) There are three deviations from the OECD Guideline No. 226 (2016), however they did not affect the results: 1. According to the OECD Guideline No. 226 (2016) the water content of the artificial soil 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. 2. 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. 3. 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. The study is considered acceptable and suitable for the risk assessment. $NOEC_{repr}$ ≥ 1000 mg test item/kg soil dry weight (equivalent to ≥ 32.14 mg of mesosulfuron-methyl + 95.44 mg of mefenpyr-diethyl/kg dry weight of the artificial soil).

Reference:	KCP 10.4.2
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Predatory mite (*Hypoaspis (Geolaelaps) aculeifer)* reproduction test in soil. Wróbel A., 2023, Study

	code G-47-20
Guideline(s):	according to the OECD Guideline No. 226 (2016)
Deviations:	Yes *Deviations from the OECD Guideline No. 226 (2016):* There are three deviations from the OECD Guideline No. 226 (2016), however they did not affect the results: 1. According to the OECD Guideline No. 226 (2016) the water content of the artificial soil 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 (Chapter 3.5.7). 2. 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 (Chapter 3.5.8) 3. 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 (Chapter 3.5.8). All above mentioned deviations did not influence the study course and results.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	The results are considered valid because the following criteria were satisfied in the control: • mean adult mortality: 0.0% (criterion: ≤ 20%), • the mean number of juveniles per vessel at the end of the test: 99.8 (criterion: ≥ 50 juveniles at the end of the test), • the coefficient of variation for the number of juveniles: 20.0% (criterion: ≤ 30%).

SUMMARY

The aims of the study were to assess the impact of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on reproduction of the predatory mite, *Hypoaspis* (*Geolaelaps*) *aculeifer* and to determine the EC_{10}, EC_{20}, EC_{50}, 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 water suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The exposure period 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.

Materials and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) batch number: 040322
Active substance:	mesosulfuron-methyl – 30.53 g/L
Safener:	mefenpyr diethyl – 90.67 g/L (Appendix No. 1)
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 74.825% air-dried industrial sand, 0.175% calcium carbonate.
Test system:	the predatory mites, *Hypoaspis* (Geolaelaps) *aculeifer* (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology. The mites were introduced 7 – 14 days after becoming adult.
Test design:	exposure time: 14 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate.
Concentrations of the test item :	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.
Test conditions:	temperature: 21.1 – 22.0°C pH at the beginning of the test: 6.44 – 6.50 pH at the end of the test: 6.34 – 6.41 soil moisture content at the beginning of the test: 18.7 – 19.5% (47.0 – 49.0% of the maximum water holding capacity) soil moisture content in the middle of the test: 18.4 – 18.7% (46.3 – 47.0% of the maximum water holding capacity) soil moisture content at the end of the test: 17.4 – 18.2% (43.7 – 45.8% of the maximum water holding capacity) light-dark cycle: 16 h light and 8 h dark light intensity at the beginning of the test: 608.4 – 647.1 lux light intensity at end of the test: 598.7 – 642.3 lux
Statistical analysis:	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, -Levene's Test on Variance Homogeneity (with Residuals), -Williams Multiple Sequential t-test Procedure. - survival – Fisher's Exact Binomial Test with Bonferroni Correction.
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC LC_{10}, LC_{20}, LC_{50}, NOEC.

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 10.0%. Mortality of the control group was equal to 0.0%.
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 98.5 and 112.3 per replicate.
The mean number of juveniles in the control group was equal to 99.8 per replicate. The results are summarized in the table given below.

Concentration [mg/kg dry weight of the artificial soil]	Adult mites			Number of juveniles (mean)
	Number of tested mites	Dead mites after 14 days of exposure		
		No.	%	
control	80	0	0.0	99.8
5.6	40	0	0.0	102.5
10.0	40	1	2.5	98.5
18.0	40	1	2.5	112.3
32.0	40	1	2.5	103.5
56.0	40	0	0.0	110.3
100.0	40	0	0.0	106.3
180.0	40	0	0.0	109.0
320.0	40	1	2.5	102.8
560.0	40	4	10.0	104.8
1000.0	40	4	10.0	105.3

Endpoint values – the impact of the test item on reproduction and on mortality of the predatory mites (*Hypoaspis aculeifer*).

Endpoint	Value [mg of the test item/kg dry weight of the artificial soil]	Value [mg of mesosulfuron-methyl/kg dry weight of the artificial soil]	Value [mg of mefenpyr-diethyl/kg dry weight of the artificial soil]
EC_{10}	> 1000.0	> 32.14	> 95.44
EC_{20}	> 1000.0	> 32.14	> 95.44
EC_{50}	> 1000.0	> 32.14	> 95.44
NOEC (reproduction)	≥ 1000.0	≥ 32.14	≥ 95.44
LC_{10}	> 1000.0	> 32.14	> 95.44
LC_{20}	> 1000.0	> 32.14	> 95.44
LC_{50}	> 1000.0	> 32.14	> 95.44
NOEC (survival)	≥ 1000.0	≥ 32.14	≥ 95.44

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1.1.1 Study 16

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. All the validity criterion were met. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.5
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Soil Microorganisms: Nitrogen Transformation Test. Wróbel A., 2023, Study code G-48-20
Guideline(s):	OECD Guideline No. 216 (2000)/EU Method C.21
Deviations:	Yes *Deviation from the OECD Guideline No. 216 (2000), the EU Method C.21:* According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm and time duration between 18 to 24 hours. The modification resulted from the optimization of the nitrate extraction
GLP:	Yes

Acceptability:	
Duplication (if vertebrate study)	No
Validity criterion	The coefficients of variation (CV) in the control group were 8.5, 0.4, 1.7 and 2.6%, 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%.

SUMMARY:

The aim of the study was to detect long-term adverse effects of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on 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: 0.63 mg test item/kg dry weight of soil,
- 5 x PEC: 3.15 mg test item/kg dry weight of soil.
The treated and the control soils were divided into three replicates.
On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrate. The method involves a measurement of the nitrates ions concentration in a soil extract obtained by using deionised water. The pH/ION 7320 digital meter and the NO 800 nitrate electrode were used.
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.

Materials and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD)
Active substance:	Mesosulfuron-methyl – 30.53 g/L batch no.: 040322
Safener:	mefenpyr-diethyl 90.67 g/L
Soil:	Agricultural soil collected from a place belonging to the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna.
Test design:	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. After adding the deionized water, every portion was divided into three replicates (3 x 520 g). Exposure period: 28 days.
Concentrations of the test item:	-control; - PEC: 0.63 mg test item/kg dry weight of soil - 5 x PEC: 3.15 mg test item/kg dry weight of soil
Test conditions:	temperature: 20.6 – 21.9°C, soil moisture: 45.5 – 50.9% of the maximum water holding capacity, incubation in darkness

Endpoints: The concentration of nitrate [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation. The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 – 7, 0 – 14, 0 – 28 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 – 7, 0 – 14, 0 – 28 days.

Statistical analysis:
- Shapiro-Wilk's test on Normal Distribution
- Levene's Test on Variance Homogeneity (with Residuals)
- Williams Multiple Sequential t-test Procedure

Results:

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: 0.63 mg test item/kg dry weight of soil and 5 x PEC: 3.15 mg test item/kg dry weight of soil did not exceed 25% on 28 day of analysis.

Conclusions:

On the basis of the results, it was concluded that Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) at the concentrations corresponding to the PEC: 0.63 mg test item/kg dry weight of soil (i.e. 0.02 mg of Mesosulfuron-methyl + 0.06 mg of mefenpyr-diethyl) and 5 x PEC: 3.15 mg test item/kg dry weight of soil (i.e. 0.10 mg of Mesosulfuron-methyl + 0.30 mg of mefenpyr-diethyl) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1.1.1 Study 17

Comments of zRMS:	The study was conducted to OECD guideline 227 and according to the prin-ciples of GLP. All the validity criterion are met. - Seedling emergence: ≥ 70 % (actual 91.4 – 97.1 %). - For control group: mean plant survival for the duration of the study: ≥ 90 % (actual 100 %), - Plants do not exhibit visible phytotoxic effects in the control, - Environmental conditions for a particular species are identical. The following deviations are recorded: 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 green-houses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 69.9 – 260.5 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suita-ble for plant growing.

	Deviation from Study Plan: The study finished in May 2023, not in April 2023, as it was planned. The deviations did not affect the results of the experiment. The study is considered to be reliable and suitable for the risk assessment. Pea: ER_{50} = 47.63 mL test item/ha (plant damage) Flax: ER_{50} > 500 mL test item/ha Cabbage: ER_{50} = 68.17 mL test item/ha (plant damage) Carrot: ER_{50} = 169.99 mL test item/ha (plant damage) Onion: ER_{50} = 175.09 mL test item/ha (shoot lenght) Corn: ER_{50} = 261.09 mL test item/ha (plant damage) The most sensitive species is pea taking into account the plant damage.

Reference:	KCP 10.6
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Terrestial Plant Test: Vegetative Vigour Test. Gierbuszewska A., 2023, Study code: G-49-20
Guideline(s):	OECD Guideline No. 227 (2006)
Deviations:	Yes *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 69.9 – 260.5 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the experiment.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) on vegetative vigour of terrestrial plants were met: - the seedling emergence of plants (validity criterion: at least 70%) was as follows: 91.4 – 97.1% – pea, 85.7 – 95.2% – cabbage, 70.0 – 90.0% – carrot, 70.0 – 85.0% – flax, 70.0 – 87.5% – onion, 87.5 – 92.5% – 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.

SUMMARY:

The study, aimed at evaluating the effect of Mesosulfuron 30 OD (CHR/H/MEZO 30 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 flax, carrot and onion; 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 rate were:

- pea: 3 plants/pot – 21 plants/ application rate (7 pots/ application rate);
- flax: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- cabbage: 3 plants/pot – 21 plants/ application rate (7 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. For each species, nine application rates were used. Untreated control group was conducted simultaneously. 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 exposure period finished 21 days after the spraying. At the end of the exposure, 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 ER_{10}, ER_{25}, ER_{50} and NOER.

Additionally, the ER_{50} was determined for visual phytotoxicity effects, basis on the results after 21 days of the experiment.

Materials and methods

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) batch number: 040322 active substance: mesosulfuron-methyl – 30.53 g/L safener: mefenpyr diethyl – 90.67 g/L)
Test species:	Pea (*Pisum sativum*), Flax (*Linum usitatissimum*), Cabbage (*Brassica oleracea var. capitata*), Carrot (*Daucus carota*), Onion (*Allium cepa*), Corn (Zea mays)

Soil:	Sandy loam
Study design:	number of rates: 9 + control; number of replicates/rate: 7 (pea, cabbage), 4 (flax, carrot, onion), 10 (corn). The total number of plants per application rate: 21 (pea, cabbage) or 20 (flax, carrot, onion, corn)
Exposure termination:	21 days after spraying
Application rates:	- 2.0 mL of the test item /ha (0.06 g of mesosulfuron-methyl + 0.18 g of mefenpyr diethyl/ha), - 3.9 mL of the test item /ha (0.12 g of mesosulfuron-methyl + 0.35 g of mefenpyr diethyl/ha), - 7.8 mL of the test item /ha (0.24 g of mesosulfuron-methyl + 0.71 g of mefenpyr diethyl/ha), - 15.6 mL of the test item /ha (0.48 g of mesosulfuron-methyl + 1.41 g of mefenpyr diethyl/ha), - 31.3 mL of the test item /ha (0.96 g of mesosulfuron-methyl + 2.84 g of mefenpyr diethyl/ha), - 62.5 mL of the test item /ha (1.91 g of mesosulfuron-methyl + 5.67 g of mefenpyr diethyl/ha), - 125.0 mL of the test item /ha (3.82 g of mesosulfuron-methyl + 11.33 g of mefenpyr diethyl/ha), - 250.0 mL of the test item /ha (7.63 g of mesosulfuron-methyl + 22.67 g of mefenpyr diethyl/ha), - 500.0 mL of the test item /ha (15.27 g of mesosulfuron-methyl + 45.34 g of mefenpyr diethyl/ha) In case of each species, there was one untreated control group. Volume of deionized water used to prepare the highest rate corresponded to 300 L spraying liquid/ha.
Test conditions:	temperature: 16.2 – 25.7°C, humidity: 47.2 – 78.4%, lighting: 16 h light : 8 h dark; light intensity: 69.9 – 260.5 µE/m2/s; carbon dioxide concentration: 320 – 331 ppm
Statistical analysis:	Because no change in mortality of plants was to be observed, no computations in plant number have been performed for pea, flax, cabbage, carrot and corn. In order to determine ER_{10}, ER_{25}, ER_{50} the following test were used: - plant number: probit analysis using linear max. likelihood regression, - shoot length: probit analysis using linear max. likelihood regression, probit analysis using simple linear regression, logit analysis using linear max. likelihood regression,

- shoot dry weight: probit analysis using linear max. likelihood regression. - for the plant number – Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Fisher`s Exact Binomial Test with Bonferroni Correction;
- for the shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Bartlett's Test Procedure on Variance Homogeneity, Dunnet's Multiple t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment or Williams Multiple Sequential t-test Procedure;
- for the plant shoot dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment or Step-down Jonckheere-Terpstra Test Procedure.

ER_{50} (plant damages) – probit analysis using linear max. likelihood regression
In order to determine the NOER values, the following tests were used:

Results and conclusions

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.

	Pea *Pisum sativum*	**Flax** *Linum usitatissimum*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 500.00	> 500.00	> 500.00	> 500.00	> 500.00	> 500.00
NOER	≥ 500.00	≥ 500.00	≥ 500.00	≥ 500.00	≥ 500.00	≥ 500.00
Shoot length						
ER_{50}	131.12	> 500.00	389.00	284.89	175.09	426.80
NOER	15.60	≥ 500.00	15.60	15.60	31.30	62.50
Plant dry weight						
ER_{50}	259.33	> 500.00	72.32	217.43	630.18	322.46
NOER	31.30	≥ 500.00	7.80	31.30	125.00	125.00
Plant Damage						
ER_{50}	47.63	> 500.00	68.17	169.99	195.01	261.09

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 ER50 values for plant damages at the end of the exposure period expressed as g of mesosulfuron-methyl/ha for all test species are given below.

	Pea *Pisum sativum*	**Flax** *Linum usitatissimum*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 15.27	> 15.27	> 15.27	> 15.27	> 15.27	> 15.27
NOER	≥ 15.27	≥ 15.27	≥ 15.27	≥ 15.27	≥ 15.27	≥ 15.27
Shoot length						
ER_{50}	4.00	> 15.27	11.88	8.70	5.35	13.03
NOER	0.48	≥ 15.27	0.48	0.48	0.96	1.91
Plant dry weight						
ER_{50}	7.92	> 15.27	2.21	6.64	19.24	9.84
NOER	0.96	≥ 15.27	0.24	0.96	3.82	3.82
Plant Damage						
ER_{50}	1.45	> 15.27	2.08	5.19	5.95	7.97

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 g of mefenpyr diethyl/ha for all test species are given below.

	Pea *Pisum sativum*	**Flax** *Linum usitatissimum*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 45.34	> 45.34	> 45.34	> 45.34	> 45.34	> 45.34
NOER	≥ 45.34	≥ 45.34	≥ 45.34	≥ 45.34	≥ 45.34	≥ 45.34
Shoot length						
ER_{50}	11.89	> 45.34	35.27	25.83	15.88	38.70
NOER	1.41	≥ 45.34	1.41	1.41	2.84	5.67
Plant dry weight						
ER_{50}	23.51	> 45.34	6.56	19.71	57.14	29.24
NOER	2.84	≥ 45.34	0.71	2.84	11.33	11.33
Plant Damage						
ER_{50}	4.32	> 45.34	6.18	15.41	17.68	23.67

Conclusions:

The test item, i.e. Mesosulfuron 30 OD (CHR/H/MEZO 30 OD), applied at rates ranging from 2 to 500 mL/ha, had a varied impact on vegetative vigour of pea, cabbage, carrot, onion and corn. The test item in the used application rates had no an impact on vegetative vigour of flax.

On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant number at the end of the experiment it was proved that the test item did not inhibit the process of growth of all tested species.

On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item inhibited the process of growth of pea, cabbage, carrot, onion and corn. The test item did not inhibit the process of growth of flax.

On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the dry shoot weight it was proved that the test item inhibited the process of growth of pea, cabbage, carrot, onion and corn. The test item did not inhibit the process of growth of flax.

During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of all testes plant species.

In the study, the most sensitive plant to influence of the test item was cabbage. The most resistant species was flax.

A 2.6.1.1.2 Study 18

Comments of zRMS:	The study was conducted to OECD guideline 208 and according to the principles of GLP. All the validity criterion are met. - the seedling emergence is at least 70%; (actually 75-100%), - the seedlings do not exhibit visible phytotoxic effects - the mean survival of emerged control seedlings is at least 90% for the duration of the study (actually 100%) - environmental conditions for a particular species are identical The following deviation is recorded: 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 65.82 and 147.8 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affect the results of the study. The study is considered to be reliable and suitable for the risk assessment. Pea: ER_{50} > 500 mL test item/ha Flax: ER_{50} > 500 mL test item/ha Cabbage: ER_{50} = 461.31 mL test item/ha (plant dry weight) Carrot: ER_{50} = 293.84 mL test item/ha (plant dry weight) Onion: ER_{50} > 500 mL test item/ha Corn: ER_{50} > 500 mL test item/ha The most sensitive species is carrot taking into account the plant dry weight.

Reference:	KCP 10.6
Report	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. Wróbel A., 2023, Study code G-50-20
Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	Yes *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 65.82 and 147.8 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. This deviation did not affects the results of the study.
GLP:	Yes

Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of Mesosulfuron 30 OD (CHR/H/MEZO 30 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, 85.7% – cabbage, 90.0% – flax, 100.0% – carrot, 75.0% – onion, 90.0% – corn, - the mean survival of the emerged control seedlings was 100% for each tested plant species (validity criterion: 90%); - the control seedlings did not exhibit any visible phytotoxic effects; - environmental conditions for all plants of the same species were identical.

SUMMARY

The study, aimed at evaluating the effect Mesosulfuron 30 OD (CHR/H/MEZO 30 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. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 5 (flax, carrot, onion) or 3 (pea, cabbage) 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 to the emergence of 50% of the control seedlings and after then every 1 – 3 days) and visual phytotoxicity (after 7 and 14 days after the emergence of 50% of the control seedlings). The exposure period finished 14 days after the emergence of 50% of the control seedlings. At the end of the exposure, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed.

The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER_{10}, ER_{25}, ER_{50}, and NOER. Additionally, the ER_{50} was determined for visual phytotoxicity effects, basis on the results obtained at the end exposure period.

Materials and methods:

Test item:	Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) batch number: 040322 active substance: Mesosulfuron-methyl – 30.53 g/L safener: mefenpyr-diethyl – 90.67 g/L (Appendix No. 1)
Test species:	pea (*Pisum sativum),* cabbage (Brassica oleracea var. capitata), flax (*Linum usitatissimum*), carrot (*Daucus carota*), onion (Allium cepa), corn (*Zea mays*)

Soil: Sandy loam

Study design: number of rates: 9 + control; number of replicates/rate: 7 (pea, cabbage), 4 (flax, carrot, onion), 10 (corn). The total number of seeds per application rate: 21 (pea, cabbage) and 20 (flax, carrot, onion, corn)

Exposure termination: 14 days after the emergence of 50% of the control seedlings;

Application rates: control, 2.0, 3.9, 7.8, 15.6, 31.3, 62.5, 125.0, 250.0 and 500.0 mL/ha. V

Volume of deionized water: volume of deionized water used to prepare the highest rate corresponded to 300 L spraying liquid/ha;

Test conditions: temperature: 16.6 – 23.8°C, humidity: 46.7 – 87.5%, lighting: 16 h light : 8 h dark; light intensity: 65.82 – 147.8 µE/m2 /s; carbon dioxide concentration: 366 – 381 ppm;

Statistical analysis: The ER_{10}, ER_{25} and ER_{50} values for the final number of plants - probit analysis usisng linerar max likelihood regression (all test species)

The ER_{10}, ER_{25} and ER_{50} values for shoot length were determined with probit analysis using linear max likelihood regression (pea, cabbage, onion, corn) or logit analysis using linear max likelihood regression (flax, carrot) .

The ER_{10}, ER_{25} and ER_{50} values for shoot dry weight were determined with with probit analysis using linear max likelihood regression (pea, cabbage, flax, carrot) or logit analysis using linear max likelihood regression (onion, corn) .

Additionally, the ER_{50} was determined for visual phytotoxicity effects, basis on the results obtained at the end exposure period. The probit analysis using linear max likelihood regression (all test species).

NOER (no observed effect rate) – the highest rate at which the test item is observed to have no effects on seedling emergence and seedling growth.

In order to determine the NOER values, the following tests were used:

The final number of plants: Fisher’s Exact Test with Bonferroni Correction.

The shoot length: Shapiro-Wilk's Test on Normal Distribution, Bartlett’s Test Procedure on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test or Dunnett’s Multiple t-test Procedure (onion).

The plant dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene’s Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.

Results

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:

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Flax** *Linum usitatissimum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
NOER	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0	≥ 500.0
Shoot length						
ER_{50}	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0	> 500.0
NOER	≥ 500.0	31.3	250.0	31.3	31.3	≥ 500.0
Plant dry weight						
ER_{50}	> 500.0	461.31	> 500.0	293.84	> 500.0	> 500.0
NOER	125.0	125.0	7.8	7.8	125.0	250.0
Plant Damage						
ER_{50}	> 500.0	>500.0	> 500.0	> 500.0	> 500.0	> 500.0

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 g of Mesosulfuron-methyl/ha for all test species are given below.

	Pea *Pisum sativum*	**Cabbage** *Brassica oleracea var. capitata*	**Flax** *Linum usitatissimum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Corn** *Zea mays*
Plant number at the end of the experiment						
ER_{50}	> 15.27	> 15.27	> 15.27	> 15.27	> 15.27	> 15.27
NOER	≥ 15.27	≥ 15.27	≥ 15.27	≥ 15.27	≥ 15.27	≥ 15.27
Shoot length						
ER_{50}	> 15.27	> 15.27	> 15.27	> 15.27	> 15.27	> 15.27
NOER	≥ 15.27	0.96	7.63	0.96	0.93	≥ 15.27
Plant dry weight						
ER_{50}	> 15.27	14.08	> 15.27	8.97	> 15.27	> 15.27
NOER	3.82	3.82	0.24	0.24	3.82	7.63
Plant Damage						
ER_{50}	> 15.27	>15.27	> 15.27	> 15.27	> 15.27	> 15.27

Conclusions:

On the basis of the obtained results it was proved that the test item i.e. Mesosulfuron 30 OD (CHR/H/MEZO 30 OD) had no impact on seedling emergence of the test plant species. However, impact on seedling growth was observed.

Mortality of plants was not observed. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant number it was proved that the test item slightly inhibited process of seedling emergence of flax and carrot. Seedling emergence of pea, cabbage, onion and corn was not inhibited.

On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item inhibited process of the growth of cabbage, flax, carrot and onion. Process of growth of pea and corn was not inhibited.

On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the dry shoot weight it was proved that the test item inhibited process of the growth of all test species.

During the experiment phytotoxic symptoms in cultivation of pea, cabbage, flax, carrot and corn were observed. Among phytotoxic symptoms stunted growth (pea, cabbage, flax, carrot, corn), chlorosis (pea, carrot) were observed. No phytotoxic symptoms in cultivation of onion were observed.

A 2.7 KCP 10.8 Monitoring data

Not required.