

# REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

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: PL

#### CORE ASSESSMENT

authorization

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023

zRMS Assessment: 26/07/2024

MS Finalisation date: 19/11/2024

CHR/H/MEZO 30 OD/ Vidal 30 OD, Pacyfik 30 OD  
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Applicant version

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## Version history

When	What
July 2024	zRMS Assessment
November 2024	Following commenting period

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD \***


Product name and code	CHR/H/MEZO 30 OD/ Pacyfik 30 OD,Vidal 30 OD
Formulation type	Oil dispersion [Code:OD]
Active substance(s) (incl. content)	Mesosulfuron-methyl; 30 g/L
Function	herbicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

\* Information on the detailed composition of product code/name can be found in the confidential dRR Part C.

### Justified proposals for classification and labelling

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

**Table 6.1-2: Justified proposals for classification and labelling for CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD according to Regulation (EC) No 1272/2008**

Hazard class(es), categories:	Eye Dam. 1, H318
Hazard pictograms or Code(s) for hazard pictogram(s):	
Signal word:	Danger
Hazard statement(s):	Eye Dam. 1, H318 - Causes serious eye damage.
Precautionary statement(s):	P280 – Wear <del>protective gloves/protective clothing</del> /eye protection/face protection. P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 – Immediately call a POISON CENTER or doctor.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	<b>Hazardous ingredients that must be listed on the label:</b> Calcium alkylarylsulphonate,

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**Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	No PPE Eye protection or face protection during mixing/loading and application due to the fact that the product is classified as Eye Dam. 1 H318.
Workers	Acceptable	No PPE
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary and provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

**Table 6.1-4 Critical uses and overall conclusion of exposure assessment**

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha))  critical gap for operator, worker, bystander or resident exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications)  a) per use b) per crop/season	Max. application rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Bystander	Residents
1	Winter wheat Triticum aestivum (BBCH 21-32)	F	LCTM	1 ; 1	a) 0.015	100 - 400	NA	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 [EFSA OPEX]				
Minor uses according to Article 51 (zonal uses)												
2	Spelt Triticum spelta Emmer wheat Triticum dicoccum Einkorn wheat Triticum monococcum Durum wheat Triticum durum Spring Rye Secale cereale (BBCH 21-32)	F	LCTM	1;1	a) 0.015	100-400	N/A	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 [EFSA OPEX]				

\* 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

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greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

\*\*\* e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

<b>A</b>	Exposure acceptable without PPE / risk mitigation measures
<b>R</b>	Further refinement and/or risk mitigation measures required
<b>N</b>	Exposure not acceptable/ Evaluation not possible

## Data gaps

Noticed data gaps are:

## 6.2 Toxicological Information on Active Substance

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

**Table 6.2-1: Information on active substance**

	<b>Mesosulfuron-methyl</b>
Common Name	Mesosulfuron
CAS-No.	208465-21-8
<b>Classification and proposed labelling</b>	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<p>Hazard classes (s), categories: -  <del>Aquatic Acute 1, H400</del>  <del>Aquatic Chronic 1, H410</del></p> <p>Code(s) for hazard pictogram(s): -  <del>GHS09</del></p> <p>Signal word: -  <del>Warning</del></p> <p>Hazard statement(s): -  <del>H400 – Very toxic to aquatic life.</del>  <del>H410 – Very toxic to aquatic life with long lasting effects.</del></p> <p>Precautionary statement(s): -  <del>P391 – Collect spillage.</del>  <del>P273 – Avoid release to the environment.</del>  <del>P501: Dispose of contents/container to...</del></p>
Additional C&L proposal	Not required
<b>Agreed EU endpoints</b>	
AOEL systemic	0.13 mg/kg bw/d (corrected for 2% oral absorption)
Reference	EFSA Journal 2016;14(10):4584
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>	
EFSA Conclusion for active substance	EFSA Journal 2016;14(10):4584 None

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Comments of zRMS:	<p>CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD was not a representative formulation reviewed during the Annex I inclusion/active substances renewal and was not previously evaluated in any EU countries. For the product registration no experimental acute toxicity data are available. An assessment of acute toxicity including irritancy and skin sensitisation properties of CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD has been conducted by the applicant based on the alternative method (calculation) according to the Regulation (EC) 1272/2008. Classification of all relevant ingredients were considered by the applicant. For reprotoxicity and specific target organ toxicity the alternative method (calculation) according to the Regulation (EC) 1272/2008 was applied. Details of the calculation can be found in annex 2 and in Part C.</p> <p>In order to avoid tests on animals, the use of alternative method for the purposes of hazard classification is preferred.</p> <p>CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD contains safener, but currently, according to the approach agreed in Poland, safeners are evaluated the same way as co-formulants. Proposed classification based on alternative method according to Regulation (EC) 1272/2008 is acceptable by the zRMS.</p>
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**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral (calculation method – alternative method)	Non determined – no relevant ingredient	Yes	None	I. Muchewicz (2023)
LD <sub>50</sub> dermal (calculation method – alternative method)	Non determined – no relevant ingredient	Yes	None	I. Muchewicz (2023)
LC <sub>50</sub> inhalation (calculation method – alternative method)	439.95 mg/kg bw	Yes	None	I. Muchewicz (2023)
Skin irritation (calculation method – alternative method)	Non-irritant	Yes	None	I. Muchewicz (2023)
Eye irritation (calculation method – alternative method)	Corrosive	Yes	Eye Dam. 1, H318	I. Muchewicz (2023)
Skin sensitisation, guinea pig/mouse (calculation method – alternative method)	Non-sensitising	Yes	None	I. Muchewicz (2023)
Supplementary studies for combinations of plant protection products	Not required	-		



**Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD**

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of prod- uct (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Mesosulfuron methyl (3.23% w/w))	<del>Hazard statement(s) H400 – very toxic to aquatic life H410 – very toxic to aquatic life with long lasting effects</del> None	Reg. 1272/2008	None
Toxicological properties of non- active substance(s) (relevant for classification of product)	Calcium alkylarylsulfonate (>= 2.5 - < 3.5)	Eye Dam. 1, H318 (criteria ≥ 3 %)	MSDS	Eye Dam 1, H318
Further toxicological information	No data – not required			

\* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

\*\* Material safety data sheet by the applicant

## 6.4 Toxicological Evaluation of Groundwater Metabolites (KCP 7.6.4)

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

### 6.4.1 AE F160459 (KCP 7.6.4.1)

#### Available data

According to RAR Mesosulfuron-methyl 2016 data with the following studies: Report C008354, 2000a; Report C008356, 2000b; Report C008355, 2000c; Report C008357, 2000a; were not claimed a protection They can be used in this documentation.

An overview of the results of the accepted toxicological studies for groundwater metabolite AE F160459 is given in the following table.

**Table 6.4-1: Summary of the results of toxicity studies for AE F160459**

Type of test, species (Guideline)	Result	Acceptability	Reference*
ADME studies, Rat (OECD 417; US EPA Subdiv. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines.)	non-genotoxic	Yes / No / Supplementary	Report [REDACTED], 2000a
ADME studies, Rat, (OECD 417; US EPA Subdivi. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines.)	non-genotoxic		Report [REDACTED], 2000b

Type of test, species (Guideline)	Result	Acceptability	Reference*
ADME studies, Rat (OECD 417; US EPA Subdiv. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines)	non-genotoxic		Report [REDACTED], 2000c
ADME studies, Rat (OECD 417; US EPA Subdiv. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines.)	non-genotoxic		Report [REDACTED], 2000a

\* indicates that a study was reviewed at EU level

#### 6.4.2 AE F160460 (KCP 7.6.4.2)

##### Available data

The following studies: Sokolowski A., (2012), 1462301.; Bohnenberger S. (2015) 1462302, Wollny H-E. (2015) 1462303, were presented in core assessment and latest supplements of registration report Part B, Section 6: Toxicology of Atlantis 12 OD revised in 03/2020. We are obliged to rely 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.

An overview of the results of the accepted toxicological studies for groundwater metabolite AE F160460 is given in the following table.

**Table 6.4-2: Summary of the results of toxicity studies for AE F160460**

Type of test, species (Guideline)	Result	Acceptability	Reference*
Toxicity studies, <i>Salmonella Typhimurium</i> (OECD No. 471 (1997) EPA OPPTS 870.5100, EPA 712-C-98-247 (1998))	Non-genotoxic		Sokolowski A.; 2012, 1462301
Toxicity studies Chinese hamster (OECD No. 473 (1998), US EPA OPPTS 870.5375, EPA 712-C-98-223 (1998); not specified)	Non-genotoxic		Bohnenberger S.; 2015, 1462302
Toxicity studies, Chinese hamster (OECD No. 476 (1997); US EPA OPPTS 870.5300, EPA 712-C-98-221 (1998))	Non-genotoxic		Wollny H-E.; 2015, 1462303

\* indicates that a study was reviewed at EU level

### 6.4.3 AE F147447 (KCP 7.6.4.3)

#### Available data

According to RAR Mesosulfuron-methyl 2016 data with the following studies: Report [REDACTED], 2000a; Report [REDACTED], 2000b; Report [REDACTED], 2000c; Report [REDACTED], 2000a; are not claimed a protection. They can be used in this documentation.

The following studies: Sokolowski A., (2012), 1462101.; Bohnenberger S. (2015) 1462102, Wollny H-E.; (2015) 1462103.; were presented in core assessment and latest supplements of registration report Part B, Section 6: Toxicology of Atlantis 12 OD revised in 03/2020. We are obliged to rely 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

An overview of the results of the accepted toxicological studies for groundwater metabolite AE F147447 is given in the following table.

**Table 6.4-3: Summary of the results of toxicity studies for AE F147447**

Type of test, species (Guideline)	Result	Acceptability	Reference*
ADME studies, Rat, (OECD 417; US EPA Subdiv. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines.)	Non-genotoxic		Report [REDACTED], 2000b
ADME studies, Rat (OECD 417; US EPA Subdiv. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines)	Non-genotoxic		Report [REDACTED], 2000c
ADME studies, Rat (OECD 417; US EPA Subdiv. F, §85-1, 1984; EU 94/79/EC; JMAFF, 1985 Guidelines.)	Non-genotoxic		Report [REDACTED], 2000a
Toxicity studies, <i>Salmonella Typhimurium</i> (OECD No. 471 (1997) EPA OPPTS 870.5100, EPA 712-C-98-247 (1998))	Non-genotoxic		Sokołowski A., 2012, 1462101
Toxicity studies Chinese hamster (OECD No. 473 (1998), US EPA OPPTS 870.5375, EPA 712-C-98-223 (1998); not specified)	Non-genotoxic		Bohnenberger S.; 2015, 1462102
Toxicity studies, Chinese hamster (OECD No. 476 (1997); US EPA OPPTS 870.5300, EPA 712-C-98-221 (1998))	Non-genotoxic		Wollny, H-E.; 2012, 1462103

\* indicates that a study was reviewed at EU level

#### 6.4.4 BCS-CV14885 (KCP 7.6.4.4)

##### Available data

The following studies: Sokolowski A., (2012), 1490201; Bohnenberger S. (2015) 1490202; Wollny H-E.; (2015) 1490203; were presented in core assessment and latest supplements of registration report Part B, Section 6: Toxicology of Atlantis 12 OD revised in 03/2020. We are obliged to rely 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

An overview of the results of the accepted toxicological studies for groundwater metabolite BCS-CV14885 is given in the following table.

**Table 6.4-4: Summary of the results of toxicity studies for BCS-CV14885**

Type of test, species (Guideline)	Result	Acceptability	Reference*
Toxicity studies, <i>Salmonella Typhimurium</i> (OECD No. 471 (1997); EPA OPPTS 870.5100, EPA 712-C-98-247 (1998))	Non-genotoxic		Sokołowski A., 2012 1490201
Toxicity studies Chinese hamster (OECD No. 473 (1998), US EPA OPPTS 870.5375, EPA 712-C-98-223 (1998); not specified)	Non-genotoxic		Bohnenberger S.; 2015, 1490202
Chinese hamster (OECD No. 476 (1997); EPA OPPTS 870.5300, EPA 712-C-98-221 (1998))	Non-genotoxic		Wollny, H-E.; 2015, 1490203

\* indicates that a study was reviewed at EU level

#### 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD**

	Mesosulfuron-methyl	
	Value	Reference
Concentrate	2570 %	EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1, 24 October 2018
Dilution	70 %	EFSA Journal 2017;15(6):4873

### 6.5.1 Justification for proposed values – Mesosulfuron methyl

No data on dermal absorption for Mesosulfuron-methyl in CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4837 and SANTE/2018/10591 rev.1, 24 October 2018) are presented in the following table.

**Table 6.5-2: Default dermal absorption rates for Mesosulfuron-methyl**

	Value	Justification for value	Acceptability of justification
Concentrate	<del>25 %</del> -70%	A default dermal absorption value of <del>25</del> 70% may be applied for concentrated products that are organic solvent-formulated or in other types of formulations.	Justification accepted. Endpoint can be used for current product.
Dilution	70 %	A default dermal absorption value of 70% may be applied for concentrated products that are organic solvent-formulated or in other types of formulations.	Justification accepted. Endpoint can be used for current product.

### 6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

**Table 6.6-1: Product information and toxicological reference values used for exposure assessment**

Product name and code	CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD
Formulation type	OD
Category	Herbicide
Container size(s), short description	0.275 L- 10 L , HDPE/PA 0.312 L- 10 L, HDPE/F 0.25 L-20 L HDPE/EvOH
Active substance(s) (incl. content)	<b>Mesosulfuron methyl</b> 30 g/L
AOEL systemic	0.13 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: <del>25</del> 70% Dilution: 70 % (Default)

### 6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

### 6.6.2 Operator exposure (KCP 7.2.1)

#### 6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

**Table 6.6-2: Exposure models for intended uses**

Critical use(s)	Winter wheat (max. 0,5 L product/ha)
Model(s)	AOEM 30.03.2015

**Table 6.6-3: Estimated operator exposure**

		Mesosulfuron-methyl	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor-mounted boom spray application outdoors to low crops Application rate: 0.015 kg a.s./ha			
AOEM	no PPE*	0,0306505	23,58

\* no PPE: Operator wearing T-shirt and shorts

\*\* no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

**Table 6.6-2: Exposure models for intended uses**

Critical use(s)	Field crops (use no 1,2 from critical GAP table)
Model(s)	OPEX v.1.0.2

**Table 6.6-3: Estimated operator exposure**

		Mesosulfuron-methyl	
Model data	Level of PPE	Total systemic exposure (mg/kg bw/day)	% of systemic AOEL
Vehicle-mounted application outdoors to field crops Application rate: 1 × 0.015 kg a.s./ha			

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OPEX v.1.02	no PPE*	0.04-0.12	32.9-89.1
	with PPE **	0.03-0.08	23-62.6

\* no PPE: Operator wearing T-shirt and shorts

\*\* no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

### 6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.3	The applicant presented calculations for the application of CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD on field crops: max dose 1x0.5 L/ha covering both uses (no. 1 and 2) from critical GAP table. The exposure calculations were conducted by the applicant using the EFSA online calculator 2022 v 1.0.0. (OPEX). The evaluator has revised operator exposure using higher default value for dermal absorption for concentrate (70% instead of 25%), since concentration of a.s in the product is below 5% thus, according to revised EFSA guidance document on dermal absorption, plant protection product should be considered a "dilution". The revised calculations:																										
	<table> <tr> <th>Model data</th><th>Level of PPE</th><th>Total absorbed dose [mg/kg bw per day]</th><th>% of systemic AOEL</th></tr> <tr> <td colspan="4">Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal</td></tr> <tr> <td rowspan="4">Mesosulfuron-methyl</td><td colspan="3">Number of applications and application rate: 1 x 0.015 kg a.s./ha</td></tr> <tr> <td colspan="3">Dermal absorption (concentrate): 70 %</td></tr> <tr> <td colspan="3">Dermal absorption (in-use dilution): 70 %</td></tr> <tr> <td>M/L: Workwear App: Workwear</td><td>0.08</td><td>62.6</td></tr> <tr> <td></td><td>M/L: no PPE App: no PPE</td><td>0.12</td><td>89.1</td></tr> </table>			Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal				Mesosulfuron-methyl	Number of applications and application rate: 1 x 0.015 kg a.s./ha			Dermal absorption (concentrate): 70 %			Dermal absorption (in-use dilution): 70 %			M/L: Workwear App: Workwear	0.08	62.6		M/L: no PPE App: no PPE	0.12
Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL																								
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal																											
Mesosulfuron-methyl	Number of applications and application rate: 1 x 0.015 kg a.s./ha																										
	Dermal absorption (concentrate): 70 %																										
	Dermal absorption (in-use dilution): 70 %																										
	M/L: Workwear App: Workwear	0.08	62.6																								
	M/L: no PPE App: no PPE	0.12	89.1																								
agreed endpoints 6.6.3	According to EFSA OPEX calculations, it can be concluded that the risk of operator exposure during mixing & loading and application using the tractor-mounted on field is acceptable under conditions of intended use without PPE. Due to the fact that the product CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD is classified as Eye Dam. 1 H318, eye protection would be necessary, thus the operator should wear eye protection or face protection during mixing/loading and application operations. The operator should wear the adequate workwear for its intended use within good agricultural practice.																										

## 6.6.4 Worker exposure (KCP 7.2.3)

### 6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical use(s)	Winter wheat (max. 1 x 0,5 L product/ha)
Model	AOEM 30.03.2015 r

**Table 6.6-5: Estimated worker exposure**

		Mesosulfuron-methyl	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0,015 kg a.s./ha	
2 hours/day , TC: 12500 cm <sup>2</sup> /person/h Body weight: 60 kg	no PPE <sup>(1)</sup>	0,0131250	10,10
	with PPE <sup>(2)</sup>	0,0014700	1,13

(1) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

(2) with PPE: type of PPE / see 'Instructions for use'

**Table 6.6-4 Exposure models for intended uses**

Critical use(s)	Field crops (use no 1,2 from critical GAP table)
Model(s)	OPEX v.1.0.2

**Table 6.6-5 Estimated worker exposure**

		Mesosulfuron-methyl	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		1 x 0,015 kg a.s./ha	
Re-entry activity		Inspection, irrigation	
2 hours/day , TC: 12500 cm <sup>2</sup> /person/h Body weight: 60 kg	no PPE <sup>(1)</sup>	0,01	10,1
	with PPE <sup>(2)</sup>	0,001	1,1

(1) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

(2) with PPE: type of PPE / see 'Instructions for use'



#### 6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not required.

#### 6.6.4.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses ~~and considering above mention~~ without PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.4	The applicant presented calculations for worker exposure after entry into a previously treated area or handling a crop treated with CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD on winter wheat: max dose 1x0.5 L/ha (Field). The exposure calculations were conducted using the EFSA online calculator 2022 v 1.0.0. (OPEX). The calculations provided by the applicant were done correctly.
agreed endpoints 6.6.4	According to EFSA OPEX calculations, it can be concluded that the risk of worker exposure during re-entry activities on area treated with CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD is acceptable under conditions of intended use without PPE, but the worker should wear an adequate workwear within good agricultural practice. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

#### 6.6.5 Bystander and resident exposure (KCP 7.2.2)

##### 6.6.5.1 Estimation of bystander and resident exposure

Because there is no AAOEL value risk assessment for bystander is the same like risk assessment for resident.

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to Mesosulfuron-methyl. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

**Table 6.6-6: Exposure models for intended uses**

Critical use(s)	Winter wheat (max. 1 x 0.5 L product/ha)
Model	AOEM 30.03.2015 r

**Table 6.6-7: Estimated bystander and resident exposure**

	Mesosulfuron-methyl	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0,015 kg a.s./ha		
Residents (adult)	0,0013877	1,07

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Drift rate: 0,22% (2-3 m) Body weight: 60 kg		
Residents (children) Drift rate: 0.18% (2-3 m) Body weight: 10kg	0.0041560	3,20

**Table 6.6-6: Exposure models for intended uses**

Critical use(s)	Field crops (use no 1,2 from critical GAP table)
Model	OPEX v.1.0.2

**Table 6.6-7: Estimated bystander and resident exposure**

	Mesosulfuron-methyl	
Model data	Total systemic exposure (mg a.s/kg bw/day)	% of systemic AOEL
Vehicle mounted downward spraying outdoors to field crops Application rate: 1 × 0.015 kg a.s./ha		
Residents (adult) Buffer strip: 2-3 m weight: 60 kg	Spray drift 0.0007 Vapour: 0.0003 Surface deposit: 7E-5 Entry into treated crops 0.001 All pathways (mean):0.001	0.5 0.2 0.06 0.8 1.1
Residents (children) Buffer strip: 2-3 m Body weight:10 kg	Spray drift 0.003 Vapour: 0.0008 Surface deposit 0.0002 Entry into treated crops 0.002 All pathways (mean):0.004	2.2 0.6 0.1 1.4 3

### 6.6.5.2 Measurement of bystander and resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Mesosulfuron-methyl will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.5	The evaluator agrees with estimation of resident exposure after application of CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD on winter wheat (Field). The exposure estimation of resident (adult and child) to mesosulfuron-methyl applied on a field of winter wheat at dose 1x0.5 L product/ha, using tractor-mounted, calculated with the EFSA online calculator v 1.0.1. (OPEX) demonstrates that such an exposure for adult and child resident is 3 % to 1.1 % of respective AOEL, thus risk is acceptable. The calculations provided by the applicant were done correctly.
agreed endpoints 6.6.5	The exposure assessment for residents also covers bystander exposure. According to calculations, it can be concluded that there is no unacceptable risk to any resident (child and adult) and bystander after application of CHR/H/MEZO 30 OD/ Pacyfik 30 OD, Vidal 30 OD.

#### **6.6.6 Combined exposure**

Not relevant. The product contains only one active substance.

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.1 KCP 7.1.2 KCP 7.1.3 KCP 7.1.4 KCP 7.1.5 KCP 7.1.6 KCP 7.1.7	I. Muchewicz	2023	Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o. Non GLP Unpublished	N	Chemirol Sp. z o.o.
KCP 7.2.1 KCP 7.2.2 KCP 7.2.3	Stanio A.	2024	Exposure assessment for operator, worker, resident and bystander Product: MEZO 30 OD OPEX version: 1.0.2 28 June 2024 Chemirol Not GLP Unpublished	N	Chemirol Sp. z o.o.

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 7.6.4.1		2000a	Rat preliminary toxicokinetics: Metabolism - oral low dose (10 mg/kg body weight) and oral high dose (1000 mg/kg body weight) Code:(2- 14C-pyrimidyl)- AE F130060 [REDACTED] GLP: yes, Unpublished	Y	Bayer CropScience
KCP 7.6.4.1 KCP 7.6.4.3		2000b	Rat metabolism - single oral low dose (10 mg/kg body weight) (U-14C-phenyl)-AE F130060 [REDACTED] GLP: yes, Unpublished	Y	Bayer CropScience
KCP 7.6.4.1 KCP 7.6.4.3		2000c	Rat metabolism - single oral high dose (1000 mg/kg bw); [U14C-phenyl] AE F 130060; [REDACTED] GLP: yes, Unpublished	Y	Bayer CropScience
KCP 7.6.4.1 KCP 7.6.4.3		2000a	Rat metabolism -repeated oral dose (7 x 250) mg/kg body weight) (U-14C-phenyl)-AE F130060 [REDACTED] GLP yes Unpublished	Y	Bayer CropScience
KCP 7.6.4.2	Sokolowski A	2012	<i>Salmonella typhimurium</i> reverse mutation assay with AE F160460 Report No.: 1462301, Harlan CCR, Rossdorf, Germany Bayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.6.4.2	Bohnenberger S	2015	Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F160460 Report No.:1462302 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP yes Unpublished	N	Bayer CropScience
KCP 7.6.4.2	Wollny, H. E	2015	Report amendment no. 1 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE F160460 Report No.: 1462303, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report GLP: yes, Unpublished	N	Bayer CropScience
KCP 7.6.4.3	Sokolowski, A.	2012	<i>Salmonella typhimurium</i> reverse mutation assay with AE F147447 Report No.: 1462101, Harlan CCR, Rossdorf, Germany Bayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience
KCP 7.6.4.3	Bohnenberger S	2015	Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F147447 Report No.: 1462102, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience
KCP 7.6.4.3	Wollny, H. E.	2012	Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE F147447 Report No.: 1462103, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience
KCP 7.6.4.4	Sokolowski, A.	2012	<i>Salmonella typhimurium</i> reverse mutation assay with BCS-CV14885	N	Bayer

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Report No.: 1490201 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, Unpublished		CropScience
KCP 7.6.4.4	Bohnenberger, S.	2015	Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with BCS-CV14885 Report No.: 1490202, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, GLP: yes, Unpublished	N	Bayer CropScience
KCP 7.6.4.4	Wollny H. E.	2015	Report amendment no. 1 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) - BCS-CV14885 Report No.: 1490203, Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report 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**

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

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

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

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



## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Comments of zRMS:	Not applicable.
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### A 2.2 Acute oral toxicity (KCP 7.1.1)

Reference:	KCP 7.1.1
Report	Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/MEZO 30 OD are known, the acute oral toxicity test is not necessary.

### Conclusion

No relevant ingredients classified in this class of hazard.

### A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Reference:	KCP 7.1.2
Report	Toxicological classification of product CHR/H/MEZO 030 OD based on

	calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 7.1.2 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Findings of severe skin irritation or corrosion in the dermal study may be used instead of performing a specific irritation study.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/MEZO 030 OD are known, the acute dermal toxicity test is not necessary.

## Conclusion

No relevant ingredients classified in this class of hazard.

## A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Reference:	KCP 7.1.3
Report	Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

Inhalation study on CHR/H/MEZO 30 OD is not required. According to point 7.1.3 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products the inhalation test must be carried out ~~since~~ where the preparation is:

- a gas or liquefied gas,
- a smoke generating formulation or fumigant,
- used with fogging equipment,
- a vapor releasing preparation,
- an aerosol,

- a powder containing a significant proportion of particles of diameter <50 µm (> 1% on a weight basis),
- to be applied from aircraft in cases where inhalation exposure is relevant,
- contains an active substance with a vapor pressure > 1x10<sup>-2</sup> Pa and is to be used in enclosed spaces such as warehouses or glasshouses,
- ~~to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 µm (> 1% on a weight basis).~~
- to be applied by spraying.

A study shall not be required if the applicant can justify an alternative approach under Regulation (EC) No 1272/2008, where applicable.

~~The active substances and the other co-formulants are not classified as acute inhalation toxic, it can be assumed that entire formulation is not classified in this class.~~ According to point 7.1.3 of part A of Annex Regulation No 284/2014, it is possible to waive from acute inhalation toxicity test.

The complete composition of the formulation with the classification of individual ingredients is available in part C.

## Materials and methods

We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

Where:

- C<sub>i</sub> - concentration of ingredient i ( % w/w or % v/v)
- i – the individual ingredient from 1 to n
- n – the number of ingredients
- ATE<sub>i</sub> - Acute Toxicity Estimate of ingredient i.

We use the table:

Table 3.1.2 Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05

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	0,5 < Category 2 ≤ 2,0 2,0 < Category 3 ≤ 10,0 10,0 < Category 4 ≤ 20,0	0,5 3 11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05 0,05 < Category 2 ≤ 0,5 0,5 < Category 3 ≤ 1,0 1,0 < Category 4 ≤ 5,0	0,005 0,05 0,5 1,5

Note 1 These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only one ingredient is relevant in this class of hazard:

- 2.5 % (Acute Tox. 4, H332)

Estimated values of LD<sub>50</sub> were taken.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{c_i}{ATE_i}} = \frac{100}{\frac{2.5}{11}} = \frac{100}{0.2273} = 439.95 \frac{mg}{kg \text{ bw}}$$

According to the table 3.1.2, result (439.95 mg/l) is higher than generic concentration level (20 mg/l). Therefore the formulation is not classified in this class of hazard.

## Conclusion

According to calculation method, the result 439.95 mg/kg bw is higher than result triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H332.

## A 2.5 Skin irritation (KCP 7.1.4)

Reference:	KCP 7.1.4
Report	Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/MEZO 030 OD are known, skin corrosive

test is not necessary.

For consideration of corrosive and irritant properties the following table applies:

Table 3.2.3 Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	$\geq 5 \%$	$\geq 1 \%$ but $< 5 \%$
Skin irritant Category 2		$\geq 10 \%$
$10 \times$ Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		$\geq 10 \%$

**Note**

The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be  $\geq 5 \%$  respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is  $< 5 \%$  but the sum of Category 1A+1B ingredients is  $\geq 5 \%$ , the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is  $< 5 \%$  but the sum of Category 1A+1B+1C ingredients is  $\geq 5 \%$  the mixture shall be classified as Skin Corrosive Category 1C.

Three ingredients are relevant in this class of hazard.

- 3.5 % (Skin Irrit. 2, H315)
- 2.5 % (Skin Irrit. 2, H315)
- 0.90 % (Skin Irrit. 2, H315)

$$C_{\text{Skin Irrit.}} = 3.5 \% + 2.5 \% + 0.90 \% = 6.9 \%$$

The result (6.9 %) is lower than generic concentration level (10%). Therefore the whole formulation is not classified as Skin Irrit. 2, H315.

## Conclusion

According to calculation method, the result 6.9 % is lower than a concentration triggering classification (10%). Therefore the whole formulation is not classified as Skin Irrit. 2, H315.

## A 2.6 Eye irritation (KCP 7.1.5)

Reference: KCP 7.1.5

Report Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023

Guideline(s): Regulation (EC) No. 1272/2008

Deviations: -

CHR/H/MEZO 30 OD/ Vidal 30 OD, Pacyfik 30 OD  
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GLP: No

Acceptability:

According to point 7.1.5 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” Eye irritation tests shall be provided, unless it is likely that severe effects on the eyes may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, eye irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Due to the fact, that all components of the formulation CHR/H/MEZO 030 OD are known, eye corrosion test is not necessary.

For consideration of corrosive and irritant properties the following table applies:

Table 3.3.3 Generic concentration limits of ingredients of a mixture classified as Skin corrosive Category 1 and/ or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2).

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	$\geq 3 \%$	$\geq 1 \%$ but $< 3 \%$
Eye Effects Category 2		$\geq 10 \%$
(10 × Eye Effects Category 1) + Eye effects Category 2		$\geq 10 \%$
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	$\geq 3 \%$	$\geq 1 \%$ but $< 3 \%$
10 × (Skin Corrosive Category 1A, 1B, 1C + Eye Effects Category 1) + Eye Effects Category 2		$\geq 10 \%$

Only one ingredient is relevant in this class of hazard.

- 3.5 % (Eye Dam. 1, H318)

The concentration of this ingredient (3.5 %) is higher than result triggering eye hazard classification (3 %). Therefore the whole formulation is classified as corrosive to eyes, **Eye Dam. 1, H318.**

## Conclusion

According to calculation method, the result 3.5 % is higher than a concentration triggering classification (3%). Therefore the whole formulation is classified as corrosive to eyes, **Eye Dam. 1, H318.**

## **A 2.7 Skin sensitisation (KCP 7.1.6)**

Reference:	KCP 7.1.6
Report	Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 7.1.6 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

”The skin sensitisation test shall be carried out unless the active substances or co-formulants are known to have sensitising properties or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method.

Consideration shall be given to the possible effects of components on the sensitising potential of the total mixture.”

Due to the fact, that all components of the formulation CHR/H/MEZO 030 OD are known, skin sensitisation test is not necessary.

The complete composition of the formulation with the classification of individual ingredients is available in part C.

### **Conclusion**

No relevant ingredients classified in this class of hazard.

## **A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)**

Not required.

## **A 2.9 Data on co-formulants (KCP 7.4)**

### **A 2.9.1 Material safety data sheet for each co- formulant**

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

### **A 2.9.2 Available toxicological data for each co-formulant**

Available toxicological data for each co-formulant can be found in the confidential dossier of this

submission (Registration Report - Part C).

## **A 2.10                    Studies on dermal absorption (KCP 7.3)**

Not required.

## **A 2.11                    Other/Special Studies**

### **A 2.11.1                Specific target organ toxicity**

Reference:	KCP 7.1.7
Report	Toxicological classification of product CHR/H/MEZO 30 OD based on calculation method taking into consideration health hazards of constituent substances; I. Muchewicz; 2023
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

For consideration of specific target organ properties the following table applies:

Table 3.8.3 Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2.

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration $\geq 10$ %	$1,0\% \leq \text{concentration} < 10\%$
Category 2 Specific Target Organ Toxicant		Concentration $\geq 10$ % [(Note 1)]

Note 1

If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration  $\geq 1,0\%$  a SDS shall be available for the mixture upon request.

We also took into account the point 3.8.3.4.5.: “Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value. Expert judgement shall be exercised.”

Two ingredients are classified as STOT SE 3.



CHR/H/MEZO 30 OD/ Vidal 30 OD, Pacyfik 30 OD  
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- 2.5 % (STOT SE 3, H335)
- 0.90 % (STOT SE 3, H335)

The sum of concentration of this ingredients (3.4 %) is below concentration triggering STOT SE 3, H335 classification of whole formulation (20%). Therefore, the product is not classified in this class of hazard.

### **Conclusions**

The sum of concentration of the ingredients (3.4 %) is lower than concentration triggering STOT SE 3, H335 classification of whole formulation (20 %). Therefore the whole product will be not classified as STOT SE 3, H335.

## **Appendix 3    Exposure calculations**

### **A 3.1                    Operator exposure calculations (KCP 7.2.1.1)**

#### **A 3.1.1                Calculations for Mesosulfuron-methyl**

CHR/H/MEZO 30 OD/ Vidal 30 OD, Pacyfik 30 OD  
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**Table A.3.1.1-1: Estimation of operator exposure towards Mesosulfuron using the AOEM**

Operator exposure for Pacyfik 30 OD/Vidal 30 OD outdoor spray applications					
Application rate of active substance	0,015 kg a.s./ha	<i>i_AppRate</i>			
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>			
Amount of active substance applied	0,75 kg a.s./day	<i>i_AmountAS</i>			
Dermal absorption of the product	25,00%	<i>i_AbsorpProduct</i>			
Dermal absorption of in-use dilution	70,00%	<i>i_AbsorInuse</i>			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	3892	14225	AOEM	
	Body	2914	66249	AOEM	
	Head	39	213	AOEM	
	Protected hands (gloves)	29	149	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	18	110	AOEM	
	Protected head (hood and face shield)	1	12	AOEM	
	Inhalation	3	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	111	1856	AOEM	
	Body	62	321	AOEM	
	Head	3	9	AOEM	
	Protected hands (gloves)	36	3223	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	2	4	AOEM	
	Inhalation	1	2	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,8390315	1,8390315	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0306505	0,0306505	
% of RVNAS	23,58%	23,58%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	21,7328731	21,7328731	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,3622146	0,3622146	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

**Table A.3.1.1-1: Estimation of operator exposure towards Mesosulfuron-methyl using the OPEX MODEL**

<b>3.1.1.1. Summary data - Short term exposure</b>				
Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOE	
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal				
Mesosulfuron-methyl	Number of applications and application rate: 1 x 0.015 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %			
	M/L: Workwear	0.03	23	
	App: Workwear			
<b>3.1.1.2. Summary data - Acute exposure</b>				
Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAO	
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal				
Mesosulfuron-methyl	Number of applications and application rate: 1 x 0.015 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %			
	M/L: Workwear + Protected hands + FP2, P2 and similar		No results!	
	App: Workwear + Protected hands + FP2, P2 and similar			

CHR/H/MEZO 30 OD/ Vidal 30 OD, Pacyfik 30 OD  
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## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for Mesosulfuron- methyl

**Table A 3.2.1-1: Estimation of worker exposure towards Mesosulfuron using the AOEM**

Worker exposure from residues on foliage for Pacyfik 30 OD/Vidal 30 OD				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,015 kg a.s./ha			<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1,0			<i>d_MAF</i>
Dermal absorption of the product	25,00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70,00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0,045 µg a.s./cm <sup>2</sup>			<i>d_DFR</i>
Working hours	2 hr			<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500 cm <sup>2</sup> /hr			<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400 cm <sup>2</sup> /hr			<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^</sup> (-3)			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^</sup> (-3)			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^</sup> (-3)			<i>d_InhalTcSort</i>
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0,7875000	0,0882000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0131250	0,0014700		
% of RVNAS	10,10%	1,13%		

**Table A 3.2.1-2: Estimation of worker exposure towards Mesosulfuron- methyl using the OPEX model.**

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA Body weight: 60 kg TC (potential): 12500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 1400 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h			
Number of applications & application rate: 1 x 0.015 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
<b>Mesosulfuron-methyl</b>			
Potential	0.01	10.1	0
Workwear	0.001	1.1	0
Workwear and gloves	0.001	1	0
Hands covered, no workwear			

### A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for Mesosulfuron-methyl

**Table A 3.3.1-1: Estimation of resident and bystander exposure towards Mesosulfuron using the AOEM**

Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	i_FormVal
Buffer strip	2-3 m	i_Buffer
Application rate of the product	0,015 kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,15 g a.s./l	d_ConcAS
Dermal absorption of product	25,00%	i_AbsorpProduct
Dermal absorption of in-use dilution	70,00%	i_Absorplnuse
Oral absorption	100,00%	i_AbsorpOralnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,045 µg a.s./cm <sup>2</sup>	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa	i_Volat
Concentration in air	0,001 mg/m <sup>3</sup>	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47 ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,327 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00010 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00022 ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person	
Exposure duration dermal	2 hours	d_ReExpDur
Exposure duration inhalation	24 hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25 hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%	d_ClothAF
Breathing rate adult	0,23 m <sup>3</sup> /day/kg	d_BreathRAAd
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%	
Drift percentage on surface (mean)	4,10%	
Turf transferable residues percentage	5,00%	d_Turf
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour	d_ReTCCh
Saliva extraction percentage	50,00%	d_SalExt
Surface area of hands mouthed	20 cm <sup>2</sup>	d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%	d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h	d_TcEntryCh

<b>1. Total</b>					
<b>1.1 1-3 year old child</b>					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0281877	0,0107000	0,0016506	0,0177188	0,0415597
Total systemic exposure per kg body weight (mg/kg a.s./day)	0,0028188	0,0010700	0,0001651	0,0017719	0,0041560
% of RVNAS	2,17%	0,82%	0,13%	1,36%	3,20%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0404820	0,0138000	0,0042924	0,0590625	0,0832644
Total systemic exposure per kg body weight (mg/kg a.s./day)	0,0006747	0,0002300	0,0000715	0,0009844	0,0013877
% of RVNAS	0,52%	0,18%	0,06%	0,76%	1,07%

**Table A 3.3.1-3: Estimation of resident and bystander exposure towards Mesosulfuron-methyl using the OPEX model.**

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l			
Number of applications and application rate: 1 x 0.015 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
<b>Mesosulfuron-methyl</b>			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.003	2.2
	Vapour (75th perc.)	0.0008	0.6
	Deposits (75th perc.)	0.0002	0.1
	Re-entry (75th perc.)	0.002	1.4
	Sum (mean)	0.004	3
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0007	0.5
	Vapour (75th perc.)	0.0003	0.2
	Deposits (75th perc.)	7e-05	0.06
	Re-entry (75th perc.)	0.001	0.8
	Sum (mean)	0.001	1.1

**Table A 3.3.1-1: Estimation of bystander exposure towards Mesosulfuron-methyl.**

Estimation of bystander exposure is covered by estimation of resident exposure. Please see Table A16 Table A 3.3.1-3.

#### **A 3.4 Combined exposure calculations for Mesosulfuron -methyl.**

Not required.

#### **Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)**

Not required.