

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: ADM.06001.H.2.B

Product name(s): EDAPTIS

Chemical active substances:

Mesosulfuron-methyl, 12 g/L

Pinoxaden, 60 g/L

Safener: Mefenpyr-diethyl, 35 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: June 2021

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September 2023, December 2023 (final Core Assessment)

Version history

When	What
June 2021	First version submitted by applicant
July 2022	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey . Not agreed or not relevant information are struck through and shaded for transparency .
September 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Information no longer relevant is struck through and shaded .
December 2023	Final report (Core Assessment updated following the second commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in green . Not agreed or not relevant information are struck through and shaded for transparency.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

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Reviewer comment:

This part of dossier summarizes data related to the toxicity and NDE assessment for the plant protection product EDAPTIS 72 OD (product code ADM.06001.H.2.B containing 12 g/L mesosulfuron-methyl; 60 g/L pinoxaden and 35 g/L safener mefenpyr-diethyl). Dossier has been submitted to support registration according art. 33 of 1107/2009 in Poland also for zonal registration for which PL was designated zRMS. Intended use of PPP is as herbicide in winter wheat, rye, triticale and spring wheat, with a maximum application rate of 1 L/ha and at latest BBCH of 39.

ADM.06001.H.2.B is a new formulation which was not a representative formulation reviewed during the Annex I inclusion/active substances renewal and has not previously been evaluated in any EU countries according to the Uniform Principles, thus it is not possible to refer to the conclusion on active substances with regard to the formulation studies. Therefore, relevant data on the plant protection product EDAPTIS 72 OD had to be generated for authorisation purposes.

For the current product registration (ADM.06001.H.2.B) no experimental acute toxicity data are available. To assess the acute toxicity properties and hazard classification of ADM.06001.H.2.B the CLP calculation method according to Regulation (EC) No 1272/2008 was applied. For these calculation data of all individual ingredients including active substances, safener, emulsifier, stabilizer and solvent were considered. Details of the calculation can be found in the confidential dossier of this submission (Registration Report - Part C).

zRMS PL in accordance with the EC recommendations to avoid tests on animals, for the purposes of hazard classification use the data obtained using the calculation method (ATEmix/additivity formula) and do not request for *in vivo* data.

Based on the CLP calculation method the formulation ADM.06001.H.2.B is not acutely toxic with respect to oral, dermal or inhalation application. The formulation is expected to be irritant to the eye and sensitizing to the skin. According to Regulation (EC) No 1272/2008 the formulation ADM.06001.H.2.B needs to be classified for eye irritation (H319) and for skin sensitization (H317). Furthermore, a classification for reproduction cat 2 (H361d) is required resulted from adopted harmonized classification of the active substance pinoxaden.

Additional hazard class for ADM.06001.H.2.B (Carc. 2; H351) has been added due to the triggering content of relevant co-formulant (for details refer Part C).

NDE assessment for operator, workers and B&R has been calculated using the AOEM model (EFSA calculator, version March 2015) and considering the worst-case exposure scenario to cover all the intended uses (highest application rate per application as well as the highest application rate per year with the shorter interval between each application). All NDE calculations provided for operator, workers and B&R resulting from use of PPP, considering all tasks according to the critical use(s), identify safe use of the product EDAPTIS 72 OD (ADM.06001.H.2.B).

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on ADM.06001.H.2.B*

Product name and code	ADM.06001.H.2.B
Formulation type	Oil dispersion [Code: OD]
Active substance(s) (incl. content)	Mesosulfuron-methyl, 12 g/L Pinoxaden, 60 g/L Safener: Mefenpyr-diethyl, 35 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 ADM.06001.H.2.B 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 ADM.06001.H.2.B:

Table 6.1-2: Justified proposals for classification and labelling for ADM.06001.H.2.B according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Eye Irrit. 2 - H319 Skin sens. 1 - H317 Repr. 2 - H361d Carc. 2 - H351
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07, GHS08, GS09
Signal word	Warning
Hazard statement(s)	H319: Causes serious eye irritation H317: May cause an allergic skin reaction H361d: Suspected of damaging the unborn child H351: Suspected of causing cancer
Precautionary statement(s)	P102, P201, P280, P302+P352, P305+P351+P338, P308 + P313 , P501
Additional labelling phrases	EUH401- To avoid risks to human health and the environment, comply with the instructions for use

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for ADM.06001.H.2.B

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) with gloves during Mixing and Loading NOTE: 1) Due to additional hazard class H351, operator should wear during all tasks protective clothing and gloves 2) Regarding classification of the product with Eye Irrit.2, H319, eye protection would be necessary
Workers	Acceptable	Work wear (arms, body and legs covered)
Residents	Acceptable	No specific measures needed
Bystanders	Not applicable	No acute AAOELs set*

*in this case exposure for bystanders resulting from use of the PPP is covered by the resident risk assessment

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary **except for gloves when mixing and loading the product.**

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders 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/syn- ergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure assess- ment				
			Method / Kind (incl. applica- tion technique ***)	Max. number (min. interval between ap- plications) a) per use b) per crop/ season	Max. applica- tion rate kg as/ha	Water L/ha min / max			Operator	Worker	Residents	Bystander	
2, 3	Winter wheat, rye, triticale, spring wheat	F	Foliar, spray- ing overall LC, TM	a) 1 b) 1	Mesosulfuron- methyl: 0.012 Pinoxaden: 0.06	80-300		Mefenpyr-diethyl applied as a saf- ener at 35 g/ha In PL applied also in tank mix with adjuvat Insert : 0,5-1,0 + 0,2 l/ha					n/a#

1	2	3	4	5	6	7	8	9	10			
								(Insert) And with Camaro 306 SE: 0,5 + 0,5 l/ha (Ca- maro 306 SE)				

* 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

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

No acute AAOELs has been set, that is why NDE calculation for bystanders are covered by the resident risk assessment

Explanation for column 10 "Acceptability of exposure assessment"

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

Data gaps

Noticed data gaps are:

- none

6.2 Toxicological Information on Active Substances

Information regarding classification of the active substances and the safener on EU endpoints and critical areas of concern identified during the EU review are given in the following tables.

Table 6.2-1: Information on mesosulfuron-methyl

	Mesosulfuron-methyl
Common Name	Mesosulfuron-methyl
CAS-No.	208465-21-8
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Classification according to Regulation (EC) No. 1272/2008: No current harmonised classification for toxicology and none proposed Mesosulfurn-methyl has harmonised classification Reg 2018/1480: Aquatic Acute 1 – H400 Aquatic Chronic 1 – H410
Additional C&L proposal	None
Agreed EU endpoints	
AOEL	0.13 mg/kg bw/d
AAOEL	No AAOEL derived, not necessary
Reference	SANTE/11827/2016 Rev 2 23 March 2017 EFSA Journal 2016;14(10):4584
Conditions to take into account/critical areas of concern with regard to toxicology	
	There is no critical area of concern

Table 6.2-2: Information on pinoxaden

	Pinoxaden
Common Name	Pinoxaden
CAS-No.	243973-20-8
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Classification according to Regulation (EC) No. 1272/2008: Acute Tox. 4 – H302 Acute Tox. 4 – H332 Eye Irrit. 2 – H319 STOT SE 3 – H335 Skin Sens. 1A – H317 Repr. 2 – H361d
Additional C&L proposal	Aquatic Acute 1 - H400 Aquatic Chronic 3 - H412
Agreed EU endpoints	
AOEL	0.1 mg/kg bw/d
Reference	SANCO/11794/2013 rev 3 29 Jan 2016 EFSA Journal 2013;11(8):3269
Conditions to take into account/critical areas of concern with regard to toxicology	
	Relevant metabolites M3, M11, M52, M54, M55 and M56 have the potential to exceed the legal parametric limit of 0.1 µg / L in groundwater for all or the majority of scenarios simulated. Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Reviewer comment: in the light of provided confirmatory data, detailed discussion regarding relevance of mentioned above metabolites in groundwater has been included in Part B10.

Table 6.2-3: Information on safener mefenpyr-diethyl

	Mefenpyr-diethyl
Common Name	Mefenpyr-diethyl
CAS-No.	135590-91-9
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Proposed in Monograph (list of endpoints) Oct 2011*: Skin irritation 2, H315
Additional C&L proposal	None
Endpoints (not agreed on EU level)	
AOEL	0.1 mg/kg bw/d
Reference	DAR (list of endpoints) Oct 2011
Conditions to take into account/critical areas of concern with regard to toxicology	
	None

*Monograph has been voluntarily prepared by AGES and ANSES in the context of zonal authorisation of plant protection products containing safener Mefenpyr-diethyl.#

#**Reviewer comment:** Please keep in mind that TRV's suggested by the two National agencies AGES and ANSES are not yet assessed at EU level.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the evaluation of the acute toxicity including irritancy and skin sensitisation according to the calculation method (according to Reg. 1272/2008) for ADM.06001.H.2.B is given in the following Table 6.3-1. Details of the calculation can be found in the confidential dossier of this submission (Registration Report - Part C).

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ADM.06001.H.2.B

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat ATEmix/additivity formula Hazard classification has been based on generic concentration limits (sum of relevant ingredients).	> 2000 mg/kg bw	Yes	None	Acute tox calculation method according to Regulation 1272/2008
LD ₅₀ dermal, rat ATEmix/additivity formula Hazard classification has been based on generic concentration limits (sum of relevant ingredients).	> 2000 mg/kg bw	Yes	None	
LC ₅₀ inhalation, rat ATEmix/additivity formula Hazard classification has been based on generic concentration limits (sum of relevant ingredients).	> 5 mg/L	Yes	None	
Skin irritation, rabbit ATEmix/additivity formula Hazard classification has been based on generic concentration limits (sum of relevant ingredients).	Non-irritant	Yes	None	
Eye irritation, rabbit ATEmix/additivity formula Hazard classification has been based on generic concentration limits (sum of relevant ingredients).	Irritant	Yes	Eye Irrit. 2 - H319	
Skin sensitisation, guinea pig ATEmix/additivity formula Hazard classification has been based on generic concentration limits (sum of relevant ingredients).	Sensitising	Yes	Skin sens. 1 - H317	
Supplementary studies for combinations of plant protection products	No data - not required	-		

Table 6.3-2: Additional toxicological information relevant for classification / labelling of ADM.06001.H.2.B

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Pinoxaden (6 % (w/w))	Skin sens. 1 - H317 (≥ 1%) Repr. 2 - H361d (≥ 3%) Pinoxaden harmonized classification according ATP 13: Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Sens. 1A H317	Reg. 1272/2008 / MSDS*	Skin sens. 1 - H317 Repr. 2 - H361d

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
		Acute Tox. 4 H332 STOT SE 3 H335 Repr. 2 H361d		
Toxicological properties of non-active substance(s) (relevant for classification of product)*	Please see confidential part C	H351: Carc. 2 H361: Repr. 2 H315: Skin irritation cat. 2 H319: Eye irritation cat. 2	Reg. 1272/2008 / MSDS*	Repr. 2 - H361 Carc. 2 – H351
Further toxicological information	No data – not required			

* Material safety data sheets by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Pinoxaden is classified with Acute Tox. 4 - H302, Acute Tox. 4 - H332, Eye Irrit. 2 - H319, STOT SE 3 - H335, Skin Sens. 1A - H317, Repr. 2 - H361d.

As required by Commission Implementing Regulation (EU) 2016/370 Syngenta addressed in the confirmatory data on pinoxaden the relevance of the groundwater metabolites M3, M11, M52, M54, M55 and M56. ADAMA has LoA and can refer to this confirmatory data. Reference is made to dRR Part B10 and the detailed assessment of the groundwater metabolites which is presented here.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in ADM.06001.H.2.B are presented in the following table. In absence of experimental data default values were considered.

Table 6.5-1: Dermal absorption rates for active substances and safener in ADM.06001.H.2.B

Mesosulfuron-methyl			
	Value	Justification for value	Acceptability of justification
Concentrate	25% 70%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 rev.1, 24 October 2018	Justification accepted. Endpoint can be used for current product
Dilution	70%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)	Justification accepted. Endpoint can be used for current product

Pinoxaden

	Value	Justification for value	Acceptability of justification
Concentrate	25%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)	Justification accepted. Endpoint can be used for current product
Dilution	70%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)	Justification accepted. Endpoint can be used for current product

Mefenpyr-diethyl (safener)

	Value	Justification for value	Acceptability of justification
Concentrate	25% 70%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 rev.1, 24 October 2018	Justification accepted. Endpoint can be used for current product
Dilution	70%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)	Justification accepted. Endpoint can be used for current product

Mesosulfuron-methyl		
	Value	Reference
Concentrate	25%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)
Dilution	70%	

Pinoxaden		
	Value	Reference
Concentrate	25%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)
Dilution	70%	

Mefenpyr-diethyl (safener)		
	Value	Reference
Concentrate	25%	Default values for oil dispersion (Guidance on dermal absorption, EFSA Journal 2017;15(6):4873)
Dilution	70%	

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	ADM.06001.H.2.B		
Formulation type	Oil-based suspension concentrate [Code: OD]		
Category	Herbicide		
Active substances Safener (incl. content)	Mesosulfuron-methyl 12 g/L	Pinoxaden 60 g/L	Safener Mefenpyr-diethyl 35 g/L
AOEL	0.13 mg/kg bw/d	0.1 mg/kg bw/d	0.1 mg/kg bw/d
AAOEL	No AAOEL derived, not necessary	None proposed	None proposed
Inhalation absorption	100%	100%	100%
Oral absorption	2%	100%	73%
Dermal absorption (Default values for organic solvent based formulation)	Concentrate: 25 70 % Dilution: 70 %	Concentrate: 25 % Dilution: 70 %	Concentrate: 25 70% Dilution: 70 %

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.

Critical uses identified are use 2 and 3.

Justification

The critical GAP has been defined following evaluation of the individual GAPs for each crop in each relevant Member State.

It takes into account:

- the maximum use rate per application of 1L ADM.06001.H.2.B (12 g/ha mesosulfuron-methyl, 60 g/ha pinoxaden and 35 g/ha mefenpyr-diethyl)
- the minimum water volume as relevant for this zone (80 L/ha)

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure model used for estimation of operator exposure to the active substances during application of ADM.06001.H.2.B according to the critical use is presented in Table 6.6-3. The outcome of the estimation is presented in Table 6.6-2. Detailed calculations are in Appendix 3.

Table 6.6-3: Exposure models for intended uses

Critical use(s)	Cereals (max. 1 L product/ha, 12 g/ha mesosulfuron-methyl, 60 g/ha pinoxaden, 35 g/ha mefenpyr-diethyl)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-4 Estimated operator long term exposure

		Mesosulfuron-methyl		Pinoxaden		Mefenpyr-diethyl (safener)	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops							
Application rate		0.012 kg a.s./ha		0.06 kg a.s./ha		0.035 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) No gloves during ML/A	0.0160 0.0399	12.29% 30.71%	0.0536	53.58%	0.0352 0.0919	35.15% 91.94%
	Gloves during ML	0.0016 0.0020	1.2% 1.52%	0.0067	6.73%	0.0042 0.0053	4.22% 5.34%

Results:

The potential total systemic exposure of the operator, who is dressed with work wear that covers the body, arms and legs, but no gloves during mixing/loading and application corresponds to about ~~12~~ **31%** of the AOEL for mesosulfuron-methyl, about 54% of the established AOEL for pinoxaden, for about ~~35~~ **92%** of the AOEL for mefenpyr-diethyl when applying ADM.06001.H.2.B to cereals.

When wearing gloves during mixing/loading the estimated operator exposure accounts for about ~~1~~ **1.5%** of the AOEL for mesosulfuron-methyl, for about 7% of the AOEL for pinoxaden and about ~~4~~ **5%** of the AOEL for mefenpyr-diethyl.

Thus the use of ADM.06001.H.2.B in cereals is at an acceptable risk for the operator, according to the EFSA-OPEX model.

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)**6.6.3.1 Estimation of worker exposure**

Table 6.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with ADM.06001.H.2.B according to the critical use. Outcome of the estimation is presented in Table 6.6-6. Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Cereals (max. 1 L product/ha, 12 g/ha mesosulfuron-methyl, 60 g/ha pinoxaden, 35 g/ha mefenpyr-diethyl)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-6: Estimated worker exposure

Model data: EFSA	Mesosulfuron-methyl		Pinoxaden		Mefenpyr-diethyl	
Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation - Outdoor , Work rate: 2 hours/day, DT ₅₀ : 30 days, DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days, Body weight: 60 kg						
Application rate:	1 x 0.012 kg a.s./ha		1x 0.06 kg a.s./ha		1x 0.035 kg a.s./ha	
Potential exposure TC: 12500 cm ² /person/h	0.0114 0.0105	8.75% 8.08%	0.0525	52.50%	0.0328 0.0306	32.81% 30.63%
Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0013 0.0012	0.98% 0.90%	0.0059	5.88%	0.0037 0.0034	3.68% 3.43%

Results:

The potential total systemic exposure of the worker, who is dressed with work wear that covers the body, arms and legs, corresponds to about 1% of the AOEL for mesosulfuron-methyl, about 6% of the established AOEL for pinoxaden, for about 4% of the AOEL for the safener mefenpyr-diethyl when entering cereal crops previously treated with ADM.06001.H.2.B .

Thus the use of ADM.06001.H.2.B in cereals is at an acceptable risk for the worker, according to the EFSA-OPEX model.

6.6.3.2 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure levels (AOEL) of mesosulfuron-methyl, pinoxaden and mefenpyr-diethyl will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)**6.6.4.1 Estimation of resident and bystander exposure**

No acute non-dietary risk assessment is included in this submission. Lack of scientific guidance or methodology is an acceptable reason for waiving according to Guidance of the European Commission.

The absence of such guidance on derivation of an appropriate reference dose (“AAOEL”) was recognized by

- the European Food Safety Authority, and
- the European Commission Standing Committee.

Therefore, this waiver is presented in line with the Guidance of the European Commission.

According to EFSA longer term exposure of bystanders is covered by the resident scenario. shows the exposure model used for estimation of resident exposure. Results of the estimations are presented in Table 6.6-8. Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure model for intended uses

Critical use(s)	Cereals (max. 1 L product/ha, 12 g/ha mesosulfuron-methyl, 60 g/ha pinoxaden, 35 g/ha mefenpyr-diethyl)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-8: Estimated resident exposure

Model data EFSA		Mesosulfuron-methyl		Pinoxaden		Mefenpyr-diethyl	
		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops, Buffer zone: 2-3 (m), Drift reduction technology: no, DT ₅₀ : 30 days. DFR: 3 µg/cm ² /kg a.s./ha, Interval between treatments: 365 days							
Application rate:		1 x 0.012 kg a.s./ha		1x 0.06 kg a.s./ha		1x 0.035 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0031 0.0028	2.35% 2.17%	0.0141	14.09%	0.0088 0.0082	8.81% 8.22%
	Vapour (75 th perc.)	0.0011	0.82%	0.0011	1.07%	0.0011	1.07%
	Deposits (75 th perc.)	0.0001	0.10% 0.09%	0.0007	0.66%	0.0004 0.0038	0.40% 0.38%
	Re-entry (75 th perc.)	0.0015 0.0014	1.18% 1.09%	0.0071	7.09%	0.0044 0.0041	4.43% 4.13%
	Sum (mean)	0.0041 0.0038	3.13% 2.96%	0.0150	14.97%	0.0097 0.0092	9.75% 9.17%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0007	0.56% 0.52%	0.0034	3.37%	0.0021 0.0020	2.11% 1.97%
	Vapour (75 th perc.)	0.0002	0.18%	0.0002	0.23%	0.0002	0.23%
	Deposits (75 th perc.)	0.0001	0.05% 0.04%	0.0003	0.29%	0.0002	0.18% 0.17%
	Re-entry (75 th perc.)	0.0009 0.0008	0.66% 0.61%	0.0039	3.94%	0.0025 0.0023	2.46% 2.30%
	Sum (mean)	0.0013 0.0012	1.00% 0.94%	0.0052	5.18%	0.0033 0.0031	3.32% 3.12%

Results

The exposure estimates for residents result in values for

- mesosulfuron-methyl accounting for about 3% and 1% of the AOEL for the child and adult scenario respectively.
- pinoxaden, accounting for about 15% and 5% of the AOEL for the child and adult scenario respectively.
- mefenpyr-diethyl accounting for about ~~10~~ **9**% and 3% of the AOEL for the child and adult scenario respectively..

It is concluded that there is no undue risk to residents upon the application of ADM.06001.H.2.B in cereals.

6.6.4.2 Measurement of resident and/or bystander exposure

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

6.6.5 Combined exposure

ADM.06001.H.2.B is a mixture of two active substances and a safener which in the risk assessment is evaluated like an active substance.

6.6.5.1 Exposure Assessment of mesosulfuron-methyl and pinoxaden and mefenpyr-diethyl in ADM.06001.H.2.B

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of Table 6.6-4 to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-9: Acute risk assessment from combined exposure

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators Vehicle mounted boom sprayers, work clothing -No gloves during mixing/loading and application	Mesosulfuron-methyl	0.1 0.307
	Pinoxaden	0.5 0.536
	Mefenpyr-diethyl	0.4 0.919
	Cumulative risk Operators (HI)	1.0 1.76
-Gloves during mixing/loading	Mesosulfuron-methyl	0.01 0.015
	Pinoxaden	0.1 0.067
	Mefenpyr-diethyl	0.04 0.053
	Cumulative risk Operators (HI)	0.1 0.135
Workers – 2 hours scouting, irrigation long work clothing.	Mesosulfuron-methyl	0.01 0.009
	Pinoxaden	0.1 0.054
	Mefenpyr-diethyl	0.04 0.034
	Cumulative risk Workers (HI)	0.1
Resident – Child Bw 10 kg Light clothing (shorts, short sleeved shirt)	Mesosulfuron-methyl	0.03
	Pinoxaden	0.2 0.15
	Mefenpyr-diethyl	0.1
	Cumulative risk Resident – Adult (HI)	0.3 0.27
Resident – Adult Bw: 60 kg Light clothing (shorts, short sleeved shirt)	Mesosulfuron-methyl	0.01
	Pinoxaden	0.1 0.05
	Mefenpyr-diethyl	0.03
	Cumulative risk Resident – Child (HI)	0.1 0.09

The Hazard Index is 1 or less. Thus combined exposure to all active substances in ADM.06001.H.2.B is not expected to present a risk for operators, workers and residents. No further refinement of the assessment is required.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

None.

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

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

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

With ADM.06001.H.2.B no experimental acute toxicity data are available. To assess the acute toxicity data and the classification of ADM.06001.H.2.B the CLP calculation method according to Regulation (EC) No 1272/2008 was applied. For these calculation data of all individual ingredients including active substances, safener, emulsifier, stabilizer and solvent were considered. Details of the calculation can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.1 Statement on bridging possibilities

Not relevant.

Comments of zRMS:	Accepted.
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A 2.2 Acute oral toxicity (KCP 7.1.1)

No new study has been submitted.

Comments of zRMS:	Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C).
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A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

No new study has been submitted.

Comments of zRMS:	Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C).
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A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No new study has been submitted.

Comments of zRMS:	Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C).
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A 2.5 Skin irritation (KCP 7.1.4)

No new study has been submitted.

Comments of zRMS:	Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C).
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A 2.6 Eye irritation (KCP 7.1.5)

No new study has been submitted.

Comments of zRMS:	Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C).
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A 2.7 Skin sensitisation (KCP 7.1.6)

No new study has been submitted.

Comments of zRMS:	Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C).
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A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are to be considered.

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)

With ADM.06001.H.2.B no dermal absorption data are available. Default values according to the Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) were used.

A 2.11 Other/Special Studies

Not relevant.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for mesosulfuron-methyl

Table A 1: Input parameters considered for the estimation of operator exposure

Substance	Mesosulfuron-methyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0.012 kg a.s./ha	Spray dilution = 0.15 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 70	Dermal for in use dilution = 70	Oral = 2	Inhalation = 100	
RVNAS	0.13 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm ² per kg a.s./ha		DT50	30 days	

Table A 2: Estimation operator exposure towards mesosulfuron-methyl according to EFSA guidance

Operator Model	Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0694	% of RVNAS	53.37%
	Acute systemic exposure mg/kg bw/day	0.8878	% of RVAAS	
Mixing and Loading	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0399	% of RVNAS	30.71%
	Acute systemic exposure mg/kg bw/day	0.1615	% of RVAAS	

Operator Model	Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0694	% of RVNAS	53.37%
	Acute systemic exposure mg/kg bw/day	0.8878	% of RVAAS	
Mixing and Loading	Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0020	% of RVNAS	1.52%
	Acute systemic exposure mg/kg bw/day	0.0234	% of RVAAS	

Substance	Mesosulfuron-methyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0.013 kg a.s./ha	Spray dilution = 0.1625 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of $\leq 5 \cdot 10^{-3} \text{ Pa}$
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3m	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 25	Dermal for in use dilution = 70	Oral = 2	Inhalation = 100	

RVNAS	0.13 mg/kg bw/day	RVAAS	Not acute toxic, thus not derived mg/kg bw/day	-
DER	3 µg a.s./cm ² per kg a.s./ha	DT50	30 days	-

Operator Model		Mixing, loading and application AOEM		
Mixing and Loading	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0160	% of RVNAS	12.29%
	Acute systemic exposure mg/kg bw/day	0.0743	% of RVAAS	#WERT!
Mixing and Loading	Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0016	% of RVNAS	1,2 %
	Acute systemic exposure mg/kg bw/day	0.0218	% of RVAAS	

A 3.1.2 Calculations for pinoxaden

Table A 3: Input parameters considered for the estimation of operator exposure

Substance	Pinoxaden	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate- 0.06 kg a.s. /ha	Spray dilution = 0.75 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <math><5*10^{-3}</math>Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 25	Dermal for in use dilution = 70	Oral = 100	Inhalation = 100	
RVNAS	0.1 mg/kg bw/day		RVAAS	0.1 mg/kg bw/day	
DFR	3 µg a.s./cm ² per kg a.s./ha		DT50	30 days	

Table A 4: Estimation of operator exposure towards pinoxaden according to EFSA guidance

Operator Model		Mixing, loading and application AOEM			
Mixing and Loading	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No	
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No	
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0536	% of RVNAS	53.58%	
	Acute systemic exposure mg/kg bw/day	0.2408	% of RVAAS	240.79%	
Mixing and Loading	Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No	
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No	
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0067	% of RVNAS	6.73%	
	Acute systemic exposure mg/kg bw/day	0.0688	% of RVAAS	68.83%	

A 3.1.3 Calculations for mefenpyr-diethyl

Table A 5: Input parameters considered for the estimation of operator exposure

Substance	Mefenpyr-diethyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0.035 kg a.s./ha	Spray dilution = 0.4375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 70	Dermal for in use dilution = 70	Oral = 73	Inhalation = 100	
RVNAS	0.1 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm ² per kg a.s./ha		DT50	30 days	

Substance	Mefenpyr diethyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate = 0.035 kg a.s./ha	Spray dilution = 0.4375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <math>< 5 \cdot 10^{-3}</math> Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 25	Dermal for in use dilution = 75	Oral = 73	Inhalation = 100	
RVNAS	0.1 mg/kg bw/day		RVAAS	Not acute toxic, thus not derived mg/kg bw/day	
DFR	3 µg a.s./cm ² per kg a.s./ha		DT50	30 days	

Table A 6: Estimation of longer term operator exposure towards mefenpyr-diethyl according to EFSA guidance

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.1548	% of RVNAS	154.81%	
	Acute systemic exposure mg/kg bw/day	1.3653	% of RVAAS		
Mixing and Loading	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No	
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No	
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0919	% of RVNAS	91.94%	
	Acute systemic exposure mg/kg bw/day	0.3710	% of RVAAS		

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.1548	% of RVNAS	154.81%	
	Acute systemic exposure mg/kg bw/day	1.3653	% of RVAAS		
Mixing and Loading	Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No	
Application	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No	
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0053	% of RVNAS	5.34%	
	Acute systemic exposure mg/kg bw/day	0.0540	% of RVAAS		

Operator Model		Mixing, loading and application AOEM		
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0588	% of RVNAS	58.78%
	Acute systemic exposure mg/kg bw/day	0.5231	% of RVAAS	#WERT!
Mixing and Loading	Gloves = No	Clothing = Work wear – arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear – arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0352	% of RVNAS	35.15%
	Acute systemic exposure mg/kg bw/day	0.1619	% of RVAAS	#WERT!
Mixing and Loading	Gloves = Yes	Clothing = Work wear – arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear – arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0042	% of RVNAS	4.22%
	Acute systemic exposure mg/kg bw/day	0.0487	% of RVAAS	#WERT!

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for mesosulfuron-methyl

Table A 7: Input parameters considered for the estimation of worker exposure

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	0.012 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1.0
Dermal absorption of the product	70.00%
Dermal absorption of the in-use dilution	70.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.036 µg a.s./cm ²
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr

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	0.013 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half life of active substance	30 days
Multiple application factor	1.0
Dermal absorption of the product	25.00%
Dermal absorption of the in use dilution	70.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.039 µg a.s./cm ²
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr

Table A 8: Estimation of worker exposure towards mesosulfuron-methyl

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0.0105	% of RVNAS	8.08%
	Working clothing mg/kg bw/day	0.0012	% of RVNAS	0.90%
	Working clothing and gloves mg/kg bw/day		% of RVNAS	

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0.0114	% of RVNAS	8.75%
	Working clothing mg/kg bw/day	0.0013	% of RVNAS	0.98%

A 3.2.2 Calculations for pinoxaden

Table A 9: Input parameters considered for the estimation of worker exposure

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	0.06 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1.0
Dermal absorption of the product	25.00%
Dermal absorption of the in-use dilution	70.00%
Dislodgeable foliar residue ($i_AppRate * i_DFR$)	0.18 $\mu\text{g a.s./cm}^2$
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm^2/hr

Table A 10: Estimation of worker exposure towards pinoxaden according to EFSA guidance

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0.0525	% of RVNAS	52.50%
	Working clothing mg/kg bw/day	0.0059	% of RVNAS	5.88%

A 3.2.3 Calculations for mefenpyr-diethyl

Table A 11: Input parameters considered for the estimation of worker exposure

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	0.035 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1.0
Dermal absorption of the product	70.00%
Dermal absorption of the in-use dilution	70.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.105 µg a.s./cm ²
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr

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	0.035 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1.0
Dermal absorption of the product	25.00%
Dermal absorption of the in-use dilution	75.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.105 µg a.s./cm ²
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment

Table A 12: Estimation of worker exposure towards mefenpyr-diethyl according to EFSA guidance

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0.0306	% of RVNAS	30.63%
	Working clothing mg/kg bw/day	0.0034	% of RVNAS	3.43%
	Working clothing and gloves mg/kg bw/day		% of RVNAS	

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0.0328	% of RVNAS	32.81%
	Working clothing mg/kg bw/day	0.0037	% of RVNAS	3.68%
	Working clothing and gloves mg/kg bw/day		% of RVNAS	-

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for mesosulfuron-methyl

Table A 13: Input parameters considered for the estimation of resident exposure

Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0.012 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.15 g a.s./l
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption	2.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.036 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Concentration in air	0.001 mg/m ³
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
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0.25 hours
Light clothing adjustment factor	18.0%
Breathing rate adult	0.23 m ³ /day/kg
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg
Drift percentage on surface (75th percentile)	5.60%
Drift percentage on surface (mean)	4.10%
Turf transferable residues percentage	5.00%
Transfer coeff. of surface deposits-adult	7300 cm ² /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour
Saliva extraction percentage	50.00%
Surface area of hands mouthed	20 cm ²
Frequency of hand to mouth activity	9.5 events/hour
Ingestion rate for mouthing of grass per day	25 cm ²
Dislodgeable residues percentage transferability for object to mouth	20.00%
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h

Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0.013 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.1625 g a.s./l
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption	2.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.039 µg a.s./cm ²
Vapour pressure of in use dilution	low volatile substances
Concentration in air	0.001 mg/m ³
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
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0.25	hours
Light clothing adjustment factor	18.0%	
Breathing rate adult	0.23	m ³ /day/kg
Breathing rate child (1-3 year old)	1.07	m ³ /day/kg
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits – adult	7300	em ² /hour
Transfer coeff. of surface deposits – child (1-3 year old)	2600	em ² /hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	em ²
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	em ²
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) – adult	7500	em ² /h
Transfer coefficient for entry into treated crops (75th percentile) – child	2250	em ² /h
Transfer coefficient for entry into treated crops (mean) – adult	5980	em ² /h
Transfer coefficient for entry into treated crops (mean) – child	1794	em ² /h

Table A 14: Estimation of resident exposure towards mesosulfuron-methyl according to EFSA guidance

Resident - child	Exposure pathway	Value	% of RVNAS	Value
	Spray drift (75th percentile) mg/kg bw/day	0.0028	% of RVNAS	2.17%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	0.82%
	Surface deposits (75th percentile) mg/kg bw/day	0.0001	% of RVNAS	0.09%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0014	% of RVNAS	1.09%
	All pathways (mean) mg/kg bw/day	0.0038	% of RVNAS	2.96%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0007	% of RVNAS	0.52%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.18%
	Surface deposits (75th percentile) mg/kg bw/day	0.0001	% of RVNAS	0.04%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0008	% of RVNAS	0.61%
	All pathways (mean) mg/kg bw/day	0.0012	% of RVNAS	0.94%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.0031	% of RVNAS	2.35%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	0.82%
	Surface deposits (75th percentile) mg/kg bw/day	0.0001	% of RVNAS	0.10%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0015	% of RVNAS	1.18%
	All pathways (mean) mg/kg bw/day	0.0041	% of RVNAS	3.13%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0007	% of RVNAS	0.56%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.18%
	Surface deposits (75th percentile) mg/kg bw/day	0.0001	% of RVNAS	0.05%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0009	% of RVNAS	0.66%
	All pathways (mean) mg/kg bw/day	0.0013	% of RVNAS	1.00%

A 3.3.2 Calculations for pinoxaden

Table A 15: Input parameters considered for the estimation of resident exposure

Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0.06 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.75 g a.s./l
Dermal absorption of product	25.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption	100.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances
Concentration in air	0.001 mg/m ³
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
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0.25 hours
Light clothing adjustment factor	18.0%
Breathing rate adult	0.23 m ³ /day/kg
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg
Drift percentage on surface (75th percentile)	5.60%
Drift percentage on surface (mean)	4.10%
Turf transferable residues percentage	5.00%
Transfer coeff. of surface deposits-adult	7300 cm ² /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour
Saliva extraction percentage	50.00%
Surface area of hands mouthed	20 cm ²
Frequency of hand to mouth activity	9.5 events/hour
Ingestion rate for mouthing of grass per day	25 cm ²
Dislodgeable residues percentage transferability for object to mouth	20.00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h

Table A 16: Estimation of resident exposure towards pinoxaden according to EFSA guidance

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.0141	% of RVNAS	14.09%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	1.07%
	Surface deposits (75th percentile) mg/kg bw/day	0.0007	% of RVNAS	0.66%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0071	% of RVNAS	7.09%
	All pathways (mean) mg/kg bw/day	0.0150	% of RVNAS	14.97%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0034	% of RVNAS	3.37%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.23%
	Surface deposits (75th percentile) mg/kg bw/day	0.0003	% of RVNAS	0.29%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0039	% of RVNAS	3.94%
	All pathways (mean) mg/kg bw/day	0.0052	% of RVNAS	5.18%

A 3.3.3 Calculations for mefenpyr-diethyl

Table A 17: Input parameters considered for the estimation of resident exposure

Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0.035 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.4375 g a.s./l
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption	73.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.105 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa Pa
Concentration in air	0.001 mg/m ³
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
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0.25 hours
Light clothing adjustment factor	18.0%
Breathing rate adult	0.23 m ³ /day/kg
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg
Drift percentage on surface (75th percentile)	5.60%
Drift percentage on surface (mean)	4.10%
Turf transferable residues percentage	5.00%
Transfer coeff. of surface deposits-adult	7300 cm ² /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour
Saliva extraction percentage	50.00%
Surface area of hands mouthed	20 cm ²
Frequency of hand to mouth activity	9.5 events/hour
Ingestion rate for mouthing of grass per day	25 cm ²
Dislodgeable residues percentage transferability for object to mouth	20.00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h

Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0.035 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.4375 g a.s./l
Dermal absorption of product	70.00%
Dermal absorption of in-use dilution	70.00%
Oral absorption	73.00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.105 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa Pa
Concentration in air	0.001 mg/m ³
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
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0.25 hours

Light clothing adjustment factor	18.0%	
Breathing rate adult	0.23	m ³ /day/kg
Breathing rate child (1-3 year old)	1.07	m ³ /day/kg
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits adult	7300	em ² /hour
Transfer coeff. of surface deposits child (1-3 year old)	2600	em ² /hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	em ²
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	em ²
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) – adult	7500	em ² /h
Transfer coefficient for entry into treated crops (75th percentile) – child	2250	em ² /h
Transfer coefficient for entry into treated crops (mean) – adult	5980	em ² /h
Transfer coefficient for entry into treated crops (mean) – child	1794	em ² /h

Table A 18: Estimation of resident exposure towards mefenpyr-diethyl according to EFSA guidance

Resident - child	Parameter	Value	% of RVNAS	Value
Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.0082	% of RVNAS	8.22%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	1.07%
	Surface deposits (75th percentile) mg/kg bw/day	0.0004	% of RVNAS	0.38%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0041	% of RVNAS	4.13%
	All pathways (mean) mg/kg bw/day	0.0092	% of RVNAS	9.17%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0020	% of RVNAS	1.97%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.23%
	Surface deposits (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.17%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0023	% of RVNAS	2.30%
	All pathways (mean) mg/kg bw/day	0.0031	% of RVNAS	3.12%

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0.0088	% of RVNAS	8.81%
	Vapour (75th percentile) mg/kg bw/day	0.0011	% of RVNAS	1.07%
	Surface deposits (75th percentile) mg/kg bw/day	0.0004	% of RVNAS	0.40%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0044	% of RVNAS	4.43%
	All pathways (mean) mg/kg bw/day	0.0097	% of RVNAS	9.75%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0.0021	% of RVNAS	2.11%
	Vapour (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.23%
	Surface deposits (75th percentile) mg/kg bw/day	0.0002	% of RVNAS	0.18%
	Entry into treated crops (75th percentile) mg/kg bw/day	0.0025	% of RVNAS	2.46%
	All pathways (mean) mg/kg bw/day	0.0033	% of RVNAS	3.32%

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 relevant.