

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: ADM.01851.H.1.A

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT/

(authorization)

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

Submission date: July 2024

MS Finalisation date: March 2025 (initial Core Assessment)

June 2025 (final Core Assessment)

Version history

When	What
July 2024	dRR version 1 submitted by applicant
March 2025	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.
June 2025	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 . Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.

Table of Contents

6	Mammalian Toxicology (KCP 7).....	4
6.1	Summary.....	4
6.2	Toxicological Information on Active Substance(s).....	6
6.3	Toxicological Evaluation of Plant Protection Product	7
6.4	Toxicological Evaluation of Groundwater Metabolites	8
6.5	Dermal Absorption (KCP 7.3).....	8
6.5.1	Justification for proposed values - ethofumesate.....	8
6.5.2	Justification for proposed values - clopyralid.....	8
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2)	9
6.6.1	Selection of critical use(s) and justification.....	9
6.6.2	Operator exposure (KCP 7.2.1)	9
6.6.2.1	Estimation of operator exposure	9
6.6.2.2	Measurement of operator exposure	12
6.6.3	Worker exposure (KCP 7.2.3).....	12
6.6.3.1	Estimation of worker exposure.....	12
6.6.3.2	Refinement of generic DFR value (KCP 7.2).....	13
6.6.3.3	Measurement of worker exposure	14
6.6.4	Resident and bystander exposure (KCP 7.2.2)	14
6.6.4.1	Estimation of resident and bystander exposure	14
6.6.4.2	Measurement of resident and/or bystander exposure	16
6.6.5	Combined exposure	16
6.6.5.1	Exposure assessment of ethofumesate and clopyralid in ADM.01851.H.1.A.....	16
Appendix 1	Lists of data considered in support of the evaluation.....	20
Appendix 2	Detailed evaluation of the studies relied upon	21
A 2.1	Statement on bridging possibilities.....	21
A 2.2	Supplementary studies for combinations of plant protection products (KCP 7.1.7).....	21
A 2.3	Data on co-formulants (KCP 7.4).....	21
A 2.4	Studies on dermal absorption (KCP 7.3)	21
A 2.5	Other/Special Studies	21
Appendix 3	Exposure calculations.....	22
A 3.1	Operator exposure calculations (KCP 7.2.1.1)	22
A 3.2	Worker exposure calculations (KCP 7.2.3.1)	28
A 3.3	Resident and bystander exposure calculations (KCP 7.2.2.1)	38
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).....	43

Reviewer general comment:

This part of dossier (B6) summarizes data related to the toxicological profile and NDE assessment for the plant protection product TAXATUM (product code ADM.01851.H.1.A) containing the active substances 500 g/L ethofumesate and 75 g/L clopyralid formulated as Suspension Concentrate for use in sugar beets and fodder beets, with a maximum application rate of 0.66 L/ha and at latest BBCH of 19.

All information has been submitted to support registration according art. 33 of 1107/2009 for the first authorization of the product ADM.01851.H.1.A in Poland also for zonal registration for which PL was designated zRMS. There are no further concerned member states (cMS) in the CZ.

The zRMS's reviewed all of the elements that are crucial for risk assessment and decision-making. Regarding evaluation of the toxicity profile of the product ADM.01851.H.1.A, in the absence of experimentally derived acute toxicity data for ADM.01851.H.1.A the Additivity Formula 3.1.3.6.1 (Reg 1272/2008) has been used to classify a mixture based on acute toxicity estimates (ATE) or converted ATE (cATE) for each ingredient.

NDE assessment for operator, workers and B&R has been calculated using the EFSA calculator, on-line version 1.02 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 ADM.01851.H.1.A.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on ADM.01851.H.1.A*

Product name and code	ADM.01851.H.1.A
Formulation type	Suspension concentrate [Code: SC]
Active substance(s) (incl. content)	Ethofumesate, 500 g/L Clopyralid, 75 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.01851.H.1.A 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 ADM.01851.H.1.A according to Regulation (EC) No 1272/2008

Hazard class(es), categories	~~Skin irritation~~ Skin Irrit. 2, ~~eye damage~~ Eye Dam.1
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS05
Signal word	Danger
Hazard statement(s)	H318 ~~cat 1~~ , H315 ~~cat 2~~
Precautionary statement(s)	P102, ~~P280, P302+P352, P305+P351+P338~~ , P501 P264, P280, P302+P352, P305+P351+P338, P332+P313, P310*
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May produce an allergic reaction. [EUH208]

* zRMS Reviewer comment reflecting Applicant concern: To avoid any doubts regarding the applied P phrases, the Reviewer decided to revise the information in Table 6.1-2. It should be noted that the phrases proposed by the Applicant were correct and only required the addition of extra phrases: P264 and P332+P313, P310

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for ADM.01851.H.1.A

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered), gloves and faceshield during mixing/loading and work wear (arms, body and legs covered) during application*
Workers	Acceptable	Task: Removing bolting sugar beets Do not enter treated crops until the spray has dried. Workers shall use workwear (arms, body and legs covered) and gloves for 6 days. Thereafter, workers shall use workwear (arms, body and legs covered). Task: Inspection, irrigation Do not enter treated crops until the spray has dried. Workers shall use workwear (arms, body and legs covered) without re-entry restriction.
Residents	Acceptable	None
Bystanders	Acceptable	None

*this additional RMM is strongly recommended due to the hazard classification of the product with H318 and H315

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in * zRMS measures stated in * zRMS Reviewer comment reflecting Applicant concern: To avoid any doubts regarding the applied P phrases, the Reviewer decided to revise the information in Table 6.1-2. It should be noted that the phrases proposed by the Applicant were correct and only required the addition of extra phrases: P264 and P332+P313, P310

Table 6.1-3 are applied.

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/synergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Exposure model]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. applica- tion rate active substance 1 / active sub- stance 2 kg as/ha a) per applica- tion b) per crop/ season	Water L/ha min / max			Operator	Worker	Residents	Bystander
1 and 2	Sugar beet BEAVA, Fodder beet BEAVAC (BBCH 10-19)	F	Foliar, spray- ing, overall	a) 3 (5) b) 3 (5)	a) 0.33 / 0.0495 b) 0.99 / 0.1485	100 - 400		Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032				

* 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

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 Substance(s)

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(s)

	Active substance 1	Active substance 2
Common Name	Ethofumesate	Clopyralid
CAS-No.	26225-79-6	1702-17-6
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: None Code for hazard pictogram: None Signal word: None Hazard statement: None Precautionary statement(s): None Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP	Hazard classes (s), categories: Eye damage 1 Code for hazard pictogram: GHS05 Signal word: danger Hazard statement(s): H318 Precautionary statement(s): P280 Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338 If in eyes: rinse

	Active substance 1	Active substance 2
	Regulation) ATP Inserted / Updated: CLP00/ATP15	cautiously with water for several minutes, remove contact lenses, if present and easy to do. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) ATP Inserted / Updated: CLP00/ATP01 H318 Eye Dam. 1
Additional C&L proposal		
Agreed EU endpoints		
AOEL systemic	2.5 mg/kg bw/d (no correction for oral absorption)	0.15 mg/kg bw/d (no correction for oral absorption)
AAOEL	~~Not required~~ Not allocated	0.17 mg/kg bw
Reference	EFSA Conclusion 2016 EFSA Journal 2016;14(1):4374	EFSA Conclusion 2018 EFSA Journal 2018;16(8):5389
Conditions to take into account/critical areas of concern with regard to toxicology		
According to Review Report/EFSA Conclusion for active substance	Tox studies not representative of the technical specification of ai and impurities	Tox studies not representative of the technical specification of ai and impurities

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for ADM.01851.H.1.A 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.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ADM.01851.H.1.A

Type of test, species, model system (Guideline) Endpoint	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	>2000 mg/kg bw	Yes	None	Acute tox calculation methods according to Regulation 1272/2008 (refer dRR Part C)
LD ₅₀ dermal, rat	>2000 mg/kg bw	Yes	None	
LC ₅₀ inhalation, rat	>5 mg/L air	Yes	None	
Skin irritation	Irritant	Yes	H315, ~~cat-2~~ Skin Irrit. 2	
Eye irritation	Causes serious eye damage	Yes	H318, ~~cat-1~~ Eye Dam.1	
Skin sensitisation	Non-sensitising	Yes	None	
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.01851.H.1.A

	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)	Clopyralid (6.41 % (w/w))	H318 cat 1 (≥ 3%, H318 cat 1)	EFSA conclusion 2018	H318 ~~cat-1~~ Eye Dam. 1

	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)
(relevant for classification of product)			Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) ATP Inserted / Updated: CLP00/ATP01 H318 Eye Dam.1	
Toxicological properties of non-active substance(s) (relevant for classification of product)	2-aminoethanol CAS No. 141-43-5 (2.2% (w/w))	H314 cat 1B (≥ 5%, cat 1) (>1% <5%, H315 cat 2)	MSDS	H315 cat 2 Skin Irrit. 2
Further toxicological information	No data – not required			

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

No dermal absorption studies were performed with the formulation ADM.01851.H.1.A. Default values for water-based formulations defined in the EFSA Guidance document on dermal absorption (EFSA Journal 2017;15(6):4873) of 10% for the concentrate and 50% for the dilution are considered.

Table 6.5-1: Dermal absorption rates for active substances in ADM.01851.H.1.A

	Ethofumesate		Clopyralid	
	Value	Reference	Value	Reference
Concentrate	10%	Default values for water-based formulations (EFSA Journal 2017;15(6):4873)	10%	Default values for water-based formulations (EFSA Journal 2017;15(6):4873)
Dilution	50%		50%	

6.5.1 Justification for proposed values - ethofumesate

No data on dermal absorption for ethofumesate in ADM.01851.H.1.A is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for ethofumesate

	Value	Justification for value	Acceptability of justification
Concentrate	10%	Default value	Justification accepted. Endpoint can be used for current product
Dilution	50%	Default value	Justification accepted. Endpoint can be used for current product

6.5.2 Justification for proposed values - clopyralid

No data on dermal absorption for clopyralid in ADM.01851.H.1.A is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in

the following table.

Table 6.5-3: Default dermal absorption rates for clopyralid

	Value	Justification for value	Acceptability of justification
Concentrate	10%	Default value	Justification accepted. Endpoint can be used for current product
Dilution	50%	Default value	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	ADM.01851.H.1.A	
Formulation type	Suspension concentrate [Code: SC]	
Category	Herbicide	
Active substance(s) (incl. content)	Ethofumesate Nominal: 500 g/L Actual: 512.8 g/L	Clopyralid Nominal: 75 g/L Actual: 78.95 g/L
AOEL systemic	2.5 mg/kg bw/d	0.15 mg/kg bw/d
AAOEL systemic	No AAOEL derived	0.17 mg/kg bw
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 10% (Default) Dilution: 50% (Default)	Concentrate: 10% (Default) Dilution: 50% (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.

Justification

The critical GAP has been defined following evaluation of the individual GAPs for each crop in each relevant Member State and takes into account the maximum application rate, the number of applications and water volume per hectare as relevant for this zone.

- in sugar beet/fodder beet: 3 x 0.66 L product/ha (3 x 0.33 kg a.s./ha ethofumesate and 3 x 0.0495 kg a.s./ha clopyralid) in 100 - 400 L water/ha

6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	NDE calculation (EFSA on-line model OPEX ver. 1.02) performed by the Applicant is acceptable and zRMS Reviewer agrees to the conclusions. The risk for operators is acceptable under conditions of intended uses and considering below mentioned risk mitigation measures such as Work wear (arms, body and legs covered) during M, L and A
--------------------------	--

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.01851.H.1.A according to the critical use is presented in the tables below 6.6-3 and 6.6-4

zRMS Reviewer: To maintain accuracy and eliminate redundancy, the unintentionally duplicated tables

has been removed from the report. Now, summary tables starts on page 10.

Table 6.6-2. The outcome of the estimation is presented in

Table 6.6 3: Estimated operator exposure (acute exposure)

		Ethofumesate		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		0.330 kg a.s./ha		0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Spray application outdoor (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	Not applicable. No AAOEL established.		0.1	75.4
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Spray application outdoor (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	Not applicable. No AAOEL established.		0.1	78.2

Table 6.6 4 (acute exposure) and in

Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)				
Spray application outdoor (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	Not applicable. No AAOEL established.	0.1	78.2

Table 6.6-4 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Sugar beet/fodder beet represented by “Low vegetables” (max. 3 x 0.66 L product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 Online calculator version: 1.0.2

Table 6.6-3: Estimated operator exposure (acute exposure)

Table 6.10.3: Estimated operator exposure (acute exposure)					
		Ethofumesate		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		0.330 kg a.s./ha		0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Spray application outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	Not applicable. No AAOEL established.		0.1	75.4
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Spray application outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	Not applicable. No AAOEL established.		0.1	78.2

Table 6.6-4: Estimated operator exposure (longer term exposure)

Estimated operator exposure (longer term exposure)					
		Ethofumesate		Clopyralid	
Model data	Level of PPE	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		0.330 kg a.s./ha		0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.1	4.2	0.03	18.6
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.1	4.3	0.03	19.3

To protect the operator, work wear (arms, body and legs covered) is required during mixing/loading and application. Due to ADM.01851.H.1.A having the hazard classes “skin irritation” and “eye damage”,

additional protection of skin and eyes by wearing gloves and a face shield during mixing/loading is required.

6.6.2.2 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 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)

Comments of zRMS:	NDE calculation (EFSA on-line model OPEX ver. 1.02) performed by the Applicant is acceptable and zRMS Reviewer agrees to the conclusions. Exposure for workers (entry into a previously treated area or handling a crop according to the critical uses) is acceptable under conditions of intended uses considering below mentioned risk mitigation measures such as work wear, (arms, body and legs covered) and protective gloves are used.
--------------------------	--

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.01851.H.1.A according to the critical use. Outcome of the estimation is presented in Table 6.6-6 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Sugar beet/fodder beet represented by “Low vegetables” (max. 3 x 0.66 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 Online calculator version: 1.0.2

Table 6.6-6: Estimated worker exposure (longer term exposure)

		Ethofumesate		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Removing bolting sugar beets Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 5 days					
Number of applications and application rate		3 x 0.33 kg a.s./ha		3 x 0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Body weight: 60 kg	Potential TC: 18600 cm²/person/h	3.3	132 Re-entry restriction: 12 days	0.5	329 Re-entry restriction: 52 days
	Work wear (arms, body and legs covered) TC: 4400 cm²/person/h	0.8	31.1	0.1	77.8
	Work wear (arms, body and legs covered) and gloves TC: 430 cm²/person/h	0.08	3	0.01	7.6

		Ethofumesate		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Gloves, no work wear TC: 14300 cm²/person/h	2.5	101 Re-entry restriction: 1 day	0.4	253 Re-entry restriction: 41 days
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Body weight: 60 kg	Potential TC: 18600 cm²/person/h	3.4	135 Re-entry restriction: 13 days	0.5	346 Re-entry restriction: 54 days
	Work wear (arms, body and legs covered) TC: 4400 cm²/person/h	0.8	31.9	0.1	81.9
	Work wear (arms, body and legs covered) and gloves TC: 430 cm²/person/h	0.08	3.1	0.01	8
	Gloves, no work wear TC: 14300 cm²/person/h	2.6	104 Re-entry restriction: 2 days	0.4	266 Re-entry restriction: 43 days
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 5 days					
Number of applications and application rate		3 x 0.33 kg a.s./ha		3 x 0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.6	22.1	0.08	55.3
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.06	2.5	0.009	6.2
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h	0.06	2.2	0.008	5.5
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.6	22.7	0.09	58.2
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.06	2.5	0.01	6.5
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm²/person/h	0.06	2.3	0.009	5.8

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.3.3 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 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)

Comments of zRMS:	NDE calculation (EFSA on-line model OPEX ver. 1.01) performed by the Applicant is acceptable and zRMS Reviewer agrees to the conclusions. AAOEL value has been set only for clopyralid, therefore acute exposure has been performed for this substance. Exposure for B&R is acceptable under conditions of intended uses.
--------------------------	--

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, longer term exposure assessment for residents also covers bystander exposure.

Table 6.6-7 shows the exposure model used for estimation of resident and bystander exposure to ethofumesate and clopyralid. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure) and in Table 6.6-9 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure models for intended uses

Critical use(s)	Sugar beet/fodder beet represented by “Low vegetables” (max. 3 x 0.66 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 Online calculator version: 1.0.2

Table 6.6-8: Estimated resident exposure (longer term exposure)

		Ethofumesate		Clopyralid	
Model data		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: 5 days					
Number of applications and application rate		3 x 0.33 kg a.s./ha		3 x 0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.04	1.8	0.007	4.5
	Vapour (75 th perc.)	0.0008	0.03	0.0008	0.5
	Deposits (75 th perc.)	0.007	0.3	0.001	0.7
	Re-entry (75 th perc.)	0.07	3	0.01	7.5

	Sum (mean)	0.09	3.6	0.01	9.4
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.01	0.4	0.002	1.1
	Vapour (75 th perc.)	0.0003	0.01	0.0003	0.2
	Deposits (75 th perc.)	0.003	0.1	0.0005	0.3
	Re-entry (75 th perc.)	0.04	1.7	0.006	4.1
	Sum (mean)	0.04	1.6	0.006	4.2
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.05	1.8	0.007	4.7
	Vapour (75 th perc.)	0.0008	0.03	0.0008	0.5
	Deposits (75 th perc.)	0.007	0.3	0.001	0.8
	Re-entry (75 th perc.)	0.08	3.1	0.01	7.9
	Sum (mean)	0.09	3.7	0.01	9.9
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.01	0.4	0.002	1.1
	Vapour (75 th perc.)	0.0003	0.01	0.0003	0.2
	Deposits (75 th perc.)	0.003	0.1	0.0005	0.3
	Re-entry (75 th perc.)	0.04	1.7	0.007	4.4
	Sum (mean)	0.04	1.7	0.007	4.4

Table 6.6-9: Estimated bystander exposure (acute exposure)

Table 6.10.1: Estimated bystander exposure (acute exposure)					
		Ethofumesate		Clopyralid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DFR: 3.0 µg/cm²/kg a.s./ha					
Application rate:		0.33 kg a.s./ha		0.0495 kg a.s./ha	
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)					
Bystander child Body weight: 10 kg	Drift (95 th perc.)	Not applicable. No AAOEL established.		0.02	8.9
	Vapour (95 th perc.)			0.0008	0.5
	Deposits (95 th perc.)			0.003	1.9
	Re-entry (95 th perc.)			0.01	6.6
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	Not applicable. No AAOEL established.		0.004	2.4
	Vapour (95 th perc.)			0.0003	0.2
	Deposits (95 th perc.)			0.001	0.8
	Re-entry (95 th perc.)			0.006	3.7
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)					
Bystander child Body weight: 10 kg	Drift (95 th perc.)	Not applicable. No AAOEL established.		0.02	9.3
	Vapour (95 th perc.)			0.0008	0.5
	Deposits (95 th perc.)			0.003	2
	Re-entry (95 th perc.)			0.01	6.9
Bystander adult	Drift (95 th perc.)			0.004	2.5

Body weight: 60 kg	Vapour (95 th perc.)		0.0003	0.2
	Deposits (95 th perc.)		0.001	0.8
	Re-entry (95 th perc.)		0.007	3.9

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for ethofumesate and clopyralid 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

The product is a mixture of two active substances.

6.6.5.1 Exposure assessment of ethofumesate and clopyralid in ADM.01851.H.1.A

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 systemic AOEL from Table 6.6-4, Table 6.6-6 and Table 6.6-8 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-10: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Nominal formulation contents (500 g/L ethofumesate, 75 g/L clopyralid)		
Operators – Tractor mounted boom spray application outdoors to low crops Work wear (arms, body and legs covered) M/L and A	Ethofumesate	0.042
	Clopyralid	0.186
	Cumulative risk operators (HI)	0.2
Workers – Removing bolting sugar beets Work wear (arms, body and legs covered)	Ethofumesate	0.311
	Clopyralid	0.778
	Cumulative risk workers (HI)	1.1 ~~Re-entry restriction: 4-days~~ For details refer zRMS discussion regarding HI, see below the table
Workers – Removing bolting sugar beets Work wear (arms, body and legs covered) and gloves	Ethofumesate	0.03
	Clopyralid	0.076
	Cumulative risk workers (HI)	0.1
Workers – Inspection, irrigation Work wear (arms, body and legs covered)	Ethofumesate	0.025
	Clopyralid	0.062
	Cumulative risk workers (HI)	0.08
Resident - child	Ethofumesate	
	Drift	0.018

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.0003
	Deposits	0.003
	Re-entry	0.03
	Sum of all pathways	0.036
	Clopyralid	
	Drift	0.045
	Vapour	0.005
	Deposits	0.007
	Re-entry	0.075
	Sum of all pathways	0.094
	Cumulative risk resident – child (HI)	
	Drift	0.06
	Vapour	0.006
	Deposits	0.01
	Re-entry	0.1
	Sum of all pathways	0.1
Resident - adult	Ethofumesate	
	Drift	0.004
	Vapour	0.0001
	Deposits	0.001
	Re-entry	0.017
	Sum of all pathways	0.016
	Clopyralid	
	Drift	0.011
	Vapour	0.002
	Deposits	0.003
	Re-entry	0.041
	Sum of all pathways	0.042
	Cumulative risk resident – adult (HI)	
	Drift	0.01
	Vapour	0.002
	Deposits	0.004
	Re-entry	0.06
	Sum of all pathways	0.06
Actual formulation contents (512.8 g/L ethofumesate, 78.95 g/L clopyralid)		
Operators – Tractor mounted boom spray application outdoors to low crops Work wear (arms, body and legs covered) M/L and A	Ethofumesate	0.043
	Clopyralid	0.193
	Cumulative risk operators (HI)	0.2
Workers – Removing bolting sugar beets	Ethofumesate	0.319
	Clopyralid	0.819

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Work wear (arms, body and legs covered)	Cumulative risk workers (HI)	1.1 ~~Re-entry restriction: 6 days~~ For details refer zRMS discussion regarding HI, see below the table
Workers – Removing bolting sugar beets Work wear (arms, body and legs covered) and gloves	Ethofumesate	0.031
	Clopyralid	0.08
	Cumulative risk workers (HI)	0.1
Workers – Inspection, irrigation Work wear (arms, body and legs covered)	Ethofumesate	0.025
	Clopyralid	0.065
	Cumulative risk workers (HI)	0.09
Resident - child	Ethofumesate	
	Drift	0.018
	Vapour	0.0003
	Deposits	0.003
	Re-entry	0.031
	Sum of all pathways	0.037
	Clopyralid	
	Drift	4.7
	Vapour	0.5
	Deposits	0.8
	Re-entry	7.9
	Sum of all pathways	9.9
	Cumulative risk resident – child (HI)	
	Drift	0.07
	Vapour	0.006
	Deposits	0.01
	Re-entry	0.1
	Sum of all pathways	0.1
Resident - adult	Ethofumesate	
	Drift	0.004
	Vapour	0.0001
	Deposits	0.001
	Re-entry	0.017
	Sum of all pathways	0.017
	Clopyralid	
	Drift	0.011
	Vapour	0.002
	Deposits	0.003
	Re-entry	0.044
	Sum of all pathways	0.044
	Cumulative risk resident – adult (HI)	

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Drift	0.02
	Vapour	0.002
	Deposits	0.004
	Re-entry	0.06
	Sum of all pathways	0.06

The Hazard Index is < 1. Thus, combined exposure to both active substances in ADM.01851.H.1.A is not expected to present a risk for operators, ~~workers~~, residents and bystanders. For operators during mixing/loading and application and for workers performing inspection/irrigation tasks this applies when work wear (arms, body and legs covered) is worn. No re-entry restriction is required when the worker removing bolting sugar beets wears work wear (arms, body and legs covered) and gloves. ~~No further refinement of the assessment is required.~~

zRMS:

Due to fact that for Workers Hazard Index is > 1 refinement of the assessment is required.

Overview on the target organ(s) and toxicological mode(s)/mechanism(s) of action of the active substances included in the preparation is as follow:

- for clopyralid the AOEL is 0.15 mg/kg bw per day⁷ based on the **developmental toxicity study in rat** with a maternal NOAEL of 15 mg/kg bw per day for **reduced maternal body weight gain**.
- for ethofumesate the AOEL of 2.5 mg/kg bw per day has been agreed on the basis of the relevant **short - term NOAEL** of 250 mg/kg bw per day for **increased liver weight and increased alkaline phosphatase observed in dogs treated**

Considering available data that the TRV (AOEL) values for both active substances were determined on the basis of significantly different endpoints and target organs, in the opinion of zRMS, cumulative effects of clopyralid and ethofumesate **not be expected** and the resulting health risk **not be expected**.

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

None.

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

Comments of zRMS:	zRMS agreed on hazard assessment and proposed classification of the product considering content of relevant ingredients in the mixture (Additivity formula) (for details see Part C).
-------------------	---

With ADM.01851.H.1.A no experimental acute toxicity data are available. To assess the acute toxicity data and the classification of ADM.01851.H.1.A 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

Comments of zRMS:	Agree, the toxicological profile was verified on the same product as the one requested for registration. No further comments regarding this point.
-------------------	--

Not relevant.

A 2.2 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are to be considered.

A 2.3 Data on co-formulants (KCP 7.4)

A 2.3.1 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 2.3.2 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 2.4 Studies on dermal absorption (KCP 7.3)

With ADM.01851.H.1.A no dermal absorption data are available. Default values according to the Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) were used.

A 2.5 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 ethofumesate – nominal formulation content (500 g/L)

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

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Ethofumesate
Concentration of active substance [g a.s./l or kg]	500	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	2.5		
AAOEL [mg/kg bw]			

Table A 2: Estimation of longer term operator exposure towards ethofumesate according to EF-SA guidance

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	81.5	81.5
	Body protection	Workwear	Workwear
	Body exposure	0.5	0.5
	Head protection	None	None
	Head exposure	1.7	1.7
	Inhalation protection	None	None
	Inhalation exposure	0.2	0.2
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	20.3	20.3
	Body protection	Workwear	Workwear
	Body exposure	0.3	0.3
	Head protection	None	None
	Head exposure	0.5	0.5
	Inhalation protection	None	None
	Inhalation exposure	0.07	0.07
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.1
	% of AOEL	4.2	4.2

A 3.1.2 Calculations for clopyralid – nominal formulation content (75 g/L)

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

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Clopyralid
Concentration of active substance [g a.s./l or kg]	75	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.15		
AAOEL [mg/kg bw]	0.17		

Table A 4: Estimation of longer term operator exposure towards clopyralid according to EFSA guidance

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	24.2	24.2
	Body protection	Workwear	Workwear
	Body exposure	0.1	0.1
	Head protection	None	None
	Head exposure	0.3	0.3
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	3.1	3.1
	Body protection	Workwear	Workwear
	Body exposure	0.05	0.05
	Head protection	None	None
	Head exposure	0.08	0.08
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.03	0.03
	% of AOEL	18.6	18.6

Table A 5: Estimation of acute operator exposure towards clopyralid according to EFSA guidance

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	87.8	87.8
	Body protection	Workwear	Workwear
	Body exposure	1.1	1.1

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Application (µg/kg bw per day)	Head protection	None	None
	Head exposure	1.6	1.6
	Inhalation protection	None	None
	Inhalation exposure	0.2	0.2
	Hand protection	None	None
	Hands exposure	37	37
	Body protection	Workwear	Workwear
	Body exposure	0.1	0.1
	Head protection	None	None
	Head exposure	0.2	0.2
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.1
	% of AAOEL	75.4	75.4

A 3.1.3 Combined calculations for ethofumesate (nominal formulation content: 500 g/L) and clopyralid (nominal formulation content: 75 g/L)

Table A 6: Estimation of combined longer term operator exposure towards ethofumesate and clopyralid according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Ethofumesate	Number of applications and application rate: 3 x 0.33 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.1	4.2
Clopyralid	Number of applications and application rate: 3 x 0.0495 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.03	18.6
Combined exposure			Hazard index
			M/L: Workwear App: Workwear
			0.2

A 3.1.4 Calculations for ethofumesate – actual formulation content (512.8 g/L)

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

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Ethofumesate
Concentration of active substance [g a.s./l or kg]	512.8	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying

Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	2.5		
AAOEL [mg/kg bw]			

Table A 8: Estimation of longer term operator exposure towards ethofumesate according to EF-SA guidance

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	82.8	82.8
	Body protection	Workwear	Workwear
	Body exposure	0.5	0.5
	Head protection	None	None
	Head exposure	1.8	1.8
	Inhalation protection	None	None
	Inhalation exposure	0.2	0.2
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	20.9	20.9
	Body protection	Workwear	Workwear
	Body exposure	0.3	0.3
	Head protection	None	None
	Head exposure	0.5	0.5
	Inhalation protection	None	None
	Inhalation exposure	0.07	0.07
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.1
	% of AOEL	4.3	4.3

A 3.1.5 Calculations for clopyralid – actual formulation content (78.95 g/L)

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

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Clopyralid
Concentration of active substance [g a.s./l or kg]	78.95	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.15		

AAOEL [mg/kg bw]	0.17
------------------	------

Table A 10: Estimation of longer term operator exposure towards clopyralid according to EFSA guidance

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	25	25
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.2	0.2
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.3	0.3
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	3.2	3.2
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.05	0.05
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.08	0.08
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.03	0.03
	% of AOEL	19.3	19.3

Table A 11: Estimation of acute operator exposure towards clopyralid according to EFSA guidance

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	90.9	90.9
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	1.2	1.2
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	1.7	1.7
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.2	0.2
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	38.4	38.4
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.3	0.3
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.08	0.08

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.1
	% of AAOEL	78.2	78.2

A 3.1.6 Combined calculations for ethofumesate (actual formulation content: 512.8 g/L) and clopyralid (actual formulation content: 78.95 g/L)

Table A 12: Estimation of combined longer term operator exposure towards ethofumesate and clopyralid according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Ethofumesate	Number of applications and application rate: 3 x 0.338448 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.1	4.3
Clopyralid	Number of applications and application rate: 3 x 0.052107 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.03	19.3
Combined exposure			Hazard index
			M/L: Workwear App: Workwear
			0.2

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for ethofumesate – nominal formulation content (500 g/L), re-entry activity: removing bolting sugar beets

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

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	2.5
Re-entry activity	removing bolting sugar beets	Dermal transfer coefficient - Total potential exposure [cm ² /h]	18600
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm ² /h]	4400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm ² /h]	430
Application technique	Vehicle-mounted; manual-hand held; manual-knapsack	Dermal transfer coefficient - Hands covered, no workwear [cm ² /h]	14300
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm ² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5		
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Ethofumesate		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	8		

Table A 14: Estimation of longer term worker exposure towards ethofumesate according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	197	46.7	4.6	152
Inhalation	Systemic inhalation exposure [mg a.s. per day]				
	Total systemic exposure [mg a.s. per day]	197	46.7	4.6	152
Total	Total systemic exposure [mg/kg bw per day]	3.3	0.8	0.08	2.5
	% of AOEL	132	31.1	3	101

A 3.2.2 Calculations for clopyralid – nominal formulation content (75 g/L), re-entry activity: removing bolting sugar beets

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

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.15
Re-entry activity	removing bolting sugar beets	Dermal transfer coefficient - Total potential exposure [cm ² /h]	18600

Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	4400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	430
Application technique	Vehicle-mounted; manual-hand held; manual-knapsack	Dermal transfer coefficient - Hands covered, no work-wear [cm²/h]	14300
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5		
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Clopyralid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	8		

Table A 16: Estimation of longer term worker exposure towards clopyralid according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	29.6	7	0.7	22.8
Inhalation	Systemic inhalation exposure [mg a.s. per day]				
	Total systemic exposure [mg a.s. per day]	29.6	7	0.7	22.8
Total	Total systemic exposure [mg/kg bw per day]	0.5	0.1	0.01	0.4
	% of AOEL	329	77.8	7.6	253

A 3.2.3 Combined calculations for ethofumesate (nominal formulation content: 500 g/L) and clopyralid (nominal formulation content: 75 g/L), re-entry activity: removing bolting sugar beets

Table A 17: Estimation of combined longer term worker exposure towards ethofumesate and clopyralid according to EFSA guidance

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
			removing bolting sugar beets / Outdoor Work rate: 8 hours/day Interval: 5 days Body weight: 60 kg TC (potential): 18600 cm²/h TC (workwear (arms, body and legs covered)): 4400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 430 cm²/h TC (gloves): 14300 cm²/h

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Ethofumesate Number of applications & application rate: 3 x 0.33 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	3.3	132	12
Workwear	0.8	31.1	0
Workwear and gloves	0.08	3	0
Hands covered, no workwear	2.5	101	1
Clopyralid Number of applications & application rate: 3 x 0.0495 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.5	329	52
Workwear	0.1	77.8	0
Workwear and gloves	0.01	7.6	0
Hands covered, no workwear	0.4	253	41
Combined		Hazard index	
potential		4.6	67
Workwear		1.1	4
Workwear and gloves		0.1	0
Hands covered, no workwear		3.5	55

A 3.2.4 Calculations for ethofumesate – actual formulation content (512.8 g/L), re-entry activity: removing bolting sugar beets

Table A 18: Input parameters considered for the estimation of worker exposure

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	2.5
Re-entry activity	removing bolting sugar beets	Dermal transfer coefficient - Total potential exposure [cm²/h]	18600
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	4400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	430
Application technique	Vehicle-mounted; manual-hand held; manual-knapsack	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	14300
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5		
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Ethofumesate		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		

Time [hours per day]	8
-----------------------------	---

Table A 19: Estimation of longer term worker exposure towards ethofumesate according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	202	47.9	4.7	156
Inhalation	Systemic inhalation exposure [mg a.s. per day]				
	Total systemic exposure [mg a.s. per day]	202	47.9	4.7	156
Total	Total systemic exposure [mg/kg bw per day]	3.4	0.8	0.08	2.6
	% of AOEL	135	31.9	3.1	104

A 3.2.5 Calculations for clopyralid – actual formulation content (78.95 g/L), re-entry activity: removing bolting sugar beets

Table A 20: Input parameters considered for the estimation of worker exposure

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.15
Re-entry activity	removing bolting sugar beets	Dermal transfer coefficient - Total potential exposure [cm²/h]	18600
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	4400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	430
Application technique	Vehicle-mounted; manual-hand held; manual-knapsack	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	14300
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5		
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Clopyralid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	8		

Table A 21: Estimation of longer term worker exposure towards clopyralid according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	31.2	7.4	0.7	24
Inhalation	Systemic inhalation exposure [mg a.s. per day]				
Total	Total systemic exposure [mg a.s. per day]	31.2	7.4	0.7	24

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
	Total systemic exposure [mg/kg bw per day]	0.5	0.1	0.01	0.4
	% of AOEL	346	81.9	8	266

A 3.2.6 Combined calculations for ethofumesate (actual formulation content: 512.8 g/L) and clopyralid (actual formulation content: 78.95 g/L), re-entry activity: removing bolting sugar beets

Table A 22: Estimation of combined longer term worker exposure towards ethofumesate and clopyralid according to EFSA guidance

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
removing bolting sugar beets / Outdoor Work rate: 8 hours/day Interval: 5 days Body weight: 60 kg TC (potential): 18600 cm²/h TC (workwear (arms, body and legs covered)): 4400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 430 cm²/h TC (gloves): 14300 cm²/h			
Number of applications & application rate: 3 x 0.338448 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Ethofumesate			
Potential	3.4	135	13
Workwear	0.8	31.9	0
Workwear and gloves	0.08	3.1	0
Hands covered, no workwear	2.6	104	2
Number of applications & application rate: 3 x 0.052107 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
Clopyralid			
Potential	0.5	346	54
Workwear	0.1	81.9	0
Workwear and gloves	0.01	8	0
Hands covered, no workwear	0.4	266	43
Combined		Hazard index	
potential		4.8	69
Workwear		1.1	6
Workwear and gloves		0.1	0
Hands covered, no workwear		3.7	57

A 3.2.7 Calculations for ethofumesate – nominal formulation content (500 g/L), re-entry activity: inspection, irrigation

Table A 23: Input parameters considered for the estimation of worker exposure

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	2.5
Re-entry activity	Inspection, irrigation (All)	Dermal transfer coefficient - Total potential exposure [cm ² /h]	12500

Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5	Inhalation task specific factor [ha/h*10⁻³]	0.01
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Ethofumesate		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Table A 24: Estimation of longer term worker exposure towards ethofumesate according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	33.2	3.7	3.3	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	33.2	3.7	3.3	NA
Total	Total systemic exposure [mg/kg bw per day]	0.6	0.06	0.06	NA
	% of AOEL	22.1	2.5	2.2	NA

A 3.2.8 Calculations for clopyralid – nominal formulation content (75 g/L), re-entry activity: inspection, irrigation

Table A 25: Input parameters considered for the estimation of worker exposure

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.15
Re-entry activity	Inspection, irrigation (All)	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3

Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5	Inhalation task specific factor [ha/h*10 ⁻³]	0.01
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Clopyralid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Table A 26: Estimation of longer term worker exposure towards clopyralid according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	5	0.6	0.5	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	5	0.6	0.5	NA
Total	Total systemic exposure [mg/kg bw per day]	0.08	0.009	0.008	NA
	% of AOEL	55.3	6.2	5.5	NA

A 3.2.9 Combined calculations for ethofumesate (nominal formulation content: 500 g/L) and clopyralid (nominal formulation content: 75 g/L), re-entry activity: inspection, irrigation

Table A 27: Estimation of combined longer term worker exposure towards ethofumesate and clopyralid according to EFSA guidance

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 5 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 3 x 0.33 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Ethofumesate			
Potential	0.6	22.1	0
Workwear	0.06	2.5	0
Workwear and gloves	0.06	2.2	0
Hands covered, no workwear			
Number of applications & application rate: 3 x 0.0495 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Clopyralid			
Potential	0.08	55.3	0
Workwear	0.009	6.2	0

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Workwear and gloves	0.008	5.5	0
Hands covered, no workwear			
Combined		Hazard index	
potential		0.8	0
Workwear		0.09	0
Workwear and gloves		0.08	0
Hands covered, no workwear			0

A 3.2.10 Calculations for ethofumesate – actual formulation content (512.8 g/L), re-entry activity: inspection, irrigation

Table A 28: Input parameters considered for the estimation of worker exposure

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	2.5
Re-entry activity	Inspection, irrigation (All)	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5	Inhalation task specific factor [ha/h*10⁻³]	0.01
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Ethofumesate		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Table A 29: Estimation of longer term worker exposure towards ethofumesate according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	34	3.8	3.4	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	34	3.8	3.4	NA
Total	Total systemic exposure [mg/kg bw per day]	0.6	0.06	0.06	NA
	% of AOEL	22.7	2.5	2.3	NA

A 3.2.11 Calculations for clopyralid – actual formulation content (78.95 g/L), re-entry activity: inspection, irrigation

Table A 30: Input parameters considered for the estimation of worker exposure

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.15
Re-entry activity	Inspection, irrigation (All)	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Low vegetables	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.66	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	3	DT50 foliar worker [days]	30
Interval between multiple applications [days]	5	Inhalation task specific factor [ha/h*10 ⁻³]	0.01
Multiple application factor	2.68		
Body weight (kg)	60		
Name of active substance	Clopyralid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Table A 31: Estimation of longer term worker exposure towards clopyralid according to EFSA guidance

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	5.2	0.6	0.5	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	5.2	0.6	0.5	NA
Total	Total systemic exposure [mg/kg bw per day]	0.09	0.01	0.009	NA
	% of AOEL	58.2	6.5	5.8	NA

A 3.2.12 Combined calculations for ethofumesate (actual formulation content: 512.8 g/L) and clopyralid (actual formulation content: 78.95 g/L), re-entry activity: inspection, irrigation

Table A 32: Estimation of combined longer term worker exposure towards ethofumesate and clopyralid according to EFSA guidance

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
--------------	--	--------------------	-----------------------------

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation (All) / Outdoor Work rate: 2 hours/day Interval: 5 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 3 x 0.338448 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Ethofumesate			
Potential	0.6	22.7	0
Workwear	0.06	2.5	0
Workwear and gloves	0.06	2.3	0
Hands covered, no workwear			
Number of applications & application rate: 3 x 0.052107 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Clopyralid			
Potential	0.09	58.2	0
Workwear	0.01	6.5	0
Workwear and gloves	0.009	5.8	0
Hands covered, no workwear			
Combined	Hazard index		
potential		0.8	0
Workwear		0.09	0
Workwear and gloves		0.08	0
Hands covered, no workwear			0

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for ethofumesate – nominal formulation content (500 g/L)

Table A 33: Input parameters considered for the estimation of longer term resident exposure

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: 5 days Minimum volume of water: 100 l			
Number of applications and application rate: 3 x 0.33 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Ethofumesate			

Table A 34: Estimation of longer term resident exposure towards ethofumesate according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident child Body weight: 10 kg	Drift (75th perc.)	0.04	1.8
	Vapour (75th perc.)	0.0008	0.03
	Deposits (75th perc.)	0.007	0.3
	Re-entry (75th perc.)	0.07	3
	Sum (mean)	0.09	3.6
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.01	0.4
	Vapour (75th perc.)	0.0003	0.01
	Deposits (75th perc.)	0.003	0.1
	Re-entry (75th perc.)	0.04	1.7
	Sum (mean)	0.04	1.6

A 3.3.2 Calculations for clopyralid – nominal formulation content (75 g/L)

Table A 35: Input parameters considered for the estimation of longer term resident exposure

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: 5 days Minimum volume of water: 100 l			
Number of applications and application rate: 3 x 0.0495 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Clopyralid			

Table A 36: Estimation of longer term resident exposure towards clopyralid according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident child Body weight: 10 kg	Drift (75th perc.)	0.007	4.5
	Vapour (75th perc.)	0.0008	0.5
	Deposits (75th perc.)	0.001	0.7

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident adult Body weight: 60 kg	Re-entry (75th perc.)	0.01	7.5
	Sum (mean)	0.01	9.4
	Drift (75th perc.)	0.002	1.1
	Vapour (75th perc.)	0.0003	0.2
	Deposits (75th perc.)	0.0005	0.3
	Re-entry (75th perc.)	0.006	4.1
	Sum (mean)	0.006	4.2

Table A 37: Estimation of acute bystander exposure towards clopyralid according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.02	8.9
	Vapour (95th perc.)	0.0008	0.5
	Deposits (95th perc.)	0.003	1.9
	Re-entry (95th perc.)	0.01	6.6
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.004	2.4
	Vapour (95th perc.)	0.0003	0.2
	Deposits (95th perc.)	0.001	0.8
	Re-entry (95th perc.)	0.006	3.7

A 3.3.3 Combined calculations for ethofumesate (nominal formulation content: 500 g/L) and clopyralid (nominal formulation content: 75 g/L)

Table A 38: Estimation of combined longer term resident exposure towards ethofumesate and clopyralid according to EFSA guidance

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: 5 days Minimum volume of water: 100 l			
Number of applications and application rate: 3 x 0.33 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Number of applications and application rate: 3 x 0.0495 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Ethofumesate			
Clopyralid			
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.06
	Vapour (75th perc.)		0.006
	Deposits (75th perc.)		0.01
	Re-entry (75th perc.)		0.1
	Sum (mean)		0.1
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.01
	Vapour (75th perc.)		0.002
	Deposits (75th perc.)		0.004

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
	Re-entry (75th perc.)		0.06
	Sum (mean)		0.06

A 3.3.4 Calculations for ethofumesate – actual formulation content (512.8 g/L)

Table A 39: Input parameters considered for the estimation of longer term resident exposure

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: 5 days Minimum volume of water: 100 l
Ethofumesate		Number of applications and application rate: 3 x 0.338448 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	

Table A 40: Estimation of longer term resident exposure towards ethofumesate according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident child Body weight: 10 kg	Drift (75th perc.)	0.05	1.8
	Vapour (75th perc.)	0.0008	0.03
	Deposits (75th perc.)	0.007	0.3
	Re-entry (75th perc.)	0.08	3.1
	Sum (mean)	0.09	3.7
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.01	0.4
	Vapour (75th perc.)	0.0003	0.01
	Deposits (75th perc.)	0.003	0.1
	Re-entry (75th perc.)	0.04	1.7
	Sum (mean)	0.04	1.7

A 3.3.5 Calculations for clopyralid – actual formulation content (78.95 g/L)

Table A 41: Input parameters considered for the estimation of longer term resident exposure

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: 5 days Minimum volume of water: 100 l
Clopyralid		Number of applications and application rate: 3 x 0.052107 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	

Table A 42: Estimation of longer term resident exposure towards clopyralid according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident child	Drift (75th perc.)	0.007	4.7

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Body weight: 10 kg	Vapour (75th perc.)	0.0008	0.5
	Deposits (75th perc.)	0.001	0.8
	Re-entry (75th perc.)	0.01	7.9
	Sum (mean)	0.01	9.9
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	1.1
	Vapour (75th perc.)	0.0003	0.2
	Deposits (75th perc.)	0.0005	0.3
	Re-entry (75th perc.)	0.007	4.4
	Sum (mean)	0.007	4.4

Table A 43: Estimation of acute bystander exposure towards clopyralid according to EFSA guidance

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.02	9.3
	Vapour (95th perc.)	0.0008	0.5
	Deposits (95th perc.)	0.003	2
	Re-entry (95th perc.)	0.01	6.9
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.004	2.5
	Vapour (95th perc.)	0.0003	0.2
	Deposits (95th perc.)	0.001	0.8
	Re-entry (95th perc.)	0.007	3.9

A 3.3.6 Combined calculations for ethofumesate (actual formulation content: 512.8 g/L) and clopyralid (actual formulation content: 78.95 g/L)

Table A 44: Estimation of combined longer term resident exposure towards ethofumesate and clopyralid according to EFSA guidance

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: 5 days Minimum volume of water: 100 l			
Ethofumesate	Number of applications and application rate: 3 x 0.338448 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
	Number of applications and application rate: 3 x 0.052107 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.07
	Vapour (75th perc.)		0.006
	Deposits (75th perc.)		0.01
	Re-entry (75th perc.)		0.1
	Sum (mean)		0.1
Resident adult	Drift (75th perc.)		0.02

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Body weight: 60 kg	Vapour (75th perc.)		0.002
	Deposits (75th perc.)		0.004
	Re-entry (75th perc.)		0.06
	Sum (mean)		0.06

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.