

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: GLOB1817H

Product name: **Eledura**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Halauxifen-methyl, 1.33 g/L

Cloquintocet-mexyl, 1.33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

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Version history

When	What
May 2021	Initial submission by the applicant for approval of new product.
January 2022	Version evaluated by zRMS PL
April 2022	Version modified to take into account comments of cMS and the applicant

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on GLOB1817H *

Product name and code	Eledura/GLOB1817H
Formulation type	Emulsifiable concentrate [EC]
Active substance(s) (incl. content)	Prosulfocarb: 667 g/L Diflufenian: 14 g/L Halauxifen-methyl: 1.33 g/L Cloquintocet-mexyl: 1.33 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 GLOB1817H 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 GLOB1817H according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, STOT SE3
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS 05, GHS07
Signal word	Danger
Hazard statement(s)	H302, H317, H318, H336
Precautionary statement(s)	P261, P264, P270, P271, P272, P280, P301+P312, P302+P352, P304+P340, P305+P351+P338, P310, P312, P321, P330, P333+P313, P362+P364, P363, P403+P233, P405, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains cloquintocet-mexyl

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GLOB1817H

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves during mixing/loading and application
Workers	Acceptable	None
Residents	Acceptable	5 m buffer + 50% DRT

	Result	PPE / Risk mitigation measures
Bystanders	Acceptable	5 m buffer + 50% DRT

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 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 situ- ation (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 a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Cereals (BBCH10-14)	F	Spraying, LCTM	a) 1 b) 1	a)Prosulfocarb: 2.001 b)Diflufenican: 0.042 c) Halauxifen- methyl: 0.00399 d) Cloquintocet- mexyl: 0.00399 kg/ha	200 - 300	NR	Guidance on the assessment of ex- posure of opera- tors, workers, resi- dents and bystand- ers in risk assess- ment for plant pro- tection products; EFSA Journal 2014;12(10):3874				

* 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

Data gaps should be listed in the summary to give an overview (especially for cMS).

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)

	Prosulfocarb active substance	Diflufenican active substance	Halauxifen-methyl active substance	Cloquintocet-mexyl safener
Common Name	Prosulfocarb	Diflufenican	Halauxifen-methyl	Cloquintocet-mexyl
CAS-No.	52888-80-9	83164-33-4	943831-98-9	99607-70-2
Classification and proposed labelling				
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: Acute Tox 4, Skin Sens. 1 Code for hazard pictogram: GHS07 Signal word: Warning Hazard statements: H302, H317 Precautionary statements: P261, P264, P270, P272, P273, P280, P301+P312, P330, P302+P352, P321, P333+P313, P363	Hazard classes, categories: - Code for hazard pictogram: - Signal word: - Hazard statement: - Precautionary statement: -	Hazard classes, categories: - Code for hazard pictogram: - Signal word: - Hazard statement: - Precautionary statement: -	Hazard classes, categories: Skin Sens. 1 Code for hazard pictogram: GHS07 Signal word: Warning Hazard statements: H317 Precautionary statements: P273, P280, P302+P352
Additional C&L proposal	None	None	None	None
Agreed EU endpoints				
AOEL systemic	0.007 mg/kg bw/d (corrected for 72% oral absorption)	0.11 mg/kg bw/d (corrected for 58% oral absorption)	0.058 mg/kg bw/d	0.05 mg/kg bw/d
Reference	EFSA Conclusion EFSA Scientific Report (2007) 111, 1-81	EFSA Conclusion SANCO/3782/08 – rev. 1 14 March 2008	EFSA Conclusion SANTE/10406 /2015 rev. 1, 29 May 2015 26 January 20181	DAR clodinafop-propargyl,
Conditions to take into account/critical areas of concern with regard to toxicology				
According to Review Report/EFSA Conclusion for active substance	Operator safety	None	None	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB1817H 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 GLOB1817H

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral	Study not necessary.	Yes	Acute Tox. 4; H302	Theoretical calculations (see Part C)
LD ₅₀ dermal	Study not necessary.	Yes	None	Theoretical calculations (see Part C)
LC ₅₀ inhalation	Study not necessary.	Yes	None	Theoretical calculations (see Part C)
Skin irritation	Non-irritant	Yes	None	Theoretical calculations (see Part C)
Eye irritation	Irritant	Yes	Eye Dam. 1; H318	Theoretical calculations (see Part C)
Skin sensitisation	Sensitising	Yes	Skin Sens. 1; H317	Theoretical calculations (see Part C)
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of GLOB1817H

	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 non-active substance(s) (relevant for classification of product)	Hydrocarbons, C10, aromatic Iso-butanol (≥ 20% (w/w))*	STOT SE3; H336	MSDS**	STOT SE3; H336
Further toxicological information	No data – not required			

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

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in GLOB1817H (Emulsifiable concentrate (EC)) are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in GLOB1817H

	Prosulfocarb		Diflufenican		Halauxifen-methyl		Cloquintocet-mexyl	
	Value	Reference	Value	Reference	Value	Reference	Value	Reference
Concentrate	3 %	New study reported in Appendix 2	58 %	Default	70 %	Default	70 %	Default
Dilution (1:133)	6.4 %	New study reported in Appendix 2	58 %	Default	70 %	Default	70 %	Default

6.5.1 Justification for proposed values – Prosulfocarb

Proposed dermal absorption rates for prosulfocarb are based on dermal absorption studies on a formulation identical to GLOB1817H. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of prosulfocarb/GLOB1817H that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for prosulfocarb

Test	Concentrate	Spray dilution (1:133)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	3 %	6.4 %	GLOB1817H	Yes	Not required	Justification accepted. Endpoint can be used for current product.	XXXX., 2020

* indicates that a study was reviewed at EU level

6.5.2 Justification for proposed values – Diflufenican

No data on dermal absorption for diflufenican in GLOB1817H 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 diflufenican

	Value	Justification for value	Acceptability of justification
Concentrate	58 %	Concentration in the formulation is below 50 g/L, so dermal absorption value of the dilution is also used for the concentrate.	See below
Concentrate	70 %	Concentration in the formulation is below 50 g/L, so dermal absorption value of the dilution is also used for the concentrate.	EU Guidance for dermal absorption. EFSA Journal 2017;15(6):4873
Dilution	58 %	Oral absorption is less than 70%, so oral absorption is used as surrogate for dermal absorption.	EFSA Scientific Report (2007) 122, 1-84, Conclusion on the peer review of diflufenican
Dilution	70 %	Default value.	EU Guidance for dermal absorption. EFSA Journal 2017;15(6):4873

zRMS:

According to EU Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) in exceptional cases, if oral absorption is less than 70% for formulation type such as emulsifiable concentrate (EC), oral absorption rate can be used as a surrogate dermal absorption value for (in-use) dilutions. There are usually no oral ADME studies for formulations that include co-formulants which are possibly modifying dermal absorption. For these reasons, estimates based on oral absorption should be applicable in only a limited range of circumstances after careful consideration of doses and vehicle used in the ADME studies, where bile-cannulation was also performed.

The product Eledura (GLOB1817H) is the emulsifiable concentrate therefore the default for dermal absorption according to EU Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) in case of lack of relevant experimental data would be 25 % for the concentrate and 70% for diluted product. Based on a corrigendum (minor modification) adopted by the Standing Committee on Plants, Animals, Food and Feed on 24 October 2018 2 a "dilution" is considered when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%). So for diflufenican present in product Eledura at concentration of 1.40% the default value for dermal absorption would be 70% both for the concentrate and dilution, which is higher than experimentally found oral absorption equal 58%. In the opinion of zRMS there is a very little probability that in case of diflufenican the dermal absorption may be higher than oral absorption, nevertheless additional calculation of exposure of operator, worker and residents were done using 70% dermal absorption as a default value.

6.5.3 Justification for proposed values – Halauxifen-methyl

No data on dermal absorption for halauxifen-methyl in GLOB1817H 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 6.5-4: Default dermal absorption rates for halauxifen-methyl

	Value	Justification for value	Acceptability of justification
Concentrate	70 %	Concentration in the formulation is below 50 g/L, so	See below

	Value	Justification for value	Acceptability of justification
		default dermal absorption value of the dilution is also used for the concentrate.	
Dilution	70 %	Default value	EU Guidance for dermal absorption. EFSA Journal 2017;15(6):4873

6.5.4 Justification for proposed values – Cloquintocet-mexyl

No data on dermal absorption for cloquintocet-mexyl in GLOB1817H 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 6.5-5: Default dermal absorption rates for cloquintocet-mexyl

	Value	Justification for value	Acceptability of justification
Concentrate	70 %	Concentration in the formulation is below 50 g/L, so default dermal absorption value of the dilution is also used for the concentrate.	EU Guidance for dermal absorption. EFSA Journal 2017;15(6):4873
Dilution	70 %	Default value	EU Guidance for dermal absorption. EFSA Journal 2017;15(6):4873

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	Eledura/GLOB1817H			
Formulation type	EC			
Category	Herbicide			
Container size(s), short description	0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 20 L, HDPE-F, 42-63 mm			
Active substance(s) (incl. content)	Prosulfocarb 667 g/L	Diflufenican 14 g/L	Halauxifen-methyl 1.33 g/L	Cloquintocet-mexyl 1.33 g/L
AOEL systemic	0.007 mg/kg bw/d	0.11 mg/kg bw/d	0.058 mg/kg bw/d	0.05 mg/kg bw/d Safener Cloquintocet-mexyl is a safener and does not have AOEL set in the European Union
Inhalation absorption	100%	100%	100%	100%

Oral absorption	72 %	58 %	100%	100%
Dermal absorption	Concentrate: 3 % Dilution: 6.4 % (Dilution rate: 1:133) (Based on product GLOB1817H)	Concentrate: 58 % Dilution: 58 % (Default) Concentrate: 70 % Dilution: 70 % (Default)	Concentrate: 70 % Dilution: 70 % (Default)	Concentrate: 70 % Dilution: 70 % (Default)

6.6.1 Selection of critical use(s) and justification

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

Justification

There is only one intended use.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of GLOB1817H according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Cereals (max. 3 L product/ha)
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 6.6-3: Estimated operator exposure (longer term exposure)

		Prosulfocarb		Diflufenican Dermal absorption 58%		Diflufenican Dermal absorption 70%	
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		2.001 kg a.s./ha		0.042 kg a.s./ha		0.042 kg a.s./ha	
Spray application (AOEM;	Work wear (arms, body and legs covered) M/L	0.1043765	1491.09	0.0878526	79.87		

75 th percent- tile) Body weight: 60 kg	and A						
	Work wear (arms, body and legs covered) M/L and A + Gloves M/L and A	0.0053737	75.34	0.0028768	2.62	0.00345	3.14

Calculation of operator exposure assuming 70% dermal absorption of Diflufenican

Operator exposure for Eledura outdoor spray applications

Application rate of active substance		0,042 kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied		2,1 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product		70,00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution		70,00%	<i>i_AbsorInuse</i>		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	8598	31712	AOEM	
	Body	6009	89349	AOEM	
	Head	109	598	AOEM	
	Protected hands (gloves)	56	416	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	46	307	AOEM	
	Protected head (hood and face shield)	2	34	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	311	3946	AOEM	
	Body	174	898	AOEM	
	Head	8	25	AOEM	
	Protected hands (gloves)	63	3634	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	4	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	10,6534720	0,2070517
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1775579	0,0034509
% of RVNAS	161,42%	3,14%

		Halauxifen-methyl		Cloquintocet-mexyl	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of proposed by the applicant systemic AOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		0.00399 kg a.s./ha		0.00399 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0169753	29.27	0.0169753	33.95
	Work wear (arms, body and legs covered) M/L and A + Gloves M/L and A	0.0005942	1.02	0.0005942	1.19

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.

zRMS:

The exposure to Prosulfocarb, an active substance of Eledura (GLOB1817H) of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (2.001 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 1491% of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Prosulfocarb is reduced to 75.34% of AOEL.

The exposure to Diflufenican an active substance of Eledura (GLOB1817H) of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (0.042 kg a.s./ha) using tractor-mounted/trailed boom sprayer, **taking dermal absorption value of 58%** calculated with the EFSA AOEM amounted to 79.87 % of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Diflufenican is reduced to 2.62 % of respective AOEL. **In case the operator is using protective gloves during mixing/loading and application and dermal absorption is 70% the exposure to Diflufenican is 3.14 % of respective AOEL.**

The exposure to Halauxifen-methyl an active substance of Eledura (GLOB1817H), of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (0.00399 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 29.27 % of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Halauxifen-methyl is reduced to 1.02 % of respective AOEL.

The exposure to Cloquintocet-mexyl, a safener in a product Eledura (GLOB1817H), of operator wearing

a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (0.00399 kg safener/ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 33.95 % of AOEL proposed by the applicant . In case the operator is using protective gloves during mixing/loading and application the exposure to Cloquintocet-mexyl is reduced to 1.19% of AOEL proposed by the applicant. Cloquintocet-mexyl, does not have AOEL set up in European Union, and in Poland the safeners are not considered as the active substances of the plant protection product , therefore the assessment of risk of operator to safeners is not required.

The sum of exposures of operator wearing work wear (arms, body and legs covered) and protective gloves during M/L and A to three active substances (Prosulfocarb, Diflufenican and Halauxifen-methyl) expressed as percentage of their AOELs (75.34% + 2.62 % (3.14 %) +1.02 %) is also below 100%, therefore the application of product Eledura (GLOB1817H) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator wearing protective gloves during mixing/loading and application.

Since an hazard Index for operators is < 1, the combined exposure to all active substances in Eledura (GLOB1817H) is not expected to present a risk for operators when applied in accordance with GAP. No further refinement of the assessment is required.

Summing up the application of product Eledura (GLOB1817H) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs and protective gloves during mixing/loading and application. Since the product classified as Eye Dam. 1, Skin Sens. 1, STOT SE3 the operator should wear protective gloves, eye protection or face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB1817H according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Cereals (max. 1 x 3 L product/ha)
Model	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 6.6-5: Estimated worker exposure (longer term exposure)

		Prosulfocarb		Diflufenican Dermal absorption 58%		Diflufenican Dermal absorption 70%	
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	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							
Number of applications and application rate		1 x 2.001 kg a.s./ha		1 x 0.042 kg a.s./ha		1 x 0.042 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.1600800	2286.86	0.0304500	27.68	0.0367	33.42
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0179290	256.13	0.0034104	3.10	0.00411	3.74%

		Halauxifen-methyl		Cloquintocet-mexyl	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of proposed by the applicant systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha					
Number of applications and application rate		1 x 0.00399 kg a.s./ha		1 x 0.00399 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.0034913	6.02	0.0034913	6.98
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0003910	0.67	0.0003910	0.78

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

The AOEM model predicts exposure to prosulfocarb above the acceptable limits for a worker assuming arms, body and legs covered (workwear; bare hands). To refine the risk, the generic Dislodgeable Foliar Residues (DFR) were refined (0.62 µg/cm²/kg a.s./ha) and the transfer coefficient (TC) recalculated based on the refined DFR for the use of prosulfocarb as determined in the study of XXXX, A. (2016) summarized under section 6.6.3.3 below.

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

		Prosulfocarb	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 0.62 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 x 2.001 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 601 cm ² /person/h	0.00159	22.72

Calculation of worker exposure assuming 70% dermal absorption of Diflufenican

Worker exposure from residues on foliage for Eledura			
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		0,042	kg a.s./ha
Number of applications		2	
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)		0,126	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		cm ² /hr
Inhalation transfer coefficient for automated applications		NA	ha/hr*10 [^] (-3)
Inhalation transfer coefficient for cutting ornamentals		NA	ha/hr*10 [^] (-3)
Inhalation transfer coefficient for sorting / bundling ornamentals		NA	ha/hr*10 [^] (-3)
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	2,2054796	0,2470137	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0367580	0,0041169	
% of RVNAS	33,42%	3,74%	

6.6.3.3 Measurement of worker exposure

Since worker exposure estimations carried out for prosulfocarb indicated that the acceptable operator exposure level (AOEL) was exceeded under conditions of intended uses, a field study measuring the worker exposure has been provided. A summary of the study is presented below. For the detailed evaluation of new studies please refer to Appendix 4. No detailed summaries are provided if the study was already assessed and accepted at EU level.

A worker exposure study was performed using an 800 g/L EC formulation of prosulfocarb in 2015, in Northern France. Based on this study, the generic Dislodgeable Foliar Residues were refined and the transfer coefficient was recalculated. The study is summarized below.

Report:	XXXX. A (2016). Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe, 2015.xxxxx, France Laboratory Report No. RB424, issue date 29 December 2015. Unpublished. Syngenta File No. A8545G_10414
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The purpose of the study was the determination of dermal and inhalation exposure of re-entry workers during typical tasks related to crop scouting activities following a tractor boom application of A8545G (emulsifiable concentrate formulation of 800 g/L prosulfocarb) on cereal crops at BBCH stage 25-26. The study was conducted under field conditions.

Twelve operators were recruited and monitored. The dermal and inhalation exposure of these subjects to the test substance was monitored at three locations in Northern France (4 workers per site) for a duration of 2 hours for each worker, which is considered a representative duration for crop inspection activities according to the EFSA guidance¹ on non-dietary exposure assessment.

Dermal exposure to the test substance was measured by workers wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a cotton/polyester coverall, which is considered to be representative of the clothing workers would normally wear. The inner dosimeter consisted of a long-sleeved T-shirt, leggings and cotton socks, covering arms, legs, feet and torso. Head exposure was measured by face/neck wipes. Nitrile dosimeter gloves were used for the determination of potential hand exposure. Actual dermal exposure of the hands beneath protective gloves was determined by the hand wash procedure. Inhalation exposure was measured by means of personal air sampling pumps connected to OVS XAD-2 air sampling tubes located in the operator's breathing zone.

The test substance was applied at a representative, label-recommended rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha. Applications were made to crops 1-2 hours before the workers re-entered the field in order to allow the spray to dry.

Samples of each dosimeter matrix were fortified in the field to assess potential degradation of prosulfocarb due to exposure to environmental conditions, handling, packaging, shipping, and storage.

All worker dosimeter samples collected were analysed for residues of prosulfocarb. For each worker, potential dermal exposure (PDE), actual dermal exposure (ADE), hand exposure with gloves, actual hand exposure for protected hands beneath gloves and (potential) inhalation exposure were calculated.

Dislodgeable foliar residue (DFR) measurements were also collected at the same time as the worker re-entry scouting activities were being undertaken. These DFR measurements enable calculation of a transfer coefficient for workers scouting in early post emergence cereal crops.

Based on this study, the generic Dislodgeable Foliar Residues were refined to 0.62 µg a.i./cm² and the transfer coefficient was recalculated to 601 cm²/h.

zRMS:

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (2.001 kg a.s./ha) as foreseen in GAP, to Prosulfocarb, an active substance of Eledura (GLOB1817H), calculated with the EFSA AOEM, assuming standard DFR and TC amounted 256.13% of respective AOEL. However when empirical DFR of 0.62 µg/cm²/kg a.s./ha and TC of 601 cm²/person/h were taken into account in calculation the worker exposure amounted to 22.72 % of AOEL for Prosulfocarb, thus not causing an unacceptable risk

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (0.042 kg a.s./ha) as foreseen in GAP, to Diflufenican, an active substance of Eledura (GLOB1817H), assuming dermal absorption of 58% calculated with the EFSA AOEM, assuming standard DFR and TC amounted 3.1 % of respective AOEL, thus not causing an unacceptable risk. In case a default value for dermal absorption has been 70 % in line with EU Dermal Absorption Guidance the worker exposure amounted to 3.74%.

¹ EFSA 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 [55 pp.]

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (0.00399 kg a.s./ha) as foreseen in GAP, to Halauxifen-methyl, an active substance of Eledura (GLOB1817H), calculated with the EFSA AOEM, assuming standard DFR and TC amounted 0.67 % of respective AOEL, thus not causing an unacceptable risk.

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (0.00399 kg safener /ha) as foreseen in GAP, to Cloquintocet-mexyl, a safener of Eledura (GLOB1817H), calculated with the EFSA AOEM, assuming standard DFR and TC amounted 0.78 % of AOEL proposed by the applicant. Cloquintocet-mexyl, does not have AOEL set up in European Union, and in Poland the safeners are not considered as the active substances of the plant protection product, therefore the assessment of risk of worker to safeners is not required.

Thus, it is concluded that the application of product Eledura (GLOB1817H) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

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, exposure assessment for residents also covers bystander exposure.

Table 6.6-7 shows the exposure model(s) used for estimation of resident and bystander exposure to prosulfocarb, diflufenican, halauxifen-methyl and cloquintocet-mexyl. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure models for intended uses

Critical use(s)	Cereals (max.1 x 3 L product/ha)
Model	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 (longer term exposure)

		Prosulfocarb		Diflufenican Dermal absorption 58%	
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					
Number of applications and application rate		1 x 2.001 kg a.s./ha		1 x 0.042 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0347793	496.85	0.0065411	5.95
	Vapour (75 th perc.)	0.0010700	15.29	0.0010700	0.97
	Deposits (75 th perc.)	0.0030345	43.35	0.0003745	0.34
	Re-entry (75 th perc.)	0.0216108	308.73	0.0041108	3.74
	Sum (mean)	0.0397651	568.07	0.0082245	7.48
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0082593	117.99	0.0015654	1.42
	Vapour (75 th perc.)	0.0002300	3.29	0.0002300	0.21
	Deposits (75 th perc.)	0.0008725	12.46	0.0001660	0.15
	Re-entry (75 th perc.)	0.0120060	171.51	0.0022838	2.08
	Sum (mean)	0.0143777	205.40	0.0029161	2.65

Calculation of resident exposure assuming 70% dermal absorption of Diflufenican

Resident exposure for Eledura					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0,042 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0,21 g a.s./l				
Dermal absorption of product	70,00%				
Dermal absorption of in-use dilution	70,00%				
Oral absorption	58,00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,126 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0,001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0,23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0,2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0,00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0,12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0,12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00014 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 m³/day/kg				
Breathing rate child (1-3 year old)	1,07 m³/day/kg				
Drift percentage on surface (75th percentile)	2,30%				
Drift percentage on surface (mean)	1,80%				
Turf transferable residues percentage	5,00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50,00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9,5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20,00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0262532	0,0107000	0,0018398	0,0496233	0,0662003
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0026253	0,0010700	0,0001840	0,0049623	0,0066200
% of RVNAS	2,39%	0,97%	0,17%	4,51%	6,02%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0287050	0,0138000	0,0049373	0,1654110	0,1643684
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0004784	0,0002300	0,0000823	0,0027568	0,0027395
% of RVNAS	0,43%	0,21%	0,07%	2,51%	2,49%

		Halauxifen-methyl		Cloquintocet-mexyl	
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					
Number of applications and application rate		1 x 0.00399 kg a.s./ha		1 x 0.00399 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0007498	1.29	0.0007498	1.50
	Vapour (75 th perc.)	0.0010700	1.84	0.0010700	2.14
	Deposits (75 th perc.)	0.0000439	0.08	0.0000439	0.09
	Re-entry (75 th perc.)	0.0004713	0.81	0.0004713	0.94
	Sum (mean)	0.0018909	3.26	0.0018909	3.78
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001795	0.31	0.0001795	0.36
	Vapour (75 th perc.)	0.0002300	0.40	0.0002300	0.46
	Deposits (75 th perc.)	0.0000190	0.03	0.0000190	0.04
	Re-entry (75 th perc.)	0.0002618	0.45	0.0002618	0.52
	Sum (mean)	0.0005380	0.93	0.0005380	1.08

The AOEM model predicts exposure to Prosulfocarb above the acceptable limits for residents living near fields treated with GLOB1817H. To refine the risk, the generic Dislodgeable Foliar Residues (DFR) were refined and the transfer coefficient (TC) recalculated based on the refined DFR for the use of Prosulfocarb. Reference is made to section 6.6.3.3 for the study summary in which the DFR measurements were performed. Refined calculations for the resident exposure are shown below.

Table 6.6-9: Estimated resident exposure (longer term exposure)

		Prosulfocarb	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes – 50% DT ₅₀ : 30 days DFR: 0.62 µg/cm ² /kg a.s./ha TC adult: 601 cm ² /h			
Number of applications and application rate		1 x 2.001 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0049	69.81
	Vapour (75 th perc.)	0.00107	15.29
	Deposits (75 th perc.)	0.0012463	17.80
	Re-entry (75 th perc.)	0.00036	5.11
	Sum (mean)	0.005694	81.34

Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0011	15.22
	Vapour (75 th perc.)	0.00023	3.29
	Deposits (75 th perc.)	0.0003584	5.12
	Re-entry (75 th perc.)	0.00020	2.84
	Sum (mean)	0.001260	18.00

Using the refined DFR and TC values, the risk for residents is acceptable when using a buffer zone of 5 m, 50% drift reducing techniques and a water volume of 200 L/ha.

To be able to calculate correctly the combined exposure, the estimated resident exposure for diflufenican, halauxifen-methyl and cloquintocet-methyl were also calculated using these mitigation measures and water volume. The results are summarized in the table below.

Table 6.6-10: Estimated resident exposure (longer term exposure)

		Diflufenican	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes – 50% DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			
Number of applications and application rate		1 x 0.042 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0010879	0.99
	Vapour (75 th perc.)	0.0010700	0.97
	Deposits (75 th perc.)	0.0000769	0.07
	Re-entry (75 th perc.)	0.0041108	3.74
	Sum (mean)	0.0050085	4.55
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001982	0.18
	Vapour (75 th perc.)	0.0002300	0.21
	Deposits (75 th perc.)	0.0000341	0.03
	Re-entry (75 th perc.)	0.0022838	2.08
	Sum (mean)	0.0021799	1.98

		Halauxifen-methyl		Cloquintocet-mexyl	
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: 5 m Drift reduction technology: yes – 50% DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha					

Number of applications and application rate		1 x 0.00399 kg a.s./ha		1 x 0.00399 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0001247	0.22	0.0001247	0.25
	Vapour (75 th perc.)	0.0010700	1.84	0.0010700	2.14
	Deposits (75 th perc.)	0.0000090	0.02	0.0000090	0.02
	Re-entry (75 th perc.)	0.0004713	0.81	0.0004713	0.94
	Sum (mean)	0.0015217	2.62	0.0015217	3.04
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0000227	0.04	0.0000227	0.05
	Vapour (75 th perc.)	0.0002300	0.40	0.0002300	0.46
	Deposits (75 th perc.)	0.0000039	0.01	0.0000039	0.01
	Re-entry (75 th perc.)	0.0002618	0.45	0.0002618	0.52
	Sum (mean)	0.0004536	0.78	0.0004536	0.91

Additional assessment of exposure of residents provided by the applicant

Calculation of TC values for residents and bystanders

The EFSA guidance derives TC values for residents and bystanders entering treated crops by calculating the appropriate percentiles from the datasets for crop inspection for individuals with lower legs and lower arms uncovered. It is possible to derive similar values from this study as the upper and lower arms and legs were analysed and reported separately.

Consequently, the appropriate dosimeters to calculate dermal exposure for residents and bystanders are considered to be: Outer dosimeter: lower arm, lower leg (i.e. excluding upper arm and leg and torso, which are considered to be clothed)

Inner dosimeter: lower arm, upper arm, lower leg, upper leg, front torso, rear torso, socks

Hands: hand wash and protective gloves. It should be noted that the workers in the study were engaged in activities which involved a considerable amount of contact between the hands and treated foliage. Hand exposure as measured on gloves and hand wash was the highest contributor to overall exposure. As such, the TC values are protective of members of the public who are walking through treated fields.

Table B.6.4.3-4: Dermal exposure and DFR results for re-entry workers performing crop inspection in early growth stage arable crops

SITE		1				2				3			
WORKER		1	2	3	4	5	6	7	8	9	10	11	12
Bodyweight (kg)		78	76	94	94	60	80	66	85	54	76	90	86
Outer dosimeter	Lower arm	361.95	72.99	17.61	8.76	54.99	126.37	101.2	119.57	96.43	36.44	28.49	28.97
(µg/sample)	Upper arm	28.13	42.36	10.73	4.48	20.2	28.21	89.7	163.63	39.49	37.45	49.22	37.92
	Front torso	88.82	27.54	26.77	42.88	39.13	58.53	231.88	237.54	183.5	312.78	206.75	214.02
	Rear torso	104.75	48.56	66.23	40.03	50.34	74.59	300.3	192.43	66.77	174.19	117.36	108.31
	Lower leg	817.54	233.2	911.7	167.63	763.24	653.12	1529.85	754.75	346.48	1193.3	489.08	648.34
	Upper leg	187.03	112.52	69.63	23.72	44.32	101.38	564.34	301.67	115.71	231.61	227.53	94.97
Inner dosimeter	Lower arm	0.33	0.58	0.42	0.52	0.06	2.48	2.804	5.62	0.00	0.00	0.00	0.00
(µg/sample)	Upper arm	0.12	0.08	0.54	0.3	0.04	0.06	0.237	0.24	0.00	0.00	0.00	0.00
	Front torso	0.07	1.33	2.65	0.04	0.16	3.6	7.24	3.33	0.00	0.00	0.00	0.00
	Rear torso	0.03	0.74	1.99	0.42	0.15	4.25	3.52	5.1	0.00	0.00	0.00	0.00
	Lower leg	524.03	128.3	543.01	441.22	280.31	455.6	301.06	323.16	230.24	189.06	212.26	386.77
	Upper leg	78.05	5.58	61.56	27.52	45.77	142.25	146.32	50.85	0.00	0.00	0.00	0.00
(µg/sample)	Socks	44.28	0.28	0.38	76.54	3.33	0.57	46.98	25.41	0.12	0.46	0.11	0.31
(µg/L)	Hand wash	0.28	0.22	4.46	0.15	0.52	0.36	0.37	18.74	0.34	0.46	0.51	0.42
(µg/sample)	Nitrile gloves	2769.97	118.59	305.62	84.28	2309.24	4111.7	1270.18	1569.7	593.42	2053.19	1338.22	762.42
(µg/sample)	Face/neck wipes	1.28	2.27	0.32	0.22	1.4	8.05	2.82	3.39	3.9	4.45	2.87	4.09
Total dermal exposure for resident/bystander (µg)		4597.93	564.16	1850.26	807.6	3459.21	5508.41	3412.58	2879.86	1346.15	3575.24	2175.96	1893.16
Applic. rate (kg a.i./ha)		3.912				3.784				4.000			
DFR (µg/cm ²)	sample 1	0.993	1.889	1.554	1.231	3.377	2.133	2.494	2.399	3.075	2.459	2.047	2.372
	sample 2	0.883	1.836	1.51	1.539	3.522	2.5	3.453	2.855	2.885	2.482	3.068	3.221
	sample 3	0.833	1.653	1.557	1.216	3.175	2.378	2.463	3.676	3.365	3.331	2.61	4.871
	Mean	0.903	1.793	1.540	1.329	3.358	2.337	2.803	2.977	3.108	2.757	2.575	3.488
	Mean/kg a.i./ha	0.231	0.458	0.394	0.340	0.887	0.618	0.741	0.787	0.777	0.689	0.644	0.872
Exposure time (h)		2	2	2	2.033	2.050	2	2	2	2.017	2	2	2

Values in red indicate dosimeters which were not included in the calculation of dermal exposure for the resident or bystander, such that an individual with exposed lower arms and lower legs is represented.

In order to calculate TC values for each replicate, each worker in the study has an associated DFR value. According to the EFSA guidance, TC values are calculated as follows:

$$TC \text{ (cm}^2\text{/h)} = DE \text{ (µg/h)} / DFR \text{ (µg/cm}^2\text{)}$$

This calculation can be carried out for the resident and bystander in the same way using the total dermal exposure values calculated above expressed as µg/h, taking into account the specific exposure durations recorded. The table below shows the calculated TC values for each individual as well as the mean and empirical and parametric 75th and 95th percentile values. Corresponding TC values for the child resident and bystander are also calculated taking into account the correction factor of 0.3 as identified from the EFSA guidance.

Table B.6.4.3-5: Calculation of TC values for resident and bystander

Replicate	1	2	3	4	5	6	7	8	9	10	11	12
Dermal exposure (µg)	4597.93	564.16	1850.26	807.60	3459.21	5508.41	3412.58	2879.86	1346.15	3575.24	2175.96	1893.16
Exposure time (h)	2	2	2	2.033	2.05	2	2	2	2.017	2	2	2
Dermal exposure (µg/h)	2298.97	282.08	925.13	397.18	1687.42	2754.21	1706.29	1439.93	667.51	1787.62	1087.98	946.58
DFR (µg/cm ²)	0.90	1.79	1.54	1.33	3.36	2.34	2.80	2.98	3.11	2.76	2.58	3.49
TC adult (cm ² /h)	2545.92	157.35	600.60	298.93	502.51	1178.52	608.66	483.74	214.75	648.31	422.52	271.38
TC child (cm ² /h)	763.78	47.21	180.18	89.68	150.75	353.56	182.60	145.12	64.42	194.49	126.76	81.41

Parameter	Log normality	Mean	Empirical 75th	Parametric 75th	Empirical 95th	Parametric 95th
TC adult (cm ² /h)	Yes	661.10	618.58	849.62	1793.85	2009.89
TC child (cm ² /h)	Yes	198.33	185.57	254.89	538.16	602.97

For small datasets, the higher of the appropriate empirical and parametric percentiles should be used in risk assessment. Accordingly, from this evaluation, the parametric 75th percentile TC values for both adult and child resident should be used to calculate exposure during entry into treated crops. The corresponding parametric 95th percentiles could be used to calculate bystander exposure. However, it should be noted that at this point, no guidance is available for setting an appropriate endpoint for this acute exposure scenario. For the resident, the mean values should be used to calculate exposure during re-entry into treated crops when considering the sum of the 4 relevant pathways. The study is considered to be robust and the derivation of the TC values in accordance with the EFSA guidance and as such provides a valid refinement to the EFSA calculator

So the TC values to be used for the resident are the mean of 661.10 cm²/h and the 75th parametric percentile of 849.62 cm²/h for adults, and the mean of 198.33 cm²/h and the 75th parametric percentile of 254.89 cm²/h for children.

Using these TC values, the risk for residents is still acceptable with the use of the same mitigation measures as already proposed by the applicant (5 m buffer zone + 50% DRT), as shown in the calculation here below.

In summary

	% AOEL				
	Spray drift	Vapour	Surface deposit	Entry into treated crops	Total
Resident adult 75th percentile	15.22	3.29	5.12	4.02	
Resident adult mean	7.87	3.29	4.01	3.12	18.28
Resident child 75th percentile	69.81	15.29	17.80	7.23	
Resident child mean	47.01	15.29	13.93	5.62	81.85

Resident adult exposure 75th percentile	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw \times d)	0.007
Spray drift 75th percentile	
Dermal exposure (mL/person) (see table)	0.24
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00009
Systemic dermal exposure (mg a.i./person)	0.0630
Systemic inhalation exposure (mg a.i./pers)	0.0009
Total systemic exposure (mg a.i./person)	0.0639
Total systemic exposure (mg a.i./kg bw)	0.0011
% AOEL	15.22
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	0.23
Systemic exposure via inhalation (mg/d)	0.0138
Systemic exposure via inhalation (mg/d \times kg)	0.00023
% AOEL	3.29
Surface deposits	
Application rate (mg/cm^2)	0.02001
Drift percentage (%) (see table)	2.3
Turf transferable residues (%)	5
Transfer coefficient (cm^2/h)	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0215019
Systemic exposure (mg/kg bw \times d)	0.0003584
% AOEL	5.12
Entry into treated crops 75th percentile	
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Transfer coefficient (cm^2/h)	849.62
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.017
Systemic exposure (mg a.s./kg bw \times d)	0.00028
% AOEL	4.02

Resident adult exposure mean	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw \times d)	0.007
Spray drift mean	
Dermal exposure (mL/person) (see table)	0.12278
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00008
Systemic dermal exposure (mg a.i./person)	0.0322
Systemic inhalation exposure (mg a.i./pers)	0.0008
Total systemic exposure (mg a.i./person)	0.0330340
Total systemic exposure (mg a.i./kg bw)	0.0005506
% AOEL	7.87
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	0.23
Systemic exposure via inhalation (mg/d)	0.0138
Systemic exposure via inhalation (mg/d \times k)	0.00023
% AOEL	3.29
Surface deposits	
Application rate (mg/cm^2)	0.02001
Drift percentage (%) (see table)	1.8
Turf transferable residues (%)	5
Transfer coefficient (cm^2/h)	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0168276
Systemic exposure (mg/kg bw \times d)	0.0002805
% AOEL	4.01
Entry into treated crops	
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Transfer coefficient (cm^2/h)	661.1
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.013
Systemic exposure (mg a.s./kg bw \times d)	0.000
% AOEL	3.12
All pathways	
Total systemic exposure (mg a.s./d)	0.076784
Total systemic exposure (mg a.s./kg bw \times d)	0.001280
% AOEL	18.28

Resident child exposure 75th percentile	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{h})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw x d)	0.007
Spray drift 75th percentile	
Dermal exposure (mL/person) (see table)	0.17365
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00017
Systemic dermal exposure (mg a.i./person)	0.0472
Systemic inhalation exposure (mg a.i./person)	0.0017
Total systemic exposure (mg a.i./person)	0.0489
Total systemic exposure (mg a.i./kg bw)	0.0049
% AOEL	69.81
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	1.07
Systemic exposure via inhalation (mg/d)	0.0107
Systemic exposure via inhalation (mg/d x kg)	0.0107
% AOEL	15.29
Surface deposits	
<i>Dermal exposure</i>	
Application rate (mg/cm ²)	0.02001
Drift percentage (%) (see table)	2.3
Turf transferable residues (%)	5
Transfer coefficient (cm ² /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0076582
Systemic exposure (mg/kg bw x d)	0.0007658
% AOEL	10.34
<i>Hand to mouth exposure</i>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm ²)	20.00
Frequency of hand to mouth (events/h)	3.50
Systemic exposure (mg/d)	0.003148
Systemic exposure (mg/kg bw x d)	0.0003148
% AOEL	4.50
<i>Children's object to mouth</i>	
Drift percentage (%) (see table)	2.30
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (cm ²)	25
Systemic exposure (mg/d)	0.0016568
Systemic exposure (mg/kg bw x d)	0.0001657
% AOEL	2.37
<i>Total surface deposit exposure</i>	
Total systemic exposure (mg a.s./d)	0.0124630
Total systemic exposure (mg a.s./kg bw x d)	0.0012463
% AOEL	17.80
Entry into treated crops 75th percentile	
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{h})$)	0.62
Transfer coefficient	254.89
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.00506
Systemic exposure (mg a.s./kg bw x d)	0.00051
% AOEL	7.23

Resident child exposure mean	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFRI ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw x d)	0.007
Spray drift mean	
Dermal exposure (mL/person) (see table)	0.12
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00014
Systemic dermal exposure (mg a.i./person)	0.0315
Systemic inhalation exposure (mg a.i./person)	0.0014
Total systemic exposure (mg a.i./person)	0.0329044
Total systemic exposure (mg a.i./kg bw)	0.0032904
% AOEL	47.01
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	1.07
Systemic exposure via inhalation (mg/d)	0.0107
Systemic exposure via inhalation (mg/d)	0.00107
% AOEL	15.29
Surface deposits	
<i>Dermal exposure</i>	
Application rate (mg/cm ²)	0.02001
Drift percentage (%) (see table)	1.8
Turf transferable residues (%)	5
Transfer coefficient (cm ² /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0059934
Systemic exposure (mg/kg bw x d)	0.0005993
% AOEL	8.56
<i>Hand to mouth exposure</i>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm ²)	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.002464
Systemic exposure (mg/kg bw x d)	0.0002464
% AOEL	3.52
<i>Children's object to mouth</i>	
Drift percentage (%) (see table)	1.80
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (g)	25
Systemic exposure (mg/d)	0.00129665
Systemic exposure (mg/kg bw x d)	0.00012966
% AOEL	1.85
<i>Total surface deposit exposure</i>	
Total systemic exposure (mg a.s./d)	0.0097537
Total systemic exposure (mg a.s./kg bw)	0.0009754
% AOEL	13.93

Even if the correction factor for children of 0.3 would not be applied, the risk for the active substance prosulfcarb is still acceptable using the same mitigation measures.

In summary:

	% AOEL				
	Spray drift	Vapour	Surface deposit	Entry into treated crops	Total
Resident adult 75th percentile	15.22	3.29	5.12	4.02	
Resident adult mean	7.87	3.29	4.01	3.12	18.28
Resident child 75th percentile	69.81	15.29	17.80	24.09	
Resident child mean	47.01	15.29	13.93	18.75	94.97

Moreover, the worker exposure study was performed at BBCH 25-26 at a dose rate of 3.8 – 4 kg prosulfcarb/ha, while GLOB1817H is applied at BBCH 10-14 at a dose rate of 2 kg prosulfcarb/ha. Therefore the values derived from this study are considered conservative for GLOB1817H.

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 prosulfocarb, diflufenican, halauxifen-methyl and cloquintocet-mexyl 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.

zRMS:

The exposure estimation of resident (adult and child) to Prosulfocarb, an active substance of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (2.001 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, assuming standard DFR and TC, amounted 568.07 % to 205.40% of respective AOEL. However when empirical DFR of 0.62 µg/cm²/kg a.s./ha and TC of 601 cm²/person/h and drift reduction technology (50%) and 5 m buffer strip were taken into account in calculation the exposure amounted to 81.34 % of AOEL for child resident and 18.00 % of AOEL for adult resident, thus not causing an unacceptable risk

The exposure estimation of resident (adult and child) to Diflufenican, an active substance of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha (0.042 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%), assuming dermal absorption of 58% and 5 m buffer strip, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, assuming standard DFR and TC, amounted respectively 1.98 % and 4.55% % of AOEL. In case the 70% dermal absorption was taken as a default value of EU Dermal Absorption Guidance the child resident exposure amounted to 6.02% of AOEL and adult resident exposure to 2.49% of AOEL. In both cases the exposure of residents was not causing an unacceptable risk.

The exposure estimation of resident (adult and child) to Halauxifen-methyl, an active substance of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha (0.00399 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, assuming standard DFR and TC, amounted respectively 0.78 % and 2.62 % % of AOEL, thus not causing an unacceptable risk.

The exposure estimation of resident (adult and child) to Cloquintocet-mexyl, a safener of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha (0.00399 kg safener/ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, assuming standard DFR and TC, amounted respectively 0.91 % and 3.04 % of AOEL proposed by the applicant. Cloquintocet-mexyl, does not have AOEL set up in European Union, and in Poland the safeners are not considered as the active substances of the plant protection product, therefore the assessment of risk of worker to safeners is not required.

Summing up application of a product Eledura (GLOB1817H), on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip in line with GAP does not pose an unacceptable health risk for residents and bystanders.

Additional calculations (presented above) using the TC values specific for residents calculated based on the data from the worker exposure study in the draft RAR of prosulfocarb (Volume 3 -B6 (CP)) demonstrate that the exposure of adult and child residents due to application of a product Eledura (GLOB1817H), on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip in line with GAP is below AOEL for Prosulfocarb and it does not pose an unacceptable risk for adult and child residents.

6.6.5 Combined exposure

The product is a mixture of three active substances and a safener.

6.6.5.1 Exposure assessment of prosulfocarb, diflufenican, halauxifen-methyl and cloquintocet-mexyl in GLOB1817H

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 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-11: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – tractor mounted - Gloves during M/L and A	Prosulfocarb	0.7534
	Diflufenican	0.0262
	Halauxifen-methyl	0.0102
	Cloquintocet-mexyl	0.0119
	Cumulative risk operators (HI)	0.8017
Workers – inspection, irrigation	Prosulfocarb	0.2272
	Diflufenican	0.031
	Halauxifen-methyl	0.0067
	Cloquintocet-mexyl	0.0078
	Cumulative risk workers (HI)	0.2727
Resident – child – 5 m buffer + 50% DRT	Prosulfocarb	
	Drift	0.6981
	Vapour	0.1529
	Deposits	0.178
	Re-entry	0.0511
	Sum of all pathways	0.8134

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Diiflufenican	
	Drift	0.0099
	Vapour	0.0097
	Deposits	0.0007
	Re-entry	0.0374
	Sum of all pathways	0.0455
	Halauixifen-methyl	
	Drift	0.0022
	Vapour	0.0184
	Deposits	0.0002
	Re-entry	0.0081
	Sum of all pathways	0.0262
	Cloquintocet-mexyl	
	Drift	0.0025
	Vapour	0.0214
	Deposits	0.0002
	Re-entry	0.0094
	Sum of all pathways	0.0304
	Cumulative risk resident – child (HI)	
	Drift	0.7127
	Vapour	0.2024
	Deposits	0.1791
	Re-entry	0.106
	Sum of all pathways	0.9155
Resident – adult - 5 m buffer + 50% DRT	Prosulfocarb	
	Drift	0.1522
	Vapour	0.0329
	Deposits	0.0512
	Re-entry	0.0284
	Sum of all pathways	0.18
	Diiflufenican	
	Drift	0.0018
	Vapour	0.0021
	Deposits	0.0003
	Re-entry	0.0208
	Sum of all pathways	0.0198
	Halauixifen-methyl	

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Drift	0.0004
	Vapour	0.004
	Deposits	0.0001
	Re-entry	0.0045
	Sum of all pathways	0.0078
	Cloquintocet-mexyl	
	Drift	0.0005
	Vapour	0.0046
	Deposits	0.0001
	Re-entry	0.0052
	Sum of all pathways	0.0091
	Cumulative risk resident – adult (HI)	
	Drift	0.1549
	Vapour	0.0436
	Deposits	0.0517
	Re-entry	0.0589
	Sum of all pathways	0.2167

The Hazard Index is < 1. Thus, combined exposure to all active substances in GLOB1817H is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

zRMS:

Since an hazard Index for operators, workers and residents is < 1, the combined exposure to all active substances in Eledura (GLOB1817H) is not expected to present a risk for operators, workers, bystanders and residents when applied in accordance with GAP. No further refinement of the assessment is required.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2	XXXX.	2016	Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe RB424 Anadiag GLP Unpublished	N	Syngenta <i>Globachem access</i>
KCP 7.3	XXXX.	2020	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1817H through human skin membranes 20200147 Innovative Environmental Services (IES) Ltd. GLP Unpublished	N	Globachem NV

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
None					

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Bridging was not performed.

A 2.2 Acute oral toxicity (KCP 7.1.1)

No tests were performed on GLOB1817H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

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

No tests were performed on GLOB1817H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No tests were performed on GLOB1817H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.5 Skin irritation (KCP 7.1.4)

No tests were performed on GLOB1817H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.6 Eye irritation (KCP 7.1.5)

No tests were performed on GLOB1817H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

A 2.7 Skin sensitisation (KCP 7.1.6)

No tests were performed on GLOB1817H in the interest of animal welfare. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011).

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

None.

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)

A 2.10.1 Study 1 – Prosulfocarb in GLOB1817H

Comments of zRMS:	<p>The study performed according to international guidelines and in GLP conditions is acceptable .</p> <p>The results of the study were used in line with recommendations of the EU Dermal absorption guidelines (EFSA Journal 2017;15(6):4873) to derive the following dermal absorption values through human skin for assessment of dermal exposure:</p> <ul style="list-style-type: none"> - 3.0 % for the concentrated product and - 6.4 % for the diluted product (1:133)
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Reference	KCP 7.3
Report	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1817H through human skin membranes, XXXX., 2020, 20200147
Guideline(s)	Yes, OECD 428, Council Regulation (EC) No 440/2008, Method B45
Deviations	Yes, due to a low recovery (< 95%) at the low dose level the test was repeated and an evaporation of the radiolabeled prosulfocarb during the experimental phase was trapped by a charcoal filter paper.
GLP	Yes
Acceptability	YES
Duplication (if vertebrate study)	No

Materials and methods

Test material	Name (Lot/Batch No.)	XXV/43/A/1
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Product	Test preparation	spiking
	Specific activity	7161 kBq/mg
	Radiochemical purity	96.81%
	Name (Lot/Batch No.)	KS010420
	Company code	GLOB1817H
	Concentration a.s.	667 g/L
Blank product	Formulation type	EC
	Name (Lot/Batch No.)	-
	Concentration a.s.	-

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	3 ml/h
	Exposed skin area	1 cm ²
	Cover	open
Membrane	Skin type	dermatomed
	Skin thickness range	400 µm
	Skin donors age	29-61
	Skin donors sex	m+f
	Location	abdomen + breast
	Source	ex vivo
	Integrity test	y
Receptor	Receptor medium	Phosphate buffered saline with 5% Volpo N20
	Solubility in receptor medium	y
Sample Time	Exposure time	6 h
	Observation time	24 h
Sampling	Sample intervals	1-2 h
Washing		post exposure + post observation
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks:		

Tested doses	Concentrate	Spray dilution 1
Target concentration [mg/ml]	667	5
Area dose [µg/cm ²]	6670	50
Total dose [µg/cell]	6670	50
Specific activity [kBq/ml]	1529	565
No. of donors	4	7
No of cells used/valid cells	7/8*	13/13

*one cell was excluded due to a low recovery (< 90%)

Results and discussions

Table A 1: In-vitro dermal penetration of active substance formulated as product GLOB1817H / Eledura through human skin - Recovery data

Dose group	High dose		Low dose	
	(Formulation concentrate)		(Spray dilution 1:133)	
Target concentration [mg/mL]	667		5	
Target dose [µg/cm ²]	6670		50	
Mean actual applied dose [µg/cm ²]	6659		50.7	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.

Dislodgeable dose				
Skin washing after 6 + 24 h	94.41	4.23	83.67	7.66
Donor chamber wash	0.47	0.98	0.94	0.59
Dose associated to skin				
Tape strips: 1 st sample, strips 1 + 2	0.70	0.55	9.27	5.74
Tape strips: 2 nd sample; strips 3 – 10	0.19	0.22	0.57	0.43
Skin preparation	0.81	1.63	1.14	0.94
Absorbed dose				
Receptor fluid	0.16	0.11	2.87	1.65
Receptor chamber wash	0.05	0.06	0.20	0.18
Total recovery¹	96.79	2.26	98.66	2.25
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}]	No [30.26% ± 11.20]		No [42.59% ± 7.54]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	1.21	1.96	4.78	2.67
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate normalised ³				
Relevant absorption estimate ⁴	3.005		6.383	
Absorption estimates used for risk assessment⁵	3		6.4	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

³ According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

⁴ In accordance with the EFSA Guidance on Dermal Absorption, the standard deviation corrected for the number of replicates was added to the mean% dermal penetration.

⁵ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint:

The dermal penetration of prosulfocarb formulated as GLOB1817H through human dermatomed skin was determined in vitro. The amount of applied dose penetrating within 24 hours was determined to be 1.21 ± 1.96 % (mean ± standard deviation) and 4.78 ± 2.67 % for the formulation concentrate and the 1:133 spray dilution, respectively. The dermal penetration estimates to be used for risk assessment were set at 3% and 6.4% for the formulation concentrate and the 1:133 spray dilution based on the EFSA guidance criteria.

A 2.11 Other/Special Studies

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Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Prosulfocarb

Table A 2: Estimation of longer term operator exposure towards prosulfocarb according to EFSA guidance, including input parameters

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	2.001	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	100.05	kg a.s./day	L.AmountAS		
Dermal absorption of the product	3.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	6.40%		L.AbsorpUse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	168340	642414	AOEM	
	Body	90854	274530	AOEM	
	Head	5191	28470	AOEM	
	Protected hands (gloves)	690	19817	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1409	14632	AOEM	
	Protected head (hood and face shield)	83	1612	AOEM	
	Inhalation	15	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	ork wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	14840	66857	AOEM	
	Body	8297	42773	AOEM	
	Head	392	1183	AOEM	
	Protected hands (gloves)	517	5703	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	228	558	AOEM	
	Inhalation	10	41	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	ork wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	9.4623977	6.2625906	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1577066	0.1043765	
% of RVNAS	2252.95%	1491.09%	

Table A 13: Estimation of longer term operator exposure towards prosulfocarb according to EFSA guidance, including input parameters – gloves M/L and A

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	2.001	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	100.05	kg a.s./day	L.AmountAS		
Dermal absorption of the product	3.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	6.40%		L.AbsorInuse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	168340	642414	AOEM	
	Body	90854	274530	AOEM	
	Head	5191	28470	AOEM	
	Protected hands (gloves)	690	19817	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1409	14632	AOEM	
	Protected head (hood and face shield)	83	1612	AOEM	
	Inhalation	15	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		cl. in AOEM model	
	Clothing	ork wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	14840	66857	AOEM	
	Body	8297	42773	AOEM	
	Head	392	1183	AOEM	
	Protected hands (gloves)	517	5703	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	228	558	AOEM	
	Inhalation	10	41	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		cl. in AOEM model	
	Clothing	ork wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	9.4623977	0.3164238	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bwt/day)	0.1577066	0.0052737	
% of RVNAS	2252.95%	75.34%	

A 3.1.2 Calculations for Diflufenican

Table A 14: Estimation of longer term operator exposure towards diflufenican according to EFSA guidance, including input parameters

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	0.042	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	2.1	kg a.s./day	L.AmountAS		
Dermal absorption of the product	58.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	58.00%		L.AbsorInUse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	8598	31712	AOEM	
	Body	6009	89349	AOEM	
	Head	109	598	AOEM	
	Protected hands (gloves)	56	416	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	46	307	AOEM	
	Protected head (hood and face shield)	2	34	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	work wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	311	3946	AOEM	
	Body	174	898	AOEM	
	Head	8	25	AOEM	
	Protected hands (gloves)	63	3634	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	4	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	work wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.8282113	5.2711551	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1471369	0.0878526	
% of RVNAS	133.76%	79.87%	

Table A 15: Estimation of longer term operator exposure towards diflufenican according to EFSA guidance, including input parameters – gloves

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	0.042	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	2.1	kg a.s./day	L.AmountAS		
Dermal absorption of the product	58.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	58.00%		L.AbsorInuse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	8598	31712	AOEM	
	Body	6009	89349	AOEM	
	Head	109	598	AOEM	
	Protected hands (gloves)	56	416	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	46	307	AOEM	
	Protected head (hood and face shield)	2	34	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		cl. in AOEM model	
	Clothing	ork wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	311	3946	AOEM	
	Body	174	898	AOEM	
	Head	8	25	AOEM	
	Protected hands (gloves)	63	3634	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	4	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		cl. in AOEM model	
	Clothing	ork wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.8262113	0.1726059	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bwt/day)	0.1471369	0.0028768	
% of RVNAS	133.76%	2.62%	

A 3.1.3 Calculations for Halauxifen-methyl

Table A 16: Estimation of longer term operator exposure towards halauxifen-methyl according to EFSA guidance, including input parameters

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	0.00399	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	0.1995	kg a.s./day	L.AmountAS		
Dermal absorption of the product	70.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	70.00%		L.AbsorpInuse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	1404	5072	AOEM	
	Body	1149	45092	AOEM	
	Head	10	57	AOEM	
	Protected hands (gloves)	12	40	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	6	29	AOEM	
	Protected head (hood and face shield)	0	3	AOEM	
	Inhalation	2	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	ork wear - arms, body and legs covered		eI. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	30	704	AOEM	
	Body	17	85	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	18	2762	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	0	1	AOEM	
	Inhalation	0	1	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	ork wear - arms, body and legs covered		eI. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted	

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.8299443	1.0185171	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0304991	0.0169753	
% of RVNAS	52.58%	29.27%	

Table A 17: Estimation of longer term operator exposure towards halauxifen-methyl according to EFSA guidance, including input parameters – gloves

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	0.00399	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	0.1995	kg a.s./day	L.AmountAS		
Dermal absorption of the product	70.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	70.00%		L.AbsorInUse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	1404	5072	AOEM	
	Body	1149	45092	AOEM	
	Head	10	57	AOEM	
	Protected hands (gloves)	12	40	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	6	29	AOEM	
	Protected head (hood and face shield)	0	3	AOEM	
	Inhalation	2	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		cl. in AOEM model		
Clothing	work wear - arms, body and legs covered		cl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	30	704	AOEM	
	Body	17	85	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	18	2762	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	0	1	AOEM	
	Inhalation	0	1	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		cl. in AOEM model	
Clothing	work wear - arms, body and legs covered		cl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted		

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.8299443	0.0356522	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0304991	0.0005942	
% of RVNAS	52.58%	1.02%	

A 3.1.4 Calculations for Cloquintocet-mexyl

Table A 18: Estimation of longer term operator exposure towards cloquintocet-mexyl according to EFSA guidance, including input parameters

Operator exposure for GLOB1817H outdoor spray applications					
Application rate of active substance	0.00399	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	0.1995	kg a.s./day	L.AmountAS		
Dermal absorption of the product	70.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	70.00%		L.AbsorInUse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	1404	5072	AOEM	
	Body	1149	45092	AOEM	
	Head	10	57	AOEM	
	Protected hands (gloves)	12	40	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	6	29	AOEM	
	Protected head (hood and face shield)	0	3	AOEM	
	Inhalation	2	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	work wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	30	704	AOEM	
	Body	17	85	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	18	2762	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	0	1	AOEM	
	Inhalation	0	1	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	work wear - arms, body and legs covered		cl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.8299443	1.0185171
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0304991	0.0169753
% of RVNAS	61.00%	33.95%

Table A 19: Estimation of longer term operator exposure towards cloquintocet-mexyl according to EFSA guidance, including input parameters – gloves

Operator exposure for GLOB1817H outdoor spray applications				
Application rate of active substance	0.00399 kg a.s./ha	L.AppRate		
Assumed area treated	50 ha/day	L.AreaTreated		
Amount of active substance applied	0.1995 kg a.s./day	L.AmountAS		
Dermal absorption of the product	70.00%	L.AbsorpProduct		
Dermal absorption of in-use dilution	70.00%	L.AbsorInUse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Season	not relevant			

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Hands	1404	5072	AOEM		
Body	1149	45092	AOEM		
Head	10	57	AOEM		
Protected hands (gloves)	12	40	AOEM		
Protected body (workwear or protective garment and sturdy footwear)	6	29	AOEM		
Protected head (hood and face shield)	0	3	AOEM		
Inhalation	2	28	AOEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves	Yes		cl. in AOEM model		
Clothing	ork wear - arms, body and legs covered		cl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Hands	30	704	AOEM		
Body	17	85	AOEM		
Head	1	2	AOEM		
Protected hands (gloves)	18	2762	AOEM		
Protected body (workwear or protective garment and sturdy footwear)	0	1	AOEM		
Inhalation	0	1	AOEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves	Yes		cl. in AOEM model		
Clothing	ork wear - arms, body and legs covered		cl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted		

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.8299443	0.0356522	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0304991	0.0005942	
% of RVNAS	61.00%	1.19%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Prosulfocarb

Table A 20: Estimation of longer term worker exposure towards prosulfocarb according to EFSA guidance, including input parameters

Worker exposure from residues on foliage for GLOB1817H				
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	2.001	kg a.s./ha	<i>i_AppRate</i>	
Number of applications	1		<i>i_AppNo</i>	
Interval between multiple applications	365	days	<i>i_AppInt</i>	
Half-life of active substance	30	days	<i>d_HalfLifeAS</i>	
Multiple application factor	1.0		<i>d_MAF</i>	
Dermal absorption of the product	3.00%		<i>i_AbsorpProduct</i>	
Dermal absorption of the in-use dilution	6.40%		<i>i_AbsorpInuse</i>	
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	6.003	µg a.s./cm ²	<i>d_DFR</i>	
Working hours	2	hr	<i>d_WorkHr</i>	
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr	<i>d_DermTcUCV</i>	
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr	<i>d_DermTcCV1</i>	
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm ² /hr	<i>d_DermTcCV2</i>	
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)	<i>d_InhalTcAut</i>	
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)	<i>d_InhalTcCut</i>	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)	<i>d_InhalTcSort</i>	
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	9.6048000	1.0757376	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1600800	0.0179290		
% of RVNAS	2286.86%	256.13%		

Table A 21: Estimation of longer term worker exposure towards prosulfocarb according to EFSA guidance, including input parameters – refined DFR and TC

Worker exposure	
DFR	0.62
TC	601
T	2
Dosis	2.001
Dermal absorption (%)	6.4
PDE (mg a.s./d)	1.491
Systemic exposure (mg a.s./d)	0.09544
Worker exposure (mg a.s./kg bw x d)	0.00159
AOEL	0.007
% AOEL	22.72

A 3.2.2 Calculations for Diflufenican

Table A 22: Estimation of longer term worker exposure towards diflufenican according to EFSA guidance, including input parameters

Worker exposure from residues on foliage for GLOB1817H				
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	0.042 kg a.s./ha			<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	58.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	58.00%			<i>i_Absorpnuse</i>
Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$)	0.126 µg a.s./cm ²			<i>d_DFR</i>
Working hours	2 hr			<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr			<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr			<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm ² /hr			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1.8270000	0.2046240	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0304500	0.0034104		
% of RVNAS	27.68%	3.10%		

A 3.2.3 Calculations for Halauxifen-methyl

Table A 23: Estimation of longer term worker exposure towards halauxifen-methyl according to EFSA guidance, including input parameters

Worker exposure from residues on foliage for GLOB1817H				
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	0.00399 kg a.s./ha			<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	70.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70.00%			<i>i_Absorpnuse</i>
Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$)	0.01197 µg a.s./cm ²			<i>d_DFR</i>
Working hours	2 hr			<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr			<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr			<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm ² /hr			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0.2094750	0.0234612	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0034913	0.0003910		
% of RVNAS	6.02%	0.67%		

A 3.2.4 Calculations for Cloquintocet-mexyl

Table A 24: Estimation of longer term worker exposure towards cloquintocet-mexyl according to EFSA guidance, including input parameters

Worker exposure from residues on foliage for GLOB1817H				
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	0.00399	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	70.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	70.00%			i_AbsorpInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.01197	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm ² /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ⁻³		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ⁻³		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ⁻³		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	0.2094750	0.0234612	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0034913	0.0003910		
% of RVNAS	6.98%	0.78%		

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Prosulfocarb

Table A 25: Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters

Resident exposure for GLOB1817H					
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	2.001 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	20.01 g a.s./l				
Dermal absorption of product	3.00%				
Dermal absorption of in-use dilution	6.40%				
Oral absorption	72.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	6.003 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
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 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/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 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile)	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile)	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.3477930	0.0107000	0.0303448	0.2161080	0.3976510
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0347793	0.0010700	0.0030345	0.0216108	0.0397651
% of RVNAS	496.85%	15.29%	43.35%	308.73%	568.07%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4955597	0.0138000	0.0523526	0.7203600	0.8626643
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0082593	0.0002300	0.0008725	0.0120060	0.0143777
% of RVNAS	117.99%	3.29%	12.46%	171.51%	205.40%

Table A 26: Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters - refined

Resident adult exposure 75th percentile	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw \times d)	0.007
Spray drift 75th percentile	
Dermal exposure (mL/person) (see table)	0.24
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00009
Systemic dermal exposure (mg a.i./person)	0.0630
Systemic inhalation exposure (mg a.i./pers)	0.0009
Total systemic exposure (mg a.i./person)	0.0639
Total systemic exposure (mg a.i./kg bw)	0.0011
% AOEL	15.22
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	0.23
Systemic exposure via inhalation (mg/d)	0.0138
Systemic exposure via inhalation (mg/d \times kg)	0.00023
% AOEL	3.29
Surface deposits	
Application rate (mg/cm ²)	0.02001
Drift percentage (%) (see table)	2.3
Turf transferable residues (%)	5
Transfer coefficient (cm ² /h)	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0215019
Systemic exposure (mg/kg bw \times d)	0.0003584
% AOEL	5.12
Entry into treated crops 75th percentile	
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Transfer coefficient (cm ² /h)	601
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.012
Systemic exposure (mg a.s./kg bw \times d)	0.00020
% AOEL	2.84

Resident adult exposure mean	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw x d)	0.007
Spray drift mean	
Dermal exposure (mL/person) (see table)	0.12278
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00008
Systemic dermal exposure (mg a.i./person)	0.0322
Systemic inhalation exposure (mg a.i./person)	0.0008
Total systemic exposure (mg a.i./person)	0.0330340
Total systemic exposure (mg a.i./kg bw)	0.0005506
% AOEL	7.87
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	0.23
Systemic exposure via inhalation (mg/d)	0.0138
Systemic exposure via inhalation (mg/d x kg)	0.00023
% AOEL	3.29
Surface deposits	
Application rate (mg/cm^2)	0.02001
Drift percentage (%) (see table)	1.8
Turf transferable residues (%)	5
Transfer coefficient (cm^2/h)	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0168276
Systemic exposure (mg/kg bw x d)	0.0002805
% AOEL	4.01
Entry into treated crops	
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Transfer coefficient (cm^2/h)	601
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.012
Systemic exposure (mg a.s./kg bw x d)	0.000
% AOEL	2.84
All pathways	
Total systemic exposure (mg a.s./d)	0.075591
Total systemic exposure (mg a.s./kg bw)	0.001260
% AOEL	18.00

Resident child exposure 75th percentile	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR ($\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$)	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw x d)	0.007
Spray drift 75th percentile	
Dermal exposure (mL/person) (see table)	0.17965
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00017
Systemic dermal exposure (mg a.i./person)	0.0472
Systemic inhalation exposure (mg a.i./person)	0.0017
Total systemic exposure (mg a.i./person)	0.0489
Total systemic exposure (mg a.i./kg bw)	0.0049
% AOEL	69.81
Vapour	
Vapour concentration ($\mu\text{g}/\text{m}^3$)	1
Average breathing rate ($\text{m}^3/\text{d} \times \text{kg}$)	1.07
Systemic exposure via inhalation (mg/d)	0.0107
Systemic exposure via inhalation (mg/d x kg)	0.00107
% AOEL	15.29

Surface deposits	
<i>Dermal exposure</i>	
Application rate (mg/cm ²)	0.02001
Drift percentage (%) (see table)	2.3
Turf transferable residues (%)	5
Transfer coefficient (cm ² /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0076582
Systemic exposure (mg/kg bw x d)	0.0007658
% AOEL	10.94
<i>Hand to mouth exposure</i>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm ²)	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.003148
Systemic exposure (mg/kg bw x d)	0.0003148
% AOEL	4.50
<i>Children's object to mouth</i>	
Drift percentage (%) (see table)	2.30
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (cm ³)	25
Systemic exposure (mg/d)	0.0016568
Systemic exposure (mg/kg bw x d)	0.0001657
% AOEL	2.37
<i>Total surface deposit exposure</i>	
Total systemic exposure (mg a.s./d)	0.0124630
Total systemic exposure (mg a.s./kg bw x d)	0.0012463
% AOEL	17.80
Entry into treated crops 75th percentile	
DFR (µg/(cm ² x kg a.s. x ha))	0.62
Transfer coefficient	180.30
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.00358
Systemic exposure (mg a.s./kg bw x d)	0.00036
% AOEL	5.11
Resident child exposure mean	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2001
Water volume (L/ha)	200
Concentration (mg a.i./mL)	10.005
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	6.4
DFR (µg/(cm ² x kg a.s. x ha))	0.62
Vapour pressure (Pa)	0.00079
Oral absorption (%)	72
AOEL (mg a.i./kg bw x d)	0.007
Spray drift mean	
Dermal exposure (mL/person) (see table)	0.12
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00014
Systemic dermal exposure (mg a.i./person)	0.0315
Systemic inhalation exposure (mg a.i./pers)	0.0014
Total systemic exposure (mg a.i./person)	0.0329044
Total systemic exposure (mg a.i./kg bw)	0.0032904
% AOEL	47.01
Vapour	
Vapour concentration (µg/m ³)	1
Average breathing rate (m ³ /d x kg)	1.07
Systemic exposure via inhalation (mg/d)	0.0107
Systemic exposure via inhalation (mg/d x kg)	0.00107
% AOEL	15.23

Surface deposits	
<i>Dermal exposure</i>	
Application rate (mg/cm ²)	0.02001
Drift percentage (%) (see table)	1.8
Turf transferable residues (%)	5
Transfer coefficient (cm ² /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.064
Systemic exposure (mg/d)	0.0059934
Systemic exposure (mg/kg bw x d)	0.0005993
% AOEL	8.56
<i>Hand to mouth exposure</i>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm ²)	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.002464
Systemic exposure (mg/kg bw x d)	0.0002464
% AOEL	3.52
<i>Children's object to mouth</i>	
Drift percentage (%) (see table)	1.80
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (cm ²)	25
Systemic exposure (mg/d)	0.00129665
Systemic exposure (mg/kg bw x d)	0.00012966
% AOEL	1.85
<i>Total surface deposit exposure</i>	
Total systemic exposure (mg a.s./d)	0.0097537
Total systemic exposure (mg a.s./kg bw x d)	0.0009754
% AOEL	13.93
Entry into treated crops	
DFR (µg/(cm ² x kg a.s. x ha))	0.62
Transfer coefficient (cm ² /h)	180.3
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.001
Dermal absorption (%)	6.4
Systemic exposure (mg a.s./d)	0.004
Systemic exposure (mg a.s./kg bw x d)	0.00036
% AOEL	5.11
All pathways	
Total systemic exposure (mg a.s./d)	0.056937
Total systemic exposure (mg a.s./kg bw x d)	0.005694
% AOEL	81.34

A 3.3.2 Calculations for Diflufenican

Table A 27: Estimation of longer term resident exposure towards diflufenican according to EFSA guidance, including input parameters

Resident exposure for GLOB1817H					
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	0.042 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.42 g a.s./l				
Dermal absorption of product	58.00%				
Dermal absorption of in-use dilution	58.00%				
Oral absorption	58.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.126 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
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 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/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 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile)	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile)	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0654113	0.0107000	0.0037446	0.0411075	0.0822447
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0065411	0.0010700	0.0003745	0.0041108	0.0082245
% of RVNAS	5.95%	0.97%	0.34%	3.74%	7.48%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0939254	0.0138000	0.0099584	0.1370250	0.1749640
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0015654	0.0002300	0.0001660	0.0022838	0.0029161
% of RVNAS	1.42%	0.21%	0.15%	2.08%	2.65%

Table A 28: Estimation of longer term resident exposure towards diflufenican according to EFSA guidance, including input parameters - refined

Resident exposure for GLOB1817H					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.042 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.21 g a.s./l				
Dermal absorption of product	58.00%				
Dermal absorption of in-use dilution	58.00%				
Oral absorption	58.00%				
Dislodgeable foliar residue (L_AppRate*I_DFR)	0.126 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 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 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentil	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentil	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0108794	0.0107000	0.0007690	0.0411075	0.0500855
Total systemic exposure per kg body weight (mg a.s./kg body weight/day)	0.0010879	0.0010700	0.0000769	0.0041108	0.0050085
% of RYNAS	0.99%	0.97%	0.07%	3.74%	4.55%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0118937	0.0138000	0.0020450	0.1370250	0.1307948
Total systemic exposure per kg body weight (mg a.s./kg body weight/day)	0.0001982	0.0002300	0.0000341	0.0022838	0.0021799
% of RYNAS	0.18%	0.21%	0.03%	2.08%	1.98%

A 3.3.3 Calculations for Halauxifen-methyl

Table A 29: Estimation of longer term resident exposure towards halauxifen-methyl according to EFSA guidance, including input parameters

Resident exposure for GLOB1817H					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	2-3 m				i_Buffer
Application rate of the product	0.00399 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.0399 g a.s./l				d_ConcAS
Dermal absorption of product	70.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_AbsorpInuse
Oral absorption	100.00%				i_AbsorpOralinuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.01197 µg a.s./cm ²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa				i_Volat
Concentration in air	0.001 mg/m ³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m ³ /day/kg				d_BreathRad
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm ²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm ²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile)	7500 cm ² /h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile)	2250 cm ² /h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0074979	0.0107000	0.0004391	0.0047132	0.0189087
Total systemic exposure per kg body weight (a.s./kg bw/day)	0.0007498	0.0010700	0.0000439	0.0004713	0.0018909
% of RVNAS	1.29%	1.84%	0.08%	0.81%	3.26%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0107682	0.0138000	0.0011418	0.0157106	0.0322775
Total systemic exposure per kg body weight (a.s./kg bw/day)	0.0001795	0.0002300	0.0000190	0.0002618	0.0005380
% of RVNAS	0.31%	0.40%	0.03%	0.45%	0.93%

Table A 30: Estimation of longer term resident exposure towards halauxifen-methyl according to EFSA guidance, including input parameters – refined

Resident exposure for GLOB1817H					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.00399 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.01995 g a.s./l				
Dermal absorption of product	70.00%				
Dermal absorption of in-use dilution	70.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (I_AppRate*_L_DFR)	0.01197 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 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 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentil	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentil	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)		Surface deposits (75th percentile)	
Entry into treated crops (75th percentile)		All pathways (mean)			
Total systemic exposure (mg a.s./day)	0.0012470	0.0107000	0.0000902	0.0047132	0.0152170
Total systemic exposure per kg body weight (mg a.s./kg body wt/day)	0.0001247	0.0010700	0.0000090	0.0004713	0.0015217
% of RVNAS	0.22%	1.84%	0.02%	0.81%	2.62%
1.2 Adult					
Spray drift		Vapour		Surface deposits	
Entry into treated crops		All pathways (mean)			
Total systemic exposure (mg a.s./day)	0.0013635	0.0138000	0.0002345	0.0157106	0.0272139
Total systemic exposure per kg body weight (mg a.s./kg body wt/day)	0.0000227	0.0002300	0.0000039	0.0002618	0.0004536
% of RVNAS	0.04%	0.40%	0.01%	0.45%	0.78%

A 3.3.4 Calculations for Cloquintocet-mexyl

Table A 31: Estimation of longer term resident exposure towards cloquintocet-mexyl according to EFSA guidance, including input parameters

Resident exposure for GLOB1817H					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted			<i>i_AppEquip</i>	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			<i>i_FormVal</i>	
Buffer strip	2-3 m			<i>i_Buffer</i>	
Application rate of the product	0.00399 kg a.s./ha			<i>i_AppRate</i>	
Concentration of active substance (in-use dilution for liquid applications)	0.0399 g a.s./l			<i>d_ConcAS</i>	
Dermal absorption of product	70.00%			<i>i_AbsorpProduct</i>	
Dermal absorption of in-use dilution	70.00%			<i>i_AbsorpInuse</i>	
Oral absorption	100.00%			<i>i_AbsorpOrallnuse</i>	
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.01197 µg a.s./cm ²			<i>d_DFR</i>	
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa			<i>i_Volat</i>	
Concentration in air	0.001 mg/m ³			<i>d_AirCon</i>	
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			<i>d_ReExpDur</i>	
Exposure duration inhalation	24 hours			<i>d_ReExpDurInhal</i>	
Exposure duration entry into treated crops	0.25 hours			<i>d_ExpDurTreatCrop</i>	
Light clothing adjustment factor	18.0%			<i>d_ClothAF</i>	
Breathing rate adult	0.23 m ³ /day/kg			<i>d_BreathRAAd</i>	
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg			<i>d_BreathRCh</i>	
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%			<i>d_Turf</i>	
Transfer coeff. of surface deposits-adult	7300 cm ² /hour			<i>d_ReTCAd</i>	
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour			<i>d_ReTCCh</i>	
Saliva extraction percentage	50.00%			<i>d_SalExt</i>	
Surface area of hands mouthed	20 cm ²			<i>d_AreaHM</i>	
Frequency of hand to mouth activity	9.5 events/hour			<i>d_ReFreqHM</i>	
Ingestion rate for mouthing of grass per day	25 cm ²			<i>d_MouthGrass</i>	
Dislodgeable residues percentage transferability for object to mouth	20.00%			<i>d_DRP</i>	
Transfer coefficient for entry into treated crops (75th percentile)	7500 cm ² /h			<i>d_TcEntryAd</i>	
Transfer coefficient for entry into treated crops (75th percentile)	2250 cm ² /h			<i>d_TcEntryCh</i>	
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h			<i>d_TcEntryAd</i>	
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h			<i>d_TcEntryCh</i>	
1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0074979	0.0107000	0.0004391	0.0047132	0.0189087
Total systemic exposure per kg body weight (mg a.s./kg bw/day)	0.0007498	0.0010700	0.0000439	0.0004713	0.0018909
% of RVNAS	1.50%	2.14%	0.09%	0.94%	3.78%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0107682	0.0138000	0.0011418	0.0157106	0.0322775
Total systemic exposure per kg body weight (mg a.s./kg bw/day)	0.0001795	0.0002300	0.0000190	0.0002618	0.0005380
% of RVNAS	0.36%	0.46%	0.04%	0.52%	1.08%

Table A 32: Estimation of longer term resident exposure towards cloquintocet-mexyl according to EFSA guidance, including input parameters - refined

Resident exposure for GLOB1817H					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.00399 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.01995 g a.s./l				
Dermal absorption of product	70.00%				
Dermal absorption of in-use dilution	70.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (L_AppRate*L_DFR)	0.01197 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 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 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthings of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentil	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentil	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)		Surface deposits (75th percentile)	Entry into treated crops (75th percentile)
Total systemic exposure (mg a.s./day)		0.0012470		0.0107000	
Total systemic exposure per kg body weight (mg a.s./kg body weight/day)		0.0001247		0.0010700	
% of RVNAS		0.25%		2.14%	
1.2 Adult					
Spray drift		Vapour		Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)		0.0013635		0.0138000	
Total systemic exposure per kg body weight (mg a.s./kg body weight/day)		0.0000227		0.0002300	
% of RVNAS		0.05%		0.46%	

A 3.4 Combined exposure calculations for Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-mexyl

Please refer to point 6.6.5.1.

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)

A worker exposure study was performed using an 800 g/L EC formulation of prosulfocarb in 2015, in Northern France. Based on this study, the generic Dislodgeable Foliar Residues were refined and the transfer coefficient was recalculated.

Report:	XXXX. A (2016). Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe, 2015.xxxx, France Laboratory Report No. RB424, issue date 29 December 2015. Unpublished. Syngenta File No. A8545G_10414
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Guidelines

This study was done according to OECD Series on Testing and Assessment No. 9 “Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application”, Paris 1997. OCDE/GD(97)148.

Deviations: None

GLP: Yes. Signed and dated GLP and Quality Assurance statements were provided.

Executive Summary

The purpose of the study was the determination of dermal and inhalation exposure of re-entry workers during typical tasks related to crop scouting activities following a tractor boom application of A8545G (emulsifiable concentrate formulation of 800 g/L prosulfocarb) on cereal crops at BBCH stage 25-26. The study was conducted under field conditions.

Twelve operators were recruited and monitored. The dermal and inhalation exposure of these subjects to the test substance was monitored at three locations in Northern France (4 workers per site) for a duration of 2 hours for each worker, which is considered a representative duration for crop inspection activities according to the EFSA guidance² on non-dietary exposure assessment.

Dermal exposure to the test substance was measured by workers wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a cotton/polyester coverall, which is considered to be representative of the clothing workers would normally wear. The inner dosimeter consisted of a long-sleeved T-shirt, leggings and cotton socks, covering arms, legs, feet and torso. Head exposure was measured by face/neck wipes. Nitrile dosimeter gloves were used for the determination of potential hand exposure. Actual dermal exposure of the hands beneath protective gloves was determined by the hand wash procedure. Inhalation exposure was measured by means of personal air sampling pumps connected to OVS XAD-2 air sampling tubes located in the operator’s breathing zone.

The test substance was applied at a representative, label-recommended rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha. Applications were made to crops 1-2 hours before the workers re-entered the field in order to allow the spray to dry.

² EFSA 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 [55 pp.]

Samples of each dosimeter matrix were fortified in the field to assess potential degradation of prosulfocarb due to exposure to environmental conditions, handling, packaging, shipping, and storage.

All worker dosimeter samples collected were analysed for residues of prosulfocarb. For each worker, potential dermal exposure (PDE), actual dermal exposure (ADE), hand exposure with gloves, actual hand exposure for protected hands beneath gloves and (potential) inhalation exposure were calculated.

Dislodgeable foliar residue (DFR) measurements were also collected at the same time as the worker re-entry scouting activities were being undertaken. These DFR measurements enable calculation of a transfer coefficient for workers scouting in early post emergence cereal crops.

Materials

Test Material:	DEFI, A8545G
Description:	Formulation type, Emulsifiable concentrate
Lot/Batch #:	BSN4DO220
Stability of test compound:	Stable when stored in cool dry conditions.

Study Design and Methods

Field phase dates:	Start: 13 th March 2015 End: 19 th March 2015
Experimental dates:	5 th March 2015 to 16 th September 2015

Study Description:

Twelve workers (9 male and 3 female) were recruited and monitored for the study. These subjects all had experience in the tasks they were required to perform. All subjects were required to give their informed consent to participate in the study, which was conducted at three sites in Northern France.

The test substance was applied to winter wheat at a representative, label-recommended rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha. The applications were made using field crop boom sprayers owned by the spray applicators. These applications were made before the workers re-entered the field.

Each of the three trial sites was sub-divided into four individual 1 ha blocks, one per worker. Workers entered the field 1-2 hours after the spray application had been made and performed a typical scouting activity. This activity involved passing through the crop on a row to row basis, periodically bending to touch the plants to inspect them. The frequency of the hand to crop contact varied between workers. The monitoring period for the scouting task was 2 hours, which is considered a representative timescale for this type of activity according to the EFSA guidance on non-dietary exposure assessment.

The dermal and inhalation exposure of the workers to the test substance was monitored during the re-entry activity. Dermal exposure to the test substance was measured by workers wearing standardised whole-body outer and inner dosimeters. The outer dosimeter consisted of a cotton/polyester coverall, which is considered to be representative of the clothing workers would normally wear. The inner dosimeter consisted of a long-sleeved cotton T-shirt, cotton leggings and cotton socks, covering arms, legs, feet and torso. This was worn over the operator's regular underwear and directly under the outer dosimeter.

Head exposure was measured by face/neck wipes taken at the end of the working day. Two wipes (10 cm × 10 cm) were moistened with 4 mL diluted soap solution (5 mL pH neutral liquid soap: 1000 mL de-ionised water); one was used to wipe the face and the other was used to wipe the neck. Both wipes were

taken as one sample, collected in a polyethylene bag and put into a freezer at the end of each day and stored until transport to the analytical facility.

Nitrile gloves were worn by workers throughout the monitored task. After the end of the task gloves were removed by the study personnel, put in a plastic bag and stored in a freezer at the end of the day until transport to the analytical facility.

Actual dermal exposure of the hands beneath protective gloves was determined using a hand wash procedure carried out once at the end of the monitoring period with 2 portions of 500 mL of diluted soap solution (5 mL pH neutral liquid soap: 1000 mL de-ionised water). Solutions were combined and collected in HDPE bottles, put into a freezer at the end of each day and stored until transport to the analytical facility.

Inhalation exposure was measured by means of personal air sampling pumps connected to OVS XAD-2 air sampling tubes located in the operator's breathing zone. The pump was operated for the duration of the exposure-monitoring period, and the duration time was recorded. The pump was calibrated to a sample flow rate of approximately 1.5 L/min. The air flow rate was measured before and after use and the average airflow rate was calculated. The pumps were checked periodically, throughout the monitoring period, to ensure that they were running. At the conclusion of the exposure monitoring period the sampling device was disconnected and the XAD-2/OVS tube was sealed. The samples were put in a freezer at the end of each day until transport to the analytical facility.

Study details are given in the table below:

Table A4-1: Summary of study parameters for re-entry workers performing crop inspection in early post-emergence cereals

Study type			Passive dosimetry: Matrices were: cotton/polyester coverall, underwear with long sleeves and long legs; Nitrile gloves, hand wash, face wipes, OVS air filters				
Crop			Cereals, early post emergent				
Number of replicates			12				
Spraying equipment			Vehicle mounted boom sprayers				
Protective clothing			Cotton/polyester coverall and nitrile rubber gloves.				
Site	Operator	Total time scouting[min]	Area of treated plot (ha)	Crop / Growth stage	kg a.s. /ha	Frequency of scouting activities	
						Touching plants (n)	Crouching (n)
1	1	120	5.66	Winter wheat / 25-26	3.912	100+	81
	2	120				37	37
	3	120				18	5
	4	122				9	8
2	5	123	5.5	Winter wheat / 25-26	3.784	26	19
	6	120				54	54
	7	120				57	37
	8	120				147	43
3	9	121	6	Winter wheat /26	4	42	36
	10	120				23	19
	11	120				40	20
	12	120				106	21

The dosimeters acted as collection media for the test substance and were removed at the end, with the assistance of a member of the monitoring team. At the end of the monitoring period, the inner and outer

dosimeters were sectioned into six samples (front torso, back torso, lower arms, upper arms, lower legs, upper legs), and each sample was wrapped in aluminium foil, labelled and put into a plastic bag. The samples were put into a freezer at the end of each day and stored until transport to the analytical facility.

All worker dosimeter samples collected were analysed for residues of prosulfocarb. For each worker, potential dermal exposure (PDE), actual dermal exposure (ADE), hand exposure with gloves, hand exposure for protected hands beneath gloves and (potential) inhalation exposure was calculated.

Dislodgeable foliar residue (DFR) measurements were also collected at the same time as the worker re-entry scouting activities were being undertaken to enable calculation of a transfer coefficient for workers scouting in early post emergence cereal crops. These samples were collected from a smaller area of 60 m² which was located within each worker's 1 ha work zone. The re-entry worker had no access to this sub-plot. Before application of prosulfocarb was made to the crop the leaf weight to surface area ratio was determined (for each site). From this analysis the minimum number of wheat leaves required to represent a total leaf area (both sides) of a minimum 400 cm² was determined prior to sample collection. Three replicates of treated leaves were collected from each of the trial sub-plots. Leaf samples were collected in glass bottles and stored in cool conditions prior to sample analysis. 400 mL of 0.01% Aerosol OT-100 detergent solution was used for the dislodging procedure. Once added to the leaf samples the jars were shaken for 10 minutes. Dislodging solution was then removed, replaced with new 400 mL solution and the jars shaken for a further 10 minutes. Finally, the dislodging solutions from both sessions were pooled and retained in plastic bottles. All DFR samples were extracted with dislodging solution within 4 hours of sampling.

Results

With the exception of the recoveries for the Site 3, inner dosimeter, low level field fortification samples, field fortifications for all dosimeters were in the range of 70% to 110% and no corrections to the dosimeter samples were necessary. Recoveries for the Site 3, inner dosimeter, low level field fortification samples were < 70% and ambient samples with low levels of analyte detected were corrected to 100%. These included the samples for the lower and upper arm, front and rear torso and upper leg. However, the lower leg samples were not corrected, as the workers exposure samples were above the high level fortification level where acceptable field recovery had been achieved.

A summary of the worker exposure results is presented in the table below. For the calculation of potential inhalation exposure an inhalation rate of 21 L/min was assumed.

Table A4-2: Individual Dermal and Inhalation exposures for re-entry workers performing crop inspection in early post-emergence cereals

Operator	Residue (prosulfocarb)					
	1	2	3	4	5	6
Outer dosimeter (µg/sample)	1588.22	537.17	1102.67	287.5	972.22	1042.2
Inner dosimeter (µg/sample)	602.63	136.61	610.17	470.02	326.49	608.24
Socks (µg/sample)	44.28	0.28	0.38	76.54	3.33	0.57
Face/neck wipes (µg/sample)	1.28	2.27	0.32	0.22	1.4	8.05
Nitrile Gloves (µg/sample)	2769.97	118.59	305.62	84.28	2309.24	4111.7
Hand wash (µg/L)	0.28	0.22	4.46	0.15	0.52	0.36
PDE (mg)	5.007	0.795	2.024	0.919	3.613	5.771

	Residue (prosulfocarb)					
Operator	1	2	3	4	5	6
ADE (mg) - no gloves	3.418	0.258	0.921	0.631	2.641	4.729
ADE (mg) – with gloves	0.648	0.139	0.615	0.547	0.332	0.617
PIE (mg)	0.016	0.012	0.009	0.003	0.012	0.024
DFR ($\mu\text{g}/\text{cm}^2$) – Mean value	0.903	1.793	1.540	1.329	3.358	2.337
DFR ($\mu\text{g}/\text{cm}^2/\text{kg}$ a.s./ha)	0.231	0.458	0.394	0.340	0.887	0.618
TC (cm^2/h) Actual no gloves	1892.82	71.95	298.95	233.64	383.65	1011.75
	Residue (prosulfocarb)					
Operator	7	8	9	10	11	12
Outer dosimeter ($\mu\text{g}/\text{sample}$)	2817.27	1769.59	848.38	1985.77	1118.43	1132.53
Inner dosimeter ($\mu\text{g}/\text{sample}$)	461.181	388.3	305.46	286.94	316.68	448.61
Socks ($\mu\text{g}/\text{sample}$)	46.98	25.41	0.12	0.46	0.11	0.31
Face/neck wipes ($\mu\text{g}/\text{sample}$)	2.82	3.39	3.9	4.45	2.87	4.09
Nitrile Gloves ($\mu\text{g}/\text{sample}$)	1270.18	1569.7	593.42	2053.19	1338.22	762.42
Hand wash ($\mu\text{g}/\text{L}$)	0.37	18.74	0.34	0.46	0.51	0.42
PDE (mg)	4.599	3.775	1.752	4.331	2.777	2.348
ADE (mg) - no gloves	1.782	2.006	0.903	2.345	1.658	1.216
ADE (mg) – with gloves	0.511	0.436	0.310	0.292	0.320	0.453
PIE (mg)	0.035	0.031	0.023	0.018	0.014	0.013
DFR ($\mu\text{g}/\text{cm}^2$) – Mean value	2.803	2.977	3.108	2.757	2.575	3.488
DFR ($\mu\text{g}/\text{cm}^2/\text{kg}$ a.s./ha)	0.741	0.787	0.777	0.689	0.644	0.872
TC (cm^2/h) Actual no gloves	317.75	336.88	144.09	425.32	322.02	174.29

PDE = the sum of residues of outer dosimeter, inner dosimeter, nitrile gloves, hand-wash and face/neck wipes.

ADE (no protective gloves) = the sum of residues of inner dosimeter, nitrile gloves, hand-wash and face/neck wipes.

Potential Inhalation exposure = Residues measured in the breathing zone extrapolated to an inhalation rate of 21 L/min.

Conclusions

The study is considered to provide suitable data for the estimation of dermal and inhalation exposure for workers re-entering early growth stage cereal crops to perform scouting activities soon after the spray application had been applied.

Estimation of worker exposure based on measured data – prosulfocarb

Statistical analysis shows the dermal and inhalation data within the study are log normally distributed. The table below shows the geometric mean and empirical and parametric 75th percentiles calculated for total

systemic exposure, both with and without gloves. The transfer coefficient calculated for this work task is also given.

Table A4-3: Summary statistics calculated from the exposure study

	Geometric mean	Empirical 75 th percentile	Parametric 75 th percentile
Total systemic exposure – no gloves (mg/kg bw/day)	0.0006	0.0011*	0.0010
Total systemic exposure – with gloves (mg/kg bw/day)	0.0003	0.0005*	0.0004
Transfer coefficient – No gloves (cm ² /hr)	324.4	394.1	601.0*
Transfer coefficient – With gloves (cm ² /hr)	89.2	149.0	148.2

*Values given in bold are the higher of the empirical and parametric estimate and are used for the exposure assessment.

The empirical 75th percentile value for total systemic exposure for workers performing crop inspections in early growth stage cereal crops is 0.0011 mg/kg bw/day, which corresponds to 15% of the agreed systemic AOEL for prosulfocarb. This is for workers inspecting crops with bare hands. Where protective gloves are worn the predicted exposure (0.0005 mg/kg bw/day) is 7% of the AOEL.

Using the measurements of worker exposure and concurrent measurements of dislodgeable foliar residues, the transfer coefficient for workers re-entering early growth stage cereal crops to perform scouting activities soon after the spray application had been applied was calculated according to the following algorithm:

$$TC \text{ (cm}^2\text{/h)} = \frac{\text{Dermal exposure } (\mu\text{g/day})}{\text{Dislodgeable Foliar Residue } (\mu\text{g/cm}^2) \times \text{Activity Duration (hours/day)}}$$

The empirical 75th percentile value for TC is 601 cm²/hour with bare hands and 149 cm²/hr if protective gloves are worn.

zRMS:

The study performed according to relevant OECD guidelines and in GLP conditions is acceptable and results can be used in estimation of exposure of workers. The mean empirical dislodgeable foliar residue (DFR) of prosulfocarb for 12 workers after tractor boom application of A8545G (emulsifiable concentrate formulation of 800 g/L prosulfocarb) on cereal crops at BBCH stage 25-26 at the rate of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in water volumes ranging from 100 L/ha to 150 L/ha was found to be 0.62 µg/cm²/kg a.s./ha.

Transfer coefficient was found to be 601 cm²/hour with bare hands and 149 cm²/hr if protective gloves are worn.

Since the rate of application of 4.73 to 5.0 L product/ha (3.8-4.0 kg active substance/ha) in this study was higher than that recommended for Eledura (3L product /ha (2.001 kg active substance/ha) the value of DFR is considered as a very conservative value for estimation of dermal exposure with application rate recommended in GAP>