

# REGISTRATION REPORT

## **Part B**

### **Section 6**

#### **Mammalian Toxicology**

Detailed summary of the risk assessment

Product code: GLOB1912H

Product name: **Jura Max**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

Applicant: Globachem NV

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Evaluation date: August 2022

MS Finalisation date: December 2022

## Version history

When	What
November 2021	Initial submission by the applicant for approval of new product.
August 2022	Version evaluated by zRMS PL
December 2022	Revised version taking into account comments of cMSs and the applicant
July 2023	Revised version taking into account comments cMS

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on GLOB1912H \***

Product name and code	GLOB1912H
Formulation type	Emulsifiable concentrate [EC]
Active substance(s) (incl. content)	Prosulfocarb: 667 g/L Diflufenian: 14 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 GLOB1912H 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 GLOB1912H according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	<del>Acute Tox. 4</del> , Eye Dam. 1, Skin Sens. 1, STOT SE3
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS05, GHS07
Signal word	Danger
Hazard statement(s)	<del>H302</del> , H317, H318, H336
Precautionary statement(s)	P261, <del>P264</del> , P270, P271, P272, P280, <del>P301+P312</del> , P302+P352, P304+P340, P305+P351+P338, P310, P312, P321, <del>P330</del> , P333+P313, P362+ <del>P364</del> , P403+P233, P405, P501
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GLOB1912H**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves during mixing/loading and application
Workers	Acceptable	None
Residents	Acceptable	5 m buffer or 50% DRT
Bystanders	Acceptable	5 m buffer or 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 situation (e.g. growth stage of crop)	F, F <sub>n</sub> , F <sub>pn</sub> G, G <sub>n</sub> , G <sub>pn</sub> or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha))  critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***)	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1-4	Cereals (BBCH 10-13)	F	Spraying, LCTM	a) 1 b) 1	a) Prosulfocarb: 2.134 b) Diflufenican: 0.0448	160 - 300	NR	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	R	A	R	R
5-6	Potato Pre-emergence (BBCH 0-09)	F	Spraying, LCTM	a) 1 b) 1	a) Prosulfocarb: 2.134 b) Diflufenican: 0.0448	160 - 300	NR					
7-8	Sunflower (HELAN) Pre-emergence (BBCH 0-09)	F	Spraying, LCTM	c) 1 d) 1 e)	a) Prosulfocarb: 2.134 b) Diflufenican: 0.0448	160 - 300	NR					

\* 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	Diflufenican
Common Name	Prosulfocarb	Diflufenican

	<b>Prosulfocarb</b>	<b>Diflufenican</b>
CAS-No.	52888-80-9	83164-33-4
<b>Classification and proposed labelling</b>		
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: -
Additional C&L proposal	None	None
<b>Agreed EU endpoints</b>		
AOEL systemic	0.007 mg/kg bw/d (corrected for 72% oral absorption)	0.11 mg/kg bw/d (corrected for 58% oral absorption)
Reference	EFSA Conclusion Prosulfocarb SANCO/ 2824/07 – rev. 3 10 September 2007	EFSA Conclusion Diflufenican SANCO/3782/08 – rev. 1 14 March 2008
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>		
According to Review Report/EFSA Conclusion for active substance	Operator safety	None

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB1912H 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 GLOB1912H**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral	Study not necessary.	Yes	Acute Tox. 4; H302 None	Theoretical calculations (see Part C)
LD <sub>50</sub> dermal	Study not necessary.		None	Theoretical calculations (see Part C)

LC <sub>50</sub> 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 GLOB1912H**

	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 EUH066	MSDS**	STOT SE3; H336 EUH066
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 GLOB1912H are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in GLOB1912H**

	Prosulfocarb		Diflufenican	
	Value	Reference	Value	Reference
Concentrate	<del>0.26%</del> 0.27%	New study reported in	<del>58 %</del>	Defa(EFS



	Prosulfocarb		Diflufenican	
	Value	Reference	Value	Reference
		Appendix 2	70%	EFSA Journal 2017;15(6):4873)
Dilution (1:100)	3.3%	New study reported in Appendix 2	58 % 70%	Default EFSA Journal 2017;15(6):4873)

### 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 GLOB1912H. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of prosulfocarb/GLOB1912H 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)	0.26% 0.27%	3.3%	GLOB1912H	Yes	Not required	Justification accepted. Endpoints (0.27% and 3.3%) can be used for current product.	Hassler S., 2021

\* 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 GLOB1912H 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 % 70%	Concentration in the formulation is below 50 g/L, so dermal absorption value of the dilution is also used for the concentrate.	Acceptable. See justification below
Dilution	58 %	Oral absorption is less than	Acceptable. See justification

	Value	Justification for value	Acceptability of justification
	70%	70%, so oral absorption is used as surrogate for dermal absorption.	below

#### zRMS:

According to EU Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) point 6.1.1. Consideration of the oral absorption value when setting a default value it is recommended that: “In exceptional cases, if oral absorption is less than 70% for organic solvent-based or other formulations or less than 50% for water-based/dispersed or solid formulations, this can be used as a surrogate dermal absorption value for (in-use) dilutions. If oral absorption is less than 25% for organic solvent-based or other formulations or less than 10% for water-based/dispersed or solid formulations, it can be used instead of the default value for concentrated products. 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. In case of a product Jura Max (GLOB1912H) and diflufenican no ADME studies with bile-cannulation are available for zRMS, therefore the default values could be used for dermal absorption of diflufenican from the formulation GLOB1912H.

The product Jura Max (GLOB1912H) is the emulsifiable concentrate (EC) 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 than to 50 g/L (or 50g/Kg or 5%). So for diflufenican present in the product Jura Max (GLOB1912H) at concentration of 1.43 % 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.

## 6.6 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	GLOB1912H	
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/HDPE-EVOH, HDPE/PA, 42-63 mm	
Active substance(s) (incl. content)	<b>Prosulfocarb</b> 667 g/L	<b>Diflufenican</b> 14 g/L
AOEL systemic	0.007 mg/kg bw/d	0.11 mg/kg bw/d
Inhalation absorption	100%	100%

Oral absorption	72 %	58 %
Dermal absorption	Concentrate: <del>0.26%</del> 0.27% Dilution: 3.3% (Dilution rate: 1:100) (Based on product GLOB1912H)	Concentrate: 58 % Dilution: 58 % (Default)  Concentrate: 70 % (Default) 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

The post-emergence use in cereals is covering for the pre-emergence use in cereals, as well as in potatoes and sunflower.

### 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 GLOB1912H 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. 3.2 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	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		2.134 kg a.s./ha		0.0448 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0174644	249.49	0.0923942	83.99
	Work wear (arms, body and legs	0.0014204	20.29	0.0030288	2.75

	covered) M/L and A + Gloves M/L and A				
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**Table: 6.6 3A: Estimated operator exposure (longer term exposure)**

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

Diflufenican dermal absorption: concentrate 70%. Dilution 70 %

		Prosulfocarb		Diflufenican	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops					
Application rate		2.134 kg a.s./ha		0.0448 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0177	253,87.49	0.111489	101,35
	Work wear (arms, body and legs covered) M/L and A + Gloves M/L	0.0098433	140.62	0.0067440	6.13
	Work wear (arms, body and legs covered) M/L and A + Gloves M/L and A	0.00143	20.48	0.0036339	3.3

Additional calculations below:

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

Diflufenican dermal absorption: concentrate 70%. Dilution 70 %

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

Operator exposure for Jura Max outdoor spray applications					
Application rate of active substance	2,134 kg a.s./ha	<i>i_AppRate</i>			
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>			
Amount of active substance applied	106,7 kg a.s./day	<i>i_AmountAS</i>			
Dermal absorption of the product	0,27%	<i>i_AbsorpProduct</i>			
Dermal absorption of in-use dilution	3,30%	<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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	176889	675424	AOEM	
	Body	95058	279711	AOEM	
	Head	5536	30362	AOEM	
	Protected hands (gloves)	720	21134	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1492	15605	AOEM	
	Protected head (hood and face shield)	89	1719	AOEM	
	Inhalation	15	32	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	15826	70083	AOEM	
	Body	8849	45616	AOEM	
	Head	418	1261	AOEM	
	Protected hands (gloves)	535	5746	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	243	595	AOEM	
	Inhalation	11	43	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only		
1. Total					
	Without RPE/PPE		With RPE/PPE		
Longer term					
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,6028879		1,0662558		
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0267148		0,0177709		
% of RVNAS	381,64%		253,87%		

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

**Operator exposure for Jura Max outdoor spray applications**

Application rate of active substance	2,134 kg a.s./ha	i_AppRate			
Assumed area treated	50 ha/day	d_AreaTreated			
Amount of active substance applied	106,7 kg a.s./day	i_AmountAS			
Dermal absorption of the product	0,27%	i_AbsorpProduct			
Dermal absorption of in-use dilution	3,30%	i_AbsorInuse			
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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	176889	675424	AOEM	
	Body	95058	279711	AOEM	
	Head	5536	30362	AOEM	
	Protected hands (gloves)	720	21134	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1492	15605	AOEM	
	Protected head (hood and face shield)	89	1719	AOEM	
	Inhalation	15	32	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	15826	70083	AOEM	
	Body	8849	45616	AOEM	
	Head	418	1261	AOEM	
	Protected hands (gloves)	535	5746	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	243	595	AOEM	
	Inhalation	11	43	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	
1. Total					
		Without RPE/PPE		With RPE/PPE	
Longer term					
Total systemic exposure from mixing, loading and application (mg a.s./day)		1,6028879		0,5905971	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)		0,0267148		0,0098433	
% of RVNAS		381,64%		140,62%	

**Operator exposure for Jura Max outdoor spray applications**

Application rate of active substance	2,134 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	106,7 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,27%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	3,30%	<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	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
Mixing and loading	Hands	176889	675424	AOEM	
	Body	95058	279711	AOEM	
	Head	5536	30362	AOEM	
	Protected hands (gloves)	720	21134	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1492	15605	AOEM	
	Protected head (hood and face shield)	89	1719	AOEM	
	Inhalation	15	32	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		<b>Penetration factor</b>	<b>Inhalation Protection factor</b>
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Application	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	15826	70083	AOEM	
	Body	8849	45616	AOEM	
	Head	418	1261	AOEM	
	Protected hands (gloves)	535	5746	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	243	595	AOEM	
	Inhalation	11	43	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		<b>Penetration factor</b>	<b>Inhalation Protection factor</b>
	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
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,6028879	0,0859967
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0267148	0,0014333
% of RVNAS	381,64%	20,48%

**Di flufenican dermal absorption: concentrate 70%. Dilution 70 %**

**Operator exposure for Jura Max outdoor spray applications**

Application rate of active substance	0,0448 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	2,24 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	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9036	33346	AOEM	
	Body	6288	91041	AOEM	
	Head	116	637	AOEM	
	Protected hands (gloves)	58	444	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	49	328	AOEM	
	Protected head (hood and face shield)	2	36	AOEM	
	Inhalation	5	29	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	332	4137	AOEM	
	Body	186	958	AOEM	
	Head	9	26	AOEM	
	Protected hands (gloves)	66	3662	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	5	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE
<b>Longer term</b>		
Total systemic exposure from mixing, loading and application (mg a.s./day)	11,1835629	6,6893209
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1863927	0,1114887
% of RVNAS	169,45%	101,35%



Diffufenican dermal absorption: concentrate 70%. Dilution 70 %

Operator exposure for Jura Max outdoor spray applications

Application rate of active substance		0,0448 kg a.s./ha	i_AppRate		
Assumed area treated		50 ha/day	d_AreaTreated		
Amount of active substance applied		2,24 kg a.s./day	i_AmountAS		
Dermal absorption of the product		70,00%	i_AbsorpProduct		
Dermal absorption of in-use dilution		70,00%	i_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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9036	33346	AOEM	
	Body	6288	91041	AOEM	
	Head	116	637	AOEM	
	Protected hands (gloves)	58	444	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	49	328	AOEM	
	Protected head (hood and face shield)	2	36	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	332	4137	AOEM	
	Body	186	958	AOEM	
	Head	9	26	AOEM	
	Protected hands (gloves)	66	3662	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	No			1
	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)		11,1835629		0,4046381	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)		0,1863927		0,0067440	
% of RVNAS		169,45%		6,13%	

### Operator exposure for Jura Max outdoor spray applications

Application rate of active substance	0,0448 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	2,24 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	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9036	33346	AOEM	
	Body	6288	91041	AOEM	
	Head	116	637	AOEM	
	Protected hands (gloves)	58	444	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	49	328	AOEM	
	Protected head (hood and face shield)	2	36	AOEM	
	Inhalation	5	29	AOEM	
	<b>Protective Equipment</b>	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	332	4137	AOEM	
	Body	186	958	AOEM	
	Head	9	26	AOEM	
	Protected hands (gloves)	66	3662	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	5	AOEM	
	<b>Protective Equipment</b>	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
	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)	11,1835629	0,2180318
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1863927	0,0036339
% of RVNAS	169,45%	3,30%

### 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 of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying JURA MAX ( GLOB1912H) on cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha ) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 253,87% of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Prosulfocarb is reduced to 20.48% of AOEL.

The exposure to Diflufenican of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying JURA MAX ( GLOB1912H) on cereals at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 101.35 % of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Diflufenican is reduced to 3.3% of AOEL.

The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) and protective gloves during mixing/loading and application to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product JURA MAX ( GLOB1912H according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator

Summing up, the application of product JURA MAX ( GLOB1912H) 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 and Skin Sens. 1 the operator should wear protective gloves, eye protection/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 GLOB1912H 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 3.2 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	
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
Inspection, irrigation Outdoor Work rate: 2 hours/day DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha					
Number of applications and application rate		1 x 2.134 kg a.s./ha		1 x 0.0448 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.0880275	1257.54	0.0324800	29.53
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0098591	140.84	0.0036378	3.31

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

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%  
 Diflufenican dermal absorption: concentrate 70%. Dilution 70 %

		Prosulfocarb		Diflufenican	
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
Inspection, irrigation Outdoor Work rate: 2 hours/day DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha					
Number of applications and application rate		1 x 2.134 kg a.s./ha		1 x 0.0448 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.0880275	1257.54	0.0392	35,64
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0098591	140.84	0.00439	3.99

Estimated worker exposure (longer term exposure)

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

**Worker exposure from residues on foliage for Jura Max**

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	2,134 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1,0
Dermal absorption of the product	0,27%
Dermal absorption of the in-use dilution	3,30%
Dislodgeable foliar residue (i_AppRate*i_DFR)	6,402 µg a.s./cm <sup>2</sup>
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**1. Total**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5,2816500	0,5915448	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0880275	0,0098591	
% of RVNAS	1257,54%	140,84%	

Diflufenican dermal absorption: concentrate 70%. Dilution 70 %

Worker exposure from residues on foliage for Jura Max			
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	0,0448 kg a.s./ha		
Number of applications	1		
Interval between multiple applications	365 days		
Half-life of active substance	30 days		
Multiple application factor	1,0		
Dermal absorption of the product	70,00%		
Dermal absorption of the in-use dilution	70,00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,1344 µg a.s./cm²		
Working hours	2 hr		
Dermal transfer coefficient - Total potential exposure	12500 cm²/hr		
Dermal transfer coefficient - arms, body and legs covered	1400 cm²/hr		
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm²/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)	2,3520000	0,2634240	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0392000	0,0043904	
% of RVNAS	35.64%	3.99%	

### 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/cm<sup>2</sup>/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 Perny, A. (2016) summarized under section 6.6.3.3 below.

**Table 6.6-7: 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 <sub>50</sub> : 30 days DFR: 0.62 µg/cm <sup>2</sup> /kg a.s./ha			
Number of applications and application rate		1 x 2.134 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 601 cm <sup>2</sup> /person/h	0.00087	12.50

**Table 6.6-8A: Estimated worker exposure (longer term exposure) - refined**

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

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 <sub>50</sub> : 30 days DFR: 0.62 µg/cm <sup>2</sup> /kg a.s./ha			
Number of applications and application rate		1 x 2.134 kg a.s./ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h 601 cm <sup>2</sup> /person/h	0.0020375	29.11

**Worker exposure from residues on foliage for Jura Max**

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	2,134 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1,0
Dermal absorption of the product	0,27%
Dermal absorption of the in-use dilution	3,30%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,32308 µg a.s./cm <sup>2</sup>
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**1. Total**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,0915410	0,1222526	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0181924	0,0020375	
% of RVNAS	259,89%	29,11%	

### 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 0. 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.

<b>Report:</b>	Perny. 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. ANADIAG, 16, rue Ampère, 67500 HAGUENAU, 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 guidance<sup>1</sup> 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.

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<sup>1</sup> 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.]



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./cm<sup>2</sup> and the transfer coefficient was recalculated to 601 cm<sup>2</sup>/h.

#### **zRMS:**

The study performed with an EC formulation containing 800 g/L prosulfocarb in order to determine Dislodgeable foliar residue (DFR) and dermal/inhalation exposure of re-entry workers during typical tasks related to crop scouting activities following a tractor boom application of formulation on cereal crops is acceptable.

The Dislodgeable Foliar Residues (DFR) of Prosulfocarb equal 0.62 µg a.s./cm<sup>2</sup> calculated as the average value obtained from the twelve treated plots was used to determine worker exposure.

#### **zRMS evaluation of worker exposure**

The exposure to Prosulfocarb, an active substance of a product JURA MAX ( GLOB1912H) 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 treated with a product JURA MAX ( GLOB1912H) at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 29.11 % of respective AOEL.

The exposure to Diflufenican, an active substance of a product JURA MAX ( GLOB1912H), 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 treated with a product JURA MAX ( GLOB1912H) at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 3.99 % of respective AOEL.

The sum of exposures of worker wearing a work clothing (long sleeved shirt, long trousers) to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product JURA MAX ( GLOB1912H) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of worker.

Thus, it is concluded that the application of a product JURA MAX ( GLOB1912H) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers).

### **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 and diflufenican. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure). Detailed calculations are in Appendix 3.

**Table 6.6-9: Exposure models for intended uses**

Critical use(s)	Cereals (max.1 x 3.2 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 6.6-10: Estimated resident exposure (longer term exposure)**

		Prosulfocarb		Diflufenican	
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 <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha					
Number of applications and application rate		1 x 2.134 kg a.s./ha		1 x 0.0448 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0193524	276.46	0.0069772	6.34
	Vapour (75 <sup>th</sup> perc.)	0.0010700	15.29	0.0010700	0.97
	Deposits (75 <sup>th</sup> perc.)	0.0022730	32.47	0.0003994	0.36
	Re-entry (75 <sup>th</sup> perc.)	0.0118837	169.77	0.0043848	3.99
	<b>Sum (mean)</b>	0.0229665	328.09	0.0087014	7.91
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0045590	65.13	0.0016698	1.52
	Vapour (75 <sup>th</sup> perc.)	0.0002300	3.29	0.0002300	0.21
	Deposits (75 <sup>th</sup> perc.)	0.0004798	6.85	0.0001770	0.16
	Re-entry (75 <sup>th</sup> perc.)	0.0066021	94.32	0.0024360	2.21
	<b>Sum (mean)</b>	0.0080253	114.65	0.0030951	2.81

The AOEM model predicts exposure to Prosulfocarb above the acceptable limits for residents living near fields treated with GLOB1912H. 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 6.6-11: 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: no DT <sub>50</sub> : 30 days DFR: 0.62 µg/cm <sup>2</sup> /kg a.s./ha TC adult: 601 cm <sup>2</sup> /h			
Number of applications and application rate		1 x 2.134 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0067	95.86
	Vapour (75 <sup>th</sup> perc.)	0.00107	15.29
	Deposits (75 <sup>th</sup> perc.)	0.0009335	13.34
	Re-entry (75 <sup>th</sup> perc.)	0.00020	2.81
	Sum (mean)	0.006515 0.0061682	93.07 88.32
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0015	20.91
	Vapour (75 <sup>th</sup> perc.)	0.00023	3.29
	Deposits (75 <sup>th</sup> perc.)	0.0001971	2.82
	Re-entry (75 <sup>th</sup> perc.)	0.00011	1.56
	Sum (mean)	0.001250 0.0018755	17.86 26.79
		Prosulfocarb	
Model data		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: yes – 50% DT <sub>50</sub> : 30 days DFR: 0.62 µg/cm <sup>2</sup> /kg a.s./ha TC adult: 601 cm <sup>2</sup> /h			
Number of applications and application rate		1 x 2.134 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0035	50.50
	Vapour (75 <sup>th</sup> perc.)	0.00107	15.29
	Deposits (75 <sup>th</sup> perc.)	0.0022730	32.47
	Re-entry (75 <sup>th</sup> perc.)	0.00020	2.81
	Sum (mean)	0.006406	91.51
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0014	20.51
	Vapour (75 <sup>th</sup> perc.)	0.00023	3.29
	Deposits (75 <sup>th</sup> perc.)	0.0004798	6.85

	Re-entry (75 <sup>th</sup> perc.)	0.00011	1.56
	<b>Sum (mean)</b>	0.001382	19.74

Using the refined DRF and TC values, the risk for residents is acceptable when using a buffer zone of 5 m or 50% drift reducing techniques and a water volume of 160 L/ha.

**zRMS:**

Estimated resident exposure to Prosulfocarb (longer term exposure)

Tractor mounted boom spray application outdoors to low crops

Buffer zone: 5 m

Drift reduction technology: no

DT50: 30 days

DFR: 0.62 µg/cm<sup>2</sup>/kg a.s./ha

Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

Resident exposure for Jura Max					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	5 m				i_Buffer
Application rate of the product	2,134 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	7,113333333 g a.s./l				d_ConcAS
Dermal absorption of product	0,27%				i_AbsorpProduct
Dermal absorption of in-use dilution	3,30%				i_AbsorpInuse
Oral absorption	72,00%				i_AbsorpOralinuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,32308 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				i_Volat
Concentration in air	0,001 mg/m³				d_AirCon
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				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 m³/day/kg				d_BreathRAd
Breathing rate child (1-3 year old)	1,07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	2,30%				
Drift percentage on surface (mean)	1,80%				
Turf transferable residues percentage	5,00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50,00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/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)	0,0430751	0,0107000	0,0093354	0,0245597	0,0616825
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0043075	0,0010700	0,0009335	0,0024560	0,0061682
% of RVNAS	61,54%	15,29%	13,34%	35,09%	88,12%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0464482	0,0138000	0,0118239	0,0818656	0,1125302
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0007741	0,0002300	0,0001971	0,0013644	0,0018755
% of RVNAS	11,06%	3,29%	2,82%	19,49%	26,79%

## zRMS:

Estimated resident exposure to Prosulfocarb(longer term exposure  
Tractor mounted boom spray application outdoors to low crops  
Buffer zone: 2-3 m  
Drift reduction technology: Yes  
DT50: 30 days  
DFR: 0.62 µg/cm<sup>2</sup>/kg a.s./ha  
Prosulfocarb dermal absorption: concentrate 0.27%, dilution 3.3%

Resident exposure for Jura Max					
Croptype		Cereals			
Application method		Downward spraying			
Application equipment		Vehicle-mounted-Drift Reduction			i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip		2-3 m			i_Buffer
Application rate of the product		2,134 kg a.s./ha			i_AppRate
Concentration of active substance (in-use dilution for liquid applications)		7,113333333 g a.s./l			d_ConcAS
Dermal absorption of product		0,27%			i_AbsorpProduct
Dermal absorption of in-use dilution		3,30%			i_Absorplnuse
Oral absorption		72,00%			i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*_i_DFR)		1,32308 µg a.s./cm²			d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa			i_Volat
Concentration in air		0,001 mg/m³			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 m³/day/kg			d_BreathRAAd
Breathing rate child (1-3 year old)		1,07 m³/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 cm²/hour			d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)		2600 cm²/hour			d_ReTCCh
Saliva extraction percentage		50,00%			d_SolExt
Surface area of hands mouthed		20 cm²			d_AreaHM
Frequency of hand to mouth activity		9,5 events/hour			d_ReFreqHM
Ingestion rate for mouthing of grass per day		25 cm²			d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth		20,00%			d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult		7500 cm²/h			d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child		2250 cm²/h			d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult		5980 cm²/h			d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child		1794 cm²/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)	0,0322541	0,0107000	0,0113648	0,0245597	0,0565314
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0032254	0,0010700	0,0011365	0,0024560	0,0056531
% of RVNAS	46,08%	15,29%	16,24%	35,09%	80,76%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0455901	0,0138000	0,0143943	0,0818656	0,1114125
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0007598	0,0002300	0,0002399	0,0013644	0,0018569
% of RVNAS	10,85%	3,29%	3,43%	19,49%	26,53%

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

**Table 6.6-12: 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: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha			
Number of applications and application rate		1 x 0.0448 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0029012	2.64
	Vapour (75 <sup>th</sup> perc.)	0.0010700	0.97
	Deposits (75 <sup>th</sup> perc.)	0.0001640	0.15
	Re-entry (75 <sup>th</sup> perc.)	0.0043848	3.99
	Sum (mean)	0.0062965 0.0064737	5.72 5.89
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0005286	0.48
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.21
	Deposits (75 <sup>th</sup> perc.)	0.0000727	0.07
	Re-entry (75 <sup>th</sup> perc.)	0.0024360	2.21
	Sum (mean)	0.0025021 0.0028184	2.27 2.56
		Diflufenican	
Model data		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: yes – 50% DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha			
Number of applications and application rate		1 x 0.0448 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0021804	1.98
	Vapour (75 <sup>th</sup> perc.)	0.0010700	0.97
	Deposits (75 <sup>th</sup> perc.)	0.0001997	0.18
	Re-entry (75 <sup>th</sup> perc.)	0.0043848	3.99
	Sum (mean)	0.0059133 0.0062371	5.38 5.67
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0005218	0.47
	Vapour (75 <sup>th</sup> perc.)	0.0002300	0.21
	Deposits (75 <sup>th</sup> perc.)	0.0000885	0.08
	Re-entry (75 <sup>th</sup> perc.)	0.0024360	2.21

	<b>Sum (mean)</b>	0.0024850	2.26
		0.0028119	2.56

### zRMS:

Estimated resident exposure to diflufenican: dermal absorption: concentrate 70%. Dilution 70 %  
Tractor mounted boom spray application outdoors to low crops  
Buffer zone: 5 m  
Drift reduction technology: no

Resident exposure for Jura Max					
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	0,0448 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0,149333333 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)	0,1344 µg a.s./cm <sup>2</sup>				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				
Concentration in air	0,001 mg/m <sup>3</sup>				
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 m <sup>3</sup> /day/kg				
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 cm <sup>2</sup> /hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour				
Saliva extraction percentage	50,00%				
Surface area of hands mouthed	20 cm <sup>2</sup>				
Frequency of hand to mouth activity	9,5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>				
Dislodgeable residues percentage transferability for object to mouth	20,00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h				
<b>1. Total</b>					
<b>1.1 1-3 year old child</b>					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0186689	0,0107000	0,0019620	0,0529200	0,0647373
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0018669	0,0010700	0,0001962	0,0052920	0,0064737
% of RVNAS	1,70%	0,97%	0,18%	4,81%	5,89%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0204125	0,0138000	0,0052653	0,1764000	0,1691066
Total systemic exposure per kg body weight (mg a.s./day/kg)	0,0003402	0,0002300	0,0000878	0,0029400	0,0028184
% of RVNAS	0,31%	0,21%	0,08%	2,67%	2,56%



# zRMS:

Estimated resident exposure to diflufenican: dermal absorption: concentrate 70%. Dilution 70 %

Tractor mounted boom spray application outdoors to low crops

Buffer zone: 2-3 m

Drift reduction technology: YES

Resident exposure for Jura Max					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0,0448 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0,149333333 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)	0,1344 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa				
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) - 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)	0,0140312	0,0107000	0,0023885	0,0529200	0,0623709
Total systemic exposure per kg body weight	0,0014031	0,0010700	0,0002389	0,0052920	0,0062371
% of RVNAS	1,28%	0,97%	0,22%	4,81%	5,67%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0201510	0,0138000	0,0064100	0,1764000	0,1687145
Total systemic exposure per kg body weight	0,0003359	0,0002300	0,0001068	0,0029400	0,0028119
% of RVNAS	0,31%	0,21%	0,10%	2,67%	2,56%

#### 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 and diflufenican 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.

During the commenting period cMS DE has presented an approach to assess the risk of skin sensitisation of residents which supported by zRMS PL therefore is included below to address this issue:

##### Potentially sensitising spray dilution – exposure of residents/bystanders

The active substance prosulfocarb is classified as Skin Sens. 1, H317. Consequently, the spray dilution must be considered as sensitizing in analogy to Regulation (EC) No. 1272/2008 (concentration of prosulfocarb is 7.1 g/L to 14.2 g/L when applying 2.134 kg a.s./ha in 150-300 L water/ha, concentration of the a.s. is > 1% for a water volume < 215L/ha. In fact dilution of 2.134 kg a.s./ha in a water volume < 215L/ha will produce a concentration of a.s. in spray dilution slightly above 1% which is a generic concentration limit required for classification of the mixture as Skin Sens. 1, thus spray will require classification Skin Sens. 1.

This may pose a risk for residents and bystanders, who cannot protect themselves with PPEs from the properties of the spray drift.

In absence of a harmonised approach for plant protection products, DE has considered a procedure proposed for biocidal products by MS France as acceptable interim solution (ECHA, 2017. Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C). European Chemicals Agency. Version 4.0, December 2017, pp. 281-284.).

The overall procedure consists of four consecutive steps. Firstly, a critical surface dose is derived from the experimental data (NESIL, No Expected Sensitisation Induction Level). This threshold is related to the concentration at which an effect is observed in the experiment (i.e. an EC<sub>3</sub> value from a LLNA).

Secondly, Safety Assessment Factors (SAF) are defined. The use of these factors should account for uncertainty inherent to the procedure and biological variability, thus, avoiding underestimation of the risk associated with real exposure.

Thirdly, SAFs are used to derive a limit value for exposure (AEC or AEL, Acceptable Exposure Concentration or Acceptable Exposure Level) based on the NESIL identified in the first step.

Finally, the AEC/AEL can be compared to the predicted dermal exposure of bystanders and residents towards spray drift, as proposed in the corresponding EFSA guidance (EFSA Guidance on exposure; EFSA, 2014).

It is assumed that acute exposure is relevant, thus, the 95<sup>th</sup> percentile drift values should be used.

Following the procedure outlined in the ECHA BPR guidance (2017), the following calculation can be made:

During the approval of the active substance prosulfocarb, a LLNA-study was evaluated. An EC<sub>3</sub>-value of 3.125% could be calculated based on the study data, and is used as starting point:

$$\text{NESIL} = \text{EC}_3 \times \text{Conversion Factor} = 3.125 \times 250 = 781.25 \mu\text{g}/\text{cm}^2$$

Conversion factor accounts for a volume of 25μL of a (aqueous) solution which was spread on a mouse ear with an estimated surface area of 1cm<sup>2</sup> (LLNA standard procedure)

$$\text{SAF} = \text{IRS} \times \text{IS} \times \text{DR} \times \text{M} \times \text{UC} = 2.5 \times 10 \times 3 \times 1 \times 3 = 225$$

IRS...Inter-species variability; IS...Intra-species variability; DR...Dose-response; M...Matrix; UC...Use conditions; factors derived based on suggestions in ECHA BPR guidance (2017)

$$\text{AEL} = \text{NESIL}/\text{SAF} = 781.25/225 = 3.47 \mu\text{g}/\text{cm}^2$$

Spray dilution: 2134 g prosulfocarb in 150 L water (14.2 g/L, ca. 1.42 %)

Application: Low crop, tractor-mounted, no drift-reduction

Dermal Exposure: values for bystander (child), 95<sup>th</sup> percentile (from EFSA, 2014; Table 19)

at 2-3 m distance, no drift-reduction: 0.74 mL

at 5 m distance, no drift-reduction: 0.48 mL

at 10 m distance, no drift-reduction: 0.39 mL

Body surface area, child (EFSA, 2014): 4800 cm<sup>2</sup>

at 2-3m distance

0.74 mL spray solution (14.2 g/L, ca. 1.42 % w/w)

0.74 mL x 14.2 mg/L = 10.508 mg = 10508 µg

10508 µg/4800cm<sup>2</sup> = 2.189 µg/cm<sup>2</sup> (expected dermal dose)

This is equal to app. 63 % AEL (at 2-3m distance, without drift-reduction). Thus, no further measures required to protect residents/bystanders from potentially sensitising spray solution.

#### zRMS:

The exposure estimation of resident (adult and child) to Prosulfocarb, an active substance of a product JURA MAX ( GLOB1912H) applied on a field of cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, assuming buffer zone: 2-3 m , no drift reduction technology, DT50: 30 days and DFR: 3 µg/cm<sup>2</sup>/kg a.s./ha, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is 114.65% of AOEL and for child resident 320%% of AOEL, therefore the risk would be unacceptable, and risk refinement is needed using relevant risk management measures such as increased buffer zone or drift reduction technology.

When product JURA MAX ( GLOB1912H) is applied on a field of cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, assuming buffer zone of 5 m, tractor-mounted/trailed boom sprayer without drift reduction technology the estimated exposure to Prosulfocarb, an active substance of a product JURA MAX ( GLOB1912H) of resident (adult and child) has been reduced to 26.79% and to 88.12% of AOEL respectively, thus is acceptable

When product JURA MAX ( GLOB1912H) is applied on a field of cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, assuming use of Drift Reduction Technology and buffer zone of 2-3 m, the estimated exposure to Prosulfocarb, an active substance of a product JURA MAX (GLOB1912H) of resident adult and child amounted to 26.53% and to 80.76% of AOEL respectively, thus is acceptable.

The estimated exposure of resident (adult and child) to Diflufenican, an active substance of a product JURA MAX ( GLOB1912H) applied at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM and assuming buffer zone of 5 m, but not drift reduction technology, amounted 5.89% of AOEL for child resident and 2.56% of respective AOEL for adult resident. .

The estimated exposure of resident (adult and child) to Diflufenican, an active substance of a product JURA MAX ( GLOB1912H) applied at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM and assuming an use of drift reduction technology and buffer zone of 2-3 m, amounted 5.67% of AOEL for child resident and 2.56% of respective AOEL for adult resident.

No bystander acute exposure estimation for Prosulfocarb and for Diflufenican is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Prosulfocarb and Diflufenican as a result of application of a product JURA MAX ( GLOB1912H)with accordance with intended use within good agricultural practice.

Summing up application of a product JURA MAX ( GLOB1912H) in line with GAP on low crops at maximal dose of 3.2 L product/ha, using tractor-mounted/trailed boom sprayer does not pose an unacceptable health risk for residents and bystanders, providing that risk mitigation measures are used, either buffer zone of 5 m or drift reduction technology.

## 6.6.5 Combined exposure

The product is a mixture of two active substances.

### 6.6.5.1 Exposure assessment of prosulfocarb and diflufenican in GLOB1912H

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 6.6-13: Risk assessment from combined exposure (longer term exposure)**

Application scenario	Active ingredient	Estimated exposure / % of AOEL	
		(HQ)	(HI)
Operators – tractor mounted – gloves during M/L and A	Prosulfocarb	20.29	20.48
	Diflufenican	2.75	3.3
	<b>Cumulative risk operators (HI)</b>	<b>23.04</b>	<b>23.78</b> <b>0.24</b>
Workers – inspection, irrigation	Prosulfocarb	12.5	29.11
	Diflufenican	3.31	3.99
	<b>Cumulative risk workers (HI)</b>	<b>15.81</b>	<b>33.10</b> <b>0.33</b>
Resident – child – 5 m buffer zone	Prosulfocarb		
	Drift	95.86	

Application scenario	Active ingredient	Estimated exposure / % of AOEL		
		(HQ)		(HI)
	Vapour	15.29		
	Deposits	13.34		
	Re-entry	2.81		
	Sum of all pathways	93.07	88.32	0.88
	Diflufenican			
	Drift	2.64		
	Vapour	0.97		
	Deposits	0.15		
	Re-entry	3.99		
	Sum of all pathways	5.72	5.89	0.06
	<b>Cumulative risk resident – child (HI)</b>			
	Drift	98.5		
	Vapour	16.3		
	Deposits	13.5		
	Re-entry	6.8		
	<b>Sum of all pathways</b>	<b>98.8</b>	<b>94.04</b>	<b>0.94</b>
Resident – child – 50% DRT	Prosulfocarb			
	Drift	50.5		
	Vapour	15.29		
	Deposits	32.47		
	Re-entry	2.81		
	Sum of all pathways	91.51	80.76%	0.81
	Diflufenican			
	Drift	1.98		
	Vapour	0.97		
	Deposits	0.18		
	Re-entry	3.99		
	Sum of all pathways	5.38	5.67	0.06
	<b>Cumulative risk resident – child (HI)</b>			
	Drift	52.5		
	Vapour	16.3		
	Deposits	32.7		
	Re-entry	6.8		
	<b>Sum of all pathways</b>	<b>96.9</b>	<b>86.43</b>	<b>0.86</b>
Resident – adult – 5 m buffer zone	Prosulfocarb			
	Drift	20.91		

Application scenario	Active ingredient	Estimated exposure /		
		% of AOEL		
		(HQ)		(HI)
	Vapour	3.29		
	Deposits	2.82		
	Re-entry	1.56		
	Sum of all pathways	17.86	26.79	0.27
	Diiflufenican			
	Drift	0.48		
	Vapour	0.21		
	Deposits	0.07		
	Re-entry	2.21		
	Sum of all pathways	2.27	2.56	0.03
	<b>Cumulative risk resident – adult (HI)</b>			
	Drift	21.4		
	Vapour	3.5		
	Deposits	2.9		
	Re-entry	3.8		
	<b>Sum of all pathways</b>	<b>20.1</b>	<b>29.35</b>	
Resident – adult – 50% DRT	Prosulfocarb			
	Drift	20.51		
	Vapour	3.29		
	Deposits	6.85		
	Re-entry	1.56		
	Sum of all pathways	19.74	26.55	
	Diiflufenican			
	Drift	0.47		
	Vapour	0.21		
	Deposits	0.08		
	Re-entry	2.21		
	Sum of all pathways	2.26	2.56	
	<b>Cumulative risk resident – adult (HI)</b>			
	Drift	21.0		
	Vapour	3.5		
	Deposits	6.9		
	Re-entry	3.8		
	<b>Sum of all pathways</b>	<b>22.0</b>	<b>29.11</b>	

The Hazard Index is < 1. Thus, combined exposure to all active substances in GLOB1912H is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment

is required.

**zRMS:**

Since hazard index of combined exposure, calculated as sum of exposures to both active substances expressed as a decimal fraction of respective AOEL for each active substance of product JURA MAX (GLOB1912H), is below 1, the combined exposures of operator, worker and residents to both substances are considered as not posing an unacceptable risk.

## 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	Perny 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 RB424 Anadiag GLP Unpublished	N	Syngenta <i>Globachem access</i>
KCP 7.3	Hassler S.	2021	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1912H through human skin membranes 20200297 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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
None					

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
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 GLOB1912H 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).

Comments of zRMS:	The evaluation of acute oral toxicity of a product Jura Max (GLOB1912H) has been done based on known classification of its ingredients using rules given in Regulation 1272/2008, point 3.1.3.6.1.( see part C)  Jura Max (GLOB1912H) <b>does not</b> requires classification for oral acute toxicity as Acute Tox. 4; H302
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### A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

No tests were performed on GLOB1912H 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).

Comments of zRMS:	The evaluation of the applicant is accepted. Jura Max (GLOB1912H) does not require classification for acute dermal toxicity. (see part C)
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### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No tests were performed on GLOB1912H 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).

Comments of zRMS:	The evaluation of the applicant is accepted. Jura Max (GLOB1912H) does not require classification for acute inhalation toxicity (see part C)
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### A 2.5 Skin irritation (KCP 7.1.4)

No tests were performed on GLOB1912H 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).

Comments of zRMS:	The evaluation of the applicant is accepted. Since concentration of the only ingredient classified as Skin Irrit. 2 is below 10 %, the formulation Jura Max (GLOB1912H) <b>does not</b> require classification for skin irritation. (see part C)
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#### **A 2.6 Eye irritation (KCP 7.1.5)**

No tests were performed on GLOB1912H 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).

Comments of zRMS:	The evaluation of the applicant is accepted. Since concentration of one ingredient classified as Eye Dam. 1 is above 3 % a formulation Jura Max (GLOB1912H) require classification for eye irritation to category 1 as Eye Dam. 1; H318 Causes serious eye damage.
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#### **A 2.7 Skin sensitisation (KCP 7.1.6)**

No tests were performed on GLOB1912H 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).

Comments of zRMS:	The evaluation of the applicant is accepted. Since concentration of the active substance Prosulfocarb the only ingredient classified as Skin Sens. 1 is well above 1 % a formulation Jura Max (GLOB1912H) require classification for skin sensitisation to category 1 as Skin Sens. 1 ; H317: May cause an allergic skin reaction. ( see part C)
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## **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 GLOB1912H**

Comments of zRMS:	<p>The study performed on formulation LOB1912H according to relevant OECD method and in GLP conditions is acceptable.</p> <p>The number of replicates for the concentrate was 12 and for dilution 13.</p> <p>According to EFSA Guidance on Dermal Absorption the absorption (mean value) + ks, where s is the sample standard deviation:</p> <p>Mean absorption of the concentrate: <math>0.21 + 0.64 \times 0.09 = 0.21 + 0.058 = 0.267\%</math></p> <p>Mean absorption of the 1:100 spray dilution : <math>2.53 + 0.60 \times 1.27 = 2.53 + 0.763 = 3.292</math></p> <p>Thus, the dermal penetration estimates to be used for risk assessment is 0.27% for the concentrate and 3.3% for the spray dilution based on the EFSA guidance criteria</p>
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Reference	KCP 7.3
Report	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1912H through human skin membranes, Hassler S., 2021, 20200297
Guideline(s)	Yes, OECD 428, Council Regulation (EC) No 440/2008, Method B45
Deviations	No
GLP	Yes
Acceptability	YES
Duplication (if vertebrate study)	No

## Materials and methods

<b>Test material</b>	Name (Lot/Batch No.)	11687SXXG013-4
	Test preparation	spiking
	Specific activity	7161 kBq/mg
	Radiochemical purity	99.1%
Product	Name (Lot/Batch No.)	PSC0100004
	Company code	GLOB1912H
	Concentration a.s.	667 g/L
	Formulation type	EC
Blank product	Name (Lot/Batch No.)	-
	Concentration a.s.	-

<b>Test system</b>		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	3 ml/h
	Exposed skin area	1 cm <sup>2</sup>
	Cover	open
Membrane	Skin type	dermatomed
	Skin thickness range	400 µm
	Skin donors age	25-86
	Skin donors sex	m+f
	Location	abdomen
	Source	ex vivo
	Integrity test	y
Receptor	Receptor medium	Phosphate buffered saline with 5% Volpo N20
	Solubility in receptor medium	y, 5183 µg/mL
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	6.7
Area dose [µg/cm <sup>2</sup> ]	6670	67
Total dose [µg/cell]	6670	67
Specific activity [kBq/ml]	2198	455
No. of donors	7	6
No of cells used/valid cells	11/12*	13/13

\*one cell was excluded due to a potential contamination of the charcoal paper at 24h sample

## Results and discussions

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

Dose group	High dose	Low dose
	(Formulation concentrate)	(Spray dilution 1:133)
Target concentration [mg/mL]	667	6.7
Target dose [µg/cm <sup>2</sup> ]	6670	67
Mean actual applied dose [µg/cm <sup>2</sup> ]	6691	67.1

	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
<b>Dislodgeable dose</b>				
Skin washing after 6 + 24 h	99.09	1.69	74.48	16.54
Donor chamber wash	0.07	0.04	0.75	0.45
<b>Dose associated to skin</b>				
Tape strips: 1 <sup>st</sup> sample, strips 1 + 2	0.70	0.59	21.38	15.48
Tape strips: 2 <sup>nd</sup> sample; strips 3 – 10	0.09	0.02	0.45	0.47
Skin preparation	0.03	0.02	0.52	0.45
<b>Absorbed dose</b>				
Receptor fluid	0.08	0.07	1.51	0.44
Receptor chamber wash	0.01	0.00	0.05	0.04
<b>Total recovery<sup>1</sup></b>	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 <sub>0.5</sub> ]	No [37.50% ± 6.78]		No [42.33% ± 4.92]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) <sup>2</sup>	0.21	0.09	2.53	1.27
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A
Absorption estimate normalised <sup>3</sup>				
Relevant absorption estimate <sup>4</sup>	0.264		3.292	
<b>Absorption estimates used for risk assessment<sup>5</sup></b>	<b>0.26</b>		<b>3.3</b>	

<sup>1</sup> Values may not calculate exactly due to rounding of figures

<sup>2</sup> In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) the radioactivity in the second tape-strip pool (3<sup>rd</sup> to n<sup>th</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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 GLOB1912H through human dermatomed skin was determined in vitro. The amount of applied dose penetrating within 24 hours was determined to be 0.21 ± 0.09 % (mean ± standard deviation) and 2.53 ± 1.27 % for the formulation concentrate and the 1:100 spray dilution, respectively. The dermal penetration estimates to be used for risk assessment were set at 0.24% and 3.3% for the formulation concentrate and the 1:100 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 GLOB1912H outdoor spray applications				
Application rate of active substance	2.134	kg a.s./ha	<i>L.AppRate</i>	
Assumed area treated	50	ha/day	<i>L.AreaTreated</i>	
Amount of active substance applied	106.7	kg a.s./day	<i>L.AmountAS</i>	
Dermal absorption of the product	0.26%		<i>L.AbsorpProduct</i>	
Dermal absorption of in-use dilution	3.30%		<i>L.AbsorpInuse</i>	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Season	not relevant			

  

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	176889	675424	AOEM	
	Body	95058	279711	AOEM	
	Head	5536	30362	AOEM	
	Protected hands (gloves)	720	21134	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1492	15605	AOEM	
	Protected head (hood and face shield)	89	1719	AOEM	
	Inhalation	15	32	AOEM	
	<b>Protective Equipment</b>	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	15826	70083	AOEM	
	Body	8849	45616	AOEM	
	Head	418	1261	AOEM	
	Protected hands (gloves)	535	5746	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	243	595	AOEM	
	Inhalation	11	43	AOEM	
	<b>Protective Equipment</b>	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
<b>Longer term</b>		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.5751396	1.0478641
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0262523	0.0174644
% of FVNAS	375.03%	249.49%



**Table A 3: Estimation of longer term operator exposure towards prosulfocarb according to EFSA guidance, including input parameters – gloves M/L and A**

Operator exposure for GLOB1912H outdoor spray applications					
Application rate of active substance	2.134	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	106.7	kg a.s./day	L.AmountAS		
Dermal absorption of the product	0.26%		L.AbsorpProduct		
Dermal absorption of in-use dilution	3.30%		L.Absorbtissue		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	176889	675424	AOEM	
	Body	95058	279711	AOEM	
	Head	5536	30362	AOEM	
	Protected hands (gloves)	720	21134	AOEM	
	Protected body (work wear or protective garment and sturdy footwear)	1492	15605	AOEM	
	Protected head (hood and face shield)	89	1719	AOEM	
	Inhalation	15	32	AOEM	
	<b>Protective Equipment</b>	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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	15826	70083	AOEM	
	Body	8849	45616	AOEM	
	Head	418	1261	AOEM	
	Protected hands (gloves)	535	5746	AOEM	
	Protected body (work wear or protective garment and sturdy footwear)	243	595	AOEM	
	Inhalation	11	43	AOEM	
	<b>Protective Equipment</b>	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
<b>Longer term</b>		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.5751396	0.0852220
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0262523	0.0014204
% of RYNAS	375.03%	20.29%

**A 3.1.2 Calculations for Diflufenican**

**Table A 4: Estimation of longer term operator exposure towards diflufenican according to EFSA guidance, including input parameters**

Operator exposure for GLOB1912H outdoor spray applications					
Application rate of active substance	0.0448	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	2.24	kg a.s./day	L.AmountAS		
Dermal absorption of the product	58.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	58.00%		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 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9036	33346	AOEM	
	Body	6288	91041	AOEM	
	Head	116	637	AOEM	
	Protected hands (gloves)	58	444	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	49	328	AOEM	
	Protected head (hood and face shield)	2	36	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	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	332	4137	AOEM	
	Body	186	958	AOEM	
	Head	9	26	AOEM	
	Protected hands (gloves)	66	3662	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	5	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)	9.2674533	5.5436528	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1544576	0.0923942	
% of RYNAS	140.42%	83.99%	

**Table A 5: Estimation of longer term operator exposure towards diflufenican according to EFSA guidance, including input parameters – gloves**

Operator exposure for GLOB1912H outdoor spray applications					
Application rate of active substance	0.0448	kg a.s./ha	L.AppRate		
Assumed area treated	50	ha/day	L.AreaTreated		
Amount of active substance applied	2.24	kg a.s./day	L.AmountAS		
Dermal absorption of the product	58.00%		L.AbsorpProduct		
Dermal absorption of in-use dilution	58.00%		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	<b>Exposure values</b>	<b>µg exposure/day mixed and loaded</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	9036	33346	AOEM	
	Body	6288	91041	AOEM	
	Head	116	637	AOEM	
	Protected hands (gloves)	58	444	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	49	328	AOEM	
	Protected head (hood and face shield)	2	36	AOEM	
	Inhalation	5	29	AOEM	
	<b>Protective Equipment</b>	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	
Application	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	<b>Exposure values</b>	<b>µg exposure/day applied</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	332	4137	AOEM	
	Body	186	958	AOEM	
	Head	9	26	AOEM	
	Protected hands (gloves)	66	3662	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	12	AOEM	
	Inhalation	2	5	AOEM	
	<b>Protective Equipment</b>	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
<b>Longer term</b>		
Total systemic exposure from mixing, loading and application (mg a.s./day)	9.2674533	0.1817275
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1544576	0.0030288
% of RVNAS	140.42%	2.75%

## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for Prosulfocarb

**Table A 6: Estimation of longer term worker exposure towards prosulfocarb according to EFSA guidance, including input parameters**

Worker exposure from residues on foliage for GLOB1912H				
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	2.134	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	0.26%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	3.30%			<i>i_Absorpinuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	6.402	µg a.s./cm <sup>2</sup>		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm <sup>2</sup> /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm <sup>2</sup> /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm <sup>2</sup> /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcSort</i>
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	5.2816500	0.5915448	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0880275	0.0098591		
% of RVNAS	1257.54%	140.84%		

**Table A 7: 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	2.134
Dermal absorption (%)	3.3
PDE (mg a.s./d)	1.590
Systemic exposure (mg a.s./d)	0.05248
Worker exposure (mg a.s./kg bw x d)	0.00087
AOEL	0.007
% AOEL	12.50

### A 3.2.2 Calculations for Diflufenican

**Table A 8: Estimation of longer term worker exposure towards diflufenican according to EFSA guidance, including input parameters**

Worker exposure from residues on foliage for GLOB1912H				
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	0.0448	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_AbsorpInuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.1344	µg a.s./cm <sup>2</sup>		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm <sup>2</sup> /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm <sup>2</sup> /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm <sup>2</sup> /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 <sup>^</sup> (-3)		<i>d_InhalTcSort</i>
<b>1. Total</b>				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1.9488000	0.2182656	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0324800	0.0036378		
% of RVNAS	29.53%	3.31%		

### A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for Prosulfocarb

**Table A 9: Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters**

Resident exposure for GLOB1912H					
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	2.134 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	21.34 g a.s./l				
Dermal absorption of product	0.26%				
Dermal absorption of in-use dilution	3.30%				
Oral absorption	72.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	6.402 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)	0.1935244	0.0107000	0.0227297	0.1188371	0.2296648
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0193524	0.0010700	0.0022730	0.0118837	0.0229665
% of RVNAS	276.46%	15.29%	32.47%	169.77%	328.09%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2735404	0.0138000	0.0287885	0.3961238	0.4815182
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0045590	0.0002300	0.0004798	0.0066021	0.0080253
% of RVNAS	65.13%	3.29%	6.85%	94.32%	114.65%

**Table A 10: Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters – refined (5m)**

<b>Resident child exposure 75th percentile</b>	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	1
Dermal absorption (%)	3.3
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
<b>Spray drift 75th percentile</b>	
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)	0.0648
Systemic inhalation exposure (mg a.i./person)	0.0023
Total systemic exposure (mg a.i./person)	0.0671
Total systemic exposure (mg a.i./kg bw)	0.0067
% AOEL	95.86
<b>Vapour</b>	
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

<b>Surface deposits</b>	
<u>Dermal exposure</u>	
Application rate (mg/cm <sup>2</sup> )	0.02134
Drift percentage (%) (see table)	2.3
Turf transferable residues (%)	5
Transfer coefficient (cm <sup>2</sup> /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0042112
Systemic exposure (mg/kg bw x d)	0.0004211
% AOEL	6.02
<u>Hand to mouth exposure</u>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm <sup>2</sup> )	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.003357
Systemic exposure (mg/kg bw x d)	0.0003357
% AOEL	4.80
<u>Children's object to mouth</u>	
Drift percentage (%) (see table)	2.30
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (c	25
Systemic exposure (mg/d)	0.001767
Systemic exposure (mg/kg bw x d)	0.0001767
% AOEL	2.52
<u>Total surface deposit exposure</u>	
Total systemic exposure (mg a.s./d)	0.0093354
Total systemic exposure (mg a.s./kg bw x	0.0009335
% AOEL	13.34
<b>Entry into treated crops 75th percentile</b>	
DFR (µg/(cm <sup>2</sup> x kg a.s. x ha))	0.62
Transfer coefficient	180.30
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.00197
Systemic exposure (mg a.s./kg bw x d)	0.00020
% AOEL	2.81



<b>Resident child exposure mean</b>	
Formulation (liquid = 1 , solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	1
Dermal absorption (%)	3.3
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
<b>Spray drift mean</b>	
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)	0.0433
Systemic inhalation exposure (mg a.i./person)	0.0019
Total systemic exposure (mg a.i./person)	0.0451768
Total systemic exposure (mg a.i./kg bw)	0.0045177
% AOEL	64.54
<b>Vapour</b>	
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

<b>Surface deposits</b>	
<u>Dermal exposure</u>	
Application rate (mg/cm <sup>2</sup> )	0.02134
Drift percentage (%) (see table)	1.8
Turf transferable residues (%)	5
Transfer coefficient (cm <sup>2</sup> /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0032957
Systemic exposure (mg/kg bw x d)	0.0003296
% AOEL	4.71
<u>Hand to mouth exposure</u>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm <sup>2</sup> )	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.002627
Systemic exposure (mg/kg bw x d)	0.0002627
% AOEL	3.75
<u>Children's object to mouth</u>	
Drift percentage (%) (see table)	1.80
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (c	25
Systemic exposure (mg/d)	0.0013828
Systemic exposure (mg/kg bw x d)	0.0001383
% AOEL	1.98
<u>Total surface deposit exposure</u>	
Total systemic exposure (mg a.s./d)	0.0073060
Total systemic exposure (mg a.s./kg bw x d)	0.0007306
% AOEL	10.44
<b>Entry into treated crops</b>	
DFR (µg/(cm <sup>2</sup> x kg a.s. x ha))	0.62
Transfer coefficient (cm <sup>2</sup> /h)	180.3
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.002
Systemic exposure (mg a.s./kg bw x d)	0.00020
% AOEL	2.81
<b>All pathways</b>	
Total systemic exposure (mg a.s./d)	0.065151
Total systemic exposure (mg a.s./kg bw x d)	0.006515
% AOEL	93.07

<b>Resident adult exposure 75th percentile</b>	
Formulation (liquid = 1 , solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	1
Dermal absorption (%)	3.3
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
<b>Spray drift 75th percentile</b>	
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)	0.0866
Systemic inhalation exposure (mg a.i./person)	0.0012
Total systemic exposure (mg a.i./person)	0.0878
Total systemic exposure (mg a.i./kg bw)	0.0015
% AOEL	20.91
<b>Vapour</b>	
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)	0.00023
% AOEL	3.29
<b>Surface deposits</b>	
Application rate ( $\text{mg}/\text{cm}^2$ )	0.02134
Drift percentage (%) (see table)	2.3
Turf transferable residues (%)	5
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0118239
Systemic exposure (mg/kg bw x d)	0.0001971
% AOEL	2.82
<b>Entry into treated crops 75th percentile</b>	
DFR ( $\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$ )	0.62
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	601
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.007
Systemic exposure (mg a.s./kg bw x d)	0.00011
% AOEL	1.56

<b>Resident adult exposure mean</b>	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	1
Dermal absorption (%)	3.3
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
<b>Spray drift mean</b>	
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)	0.0443
Systemic inhalation exposure (mg a.i./pers)	0.0011
Total systemic exposure (mg a.i./person)	0.0453799
Total systemic exposure (mg a.i./kg bw)	0.0007563
% AOEL	10.80
<b>Vapour</b>	
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
<b>Surface deposits</b>	
Application rate ( $\text{mg}/\text{cm}^2$ )	0.02134
Drift percentage (%) (see table)	1.8
Turf transferable residues (%)	5
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0092535
Systemic exposure (mg/kg bw x d)	0.0001542
% AOEL	2.20
<b>Entry into treated crops</b>	
DFR ( $\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$ )	0.62
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	601
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.007
Systemic exposure (mg a.s./kg bw x d)	0.000
% AOEL	1.56
<b>All pathways</b>	
Total systemic exposure (mg a.s./d)	0.074993
Total systemic exposure (mg a.s./kg bw x d)	0.001250
% AOEL	17.86

**Table A 11:** Estimation of longer term resident exposure towards prosulfocarb according to EFSA guidance, including input parameters – refined (50% DRT)

<b>Resident child exposure 75th percentile</b>	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	3.3
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
<b>Spray drift 75th percentile</b>	
Dermal exposure (mL/person) (see table)	0.17965
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00022
Systemic dermal exposure (mg a.i./person)	0.0324
Systemic inhalation exposure (mg a.i./person)	0.0029
Total systemic exposure (mg a.i./person)	0.0354
Total systemic exposure (mg a.i./kg bw)	0.0035
% AOEL	50.50
<b>Vapour</b>	
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/kg bw x d)	0.00107
% AOEL	15.29
<b>Surface deposits</b>	
<u>Dermal exposure</u>	
Application rate ( $\text{mg}/\text{cm}^2$ )	0.02134
Drift percentage (%) (see table)	5.6
Turf transferable residues (%)	5
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0102534
Systemic exposure (mg/kg bw x d)	0.0010253
% AOEL	14.65
<u>Hand to mouth exposure</u>	
Saliva extraction factor (%)	50.00
Surface area of hands ( $\text{cm}^2$ )	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.008174
Systemic exposure (mg/kg bw x d)	0.0008174
% AOEL	11.68
<u>Children's object to mouth</u>	
Drift percentage (%) (see table)	5.60
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day ( $\text{cm}^2$ )	25
Systemic exposure (mg/d)	0.0043021
Systemic exposure (mg/kg bw x d)	0.0004302
% AOEL	6.15
<u>Total surface deposit exposure</u>	
Total systemic exposure (mg a.s./d)	0.0227297
Total systemic exposure (mg a.s./kg bw x d)	0.0022730
% AOEL	32.47
<b>Entry into treated crops 75th percentile</b>	
DFR ( $\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$ )	0.62
Transfer coefficient	180.30
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.00197
Systemic exposure (mg a.s./kg bw x d)	0.00020
% AOEL	2.81

<b>Resident child exposure mean</b>	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	3.3
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
<b>Spray drift mean</b>	
Dermal exposure (mL/person) (see table)	0.18
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00017
Systemic dermal exposure (mg a.i./person)	0.0325
Systemic inhalation exposure (mg a.i./person)	0.0023
Total systemic exposure (mg a.i./person)	0.0347495
Total systemic exposure (mg a.i./kg bw)	0.0034750
% AOEL	49.64
<b>Vapour</b>	
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

<b>Surface deposits</b>	
<u>Dermal exposure</u>	
Application rate (mg/cm <sup>2</sup> )	0.02134
Drift percentage (%) (see table)	4.1
Turf transferable residues (%)	5
Transfer coefficient (cm <sup>2</sup> /h)	2600
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0075070
Systemic exposure (mg/kg bw x d)	0.0007507
% AOEL	10.72
<u>Hand to mouth exposure</u>	
Saliva extraction factor (%)	50.00
Surface area of hands (cm <sup>2</sup> )	20.00
Frequency of hand to mouth (events/h)	9.50
Systemic exposure (mg/d)	0.005985
Systemic exposure (mg/kg bw x d)	0.0005985
% AOEL	8.55
<u>Children's object to mouth</u>	
Drift percentage (%) (see table)	4.10
Dislodgeable residues percentage (%)	20
Ingestion rate for mouthing grass/day (c	25
Systemic exposure (mg/d)	0.0031498
Systemic exposure (mg/kg bw x d)	0.000315
% AOEL	4.50
<u>Total surface deposit exposure</u>	
Total systemic exposure (mg a.s./d)	0.0166414
Total systemic exposure (mg a.s./kg bw x	0.0016641
% AOEL	23.77
<b>Entry into treated crops</b>	
DFR (µg/(cm <sup>2</sup> x kg a.s. x ha))	0.62
Transfer coefficient (cm <sup>2</sup> /h)	180.3
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.002
Systemic exposure (mg a.s./kg bw x d)	0.00020
% AOEL	2.81
<b>All pathways</b>	
Total systemic exposure (mg a.s./d)	0.064059
Total systemic exposure (mg a.s./kg bw x	0.006406
% AOEL	91.51

<b>Resident adult exposure 75th percentile</b>	
Formulation (liquid = 1 , solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	3.3
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
<b>Spray drift 75th percentile</b>	
Dermal exposure (mL/person) (see table)	0.47
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.0001
Systemic dermal exposure (mg a.i./person)	0.0848
Systemic inhalation exposure (mg a.i./person)	0.0013
Total systemic exposure (mg a.i./person)	0.0861
Total systemic exposure (mg a.i./kg bw)	0.0014
% AOEL	20.51
<b>Vapour</b>	
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)	0.00023
% AOEL	3.29
<b>Surface deposits</b>	
Application rate ( $\text{mg}/\text{cm}^2$ )	0.02134
Drift percentage (%) (see table)	5.6
Turf transferable residues (%)	5
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0287885
Systemic exposure (mg/kg bw x d)	0.0004798
% AOEL	6.85
<b>Entry into treated crops 75th percentile</b>	
DFR ( $\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$ )	0.62
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	601
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.007
Systemic exposure (mg a.s./kg bw x d)	0.00011
% AOEL	1.56



<b>Resident adult exposure mean</b>	
Formulation (liquid = 1, solid = 2)	1
Dose rate a.i. (g/ha)	2134
Water volume (L/ha)	160
Concentration (mg a.i./mL)	13.3375
MAF	1
Drift reduction (0.5 or 1)	0.5
Dermal absorption (%)	3.3
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
<b>Spray drift mean</b>	
Dermal exposure (mL/person) (see table)	0.22318
Light clothing adjustment factor (%)	18
Inhalation exposure (mL/person) (see table)	0.00009
Systemic dermal exposure (mg a.i./person)	0.0403
Systemic inhalation exposure (mg a.i./pers)	0.0012
Total systemic exposure (mg a.i./person)	0.0414746
Total systemic exposure (mg a.i./kg bw)	0.0006912
% AOEL	9.87
<b>Vapour</b>	
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
<b>Surface deposits</b>	
Application rate ( $\text{mg}/\text{cm}^2$ )	0.02134
Drift percentage (%) (see table)	4.1
Turf transferable residues (%)	5
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	7300
Duration of exposure (h)	2
Dermal absorption (%)	0.033
Systemic exposure (mg/d)	0.0210773
Systemic exposure (mg/kg bw $\times$ d)	0.0003513
% AOEL	5.02
<b>Entry into treated crops</b>	
DFR ( $\mu\text{g}/(\text{cm}^2 \times \text{kg a.s.} \times \text{ha})$ )	0.62
Transfer coefficient ( $\text{cm}^2/\text{h}$ )	601
Timing exposure (hours)	0.25
Dose rate (kg a.i./ha)	2.134
Dermal absorption (%)	3.3
Systemic exposure (mg a.s./d)	0.007
Systemic exposure (mg a.s./kg bw $\times$ d)	0.000
% AOEL	1.56
<b>All pathways</b>	
Total systemic exposure (mg a.s./d)	0.082912
Total systemic exposure (mg a.s./kg bw $\times$ d)	0.001382
% AOEL	19.74

### A 3.3.2 Calculations for Diflufenican

**Table A 12:** Estimation of longer term resident exposure towards diflufenican according to EFSA guidance, including input parameters

Resident exposure for GLOB1912H					
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	0.0448 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.448 g a.s./l				d_ConcAS
Dermal absorption of product	58.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	58.00%				i_AbsorpInuse
Oral absorption	58.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.1344 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				i_Volat
Concentration in air	0.001 mg/m³				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 m³/day/kg				d_BreathRAAd
Breathing rate child (1-3 year old)	1.07 m³/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 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile)	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile)	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/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)	0.0697721	0.0107000	0.0039943	0.0438480	0.0870144
Total systemic exposure per kg body weight (mg a.s./kg/day)	0.0069772	0.0010700	0.0003994	0.0043848	0.0087014
% of RVNAS	6.34%	0.97%	0.36%	3.99%	7.91%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1001871	0.0138000	0.0106223	0.1461600	0.1857083
Total systemic exposure per kg body weight (mg a.s./kg/day)	0.0016698	0.0002300	0.0001770	0.0024360	0.0030951
% of RVNAS	1.52%	0.21%	0.16%	2.21%	2.81%

**Table A 13: Estimation of longer term resident exposure towards diflufenican according to EFSA guidance, including input parameters – refined (5m buffer zone)**

Resident exposure for GLOB1912H					
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	0.0448 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.28 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)	0.1344 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)	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)	0.0290116	0.0107000	0.0016405	0.0438480	0.0629647
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0029012	0.0010700	0.0001640	0.0043848	0.0062965
% of RVNAS	2.64%	0.97%	0.15%	3.99%	5.72%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0317165	0.0138000	0.0043627	0.1461600	0.1501253
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0005286	0.0002300	0.0000727	0.0024360	0.0025021
% of RVNAS	0.48%	0.21%	0.07%	2.21%	2.27%

**Table A 14: Estimation of longer term resident exposure towards diflufenican according to EFSA guidance, including input parameters – refined (50% DRT)**

Resident exposure for GLOB1912H					
Croptype			Cereals		
Application method			Downward spraying		
Application equipment			Vehicle-mounted-Drift Reduction		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip			2-3 m		i_Buffer
Application rate of the product			0.0448 kg a.s./ha		i_AppRate
Concentration of active substance (in-use dilution for liquid applications)			0.28 g a.s./l		d_ConcAS
Dermal absorption of product			58.00%		i_AbsorpProduct
Dermal absorption of in-use dilution			58.00%		i_Absorplnuse
Oral absorption			58.00%		i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)			0.1344 µg a.s./cm²		d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa		Pa		i_Volat
Concentration in air			0.001 mg/m³		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 m³/day/kg		d_BreathRAD
Breathing rate child (1-3 year old)			1.07 m³/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 cm²/hour		d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)			2600 cm²/hour		d_ReTCCh
Saliva extraction percentage			50.00%		d_SalExt
Surface area of hands mouthed			20 cm²		d_AreaHM
Frequency of hand to mouth activity			9.5 events/hour		d_ReFreqHM
Ingestion rate for mouthing of grass per day			25 cm²		d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth			20.00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile)			7500 cm²/h		d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile)			2250 cm²/h		d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult			5980 cm²/h		d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child			1794 cm²/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)	0.0218038	0.0107000	0.0019971	0.0438480	0.0591326
Total systemic exposure per kg body	0.0021804	0.0010700	0.0001997	0.0043848	0.0059133
% of RVNAS	1.98%	0.97%	0.18%	3.99%	5.38%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0313085	0.0138000	0.0053111	0.1461600	0.1490996
Total systemic exposure per kg body	0.0005218	0.0002300	0.0000885	0.0024360	0.0024850
% of RVNAS	0.47%	0.21%	0.08%	2.21%	2.26%

### A 3.4 Combined exposure calculations for Prosulfocarb and Diflufenican

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.

<b>Report:</b>	Perny. 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. ANADIAG, 16, rue Ampère, 67500 HAGUENAU, 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 guidance<sup>2</sup> 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.

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<sup>2</sup> 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

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

## Study Design and Methods

<b>Field phase dates:</b>	Start: 13 <sup>th</sup> March 2015 End: 19 <sup>th</sup> March 2015
<b>Experimental dates:</b>	5 <sup>th</sup> March 2015 to 16 <sup>th</sup> 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 m<sup>2</sup> 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 cm<sup>2</sup> 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 (µg/cm <sup>2</sup> ) – Mean value	0.903	1.793	1.540	1.329	3.358	2.337
DFR (µg/cm <sup>2</sup> /kg a.s./ha)	0.231	0.458	0.394	0.340	0.887	0.618
TC (cm <sup>2</sup> /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 (µg/sample)	2817.27	1769.59	848.38	1985.77	1118.43	1132.53
Inner dosimeter (µg/sample)	461.181	388.3	305.46	286.94	316.68	448.61
Socks (µg/sample)	46.98	25.41	0.12	0.46	0.11	0.31
Face/neck wipes (µg/sample)	2.82	3.39	3.9	4.45	2.87	4.09
Nitrile Gloves (µg/sample)	1270.18	1569.7	593.42	2053.19	1338.22	762.42
Hand wash (µg/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 (µg/cm <sup>2</sup> ) – Mean value	2.803	2.977	3.108	2.757	2.575	3.488
DFR (µg/cm <sup>2</sup> /kg a.s./ha)	0.741	0.787	0.777	0.689	0.644	0.872
TC (cm <sup>2</sup> /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 operator 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 75<sup>th</sup> 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 <sup>th</sup> percentile	Parametric 75 <sup>th</sup> percentile
Total systemic exposure – no gloves (mg/kg bw/day)	0.0006	<b>0.0011*</b>	0.0010
Total systemic exposure – with gloves (mg/kg bw/day)	0.0003	<b>0.0005*</b>	0.0004
Transfer coefficient – No gloves (cm <sup>2</sup> /hr)	324.4	394.1	<b>601.0*</b>
Transfer coefficient – With gloves (cm <sup>2</sup> /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 75<sup>th</sup> 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 75<sup>th</sup> percentile value for TC is 601 cm<sup>2</sup>/hour with bare hands and 149 cm<sup>2</sup>/hr if protective gloves are worn.