

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Clopyralid, 120 g/L

Fluroxypyr-acid, 120 g/L (as fluroxypyr-meptyl, 172.9 g/L)

Florasulam, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

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## Version history

When	What
November 2023	Assessment by expert
November 2024	The final Registration Report
May 2025	Assessment after updated by Applicant

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## 6 Mammalian Toxicology (KCP 7)

In the following document, data for active substances - fluroxypyr and clopyralid - was described during its inclusion on Annex 1 process in respectively 2009 and 2004 . Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.

Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/CFF 250 EC INN VIGO is allowed to refer to EU approved reports

### 6.1 Summary

**Table 6.1-1: Information on CHR/H/CFF 250 EC \***


Product name and code	CHR/H/CFF 250 EC
Formulation type	Emulsifiable concentrate [EC]
Active substance(s) (incl. content)	Florasulam: 10 g/L Fluroxypyr: 120 g/L Clopyralid: 120 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 CHR/H/CFF 250 EC can be found in the confidential dRR Part C.

### Justified proposals for classification and labelling

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

**Table 6.1-2: Justified proposals for classification and labelling for CHR/H/CFF 20 EC according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	H302, H304, H315, H318
Hazard pictograms or Code(s) for hazard pictogram(s)	
Signal word	Danger
Hazard statement(s)	Acute Tox. 4, H302 – Harmful if swallowed Asp. Tox. 1, H304 – May be fatal if swallowed and enters airways. Skin Irrit. 2, H315 – Causes skin irritation. Eye Dam. 1, H318 – Causes serious eye damage.
Precautionary statement(s)	P264 – Wash face, hands and contaminated skin thoroughly after handling. P280 – Wear protective gloves/protective clothing/eye protection/face protection. P301 + P310 - IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P302 + P352 – IF ON SKIN: Wash with plenty of water. P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	<b>Hazardous ingredients that must be listed on the label: 1-</b> Butylpyrrolidin-2-one, Benzenesulfonic acid, C10-13 alkyl derivs., calcium salts, 2-methylpropan-1-ol, Hydrocarbons, C10-C13, aromatics,

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for CHR/H/CFF 250 EC**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	With gloves and work wear during mix/loading and application
Workers	Acceptable	With PPE
Residents	Acceptable	
Bystanders	Acceptable	

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

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

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

1	2	3	4	5	6	7	8	9	10				
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks:  (e.g. safen- er/synergist (L/ha))  critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure as- sessment				
			Method / Kind  (incl. applica- tion technique ***	Max. number (min. interval between applications)  a) per use b) per crop/ season	Max. applica- tion rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander	
	Cereals  BBCH 21-33	F	Spray	1:1	a) Florasulam 0.005 kg/ha  b) Fluroxypyr 0.060kg/ha  c) Clopyralid 0.060 kg/ha	200 - 400							

\* 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”

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

## Data gaps

N/A

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

## 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)**

	Florasulam	Fluroxypyr	Clopyralid
Common Name	Florasulam	Fluroxypyr	Clopyralid
CAS-No.	145701-23-1	69377-81-7	1702-17-6

	Florasulam	Fluroxypyr	Clopyralid
<b>Classification and proposed labelling</b>			
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<b>Hazard classes (s), categories:</b> Aquatic Chronic 1 Aquatic Acute 1  <b>Code(s) for hazard pictogram(s):</b> GHS09 GHS07  <b>Signal word:</b> Warning  <b>Hazard statement(s):</b> H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects.  <b>Precautionary statement(s):</b> P391 – Collect spillage. P273 – Avoid release to the environment. P501: Dispose of contents/container to...	<b>Hazard classes (s), categories:</b> Aquatic Acute 1 Aquatic Chronic 1  <b>Code(s) for hazard pictogram(s):</b> GHS09  <b>Signal word:</b> Warn- ing  <b>Hazard statement(s):</b> H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects.  <b>Precautionary statement(s):</b> P391 – Collect spill- age. P273 – Avoid release to the environment.	<b>Hazard classes (s), categories:</b> Eye Dam.1 <b>Code(s) for hazard pictogram(s):</b> GHS05  <b>Signal word:</b> Danger  <b>Hazard statement(s):</b> H318 <b>Precautionary statement(s):</b> P280 P305 + P351 + P338 P310
Additional C&L proposal	Not required	Not required	Not required
<b>Agreed EU endpoints</b>			
AOEL systemic	0.05 mg/kg bw/d	0.8 mg/kg bw/d	0.15 mg/kg bw/d
AAOEL systemic	-	-	0.17 mg/kg bw
Reference	EFSA Journal 2015; 13(1), 3984	EFSA Scientific Report (2007) 122, 1-84, Conclusion on the peer review of fluroxypyr	EFSA Journal 2018;16(7):5389
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>			
	Not required	Not required	<b>should pay particular attention to the protection of operators</b>

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for CHR/H/CFF 250 EC 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 CHR/H/CFF 250 EC**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral (calculation method – alternative method)	1831.50 mg/kg bw	Accepted	Acute Tox. 4, H302	(2023)
LD <sub>50</sub> dermal (calculation method – alternative method)	Non determined – no relevant ingredient	Accepted	None	(2023)
LC <sub>50</sub> inhalation (calculation method – alternative method)	Non determined – no relevant ingredient	Accepted	None	(2023)
Skin irritation, (calculation method)	Irritant	Accepted	Skin Irrit. 2, H315	(2023)
Eye irritation, (calculation method)	Corrosive	Accepted	Eye Dam. 1, H318	(2023)
Aspiration Toxicity (calculation method – alternative method)	Classified	Accepted	Asp. Tox. 1, H304	(2023)
Supplementary studies for combinations of plant protection products	No data – not required			

**Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/H/CFF 250 EC**

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Clopyralid (≥ 10% (w/w))	Eye Dam. 1, H318 (criteria ≥ 3 %)	Annex IV of Reg. 1272/2008	Eye Dam. 1, H318
Toxicological properties of non-active substance(s) (relevant for classification of product)	1-Butylpyrrolidin-2-one (> 10% (w/w))	Skin Irrit. 2, H315 (criteria ≥ 10 %)	MSDS	Skin Irrit. 2, H315
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

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

### 6.4.1 ASTCA

An overview of the results of the accepted toxicological studies for groundwater metabolite ASTCA is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

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

Type of test, species (Guide-line)	Result	Acceptability	Reference*
Salmonella Escherichia coli/ Mammalian – microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with ASTCA Metabolite of Florasulam (OECD 471 & 472)	Non-genotoxic	Accepted	[REDACTED] (13 March 2008)
Evaluation of Florasulam ASTCA Metabolite In The Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (CHO/HGPRT) Forward Mutation Assay. (OECD 476)	Non-genotoxic	Accepted	[REDACTED] (30 April 2008)
Evaluation Of Florasulam ASTCA Metabolite In An In Vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes (OECD 473)	Non-genotoxic	Accepted	[REDACTED] (2008)

\* indicates that a study was reviewed at EU level

### 6.4.2 TSA

An overview of the results of the accepted toxicological studies for groundwater metabolite TSA is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

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

Type of test, species (Guideline)	Result	Acceptability	Reference*
Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using Salmonella typhimurium. (OECD 471)	Non-genotoxic	Accepted	██████████. (2011)
In vitro Mammalian Cell Gene Forward Mutation Test at the HGPRT Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam. (OECD 476)	Non-mutagenic	Accepted	██████████ (2011)
In vitro Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peripheral Blood Lymphocytes. (OECD 473)	Non-genotoxic	Accepted	██████████ (2011)

\* indicates that a study was reviewed at EU level

#### 6.4.3 5-OH-Florasulam

An overview of the results of the accepted toxicological studies for groundwater metabolite 5-OH-Florasulam is given in the following table. Full summaries of studies on the metabolite that have not previously been considered within an EU peer review process are described in detail in Appendix 2 (A 2.11 Other/Special Studies).

**Table 6.4-3: Summary of the results of toxicity studies for 5-OH Florasulam**

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute Oral Toxicity (OECD 401)	> 5000 mg	Accepted	
Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using Salmonella typhimurium. (OECD 471)	Non-genotoxic	Accepted	██████████ (2011)
In vitro Mammalian Cell Gene Forward Mutation Test at the HGPRT Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam. (OECD 476)	Non-mutagenic	Accepted	██████████ (2011)
In vitro Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peripheral Blood Lymphocytes. (OECD 473)	Non-genotoxic	Accepted	██████████ (2011)

\* indicates that a study was reviewed at EU level

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/H/CFF 250 EC are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in CHR/H/CFF 250 EC**

	Florasulam		Fluroxypyr		Clopyralid	
	Value	Reference	Value	Reference	Value	Reference
Concentrate	70% (nominal content of florasulam in CHR/H/CFF 250 EC is 10 g/L and therefore this active substance should be treat like dilution.)	Guidance on Dermal Absorption EFSA, EFSA Journal 2017;15(6):4873	25%	Guidance on Dermal Absorption EFSA, EFSA Journal 2017;15(6):4873	25%	Guidance on Dermal Absorption EFSA, EFSA Journal 2017;15(6):4873
Dilution	70%		70%		70%	

### 6.5.1 Justification for proposed values - florasulam

No data on dermal absorption for florasulam in CHR/H/CFF 250 EC is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

**Table 6.5-2: Default dermal absorption rates for florasulam**

	Value	Justification for value	Acceptability of justification
Concentrate	70%	A default dermal absorption value of 70% may be applied for concentrated products that are oil-based/dispersed formulation, because nominal content of florasulam in CHR/H/CFF 250 EC is 10 g/L and therefore this active substance should be treat like dilution.	Accepted
Dilution	70%	A default dermal absorption value of 70% may be applied for (in use) dilutions oil-based/dispersed formulation	Accepted

### 6.5.2 Justification for proposed values – fluroxypyr

No data on dermal absorption for fluroxypyr in CHR/H/CFF 250 EC 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 fluroxypyr**

	Value	Justification for value	Acceptability of justification
Concentrate	25%	A default dermal absorption value of 25% may be applied for concentrated products that are oil-based/dispersed formulation	Accepted
Dilution	70%	A default dermal absorption value of 70% may be applied for (in use) dilutions oil-based/dispersed formulation	Accepted

### 6.5.3 Justification for proposed values - Clopyralid

No data on dermal absorption for clopyralid in CHR/H/CFF 250 EC is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) are presented in the following table.

**Table 6.5-4: Default dermal absorption rates for clopyralid**

	Value	Justification for value	Acceptability of justification
Concentrate	25%	A default dermal absorption value of 25% may be applied for concentrated products that are oil-based/dispersed formulation	Accepted
Dilution	70%	A default dermal absorption value of 70% may be applied for (in use) dilutions oil-based/dispersed formulation	Accepted

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

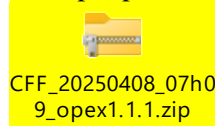
**Table 6.6-1: Product information and toxicological reference values used for exposure assessment**

Product name and code	CHR/H/CFF 250 EC		
Formulation type	SC		
Category	Herbicide		
Active substance(s) (incl. content)	<b>Florasulam</b> 12 g/L	<b>Fluroxypyr</b> 250 g/L	<b>Clopyralid</b> 312 g/L
AOEL systemic	0.05 mg/kg bw/d	0.8 mg/kg bw/d	0.15 mg/kg bw/d
AAOEL systemic	-	-	0.17
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	100%
Dermal absorption	Concentrate: 50 % Dilution: 50 %	Concentrate: 10 % Dilution: 50 %	Concentrate: 10 % Dilution: 50 %

### 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.

All input parameters can be check using Zip File for OPEX 1.1.1 program.



### 6.6.2 Operator exposure (KCP 7.2.1)

#### 6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of CHR/H/CFF 250 EC 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 (acute exposure and longer term exposure). Detailed calculations are in 0.

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

Critical use(s)	CHR/H/CFF 250 EC (max. 0.5 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

		Florasulam		Fluroxypyr		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.5 L prod./ha							
“EFSA Model” version 30.03.2015	no PPE*	0.0360834	72.17	0.0883156	11.04	0.0883156	58.88
	+ type of PPE (e.g. Gloves + work wear during mixing/loading)	0.0009311	<b>1.86</b>	0.0052571	<b>0.66</b>	0.0052571	<b>3.50</b>

		Florasulam		Fluroxypyr		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.5 L prod./ha							
<b>“EFSA Model” version 30.03.2015</b>	no PPE*	-	-	-	-	0.6666649	392.16
	+ type of PPE (e.g. Gloves + work wear during mixing/loading)	-	-	-	-	0.0680199	<b>40.01</b>

**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),**

Critical use(s)	CHR/H/CFF 250 EC (max. 0.5 L product/ha)
Model(s)	OPEX v.1.1.1

		Florasulam		Fluroxypyr		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops							

Application rate: 0.5 L prod./ha							
<b>OPEX</b> <b>1.1.1</b>	no PPE*	0.04	79.9	0.08	9.4	0.08	50.1
	+ type of PPE (e.g. Gloves + work wear during mixing/loading)	0.001	2.6	0.007	0.9	0.007	4.7

**Table 6.6-7: Estimated operator exposure (acute exposure)**

		Florasulam		Fluroxypyr		Clopyralid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops Application rate: 0.5 L prod./ha							
OPEX 1.1.1	no PPE*	-	-	-	-	0.3	188
	+ type of PPE (e.g. Gloves + work wear during mixing/loading)	-	-	-	-	0.08	46.1

**ACCEPTED: 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).**

### 6.6.2.2 Measurement of operator exposure

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

## 6.6.3 Worker exposure (KCP 7.2.3)

### 6.6.3.1 Estimation of worker exposure

Table 6.6-8 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with CHR/H/CFF 250 EC according to the critical use(s). Outcome of the estimation is presented in Table 6.6-9. Detailed calculations are in 0.

**Table 6.6-8: Exposure models for intended uses**

Critical use(s)	CHR/H/CFF 250 EC (max. 0.5 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 6.6-9: Estimated worker exposure**

		Florasulam		Fluroxypyr		Clopyralid	
Model data	Level of PPE	Total ab- sorbed dose (mg/kg/day)	% of sys- temic AOEL	Total ab- sorbed dose (mg/kg/day)	% of sys- temic AOEL	Total ab- sorbed dose (mg/kg/day)	% of sys- temic AOEL
Number of applications and application rate:		0.005 kg a.s./ha		0.06 kg a.s./ha		0.06 kg a.s. / ha	
8 hours/day <sup>(1)</sup> , TC: 0.25 cm²/person/h <sup>(2)</sup> Body weight: 60 kg	no PPE <sup>(3)</sup>	0.004375	8.75	0.0525	6.56	0.0525	35.00
	with PPE <sup>(4)</sup>	0.00049	<b>0.98</b>	0.00588	<b>0.74</b>	0.00588	<b>3.92</b>

According to Guidance on Pesticides Exposure Assessment of Operators, Workers, Residents and Bystanders, (EFSA Journal 2014;12(10):3874) to the calculation used the value of 2500 transfer coefficient (TC (cm<sup>2</sup>/h) arms, body and legs covered - workwear; bare hands) and 8 hours work/day (only crop inspection and irrigation-type). Having regard to the above values, the predicted exposure values for CHR/H/PENDIF without PPP are above 100% of systemic AOEL and therefore exposure of the worker with using PPP is acceptable

**Table 6.6-10: Exposure models for intended uses**

Critical use(s)	CHR/H/CFF 250 EC (max. 0.5 L product/ha)
Model	OPEX 1.1.1

**Table 6.6-11: Estimated worker exposure**

		Florasulam		Fluroxypyr		Clopyralid	
Model data	Level of PPE	Total ab- sorbed dose (mg/kg/day)	% of sys- temic AOEL	Total ab- sorbed dose (mg/kg/day)	% of sys- temic AOEL	Total ab- sorbed dose (mg/kg/day)	% of sys- temic AOEL
Number of applications and application rate:		0.005 kg a.s./ha		0.06 kg a.s./ha		0.06 kg a.s. / ha	
8 hours/day <sup>(1)</sup> , TC: 0.25 cm <sup>2</sup> /person/h <sup>(2)</sup> Body weight: 60 kg	no PPE <sup>(3)</sup>	0.004	8.8	0.05	6.6	0.05	35
	with PPE <sup>(4)</sup>	0.0005	0.9	0.006	0.7	0.006	3.9

**ACCEPTED:** the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE

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

Not required

### 6.6.3.3 Measurement of worker exposure

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

## 6.6.4 Resident and bystander exposure (KCP 7.2.2)

### 6.6.4.1 Estimation of resident and bystander exposure

Table 6.6.-8 shows the exposure model(s) used for estimation of bystander and resident exposure to florasulam, fluroxypyr and clopyralid. Outcome of the estimation is presented in 9. Detailed calculations are in 0.

Calculation for bystander for florasulam and fluroxypyr is covered by calculation for resident, because of lack AAOEL value for those two active substances.

**Table 6.6-12: Exposure models for intended uses**

Critical use(s)	CHR/H/CFF 250 EC (max.0.5L product/ha)
Model	“EFSA Model” version 30.03.2015

**Table 6.6-13: Estimated resident exposure (longer term exposure)**

	Florasulam		Fluroxypyr		Clopyralid	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 0.5 L prod./ha						
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0005625	1.12	0.00422	0.53	0.0039375	2.32
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0018399	3.68	0.0103092	1.29	0.0070875	4.17

Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0005625	1.12	0.00422	0.53	0.00422	2.81
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0018399	3.68	0.0103092	1.29	0.0103092	6.87

**The resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for florasulam, fluroxypyr and clopyralid will not be exceeded under conditions of intended uses.**

**Table 6.6-14: Exposure models for intended uses**

Critical use(s)	CHR/H/CFF 250 EC (max.0.5L product/ha)
Model	OPEX 1.1.1

**Table 6.6-15: Estimated resident exposure (longer term exposure)**

	Florasulam		Fluroxypyr		Clopyralid	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops Application rate: 0.5 L prod./ha						
Bystanders (adult) Drift rate: 0 % (2-3 m) Body weight: 60 kg	0.0006	1.2	0.004	0.5	0.004	2.3
Bystanders (children) Drift rate: 0 % (2-3 m) Body weight: 10 kg	0.002	3.1	0.009	1.2	0.007	4.2
Residents (adult) Drift rate: 0 % (2-3 m) Body weight: 60 kg	0.0006	1.2	0.004	0.5	0.004	2.7

Residents (children) Drift rate: 0 % (2-3 m) Body weight: 10 kg	0.002	3.1	0.009	1.2	0.009	6.2
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**ACCEPTED: the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for florasulam, fluroxypyr and clopyralid will not be exceeded under conditions of intended uses**

#### 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 florasulam, fluroxypyr and clopyralid will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

#### 6.6.5 Combined exposure

The product is a mixture of three active substances.

##### 6.6.5.1 Exposure assessment of florasulam, fluroxypyr and clopyralid in CHR/H/CFF 250 EC

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

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

**Table 6.6-16: Risk assessment from combined exposure**

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Operators –with PPE (glove + work wear during mix/loading)	Florasulam	0.0186
	Fluroxypyr	0.0066
	Clopyralid	0.0350
	<b>Cumulative risk operators (HI)</b>	<b>0.0602</b>
Workers – with PPE	Florasulam	0.0098
	Fluroxypyr	0.0074
	Clopyralid	0.0392

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
	<b>Cumulative risk workers (HI)</b>	<b>0.0564</b>
Bystander child	Florasulam	0.0368
	Fluroxypyr	0.0129
	Clopyralid	0.0417
	<b>Cumulative risk bystander – child (HI)</b>	<b>0.0914</b>
Bystander adult	Florasulam	0.0112
	Fluroxypyr	0.0053
	Clopyralid	0.0232
	<b>Cumulative risk bystander – adult (HI)</b>	<b>0.0397</b>
Resident child	Florasulam	0.0368
	Fluroxypyr	0.0129
	Clopyralid	0.0687
	<b>Cumulative risk bystander – child (HI)</b>	<b>0.1184</b>
Resident adult	Florasulam	0.0112
	Fluroxypyr	0.0053
	Clopyralid	0.0281
	<b>Cumulative risk bystander – adult (HI)</b>	<b>0.0446</b>

The Hazard Index is < 1. Thus, combined exposure to all active substances in CHR/H/CFF 250 EC is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

**Table 6.6-17: Risk assessment from combined exposure by OPEX 1.1.1**

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Operators –with PPE (glove + work wear during mix/loading)	Florasulam	0.026
	Fluroxypyr	0.009
	Clopyralid	0.047
	<b>Cumulative risk operators (HI)</b>	<b>0.082</b>
Workers – with PPE	Florasulam	0.009
	Fluroxypyr	0.007
	Clopyralid	0.039
	<b>Cumulative risk workers (HI)</b>	<b>0.055</b>
Bystander child	Florasulam	0.031
	Fluroxypyr	0.012
	Clopyralid	0.042
	<b>Cumulative risk bystander – child (HI)</b>	<b>0.085</b>

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Bystander adult	Florasulam	0.012
	Fluroxypyr	0.005
	Clopyralid	0.023
	Cumulative risk bystander – adult (HI)	0.04
Resident child	Florasulam	0.031
	Fluroxypyr	0.012
	Clopyralid	0.062
	Cumulative risk bystander – child (HI)	0.105
Resident adult	Florasulam	0.012
	Fluroxypyr	0.005
	Clopyralid	0.027
	Cumulative risk bystander – adult (HI)	0.044

**ACCEPTED:** the Hazard Index is < 1. Thus, combined exposure to all active substances in CHR/H/CFF 250 EC is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required

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

Tables considered not relevant can be deleted as appropriate.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.1 KCP 7.1.7	I. Muchewicz	2023	Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health hazards of constituent substances; Chemirol Sp. z o.o. Non GLP Unpublished	N	Chemirol Sp. z o.o.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7 /01	██████████	2008	Salmonella Escherichia coli/ Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with ASTCA Metabolite of Florasulam Covance Laboratories Inc	Y	DAS

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			DAS Report No.: 071120 (Accession Number) 257169 GLP/GEP (Y/N): Y Published: N		
KCP 7/02		2008	Evaluation of Florasulam ASTCA Metabolite in the Chinese Hamster ovary Ell/hypoxanthine-guanine-phosphoribosyl Transferase (cho/hgprt) Forward Mutation Assay Toxicology & Environmental Research and Consulting DAS Report No.: 071133 (Accession Number) 25174 GLP/GEP: Y Published: N	Y	DAS
KCP 7/03		2008	Evaluation of Florasulam ASTCA Metabolite in an in vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes Toxicology & Environmental Research and Consulting DAS Report No.: 071132 (Accession Number) 257142 GLP/GEP: Y Published: No	Y	DAS
KCP 7/04		2011	Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using Salmonella typhimurium Jai Research Foundation DAS Report No.: 110432 (Accession Number) 2010127 GLP: Y Published: N	Y	DAS
KCP 7/05		2011	In vitro Mammalian Cell Gene Forward Mutation Test at the hgprt Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam JAI Research Foundation DAS Report No: 110430 (Accession Number) 2010107 GLP/GEP: Y Published: N	Y	DAS
KCP 7/06		2011	In vitro Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peri Blood Lymphocytes Jai Research Foundation DAS Report No: 110431 (Accession Number) 2010112 GLP/GEP: Y	Y	DAS

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Published: N		
KCP 7/07		2011	5-Hydroxy Florasulam: Reverse Mutation Assay "Ames Test" Using Salmonella Typhimurium And Escherichia Coli. Safepharm Laboratories Limited P.O. Box No. 45 DERBY, DE1 2BT, UK GLP Unpublished	N	DAS
KCP 7/08		2011	<b>Evaluation Of 5-Hydroxy-Florasulam In The Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (CHO/HGPRT) Forward Mutation Assay</b> Toxicology & Environmental Research and Consulting The Dow Chemical Company Midland, Michigan 48674 GLP Y	N	DAS
KCP 7/09		2011	<b>Evaluation Of 5-Hydroxy-Florasulam In An <i>In Vitro</i> Chromosomal Aberration Assay Utilizing Rat Lymphocytes</b> Toxicology & Environmental Research and Consulting The Dow Chemical Company Midland, Michigan 48674 GLP Y	N	DAS
KCP 7/10	-	2011	<b>5-Hydroxy-Florasulam: Acute oral toxicity study in Fischer 344 Rats</b> GLP Y	Y	DAS

The following tables are to be completed by MS

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

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

Not required.

### A 2.2 Acute oral toxicity (KCP 7.1.1)

Reference: KCP 7.1.1

Report Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health hazards of constituent substances; [REDACTED]

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

Deviations: -

GLP: No

Acceptability:

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

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

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

Due to the fact, that all components of the formulation CHR/H/CFF 250 EC are known, the acute oral toxicity test is not necessary.

We use the summation method using the formula:

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

Where:

- $C_i$  - concentration of ingredient  $i$  ( % w/w or % v/v)
- $i$  – the individual ingredient from 1 to  $n$
- $n$  – the number of ingredients
- $ATE_i$  - Acute Toxicity Estimate of ingredient  $i$ .

We use the table:

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

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	1,5

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

Only one ingredient is relevant in this class of hazard:

- 27.3 % (Acute Tox. 4, H302)

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

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}} = \frac{100}{\frac{27.3}{500}} = \frac{100}{0.0546} = 1831.50 \frac{mg}{kg \text{ bw}}$$

The result 1831.50 mg/kg bw is lower than result triggering the classification (2000 mg/kg bw). Therefore the whole formulation is not classified this this hazard class, **Acute Tox. 4, H302.**

## Conclusion

**According to calculation method, the result 1831.50 mg/kg bw lower than result triggering classification. Therefore the formulation is classified as Acute Tox. 4, H302.**

According to point 7.1.1 of part A of Annex Regulation No 284/2014, it is possible to waive from performing acute oral toxicity tests.

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

**No relevant ingredients classified in this class of hazard.**

### A 2.4 Acute inhalation toxicity (KCP 7.1.3)

**No relevant ingredients classified in this class of hazard.**

### A 2.5 Skin irritation (KCP 7.1.4)

Reference: KCP 7.1.4

Report Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health hazards of constituent substances; [REDACTED]

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

Deviations: -

GLP: No

Acceptability:

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

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

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

Due to the fact, that all components of the formulation CHR/H/FETEC-PART B 110 EC are known, skin corrosive test is not necessary.

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

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

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

Note

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

Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is < 5 % but the sum of Category 1A+1B+1C ingredients is ≥ 5 % the mixture shall be classified as Skin Corrosive Category 1C.

Three ingredients are relevant in this class of hazard.

- 4.6 % (Skin Irrit. 2, H315)
- 2.8 % (Skin Irrit. 2, H315)
- 27.3 % (Skin Irrit. 2, H315)

$$C_{Skin\ Irrit.} = 4.6 \% + 2.8 \% + 27.3 \% = 34.7 \%$$

The result (34.7 %) is higher than result triggering eye hazard classification (10 %). Therefore the whole formulation is classified as **Skin Irrit. 2, H315**.

## Conclusion

**According to calculation method, the result 34.7 % is significantly higher than a concentration triggering classification (10%). Therefore the formulation is classified as Skin Irrit. 2, H315.**

## A 2.6 Eye irritation (KCP 7.1.5)

Reference:	KCP 7.1.5
Report	Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health hazards of constituent substances; [REDACTED]
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

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

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

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

Due to the fact, that all components of the formulation CHR/H/CFF 250 EC are known, eye corrosion test is not necessary.

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

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

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

Three ingredients are relevant in this class of hazard.

- 11.1 % (Eye Dam. 1, H318)
- 4.6 % (Eye Dam. 1, H318)
- 2.8 % (Eye Dam. 1, H318)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class.

$$\sum C_{SkinCorr.} + \sum C_{EyeDam} = 11.1 \% + 4.6 \% + 2.8 \% = 18.5 \%$$

The result (18.5 %) is higher than result triggering eye hazard classification (3 %).

## Conclusion

**According to calculation method, the result 18.5 % is significantly higher than a concentration triggering classification (3%). Therefore the whole formulation is classified as corrosive to eyes, Eye Dam. 1, H318.**

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

**No relevant ingredients classified in this class of hazard.**

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

Not required

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

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

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

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

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

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

Not required.

**A 2.11 Other/Special Studies**

**A 2.11.1 Specific target organ toxicity**

Reference:	KCP 7.1.7
Report	Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health hazards of constituent substances; [REDACTED]
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No
Acceptability:	

According to point 3.8.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:  
” Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following single exposure.  
Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively”

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

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

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

Note 1

If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration

≥ 1,0 % a SDS shall be available for the mixture upon request.

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

One ingredient is classified in this class of hazard. However, the concentration of this ingredient (2.8 %) is below concentration triggering STOT SE 3, H335 classification of whole formulation (20%). Therefore, the product is not classified in this class of hazard.

One ingredient is classified in this class of hazard. However, the concentration of this ingredient (2.8 %) is below concentration triggering STOT SE 3, H335 classification of whole formulation (20%). Therefore, the product is not classified in this class of hazard.

#### Conclusions

The concentration of the ingredient (2.8 %) is lower than concentration triggering STOT SE 3, H335 classification of whole formulation (20 %). Therefore the whole product will be not classified as STOT SE 3, H335.

**The concentration of the ingredient (2.8 %) is lower than concentration triggering STOT SE 3, H336 classification of whole formulation (20 %). Therefore the whole product will be not classified as STOT SE 3, H336.**

#### A 2.11.1 Aspiration Toxicity

Reference:	KCP 7.1.7
Report	Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health hazards of constituent substances; [REDACTED]
Guideline(s):	Regulation (EC) No. 1272/2008
Deviations:	-
GLP:	No

#### Acceptability:

According to point 3.10.3.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:

“A mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is  $\geq 10\%$  and the mixture has a kinematic viscosity  $\leq 20,5 \text{ mm}^2/\text{s}$ , measured at  $40^\circ\text{C}$ .”.

CHR/H/CFF 250 EC contains ingredient classified as Asp. Tox. 1, H304 at concentration higher than  $10\%$  ( $G_1 = 26.4\%$ ) and has a kinematic viscosity  $9.427 \text{ mm}^2/\text{s}$  at  $40^\circ\text{C}$

#### Conclusions

**The mixture meets the criteria that classify it as Asp. Tox. 1, H304. Therefore the formulation is classified as Asp. Tox. 1, H304.**

**A 2.12            Operator exposure calculations (KCP 7.2.1.1)**

**A 2.12.1          Calculations for florasulam**

**Table A 1: Estimation of operator exposure towards florasulam using the EFSA Model without PPP**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.005 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.25 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	<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	1671	6047	AOEM	
	Body	1346	48147	AOEM	
	Head	13	71	AOEM	
	Protected hands (gloves)	14	50	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	37	AOEM	
	Protected head (hood and face shield)	0	4	AOEM	
	Inhalation	2	28	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	<b>Exposure values</b>	<b>µg exposure/day applied</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	37	830	AOEM	
	Body	21	107	AOEM	
	Head	1	3	AOEM	
	Protected hands (gloves)	20	2835	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	1	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	



**Table A 2:**            **Estimation of operator exposure towards florasulam using the EFSA Model with gloves at mixing/loading and application and protective clothing at mixing/loading**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.005 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	0.25 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	<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	1671	6047	AOEM	
	Body	1346	48147	AOEM	
	Head	13	71	AOEM	
	Protected hands (gloves)	14	50	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	37	AOEM	
	Protected head (hood and face shield)	0	4	AOEM	
	Inhalation	2	28	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	<b>Exposure values</b>	<b>µg exposure/day applied</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	37	830	AOEM	
	Body	21	107	AOEM	
	Head	1	3	AOEM	
	Protected hands (gloves)	20	2835	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1	1	AOEM	
	Inhalation	1	1	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	

### **A 2.12.2            Calculations for Fluroxypyr**

**Table A 1:            Estimation of operator exposure towards fluroxypyr using the EFSA Model without PPP**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.06 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	3 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	<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	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	AOEM	
	Inhalation	5	29	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	<b>Exposure values</b>	<b>µg exposure/day applied</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	



**Table A 2:**            **Estimation of operator exposure towards fluroxypyr using the EFSA Model with gloves at mixing/loading and application and work wear at mixing/loading**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.06 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	3 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

*OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted*

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	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	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	<b>Exposure values</b>	<b>µg exposure/day applied</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

### **A 2.12.3            Calculations for Clopyralid**

**Table A 1: Estimation of operator exposure towards clopyralid using the EFSA Model without PPP**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.06 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	3 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	<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	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	AOEM	
	Inhalation	5	29	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	<b>Exposure values</b>	<b>µg exposure/day applied</b>		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

**1. Total**

	Without RPE/PPE	With RPE/PPE	

**Table A 2:**            **Estimation of operator exposure towards clopyralid using the EFSA Model with gloves and protective clothing at mixing/loading and gloves at application**

**Operator exposure for outdoor spray applications**

Application rate of active substance	0.06 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	3 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	11315	41864	AOEM	
	Body	7722	99105	AOEM	
	Head	156	854	AOEM	
	Protected hands (gloves)	70	594	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	63	439	AOEM	
	Protected head (hood and face shield)	2	48	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	445	5124	AOEM	
	Body	249	1283	AOEM	
	Head	12	35	AOEM	
	Protected hands (gloves)	77	3789	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	7	17	AOEM	
	Inhalation	2	5	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

## A 2.13 Worker exposure calculations (KCP 7.2.3.1)

### A 2.13.1 Calculations for florasulam

Worker exposure from residues on foliage for				
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	0.005 kg a.s./ha			<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	70.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.015 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)	0.2625000	0.0294000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0043750	0.0004900		
% of RVNAS	8.75%	0.98%		

### A 2.13.2 Calculations for fluroxypyr

Worker exposure from residues on foliage for				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.06 kg a.s./ha			<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	25.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70.00%			<i>i_AbsorpInuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.18 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)	3.1500000	0.3528000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0525000	0.0058800		
% of RVNAS	6.56%	0.74%		

### A 2.13.3 Calculations for clopyralid

Worker exposure from residues on foliage for				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.06 kg a.s./ha			<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	25.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70.00%			<i>i_AbsorpInuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0.18 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)	3.1500000	0.3528000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0525000	0.0058800		
% of RVNAS	35.00%	3.92%		

## A 2.14 Resident and bystander exposure calculations (KCP 7.2.2.1)

### A 2.14.1 Calculations for florasulam

Resident exposure for					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.005 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.025 g a.s./l				
Dermal absorption of product	70.00%				
Dermal absorption of in-use dilution	70.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*_i_DFR)	0.015 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) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	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)		Entry into treated crops (75th percentile)	
Total systemic exposure (mg a.s./day)		0.0046980		0.0059063	
Total systemic exposure per kg body weight (mg a.s./day/kg)		0.0004698		0.0005906	
% of RVNAS		0.94%		1.18%	
1.2 Adult					
Spray drift		Vapour		Entry into treated crops	
Total systemic exposure (mg a.s./day)		0.0067470		0.0196875	
Total systemic exposure per kg body weight (mg a.s./day/kg)		0.0001125		0.0003281	
% of RVNAS		0.22%		0.66%	

#### **A 2.14.2            Calculations for fluroxypyr**

Resident exposure for					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.06 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.3 g a.s./l				
Dermal absorption of product	25.00%				
Dermal absorption of in-use dilution	70.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18 µg a.s./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) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	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)	0.0563754	0.0107000	0.0066024	0.0708750	0.1030919
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0056375	0.0010700	0.0006602	0.0070875	0.0103092
% of RVNAS	0.70%	0.13%	0.08%	0.89%	1.29%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0809640	0.0138000	0.0171696	0.2362500	0.2531992
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0013494	0.0002300	0.0002862	0.0039375	0.0042200
% of RVNAS	0.17%	0.03%	0.04%	0.49%	0.53%

### **A 2.14.3            Calculations for clopyralid**

Resident exposure for					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.06 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.3 g a.s./l				
Dermal absorption of product	25.00%				
Dermal absorption of in-use dilution	70.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18 µg a.s./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) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	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)	0.0563754	0.0107000	0.0066024	0.0708750	0.1030919
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0056375	0.0010700	0.0006602	0.0070875	0.0103092
% of RVNAS	3.76%	0.71%	0.44%	4.73%	6.87%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0809640	0.0138000	0.0171696	0.2362500	0.2531992
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0013494	0.0002300	0.0002862	0.0039375	0.0042200
% of RVNAS	0.90%	0.15%	0.19%	2.63%	2.81%



Bystander exposure for					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Application rate of the product	0.06 kg a.s./ha				i_AppRate
Buffer strip	2-3 m				i_Buffer
Concentration of active substance (in-use dilution for liquid applications)	0.3 g a.s./l				d_ConcAS
Dermal absorption of product	25.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	70.00%				i_AbsorpInuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.18 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
Bystander dermal spray drift exposure - adult	1.21 ml spray dilution/person				
Bystander dermal spray drift exposure - child	0.74 ml spray dilution/person				
Bystander inhal. spray drift exposure - adult	0.00050 ml spray dilution/person				
Bystander inhal. spray drift exposure - child	0.00112 ml spray dilution/person				
Exposure duration	2 hours				d_ByExpDur
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/kg bw/day				d_BreathRAAd
Breathing rate child (1-3 year old)	1.07 m³/kg bw/day				d_BreathRCh
Drift percentage on surface (90th percentile)	8.50%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	14500 cm²/hour				d_ByTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	5200 cm²/hour				d_ByTCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	20 events/hour				d_ByFreqHM
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 - adult	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops - child	2250 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
		Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)		0.1277640	0.0107000	0.0198390	0.0708750
Total systemic exposure per kg body weight (mg/kg bw/day)		0.0127764	0.0010700	0.0019839	0.0070875
% of RVAAS		7.52%	0.63%	1.17%	4.17%
1.2 Adult					
		Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)		0.2085120	0.0138000	0.0517650	0.2362500

## A 2.15 Combined exposure calculations for florasulam, fluroxypyr and clopyralid

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Operators –with PPE (glove + work wear during mix/loading)	Florasulam	0.0186
	Fluroxypyr	0.0066
	Clopyralid	0.0350
	<b>Cumulative risk operators (HI)</b>	<b>0.0602</b>
Workers – with PPE	Florasulam	0.0098
	Fluroxypyr	0.0074
	Clopyralid	0.0392
	<b>Cumulative risk workers (HI)</b>	<b>0.0564</b>
Bystander child	Florasulam	0.0368
	Fluroxypyr	0.0129
	Clopyralid	0.0417
	<b>Cumulative risk bystander – child (HI)</b>	<b>0.0914</b>
Bystander adult	Florasulam	0.0112
	Fluroxypyr	0.0053
	Clopyralid	0.0232
	<b>Cumulative risk bystander – adult (HI)</b>	<b>0.0397</b>
Resident child	Florasulam	0.0368
	Fluroxypyr	0.0129
	Clopyralid	0.0687
	<b>Cumulative risk bystander – child (HI)</b>	<b>0.1184</b>
Resident adult	Florasulam	0.0112
	Fluroxypyr	0.0053

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
	Clopyralid	0.0281
	Cumulative risk bystander – adult (HI)	<b>0.0446</b>

**A 2.16 All Calculation by OPEX v. 1.1.1**

**7 Exposure assessment for operator, worker, resident and bystander**

Product: CFF

OPEX version: 1.1.1

08 April 2025

## 7.1 Information on product and active substance(s)

<b>Product name</b>	<b>CFF</b>
<b>Formulation type</b>	Soluble concentrates, emulsifiable concentrate, etc.
<b>Product category</b>	Herbicide
<b>Name of active substance</b>	clopyralid
<b>Concentration of active substance in product [g a.s./l or kg]</b>	120
<b>AOEL [mg/kg bw per day]</b>	0.15
<b>AAOEL [mg/kg bw]</b>	0.17
<b>Inhalation absorption [%]</b>	100
<b>Oral absorption [%]</b>	100
<b>Dermal absorption [%] (concentrate)</b>	25
<b>Dermal absorption [%] (dilution) NA [g a.s./l or kg]</b>	70
<b>Name of active substance</b>	Fluroxypyr
<b>Concentration of active substance in product [g a.s./l or kg]</b>	120
<b>AOEL [mg/kg bw per day]</b>	0.8
<b>AAOEL [mg/kg bw]</b>	
<b>Inhalation absorption [%]</b>	100
<b>Oral absorption [%]</b>	100
<b>Dermal absorption [%] (concentrate)</b>	25
<b>Dermal absorption [%] (dilution) NA [g a.s./l or kg]</b>	70
<b>Name of active substance</b>	Florasulam
<b>Concentration of active substance in product [g a.s./l or kg]</b>	10
<b>AOEL [mg/kg bw per day]</b>	0.05







AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	70
Dermal absorption [%] (dilution) NA [g a.s./l or kg]	70







## 7.2 Assessed uses

Use	Crops	Max. appli- cation rate of the prod- uct [l or kg/ha]	Unit	Max. no. of appli- cations	Interval be- tween multi- ple ap- plica- tions [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/ out- door	Appli- cation method	Type of cultiva- tion	Appli- cation tech- nique	Buffer strip [m]	Drift reduc- tion [%]
Use 1	Field crops	0.5	l/ha	1	NA	200	300	Outdoor	Down- ward spray- ing	normal	Vehicle- mount- ed	2-3	0

## 7.3 Operator

### 7.3.1 Use 1 : Field crops (Outdoor)

		Short term exposure			
		clopyralid (% AOEL)	Fluroxypyr (% AOEL)	Florasulam (% AOEL)	Combined (hazard index)
Mixing/loading	Application	Normal & vehicle-mounted			
		74.4	14	110	1.99
		50.1	9.4	79.9	1.39
		4.7	0.9	2.6	0.082

		Acute exposure			
		clopyralid (% AOEL)	Fluroxypyr (% AOEL)	Florasulam (% AOEL)	Combined (hazard index)
Mixing/loading	Application	Normal & vehicle-mounted			
		398			3.98
		188			1.88
		46.1			0.461

### 7.3.2 Scenario 1 : Normal, downward spraying, vehicle-mounted

#### 7.3.2.1 Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of sys- temic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0% Crop density: Normal			
clopyralid	Application rate: 1 x 0.06 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.08	50.1
	M/L: Potential exposure App: Potential exposure	0.1	74.4
	Application rate: 1 x 0.06 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
Fluroxypyr	M/L: Workwear App: Workwear	0.08	9.4
	M/L: Potential exposure App: Potential exposure	0.1	14
	Application rate: 1 x 0.005 kg a.s./ha Dermal absorption (concentrate): 70 % Dermal absorption (in-use dilution): 70 %		
Florasulam	M/L: Workwear App: Workwear	0.04	79.9
	Application rate: 1 x 0.005 kg a.s./ha Dermal absorption (concentrate): 70 % Dermal absorption (in-use dilution): 70 %		
Combined exposure			Haz- ard index
MLA: Workwear			1.4
ML: Workwear + Gloves AP: Workwear			0.08

#### 7.3.2.2 Summary data - Acute exposure

Model data	Level of PPE	Total ab- sorbed dose [mg/kg bw]	% of sys- temic AA- OEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0% Crop density: Normal			
clopyralid	Application rate: 1 x 0.06 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AA-OEL
	M/L: Workwear App: Workwear	0.3	No safe use (188)
	M/L: Workwear + Protected hands App: Workwear	0.08	46.1
	Application rate: 1 x 0.06 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
Fluroxypyr	M/L: Workwear App: Workwear		No results!
	M/L: NA + NA + NA App: NA + NA + NA		No results!
	Application rate: 1 x 0.005 kg a.s./ha Dermal absorption (concentrate): 70 % Dermal absorption (in-use dilution): 70 %		
Florasulam	M/L: Workwear App: Workwear		No results!
	M/L: NA + NA + NA App: NA + NA + NA		No results!
Combined exposure			Hazard index
	MLA: Workwear		1.9
	ML: Workwear + Gloves AP: Workwear		0.5

## 7.4 Worker

### 7.4.1 Use 1 : Field crops (Outdoor)

#### 7.4.1.1 Scenario 1 : Inspection, irrigation

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation; Outdoor Work rate: 2 hours/day ; Interval: NA ; Body weight: 60 kg TC (potential): 12500 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered)): 1400 cm <sup>2</sup> /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm <sup>2</sup> /h TC (gloves): NA cm <sup>2</sup> /h			
Application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
Potential	0.05	35	0
Workwear	0.006	3.9	0
Workwear and gloves	0.005	3.5	0
Application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
Potential	0.05	6.6	0
Workwear	0.006	0.7	0
Workwear and gloves	0.005	0.7	0
Application rate: 1 x 0.005 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
Potential	0.004	8.8	0
Workwear	0.0005	1	0
Workwear and gloves	0.0004	0.9	0
Combined		Hazard index	
Potential		0.5	0
Workwear		0.06	0
Workwear and gloves		0.05	0
Hands covered, no workwear			0

## 7.5 Resident

### 7.6 Use 1 : Field crops (Outdoor)

#### 7.6.1 Scenario 1 : Season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 200 l			
<b>clopyralid</b>		Application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.006	3.8
	Vapour (75th perc.)	9e-05	0.06
	Deposits (75th perc.)	0.0007	0.4
	Re-entry (75th perc.)	0.007	4.7
	Sum (mean)	0.009	6.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.001	0.9
	Vapour (75th perc.)	3e-05	0.02
	Deposits (75th perc.)	0.0003	0.2
	Re-entry (75th perc.)	0.004	2.6
	Sum (mean)	0.004	2.7
<b>Fluroxypyr</b>		Application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.006	0.7
	Vapour (75th perc.)	3e-07	4e-05
	Deposits (75th perc.)	0.0007	0.08
	Re-entry (75th perc.)	0.007	0.9
	Sum (mean)	0.009	1.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.001	0.2
	Vapour (75th perc.)	1e-07	1e-05
	Deposits (75th perc.)	0.0003	0.04
	Re-entry (75th perc.)	0.004	0.5
	Sum (mean)	0.004	0.5
<b>Florasulam</b>		Application rate: 1 x 0.005 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0005	0.9
	Vapour (75th perc.)	0.0008	1.6

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident adult Body weight: 60 kg	Deposits (75th perc.)	6e-05	0.1
	Re-entry (75th perc.)	0.0006	1.2
	Sum (mean)	0.002	3.1
	Drift (75th perc.)	0.0001	0.2
	Vapour (75th perc.)	0.0003	0.5
	Deposits (75th perc.)	2e-05	0.05
	Re-entry (75th perc.)	0.0003	0.7
	Sum (mean)	0.0006	1.2
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.05
	Vapour (75th perc.)		0.02
	Deposits (75th perc.)		0.006
	Re-entry (75th perc.)		0.07
	Sum (mean)		0.1
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.01
	Vapour (75th perc.)		0.006
	Deposits (75th perc.)		0.003
	Re-entry (75th perc.)		0.04
	Sum (mean)		0.04

## 7.7 Bystander

### 7.8 Use 1 : Field crops (Outdoor)

#### 7.8.1 Scenario 1 : Outdoor, season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 200 l			
<b>clopyralid</b>		Application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.01	7.5
	Vapour (95th perc.)	9e-05	0.05
	Deposits (95th perc.)	0.002	1.2
	Re-entry (95th perc.)	0.007	4.2
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.003	2
	Vapour (95th perc.)	3e-05	0.02
	Deposits (95th perc.)	0.0009	0.5
	Re-entry (95th perc.)	0.004	2.3
<b>Fluroxypyr</b>		Application rate: 1 x 0.06 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.01	NA
	Vapour (95th perc.)	3e-07	NA
	Deposits (95th perc.)	0.002	NA
	Re-entry (95th perc.)	0.007	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.003	NA
	Vapour (95th perc.)	1e-07	NA
	Deposits (95th perc.)	0.0009	NA
	Re-entry (95th perc.)	0.004	NA
<b>Florasulam</b>		Application rate: 1 x 0.005 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.001	NA
	Vapour (95th perc.)	0.0008	NA
	Deposits (95th perc.)	0.0002	NA
	Re-entry (95th perc.)	0.0006	NA
Bystander adult	Drift (95th perc.)	0.0003	NA

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Body weight: 60 kg	Vapour (95th perc.)	0.0003	NA
	Deposits (95th perc.)	7e-05	NA
	Re-entry (95th perc.)	0.0003	NA
Combined exposure			Hazard index
Bystander child Body weight: 10 kg	Drift (95th perc.)		0.08
	Vapour (95th perc.)		0.0005
	Deposits (95th perc.)		0.01
	Re-entry (95th perc.)		0.04
Bystander adult Body weight: 60 kg	Drift (95th perc.)		0.02
	Vapour (95th perc.)		0.0002
	Deposits (95th perc.)		0.005
	Re-entry (95th perc.)		0.02

## 7.9 Appendix

### 7.10 Operator

#### 7.10.1 Use 1 : Field crops (Outdoor)

##### 7.10.1.1 Scenario 1 : Normal, downward spraying, vehicle-mounted, drift reduction 0 %

###### Clopyralid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	clopyralid
Concentration of active substance in product [g a.s./l or kg]	120	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	25	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	70	Indoor/ outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw per day]	0.15		
AAOEL [mg/kg bw]	0.17		

Clopyralid , Per body part - Short term exposure			
Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	68.4	68.4
	Body protection	Workwear	None
	Body exposure	0.4	34.1
	Head protection	None	None
	Head exposure	0.8	0.8
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	5.2	5.2
	Body protection	Workwear	None
	Body exposure	0.08	2.9
	Head protection	None	None
	Head exposure	0.1	0.1
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.08	0.1
	% of AOEL	50.1	74.4

Clopyralid , Per body part - Acute exposure			
Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	Protected hands
	Hands exposure	251	9.8
	Body protection	Workwear	Workwear
	Body exposure	3.3	3.3
	Head protection	None	None
	Head exposure	4.8	4.8
	Inhalation protection	None	None
	Inhalation exposure	0.2	0.2
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	59.6	59.6
	Body protection	Workwear	Workwear
	Body exposure	0.2	0.2
	Head protection	None	None
	Head exposure	0.4	0.4
	Inhalation protection	None	None
	Inhalation exposure	0.09	0.09
Total	Total systemic exposure [mg/kg bw per day]	0.3	0.08
	% of AAOEL	188	46.1

Fluroxypyr , Input Data			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Fluroxypyr
Concentration of active substance in product [g a.s./l or kg]	120	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	25	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	70	Indoor/ outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw per day]	0.8		
AAOEL [mg/kg bw]			

Fluroxypyr , Per body part - Short term exposure			
Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	68.4	68.4
	Body protection	Workwear	None
	Body exposure	0.4	34.1
	Head protection	None	None
	Head exposure	0.8	0.8
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	5.2	5.2
	Body protection	Workwear	None
	Body exposure	0.08	2.9
	Head protection	None	None
	Head exposure	0.1	0.1
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.08	0.1
	% of AOEL	9.4	14

Florasulam , Input Data			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Florasulam
Concentration of active substance in product [g a.s./l or kg]	10	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	70	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	70	Indoor/ outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw per day]	0.05		
AAOEL [mg/kg bw]			

Florasulam , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	39.1	39.1
	Body protection	Workwear	Workwear
	Body exposure	0.2	0.2
	Head protection	None	None
	Head exposure	0.2	0.2
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	0.4	0.4
	Body protection	Workwear	Workwear
	Body exposure	0.007	0.007
	Head protection	None	None
	Head exposure	0.01	0.01
	Inhalation protection	None	None
	Inhalation exposure	0.009	0.009
Total	Total systemic exposure [mg/kg bw per day]	0.04	0.04
	% of AOEL	79.9	79.9

## 7.11 Worker

### 7.11.1 : Field crops (Outdoor)

#### 7.11.1.1 Scenario 1 : Inspection, irrigation, na

##### Clopyralid , Input data

Indoor/ outdoor	Outdoor	AOEL [mg/kg bw per day]	0.15
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.5	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	clopyralid		
Dermal absorption [%] (dilution)	70		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Clopyralid , Exposure per body part					
Exposure route	Description	Potential	Work-wear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	3.2	0.4	0.3	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	3.2	0.4	0.3	NA
	Total systemic exposure [mg/kg bw per day]	0.05	0.006	0.005	NA
	% of AOEL	35	3.9	3.5	NA

Fluroxypyr , Input data			
Indoor/ outdoor	Outdoor	AOEL [mg/kg bw per day]	0.8
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.5	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	Fluroxypyr		
Dermal absorption [%] (dilution)	70		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Fluroxypyr , Exposure per body part					
Exposure route	Description	Potential	Work-wear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	3.2	0.4	0.3	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	3.2	0.4	0.3	NA
	Total systemic exposure [mg/kg bw per day]	0.05	0.006	0.005	NA
	% of AOEL	6.6	0.7	0.7	NA

Florasulam , Input data			
Indoor/ outdoor	Outdoor	AOEL [mg/kg bw per day]	0.05
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.5	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	Florasulam		
Dermal absorption [%] (dilution)	70		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Florasulam , Exposure per body part					
Exposure route	Description	Potential	Work-wear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	0.3	0.03	0.03	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	0.3	0.03	0.03	NA
	Total systemic exposure [mg/kg bw per day]	0.004	0.0005	0.0004	NA
	% of AOEL	8.8	1	0.9	NA

### **Appendix 3    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)**