

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: FLD-HER 306 SE

Product name: Konik 306 SE

Chemical active substances:

2,4-D, 300 g/L  
florasulam, 6.25 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

v.2

Applicant:

Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k.

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on FLD-HER 306 SE \***



Product name and code	FLD-HER 306 SE
Formulation type	Suspo-emulsion [Code: SE]
Active substance(s) (incl. content)	2,4-D; 300 g/L and Florasulam; 6.25 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 FLD-HER 306 SE 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 FLD-HER 306 SE according to Regulation (EC) No 1272/2008**

Hazard classes, categories	Acute Tox. 4, H302 Acute Tox. 4, H332 Eye Dam. 1, H318 Skin Sens. 1, H317
Hazard pictograms or Codes for hazard pictograms	  GHS05 GHS07
Signal word	Danger
Hazard statements	H302 - Harmful if swallowed. H332 - Harmful if inhaled. H318 - Causes serious eye damage. H317 - May cause an allergic skin reaction.
Precautionary statements	P261 - Avoid breathing dust/fume/gas/mist/vapours/ spray.. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water with soap. 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. P333+P313 - If skin irritation or rash occurs: Get medical advice or attention.
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 2,4-D 2EHE (CAS No. 1928-43-4). May produce an allergic reaction. [EUH208]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for FLD-HER 306 SE**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application.
Workers	Acceptable	Work wear (arms, body and legs covered). Protective gloves are recommended.
Residents	Acceptable	Buffer zone min. 5 m from residential buildings/habitats and bystanders should be applied.
Bystanders	Acceptable	Buffer zone min. 5 m from residential buildings/habitats and bystanders should be applied.

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

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

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

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, 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 [Exposure model]	Acceptability of exposure as- sessment			
			Method / Kind  (incl. applica- tion technique ***	Max. number (min. interval between applications)  a) per use b) per crop/ season	Max. applica- tion rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1	<u>Spring cereals</u> Spring wheat Spring triticale Spring barley Oat (BBCH 12-32)	F	Spraying, LCTM	a) 1 b) 1	a) 0.18 kg 2,4-D b) 0.00375 kg florasulam	200 – 300 L/ha	-	<u>Operators</u> (EFSA model AOEM), <u>workers</u> [EFSA model AOEM, EUROPOEM II re- entry model], <u>resi- dents and bystanders</u> [EFSA model AOEM, German bystander and resi- dent model, EUROPOEM II MODEL bystander exposure]				
2	<u>Winter cereals</u> Winter wheat Winter triticale Winter barley Rye (BBCH 21-32)	F	Spraying, LCTM	a) 1 b) 1	a) 0.18 kg 2,4-D b) 0.00375 kg florasulam	200 – 300 L/ha	-					
3	<u>Cereals</u> Maize (BBCH 12-16)	F	Spraying, LCTM	a) 1 b) 1	a) 0.18 kg 2,4-D b) 0.00375 kg florasulam	200 – 300 L/ha	-					

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor

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

Explanation for column 10 "Acceptability of exposure assessment"

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

## Data gaps

No data gaps

## 6.2 Toxicological Information on Active Substances

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 substances**

	<b>2,4-D</b>	<b>florasulam</b>
Common Name	2,4-D	florasulam
CAS-No.	94-75-7	145701-23-1
<b>Classification and proposed labelling</b>		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: Acute Tox. 4, H302 Eye Dam. 1, H318 Skin Sens. 1, H317 STOS SE 3 H335 Code(s) for hazard pictograms: GHS05 GHS 07 Signal word: Danger Hazard statements: H302 Harmful if swallowed H318 Causes serious eye damage H317 May cause an allergic skin reaction H335 May cause respiratory irritation Precautionary statement(s): -	Hazard classes (s), categories: none Code(s) for hazard pictogram(s): none Signal word: none Hazard statement(s): none Precautionary statement(s): none
Additional C&L proposal	NR	NR
<b>Agreed EU endpoints</b>		
AOEL systemic	0.02 mg/kg bw/d	0.05 mg/kg bw/d
Reference	EFSA Journal 2014;12(9):3812	EFSA Journal 2015; 13(1):3984
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>		
According to Commission Implementing Regulation (EU)	<i>Commission Implementing Regulation (EU) 2015/2033:</i> In this overall assessment Member States shall pay particular attention to the risk to consumers in cases of uses above 750 g/ha.	<i>Commission Implementing Regulation (EU) 2015/1397:</i> None.

	<b>2,4-D</b>	<b>florasulam</b>
According to EFSA Journal	<p><i>EFSA Journal 2014;12(9):3812:</i> 2,4-D is not classified or proposed to be classified as carcinogenic category 2 or toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. However, adverse effects on endocrine organs have been observed in apical studies that may be endocrine-mediated, which should be further clarified to assess their relevance on the developing offspring.</p> <p>The batches used in the key toxicological and ecotoxicological studies do not fully support the currently proposed technical specifications as it appears that some impurities have not been tested at an appropriate level.</p>	<p><i>EFSA Journal 2015; 13(1):3984:</i> No critical areas of concerns were identified.</p>

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for FLD-HER 306 SE is given in the following tables. No studies submitted with this application. Classification based on composition of the product.

**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for FLD-HER 306 SE**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat (OECD xxx)	Estimation based on composition of the product (additivity formula)	Acceptable	Acute Tox. 4, H302 Harmful if swallowed.	-
LD <sub>50</sub> dermal, rat (OECD xxx)	Estimation based on composition of the product (additivity formula)	Acceptable	None.	-
LC <sub>50</sub> inhalation, rat (OECD xxx)	Estimation based on composition of the product (additivity formula)	Acceptable	Acute Tox. 4, H332 Harmful if inhaled.	-
Skin irritation, model system (OECD xxx)	Estimation based on composition of the product (additivity formula)	Acceptable	None.	-
Eye irritation, model	Estimation based on	Acceptable	Eye Dam. 1, H318	-



system (OECD xxx)	composition of the product (additivity formula)		Causes serious eye damage.	
Skin sensitisation, guinea pig/mouse (OECD xxx, Buehler (xx applications)/M&K/LLNA)	Estimation based on composition of the product	Acceptable	Skin Sens. 1, H317 May cause an allergic skin reaction.	-
Supplementary studies for combinations of plant protection products	-	-	-	-

**Table 6.3-2: Additional toxicological information relevant for classification/labelling of FLD-HER 306 SE**

	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)	2,4-D 2EHE CAS: 1928-43-4 (42.5% (w/w))	Acute Tox. 4, H302 Harmful if swallowed. (Oral (mg/kg bodyweight): 300 < ATE ≤ 2 000)  Acute Tox. 4, H332 Harmful if inhaled. (Dust/mist (mg/l): 1.0 < ATE ≤ 5.0)  Skin Sens. 1, H317 May cause an allergic skin reaction. (criteria ≥ 0.1 %)	Reg. 1272/2008	Acute Tox. 4, H302 Harmful if swallowed.  Acute Tox. 4, H332 Harmful if inhaled.  Skin Sens. 1, H317 May cause an allergic skin reaction.
Toxicological properties of non-active substance(s) (relevant for classification of product)	Alcohols, C12-15, ethoxylated CAS: 68131-39-5, >4% (w/w))*  Ethoxylated polyarylphenol sulfated CAS: 119432-41-6, >4% (w/w))*	Eye Dam. 1, H318 Causes serious eye damage. (criteria ≥ 3%)	Reg. 1272/2008	Eye Dam. 1, H318 Causes serious eye damage.
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

For 2,4-D all metabolites concentrations were predicted to stay below 0.1 µg/L for all scenarios – no groundwater assessment is required.

The  $PEC_{gw}$  for florasulam and its metabolites 5-OH-florasulam and DFP-ASTCA were below the trigger value of 0.1 µg/L for all scenarios.  $PEC_{gw}$  for the metabolites ASTCA and TSA were above 0.1 µg/L but these metabolites are of no toxicological concern so it may be therefore concluded that the threshold of concern 0.75 µg/L is not exceeded.

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in FLD-HER 306 SE are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in FLD-HER 306 SE**

	2,4-D		florasulam	
	Value	Reference	Value	Reference
Concentrate	25%	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption	25%	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption
Dilution	70%	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption	70%	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption

### 6.5.1 Justification for proposed values – 2,4-D

No data on dermal absorption for 2,4-D in FLD-HER 306 SE 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 2,4-D**

	Value	Justification for value	Acceptability of justification
Concentrate	25%	According to EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption a default dermal absorption value of 25% may be applied for concentrated products that are organic solvent-formulated (a) or in other (b) types of formulations.	Acceptable
Dilution	70%	According to EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption a default dermal absorption value of 70% may be applied for (in use) dilutions of organic solventformulated (a) or in other (b) types of formulations.	Acceptable

- (a): Formulation types: emulsifiable concentrate (EC), emulsion, oil in water (EW), suspo-emulsion (SE), dispersible concentrate (DC), oil miscible liquids (OL/OF), oil-based suspension concentrates (OD), emulsion for seed treatment (ES), microemulsion (ME).  
(b): Formulation types: bait concentrate (CB), capsule suspension (CS), gel for direct application (GEL/GD), bait, ready for use (RB), mixture of capsule suspension and suspension concentrate (ZC), seed coated with a pesticide (PS), experimental solution of active substances in solvent (AD).

## 6.5.2 Justification for proposed values - florasulam

No data on dermal absorption for florasulam in FLD-HER 306 SE 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 florasulam**

	Value	Justification for value	Acceptability of justification
Concentrate	25%	According to EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption a default dermal absorption value of 25% may be applied for concentrated products that are organic solvent-formulated (a) or in other (b) types of formulations.	Acceptable
Dilution	70%	According to EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption a default dermal absorption value of 70% may be applied for (in use) dilutions of organic solventformulated (a) or in other (b) types of formulations.	Acceptable

(a): Formulation types: emulsifiable concentrate (EC), emulsion, oil in water (EW), suspo-emulsion (SE), dispersible concentrate (DC), oil miscible liquids (OL/OF), oil-based suspension concentrates (OD), emulsion for seed treatment (ES), microemulsion (ME).

(b): Formulation types: bait concentrate (CB), capsule suspension (CS), gel for direct application (GEL/GD), bait, ready for use (RB), mixture of capsule suspension and suspension concentrate (ZC), seed coated with a pesticide (PS), experimental solution of active substances in solvent (AI).

## 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	FLD-HER 306 SE	
Formulation type	Suspo-emulsion [SE]	
Category	Herbicide	
Active substance(s) (incl. content)	<b>2,4-D</b> 300 g/L	<b>florasulam</b> 6.25 g/L
AOEL systemic	0.02 mg/kg bw/d	0.05 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 25% Dilution: 70% (Default)	Concentrate: 25% Dilution: 70% (Default)

### 6.6.1 Selection of critical use(s) and justification

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

## 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 FLD-HER 306 SE according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-33 (longer term exposure). Detailed calculations are in Appendix 3.

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

Critical uses	Cereals (including maize) (max. 0.6 L product/ha)
Model	EFSA model AOEM (Agricultural Operator Exposure 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 6.6-3: Estimated operator exposure (longer term exposure)**

		2,4-D		florasulam	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted					
Application rate		1 x 0.18 kg a.s./ha		1 x 0.00375 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential exposure	0.2062919	1031.46	0.0107604	21.52
	Work wear (arms, body and legs covered) M/L and A	0.1288731	644.37	0.0060240	12.05
	Work wear (arms, body and legs covered) M/L and A + gloves	0.0056908	<b>28.45</b>	0.0003689	<b>0.74</b>

According to the model calculations, it can be concluded that the risk for the operator using FLD-HER 306 SE (KONIK) on intended uses presented in GAP table is acceptable when operator is equipped with work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application.

**Implication for labelling: P280: Wear protective gloves**

### 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 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with FLD-HER 306 SE according to the critical uses. Outcome of the estimation is presented in Table 6.6-55 (longer term exposure). Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical uses	Cereals (including maize) (max. 0.6 L product/ha)
Model	EFSA model AOEM (Agricultural Operator Exposure 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] EUROPOEM II re-entry model [Hemmen et al (2002) Post-application exposure of workers to pesticides in agriculture. Report of the re-entry working group. EUROPOEM II project. FAIR3 CT96-1406]

**Table 6.6-5: Estimated worker exposure (longer term exposure)**

Model data	Level of PPE	2,4-D		florasulam	
		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day, DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: NA					
EFSA model AOEM					
Number of applications and application rate		1 x 0.18 kg a.s./ha		1 x 0.00375 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.1575000	787.50	0.0032813	6.56
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0176400	88.20	0.0003675	0.74
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-	-	-
EUROPOEM II re-entry model					
Number of applications and application rate		1 x 0.18 kg a.s./ha		1 x 0.00375 kg a.s./ha	

Model data	Level of PPE	Total absorbed dose (mg a.s./day)	% of systemic AOEL	Total absorbed dose (mg a.s./day)	% of systemic AOEL
Body weight: 60 kg TC: 0.15 m <sup>2</sup> /h	Without PPE	1.134	95	0.024	1
	With PPE (gloves)	0.227	<b>19</b>	0.005	<b>0</b>

The results of the exposure estimations show that the use of FLD-HER 306 SE(KONIK) according to the list of intended uses presented in GAP Table, causes no health risk for the worker assuming the workwear (arms, body and legs covered) is used. The calculated exposure level to 2,4-D and florasulam is lower than the value of AOELs for these active substances.

However, it is forbidden to re-enter area treated with FLD-HER 306 SE(KONIK) containing 2,4-D (300 g/L) and florasulam (6.25 g/L) until spray deposit on plant surfaces has dried. Taking into account hygienic rules, it is recommended that a worker inspecting treated area was dressed properly (long trousers, long-sleeve shirt) and equipped with protective gloves.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

**Implication for labelling: P280: Wear protective gloves**

#### 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

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

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

Table 6.6-6 shows the exposure models used for estimation of resident and bystander exposure to 2,4-D and florasulam. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term resident exposure). Detailed calculations are in Appendix 3.

**Table 6.6-6: Exposure models for intended uses**

Critical uses	Cereals (including maize) (max. 0.6 L product/ha)
Models	EFSA model AOEM (Agricultural Operator Exposure 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] German bystander and resident model EUROPOEM II MODEL bystander exposure
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**Table 6.6-7: Estimated resident exposure (longer term exposure)**

Model data		2,4-D		florasulam	
		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>EFSA model AOEM</b>					
Cereals Outdoor Downward spraying Vehicle-mounted <b>Buffer zone: 5 (m)</b> Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: NA					
Number of applications and application rate		1 x 0.18 kg a.s./ha		1 x 0.00375 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0113	56.26	0.0002	0.47
	Vapour (75 <sup>th</sup> perc.)	0.0011	5.35	0.0011	2.14
	Deposits (75 <sup>th</sup> perc.)	0.0008	4.07	0.0000	0.03
	Re-entry (75 <sup>th</sup> perc.)	0.0213	106.31	0.0004	0.89
	<b>Sum (mean)</b>	0.0249	<b>124.36</b>	0.0016	<b>3.13</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0249	10.25	0.0000	0.09
	Vapour (75 <sup>th</sup> perc.)	0.0021	1.15	0.0002	0.46
	Deposits (75 <sup>th</sup> perc.)	0.0002	1.76	0.0000	0.01
	Re-entry (75 <sup>th</sup> perc.)	0.0004	59.06	0.0002	0.49
	<b>Sum (mean)</b>	0.0118	<b>54.91</b>	0.0005	<b>0.91</b>
<b>German bystander and resident model</b> Tractor mounted boom spray application outdoors to low crops					

Number of applications and application rate	1 x 0.18 kg a.s./ha		1 x 0.00375 kg a.s./ha	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0058191	29.10	0.0001212	0.24
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.0045428	22.71	0.0000946	0.19
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0004246	2.12	0.0000088	0.02
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.0006391	3.20	0.0000133	0.03
<b>EUROPOEM II bystander model</b>				
Model data	Total absorbed dose (mg a.s./day)	% of systemic AOEL	Total absorbed dose (mg a.s./day)	% of systemic AOEL
Bystanders Body weight: 60 kg (default value)	0.160	13	0.003	0

## Conclusion

The reference value acutely toxic active substance (RVAAS) for 2,4-D and florasulam is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

The longer term exposure of residents (children) to 2,4-D via re-entry and the sum of all pathways, calculated with the EFSA calculator, was estimated to be slightly above the systemic AOEL for 2,4-D. Calculation performed with two other models (German bystander and resident model and EUROPOEM II MODEL bystander exposure) shows no exceedance of AOEL for 2,4-D. For florasulam all estimated values are below the systemic AOEL for florasulam. It can be concluded that the incidental short-time exposure of bystander and resident (children and adult) to 2,4-D and florasulam contained in the formulation FLD-HER 306 SE(KONIK) causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

Taking into account above, an additional risk mitigation measures should be included on the label:

- "After the application of product, place warning boards in visible places around the field: "No unauthorized access to the area treated with plant protection products ". The boards should remain until the plants are harvested. "
- "During spraying, a protection zone of at least 5 m away from residential buildings/habitats and bystanders should be used."

### 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 2,4-D and florasulam will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

### 6.6.5 Combined exposure

The product is a mixture of two active substances.



From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

#### 6.6.5.1 Exposure assessment of 2,4-D and florasulam in FLD-HER 306 SE

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 **Błąd! Nie można odnaleźć źródła odwołania.** converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

**Table 6.6-8: Risk assessment from combined exposure (longer term exposure)**

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – vehicle-mounted application	2,4-D	0.2845
	florasulam	0.0074
	<b>Cumulative risk operators (HI)</b>	<b>0.2919</b>

**The Hazard Index is < 1. Thus, combined exposure to all active substances in FLD-HER 306 SE(KONIK) is not expected to present a risk for operators. 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
-	-	-	-	-	-

### 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
-	-	-	-	-	-

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>

**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>

## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Not necessary.

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

Comments of zRMS:	<b>Method calculation for KONIK is acceptable</b>  <b>According to the ATE mix = 1,176 calculation method, i.e. LD50 is 300 &lt; 1,176 ≤ 2,000 therefore the product should be classified as Category 4 - oral toxicity.</b> <b>According to the Regulation EC No. 1272/2008 KONIK is classified: Acute Tox.4/H302</b>
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of FLD-HER 306 SE for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.  
For more details please refer to Part C.

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

Comments of zRMS:	<b>There is no co-formulant in the KONIK recipe classified as danger through dermal contact.</b>  <b>According to the Regulation EC No. 1272/2008, KONIK GB is unclassified.</b>
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of FLD-HER 306 SE for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.  
For more details please refer to Part C.

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

Comments of zRMS:	<b>Method calculation for KONIK is acceptable</b> <b>According to the <math>ATE_{mix} = 3.53</math>, which is <math>1.0 &lt; 3.53 \leq 5.0</math> therefore product should be classify as Category 4 – Inhalation toxicity.</b> <b>According to the Regulation EC No. 1272/2008 KONIK is classified Acute Tox.4/H322</b>
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of FLD-HER 306 SE for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details please refer to Part C.

#### A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<b>According to the GHS classification system, none of the formulation ingredients is below the additive classification trigger value according to Regulation (EC) No. 1272/2008 and then KONIK is not classified</b>
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of FLD-HER 306 SE for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details please refer to Part C.

#### A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	<b>Method calculation for KONIK is acceptable</b>  <b><math>\Sigma\%</math>Category 1 - Serious eye damage: <math>4.7\% + 4.7\% = 9.4\%</math>, which is <math>&gt; 3\%</math>, therefore product should be classify as Category 1 - Serious eye damage.</b> <b>According to the Regulation EC No. 1272/2008 KONIK is classified: Eye Dam.1/H318</b>
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of FLD-HER 306 SE for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details please refer to Part C.

## A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<b>Method calculation for KONIK is acceptable</b>  <b>Category 1B – Skin Sensitization: 42.5 %, which is &gt; 0.1 %, therefore product should be classify as Category 1 – Skin Sensitization.</b> <b>According to the Regulation EC No. 1272/2008 KONIK is classified: Skin Sens.1/ H317</b>
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of FLD-HER 306 SE for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details please refer to Part C.

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

No new/additional supplementary studies were submitted.

## 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)**

No new/additional supplementary studies were submitted.

#### **A 2.11                    Other/Special Studies**

There are no other or special studies available.

## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for 2,4-D

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

Formulation type	SE	Crop type	Cereals
Application rate (AR)	0.18 kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50 ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25 % (concentr.)	Indoor/outdoor	Outdoor
	70 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal
AOEL	0.02 mg/kg bw/d	Water soluble bag	No
AAOEL	- mg/kg bw/d	-	-

**Table A 2: Estimation of longer term operator exposure towards 2,4-D according to EF-SA guidance (AOEM EFSA model)**

Operator exposure for FLD-HER 306 SE outdoor spray applications					
Application rate of active substance	0,18 kg a.s./ha	<i>i_AppRate</i>			
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>			
Amount of active substance applied	9 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				
Outdoor spray applications, emulsifiable concentrates, etc. Downward spraying, vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	26361	98482	AOEM	
	Body	16715	136367	AOEM	
	Head	467	2561	AOEM	
	Protected hands (gloves)	144	1783	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	167	1316	AOEM	
	Protected head (hood and face shield)	7	145	AOEM	
	Inhalation	7	30	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
Application	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	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	1335	11457	AOEM	
	Body	746	3848	AOEM	
	Head	35	106	AOEM	
	Protected hands (gloves)	140	4306	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	50	AOEM	
	Inhalation	3	10	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	



#### 1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	12,3775142	0,3414496	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2062919	0,0056908	
% of RVNAS	1031,46%	28,45%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	70,1804357	4,5795926	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	1,1696739	0,0763265	

#### 2. Longer term exposure

##### 2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	6590,2899081	109,8381651	D15*i_AbsorpProduct
Body	4178,6471066	69,6441184	D16*i_AbsorpProduct
Head	116,7380725	1,9456345	D17*i_AbsorpProduct
Inhalation	7,1184030	0,1186400	D21*i_Absorplnhalation
Sum	10892,7934902	181,5465582	
With RPE/PPE (as selected above)			
Hands	35,9730593	0,5995510	D18*i_AbsorpProduct
Body	41,6621753	0,6943696	D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24
Head	116,7380725	1,9456345	D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25
Inhalation	7,1184030	0,1186400	D21*i_Absorplnhalation*G25
Sum	201,4917100	3,3581952	
water soluble	201,4917100	3,3581952	C70*F26

##### 2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	934,4372934	15,5739549	D30*i_Absorplnuse
Body	522,4758297	8,7079305	D31*i_Absorplnuse
Head	24,6939977	0,4115666	D32*i_Absorplnuse
Inhalation	3,1136291	0,0518938	D35*i_Absorplnhalation
Sum	1484,7207498	24,7453458	
With RPE/PPE (as selected above)			
Hands	97,8178416	1,6302974	D33*i_Absorplnuse
Body	14,3323936	0,2388732	D34*i_Absorplnuse or D31*i_Absorplnuse*F38
Head	24,6939977	0,4115666	D32*i_Absorplnuse*F39
Inhalation	3,1136291	0,0518938	D35*i_Absorplnuse*G39
Sum	139,9578621	2,3326310	

### 3. Acute exposure

#### 3.1 Mixing and loading

	Systemic exposure [ $\mu\text{g a.s. /day}$ ]	Systemic exposure [ $\mu\text{g a.s./kg bw/day}$ ]	Formula
<b>Without RPE/PPE</b>			
Hands	24620,4738001	410,3412300	$E15*i\_AbsorpProduct$
Body	34091,7570901	568,1959515	$E16*i\_AbsorpProduct$
Head	640,2543209	10,6709053	$E17*i\_AbsorpProduct$
Inhalation	30,2577681	0,5042961	$E21*i\_AbsorpInhalation$
Sum	59382,7429793	989,7123830	
<b>With RPE/PPE (as selected above)</b>			
Hands	445,6521739	7,4275362	$E18*i\_AbsorpProduct$
Body	329,0656257	5,4844271	$E19*i\_AbsorpProduct$ or $E16*i\_AbsorpProduct*F24$
Head	640,2543209	10,6709053	$E20*i\_AbsorpProduct$ or $E17*i\_AbsorpProduct*F25$
Inhalation	30,2577681	0,5042961	$E21*i\_AbsorpInhalation*G25$
Sum	1445,2298886	24,0871648	
water soluble loss	1445,2298886	24,0871648	$C104*F26$

#### 2.2 Application

	Systemic exposure [ $\mu\text{g a.s. /day}$ ]	Systemic exposure [ $\mu\text{g a.s./kg bw/day}$ ]	Formula
<b>Without RPE/PPE</b>			
Hands	8019,5827268	133,6597121	$E30*i\_Absorpinuse$
Body	2693,3457389	44,8890956	$E31*i\_Absorpinuse$
Head	74,4676739	1,2411279	$E32*i\_Absorpinuse$
Inhalation	10,2965362	0,1716089	$E35*i\_Absorpinhalation$
Sum	10797,6926758	179,9615446	
<b>With RPE/PPE (as selected above)</b>			
Hands	3014,4467563	50,2407793	$E33*i\_Absorpinuse$
Body	35,1517706	0,5858628	$E34*i\_Absorpinuse$ or $E31*i\_Absorpinuse*F38$
Head	74,4676739	1,2411279	$E32*i\_Absorpinuse*F39$
Inhalation	10,2965362	0,1716089	$E35*i\_Absorpinhalation*G39$
Sum	3134,3627370	52,2393789	

### A 3.1.2 Calculations for florasulam

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

Formulation type	SE		Crop type	Cereals
Application rate (AR)	0.00375	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.05	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

**Table A 4: Estimation of longer term operator exposure towards florasulam according to EFSA guidance (AOEM EFSA model)**

Operator exposure for FLD-HER 306 SE outdoor spray applications					
Application rate of active substance	0,00375	kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated	50	ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied	0,1875	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_AbsorpInuse</i>		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	1339	4833	AOEM	
	Body	1100	44286	AOEM	
	Head	10	53	AOEM	
	Protected hands (gloves)	12	37	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	5	27	AOEM	
	Protected head (hood and face shield)	0	3	AOEM	
	Inhalation	2	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		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	28	672	AOEM	
	Body	16	80	AOEM	
	Head	1	2	AOEM	
	Protected hands (gloves)	17	2742	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	0	1	AOEM	
	Inhalation	0	1	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

### 1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,6456214	0,0221368	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0107604	0,0003689	
% of RVNAS	21,52%	0,74%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	12,8503229	1,9798325	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2141720	0,0329972	

### 2. Longer term exposure

#### 2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	334,6837126	5,5780619	D15*i_AbsorpProduct
Body	274,9418135	4,5823636	D16*i_AbsorpProduct
Head	2,4320432	0,0405341	D17*i_AbsorpProduct
Inhalation	2,2492886	0,0374881	D21*i_AbsorpInhalation
Sum	614,3068578	10,2384476	
With RPE/PPE (as selected above)			
Hands	2,8952834	0,0482547	D18*i_AbsorpProduct
Body	1,3475353	0,0224589	D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24
Head	2,4320432	0,0405341	D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25
Inhalation	2,2492886	0,0374881	D21*i_AbsorpInhalation*G25
Sum	8,9241504	0,1487358	
water soluble	8,9241504	0,1487358	C70*F26

#### 2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	19,4674436	0,3244574	D30*i_Absorplnuse
Body	10,8849131	0,1814152	D31*i_Absorplnuse
Head	0,5144583	0,0085743	D32*i_Absorplnuse
Inhalation	0,4476772	0,0074613	D35*i_Absorplnuse
Sum	31,3144923	0,5219082	
With RPE/PPE (as selected above)			
Hands	11,9518968	0,1991983	D33*i_Absorplnuse
Body	0,2985915	0,0049765	D34*i_Absorplnuse or D31*i_Absorplnuse*F38
Head	0,5144583	0,0085743	D32*i_Absorplnuse*F39
Inhalation	0,4476772	0,0074613	D35*i_Absorplnuse*G39
Sum	13,2126239	0,2202104	

### 3. Acute exposure

#### 3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	1208,3168149	20,1386136	E15*i_AbsorpProduct
Body	11071,5660957	184,5261016	E16*i_AbsorpProduct
Head	13,3386317	0,2223105	E17*i_AbsorpProduct
Inhalation	27,5921710	0,4598695	E21*i_AbsorpInhalation
Sum	12320,8137134	205,3468952	
With RPE/PPE (as selected above)			
Hands	9,2844203	0,1547403	E18*i_AbsorpProduct
Body	6,8555339	0,1142589	E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24
Head	13,3386317	0,2223105	E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25
Inhalation	27,5921710	0,4598695	E21*i_AbsorpInhalation*G25
Sum	57,0707569	0,9511793	
water soluble	57,0707569	0,9511793	C104*F26

## 2.2 Application

	Systemic exposure [ $\mu\text{g a.s. /day}$ ]	Systemic exposure [ $\mu\text{g a.s./kg bw/day}$ ]	Formula
<b>Without RPE/PPE</b>			
Hands	470,7356228	7,8455937	$E30*i\_Absorplnuse$
Body	56,1113696	0,9351895	$E31*i\_Absorplnuse$
Head	1,5514099	0,0258568	$E32*i\_Absorplnuse$
Inhalation	1,1108136	0,0185136	$E35*i\_Absorplnhalation$
Sum	529,5092158	8,8251536	
<b>With RPE/PPE (as selected above)</b>			
Hands	1919,3672345	31,9894539	$E33*i\_Absorplnuse$
Body	0,7323286	0,0122055	$E34*i\_Absorplnuse$ or $E31*i\_Absorplnuse*F38$
Head	1,5514099	0,0258568	$E32*i\_Absorplnuse*F39$
Inhalation	1,1108136	0,0185136	$E35*i\_Absorplnhalation*G39$
Sum	1922,7617866	32,0460298	

## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for 2,4-D

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

Intended use(s)	Cereals, inspection, irrigation, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	0.18 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	NA days	Work rate per day (WR)	2	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm <sup>2</sup> /h
Multiple application factor (MAF)	1	TC dermal (work wear)	1400	cm <sup>2</sup> /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	NA	cm <sup>2</sup> /h
AOEL	0.02 mg/kg bw/d	Task specific factor inhalation	NA	ha/h x 10 <sup>-3</sup>
AAOEL	- mg/kg bw/d	-	-	-

**Table A 6: Estimation of longer term worker exposure towards 2,4-D according to EFSA guidance (AOEM EFSA model)**

Worker exposure from residues on foliage for FLD-HER 306 SE				
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	0,18 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_Absorplnuse</i>
Dislodgeable foliar residue ( <i>I_AppRate</i> * <i>i_DFR</i> )	0,54 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			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>			<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)	9,4500000	1,0584000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1575000	0,0176400		
% of RVNAS	787,50%	88,20%		
<b>2. Details</b>				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	9,4500000	0,1575000	$d\_DermTcUCV * d\_WorkHr * i\_DFR * i\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Work wear - arms, body and legs covered	1,0584000	0,0176400	$d\_DermTcCV1 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d\_DermTcCV2 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Inhalation				Na for outdoor activities

**Table A 7: Estimation of longer term worker exposure towards 2,4-D according to EU-ROPOEM II re-entry model**

WORKER EXPOSURE			EUROPEM II MODEL	
form	FLD-HER 306 SE		Re-entry in the field	
a.s.	2,4-D			
Parameter		Value	Unit	References, comments
<b>Re-entry activities in the field</b>				
AR	Application rate	0,18	kg a.s./ha	summary of intended uses
<b>Worker</b>				
Duration				
T		2	hours / day	default: 6 h (Europepm II)
<b>Inhalation Exposure</b>				
	no model available	-		without PPE
<b>Dermal Exposure</b>				
DFR	Dislodgeable foliar residue	30	mg a.s./m <sup>2</sup> /kg a.s./ha	default (Europepm II)
TC	Transfer coefficient	0,15	m <sup>2</sup> / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europepm II)
	Dermal Exposure	1,62	mg a.s./ day	DE = DFR x AR x TC x T
<b>Internal exposure</b>				
DA	Dermal Absorption	70	%	
	PPE-factor dermal	5		gloves*
	AOEL	1,2	mg a.s./ day	based on 60 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
	<b>Internal exposure</b>	[mg a.s./ day ]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1,134	0,227	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>1,134</b>	<b>0,227</b>	<b>sum</b>
	<b>% AOEL</b>			
	Inhalation	-	-	no model available
	Dermal	95	19	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>95</b>	<b>19</b>	<b>sum</b>

\* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

### A 3.2.2 Calculations for florasulam

**Table A 8: Input parameters considered for the estimation of worker exposure**

Intended uses	Cereals, inspection, irrigation, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	0.00375 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	NA days	Work rate per day (WR)	2	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm <sup>2</sup> /h
Multiple application factor (MAF)	1	TC dermal (work wear)	1400	cm <sup>2</sup> /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	NA	cm <sup>2</sup> /h
AOEL	0.05 mg/kg bw/d	Task specific factor inhalation	NA	ha/h x 10 <sup>-3</sup>
AAOEL	- mg/kg bw/d	-	-	-

**Table A 9: Estimation of longer term worker exposure towards florasulam according to EFSA guidance (AOEM EFSA model)**

Worker exposure from residues on foliage for FLD-HER 306 SE				
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	0,00375 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_Absorplnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0,01125 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			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>			<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)	0,1968750	0,0220500	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0032813	0,0003675		
% of RVNAS	6,56%	0,74%		
<b>2. Details</b>				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	0,1968750	0,0032813	$d\_DermTcUCV * d\_WorkHr * i\_DFR * i\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Work wear - arms, body and legs covered	0,0220500	0,0003675	$d\_DermTcCV1 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d\_DermTcCV2 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_Absorplnuse$	
Inhalation				Na for outdoor activities



**Table A 10: Estimation of longer term worker exposure towards florasulam according to EUROPOEM II re-entry model**

WORKER EXPOSURE		EUROPOEM II MODEL		
form	FLD-HER 306 SE	Re-entry in the field		
a.s.	florasulam			
Parameter		Value	Unit	References, comments
<b>Re-entry activities in the field</b>				
AR	Application rate	0,00375	kg a.s./ha	summary of intended uses
<b>Worker</b>				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
<b>Inhalation Exposure</b>				
	no model available	-		without PPE
<b>Dermal Exposure</b>				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,15	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		0,03375	mg a.s./ day	DE = DFR x AR x TC x T
<b>Internal exposure</b>				
DA	Dermal Absorption	70	%	
	PPE-factor dermal	5		gloves*
	AOEL	3	mg a.s./ day	based on 60 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
<b>Internal exposure</b>		[mg a.s./ day ]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,024	0,005	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>0,024</b>	<b>0,005</b>	<b>sum</b>
<b>% AOEL</b>				
	Inhalation	-	-	no model available
	Dermal	1	0	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>1</b>	<b>0</b>	<b>sum</b>

\* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

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

#### A 3.3.1 Calculations for 2,4-D

**Table A 11: Input parameters considered for the estimation of longer term resident exposure**

Resident exposure for FLD-HER 306 SE		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	<i>i_FormVal</i>
Buffer strip	5 m	<i>i_Buffer</i>
Application rate of the product	0,18 kg a.s./ha	<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0,9 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	25,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70,00%	<i>i_Absorpinuse</i>
Oral absorption	100,00%	<i>i_AbsorpOralinuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0,54 µg a.s./cm <sup>2</sup>	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa	<i>i_Volat</i>
Concentration in air	0,001 mg/m <sup>3</sup>	<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0,23798 ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,2175 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00017 ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,12278 ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,12 ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00008 ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00014 ml spray dilution/person	
Exposure duration dermal	2 hours	<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours	<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0,25 hours	<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%	<i>d_ClothAF</i>
Breathing rate adult	0,23 m <sup>3</sup> /day/kg	<i>d_BreathRAD</i>
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg	<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour	<i>d_ReTCAAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour	<i>d_ReTCCCh</i>
Saliva extraction percentage	50,00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm <sup>2</sup>	<i>d_AreaHM</i>
Frequency of hand to mouth activity	9,5 events/hour	<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm <sup>2</sup> /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm <sup>2</sup> /h	<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h	<i>d_TcEntryCh</i>

**Table A 12: Estimation of longer term resident exposure towards 2,4-D according to EFSA guidance (AOEM EFSA model)**

<b>1. Total</b>					
<b>1.1-1.3 year old child</b>					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1125135	0,0107000	0,0081351	0,2126250	0,2487176
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0112514	0,0010700	0,0008135	0,0212625	0,0248718
% of RVNAS	56,26%	5,35%	4,07%	106,31%	124,36%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1230215	0,0138000	0,0211554	0,7087500	0,6589665
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0020504	0,0002300	0,0003526	0,0118125	0,0109828
% of RVNAS	10,25%	1,15%	1,76%	59,06%	54,91%
<b>2. Resident exposure 75th Percentile</b>					
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments	
<b>1-3 year old child</b>					
Spray drift	0,1125135	0,0112514	$((C16 \cdot i_{AbsorInuse} \cdot (1 - d_{ClothAF})) + C18) \cdot d_{ConcAS}$		
Vapour	0,0107000	0,0010700	$d_{AirCon} \cdot d_{BreathRCh} \cdot d_{BwChild}$		
Surface deposits					
Dermal	0,0075348	0,0007535	$(i_{AppRate}/100) \cdot C29 \cdot d_{Turf} \cdot d_{ReTCCh} \cdot d_{ReExpDur} \cdot \text{MAX}(i_{AbsorpProduct}, i_{AbsorInuse}) \cdot d_{MAF} \cdot \text{IF}(i_{AppEquip} = \text{"Vehicle-mounted-Drift Reduction"}, 0.5, 1)$		
Hand to mouth	0,0003933	0,0000393	$(i_{AppRate}/100) \cdot C29 \cdot d_{Turf} \cdot d_{SalExt} \cdot d_{AreaHM} \cdot d_{ReFreqHM} \cdot d_{ReExpDur} \cdot i_{AbsorpOrallInuse} \cdot d_{MAF}$		
Object to mouth	0,0002070	0,0000207	$(i_{AppRate}/100) \cdot C29 \cdot d_{DRP} \cdot d_{MouthGrass} \cdot i_{AbsorpOrallInuse} \cdot d_{MAF}$		
Entry into treated crops					
Dermal	0,2126250	0,0212625	$(d_{TcEntryCh} \cdot 0.25 \cdot d_{DFR} \cdot d_{MAF}) / 1000 \cdot \text{MAX}(i_{AbsorpProduct}, i_{AbsorInuse})$		
Hand to mouth			$(i_{AppRate}/100) \cdot d_{Turf} \cdot d_{MAF} \cdot d_{SalExt} \cdot d_{AreaHM} \cdot d_{ReFreqHM} \cdot d_{ReExpDur} \cdot i_{AbsorpOrallInuse}$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.	
Object to mouth			$(i_{AppRate}/100) \cdot d_{DRP} \cdot d_{MouthGrass} \cdot i_{AbsorpOrallInuse} \cdot d_{MAF}$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.	
<b>Adult</b>					
Spray drift	0,1230215	0,0020504	$(C15 \cdot i_{AbsorInuse} \cdot (1 - d_{ClothAF})) + C17 \cdot d_{ConcAS}$		
Vapour	0,0138000	0,0002300	$d_{AirCon} \cdot d_{BreathRAD} \cdot d_{BwAdult}$		
Surface deposits (dermal)	0,0211554	0,0003526	$(i_{AppRate}/100) \cdot C30 \cdot d_{Turf} \cdot d_{ReTCAd} \cdot d_{ReExpDur} \cdot i_{AbsorInuse}$		
Entry into treated crops (dermal)	0,7087500	0,0118125	$(d_{TcEntryAd} \cdot 0.25 \cdot d_{DFR} \cdot d_{MAF}) / 1000 \cdot \text{MAX}(i_{AbsorpProduct}, i_{AbsorInuse})$		

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
<b>1-3 year old child</b>				
Spray drift	0,0621180	0,0062118	$((C20 * i\_Absorplnuse * (1 - d\_ClothAF)) + C22) * d\_ConcAS$	
Vapour	0,0107000	0,0010700	$d\_AirCon * d\_BreathRCh * d\_BwChild$	
Surface deposits				
Dermal	0,0058968	0,0005897	$(i\_AppRate/100) * C30 * d\_Turf * d\_ReTCCh * d\_ReExpDur * MAX(i\_AbsorpProduct, i\_Absorplnuse) * d\_MAF * IF([i\_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1])$	
Hand to mouth	0,0003078	0,0000308	$(i\_AppRate/100) * C30 * d\_Turf * d\_SoExt * d\_AreaHM * d\_ReFreqHM * d\_ReExpDur * i\_AbsorpOrallnuse * d\_MAF$	
Object to mouth	0,0001620	0,0000162	$(i\_AppRate/100) * C30 * d\_DRP * d\_MouthGrass * i\_AbsorpOrallnuse * d\_MAF$	
Entry into treated crops				
Dermal	0,1695330	0,0169533	$(d\_TcEntryMeanCh * 0.25 * d\_DFR * d\_MAF) / 1000 * MAX(i\_AbsorpProduct, i\_Absorplnuse)$	
Hand to mouth			$(i\_AppRate/100) * 1 * d\_Turf * d\_MAF * d\_SoExt * d\_AreaHM * d\_ReFreqHM * d\_ReExpDur * i\_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i\_AppRate/100) * 1 * d\_DRP * d\_MouthGrass * i\_AbsorpOrallnuse * d\_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
<b>Adult</b>				
Spray drift	0,0635001	0,0010583	$((C19 * i\_Absorplnuse * (1 - d\_ClothAF)) + C21) * d\_ConcAS$	
Vapour	0,0138000	0,0002300	$d\_AirCon * d\_BreathRAD * d\_BwAdult$	
Surface deposits (dermal)	0,0165564	0,0002759	$(i\_AppRate/100) * C30 * d\_Turf * d\_ReTCAd * d\_ReExpDur * MAX(i\_AbsorpProduct, i\_Absorplnuse) * d\_MAF * IF([i\_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1])$	
Entry into treated crops (dermal)	0,5651100	0,0094185	$(d\_TcEntryMeanAd * 0.25 * d\_DFR * d\_MAF) / 1000 * MAX(i\_AbsorpProduct, i\_Absorplnuse)$	

**Table A 13: Estimation of longer term bystander/resident exposure towards 2,4-D according to German bystander and resident model**

Estimation of bystander and resident exposure (adults and children)			
Active substance (a.s.)		2,4-D	
Product		FLD-HER 306 SE	
Intended uses	cereals	Field Crops, Tractor Mounted (FCTM)	
Treated area per day (A)	50	ha/d	
Application rate (AR)	0,18	kg a.s./ha	
Number of applications (NA)	1	1)	
1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).			
Dermal absorption (DA)	70	% (worst case, e.g. during application)	
Inhalation absorption (IA)	100	%	
Oral absorption (OA)	100	%	
Systemic AOEL	0,02	mg/kg bw/d	
Body weight (BW)	60	kg/person (adults)	
	16,15	kg/person (children)	
Distance between application and bystander or resident:			
FCTM:	1	m	
High crops not selected			
		m	
Home & garden not selected			
		m	
Drift deposit (D) for 1 appl. based on appl. technique and distance:		2,77 % (FCTM, 1 m)	
Airborne vapour concentration (AC <sub>v</sub> )			mg/m <sup>3</sup> 2)
2) 1 µg/m <sup>3</sup> for semivolatile substances, i.e. vapour pressure (20 °C): ≥ 1x10 <sup>-5</sup> - < 5x10 <sup>-3</sup> Pa; 15 µg/m <sup>3</sup> for volatile substances, i.e. vapour pressure (20 °C): ≥ 5x10 <sup>-3</sup> Pa			

### Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	cereals	Drift (D):	2,77	% (FCTM, 1 m)
Application rate (AR):	0,18 kg a.s./ha	Exposed Body Surface Area (BSA):	1	m <sup>2</sup> (adults)
			0,21	m <sup>2</sup> (children)
Body weight (BW):	60 kg/person (adults)	Specific Inhalation Exposure (I <sub>A</sub> ):	0,001	mg/kg a.s. (6 hours, adults)
	16,15 kg/person (children)		0,00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	70,00 % ('worst case')	Area Treated (A):	50	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100 %	Exposure duration (T):	5	min
AOEL:	0,02 mg/kg bw/d			

Bystander exposure towards 2,4-D					
Adults			Children		
Bystander: Dermal exposure after application in cereals (via spray drift)					
SDE <sub>B</sub> = (AR x D x BSA x DA) / BW			SDE <sub>B</sub> = (AR x D x BSA x DA) / BW		
(18 x 2,77% x 1 x 70%) / 60			(18 x 2,77% x 0,21 x 70%) / 16,15		
External exposure	0,4986	mg/person	External exposure	0,104706	mg/person
External exposure	0,00831	mg/kg bw/d	External exposure	0,00648334	mg/kg bw/d
Absorbed dose:	0,0058170	mg/kg bw/d	Absorbed dose:	0,0045383	mg/kg bw/d
Bystander: Inhalation exposure after application in cereals					
SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW			SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW		
(0,001 / 360 x 0,18 x 50 x 5 x 100%) / 60			(0,001 / 360 x 0,18 x 50 x 5 x 100%) / 16,15		
External exposure	0,000125	mg/person	External exposure	7,1839E-05	mg/person
External exposure	2,0833E-06	mg/kg bw/d	External exposure	4,4482E-06	mg/kg bw/d
Absorbed dose:	0,0000021	mg/kg bw/d	Absorbed dose:	0,0000044	mg/kg bw/d
Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>			Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>		
Total systemic exposure (absorbed dose)	0,349145	mg/person	Total systemic exposure (absorbed dose)	0,07336604	mg/person
Total systemic exposure (absorbed dose)	0,0058191	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0045428	mg/kg bw/d
% of AOEL:	29,10	%	% of AOEL:	22,71	%

## Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

<b>Intended use(s):</b>	cereals	<b>Drift (D):</b>	2,77	% (FCTM, 1 m)
<b>Application rate (AR):</b>	0,18 kg a.s./ha	<b>Transfer coefficient (TC):</b>	7300	cm <sup>2</sup> /h (adults)
<b>Number of applications (NA):</b>	1		2600	cm <sup>2</sup> /h (children)
<b>Body weight (BW):</b>	60 kg/person (adults)	<b>Turf Transferable Residues (TTR):</b>	5	%
	16,15 kg/person (children)	<b>Exposure Duration (H):</b>	2	h
<b>Dermal absorption (DA):</b>	70,00 % ('worst case')	<b>Airborne Concentration of Vapour (ACV):</b>	none	
<b>Inhalation absorption (IA):</b>	100 %	<b>Inhalation Rate (IR):</b>	16,57	m <sup>3</sup> /d (adults),
<b>Oral absorption (OA)</b>	100 %		8,31	m <sup>3</sup> /d (children)
<b>AOEL</b>	0,02 mg/kg bw/d	<b>Saliva Extraction Factor (SE):</b>	50	%
		<b>Surface Area of Hands (SA):</b>	20	cm <sup>2</sup>
		<b>Frequency of Hand to Mouth (Freq):</b>	20	events/h
		<b>Dislodgeable foliar residues (DFR):</b>	20	%
		<b>Ingestion Rate for Mouthing of Grass/Day (IgR):</b>	25	cm <sup>2</sup> /d

Resident exposure towards 2,4-D					
Adults			Children		
Residents: Dermal exposure after application in cereals (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
$(0,0018 \times 1 \times 2,77\% \times 5\% \times 7300 \times 2 \times 70\%) / 60$			$(0,0018 \times 1 \times 2,77\% \times 5\% \times 2600 \times 2 \times 70\%) / 16,15$		
External exposure	0,0363978	mg/person	External exposure	0,0129636	mg/person
External exposure	0,00060663	mg/kg bw/d	External exposure	0,0008027	mg/kg bw/d
Absorbed dose:	0,0004246	mg/kg bw/d	Absorbed dose:	0,0005619	mg/kg bw/d
Residents: Inhalation exposure to vapour					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
$(0 \times 16,57 \times 100\%) / 60$			$(0 \times 8,31 \times 100\%) / 16,15$		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		none	Absorbed dose:		none
			Residents: Oral exposure (hand-to-mouth transfer)		
			$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) /$		
			$(0,0018 \times 1 \times 2,77\% \times 5\% \times 50\% \times 20 \times 20 \times 2 \times 100\%) /$		
			External exposure	0,0009972	mg/person
			External exposure	6,1746E-05	mg/kg bw/d
			Absorbed dose	0,0000617	mg/kg bw/d
			Residents: Oral exposure (object-to-mouth transfer)		
			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			$(0,0018 \times 1 \times 2,77\% \times 20\% \times 25 \times 100\%) / 16,15$		
			External exposure	0,0002493	mg/person
External exposure	1,5437E-05	mg/kg bw/d			
Absorbed dose	0,0000154	mg/kg bw/d			
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0,02547846	mg/person	Total systemic exposure (absorbed dose)	0,01032102	mg/person
Total systemic exposure (absorbed dose)	0,0004246	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0006391	mg/kg bw/d
% of AOEL:	2,12	%	% of AOEL:	3,20	%

**Table A 14: Estimation of longer term bystander exposure towards 2,4-D according to EUROPOEM II MODEL bystander exposure**

BYSTANDER EXPOSURE			EUROPOEM II MODEL	
form	FLD-HER 306 SE		Outdoor application	
as	2,4-D			
Parameter		Value	Unit	References, comments
<b>SPRAYING Process outdoor</b>				
AR	Application rate	0,18	kg a.s. / ha	summary of intended uses
SV	Spray volume	200	L / ha	summary of intended uses
<b>Inhalation Exposure</b>				
	Default value			without PPE
SE	Surrogate Exposure Value	0,03	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation*
RR	Respiratory rate	1,25	m3 / h	default
	Inhalation Exposure	0,0338	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
<b>Dermal Exposure</b>				
	Default value			
SE	Surrogate Exposure Value	0,005		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
	Dermal Exposure	0,18	mg a.s./ day	DE = SE xSA X (AR x 100)
<b>Internal exposure</b>				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	70	%	
	AOEL	1,2	mg a.s./ day	based on 60 kg bw
		<b>Without PPE</b>		
		<b>Internal exposure</b>	[mg a.s./ day]	
	Inhalation	0,0338		IE(int) = IE x (IA/100)
	Dermal	0,126		DE(int) = DE x (DA/100)
	<b>Total</b>	<b>0,160</b>		<b>sum</b>
		<b>% AOEL</b>		
	Inhalation	2,8		%AOEL = 100 x IE(int) / AOEL
	Dermal	10,5		%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>13</b>		<b>sum</b>
*	One hour exposure is the default. It is referring to a potential 1 hour exposure, rather than the actual. It is based on the study design, and should not be lowered.			



### A 3.3.2 Calculations for florasulam

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

Resident exposure for FLD-HER 306 SE		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	<i>i_FormVal</i>
Buffer strip	5 m	<i>i_Buffer</i>
Application rate of the product	0,00375 kg a.s./ha	<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0,01875 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	25,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70,00%	<i>i_AbsorpInuse</i>
Oral absorption	100,00%	<i>i_AbsorpOrallnuse</i>
Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )	0,01125 µg a.s./cm <sup>2</sup>	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa	<i>i_Volat</i>
Concentration in air	0,001 mg/m <sup>3</sup>	<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0,23798 ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,2175 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00017 ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,12278 ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,12 ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00008 ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00014 ml spray dilution/person	
Exposure duration dermal	2 hours	<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours	<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0,25 hours	<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%	<i>d_ClothAF</i>
Breathing rate adult	0,23 m <sup>3</sup> /day/kg	<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg	<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour	<i>d_ReTCAAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour	<i>d_ReTCCh</i>
Saliva extraction percentage	50,00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm <sup>2</sup>	<i>d_AreaHM</i>
Frequency of hand to mouth activity	9,5 events/hour	<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm <sup>2</sup> /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm <sup>2</sup> /h	<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h	<i>d_TcEntryCh</i>

**Table A 16: Estimation of longer term resident exposure towards florasulam according to EFSA guidance (AOEM EFSA model)**

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)	0,0023440	0,0107000	0,0001695	0,0044297	0,0156587
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0002344	0,0010700	0,0000169	0,0004430	0,0015659
% of RVNAS	0,47%	2,14%	0,03%	0,89%	3,13%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0025629	0,0138000	0,0004407	0,0147656	0,0272410
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0000427	0,0002300	0,0000073	0,0002461	0,0004540
% of RVNAS	0,09%	0,46%	0,01%	0,49%	0,91%
2. Resident exposure 75th Percentile					
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments	
1-3 year old child					
Spray drift	0,0023440	0,0002344	$((C16*i\_Absorplnuse*(1-d\_ClothAF))+C18)*d\_ConcAS$		
Vapour	0,0107000	0,0010700	$d\_AirCon*d\_BreathRCh*d\_BwChild$		
Surface deposits					
Dermal	0,0001570	0,0000157	$(i\_AppRate/100)*C29*d\_Turf*d\_ReTCCh*d\_ReExpDur*MAX(i\_AbsorpProduct,i\_Absorplnuse)*d\_MAF*IF(i\_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))$		
Hand to mouth	0,0000082	0,0000008	$(i\_AppRate/100)*C29*d\_Turf*d\_SolExt*d\_AreaHM*d\_ReFreqHM*d\_ReExpDur*i\_AbsorpOrallnuse*d\_MAF$		
Object to mouth	0,0000043	0,0000004	$(i\_AppRate/100)*C29*d\_DRP*d\_MouthGrass*i\_AbsorpOrallnuse*d\_MAF$		
Entry into treated crops					
Dermal	0,0044297	0,0004430	$(d\_TcEntryCh*0.25*d\_DFR*d\_MAF)/1000*MAX(i\_AbsorpProduct,i\_Absorplnuse)$		
Hand to mouth			$(i\_AppRate/100)*d\_Turf*d\_MAF*d\_SolExt*d\_AreaHM*d\_ReFreqHM*d\_ReExpDur*i\_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.	
Object to mouth			$(i\_AppRate/100)*d\_DRP*d\_MouthGrass*i\_AbsorpOrallnuse*d\_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.	
Adult					
Spray drift	0,0025629	0,0000427	$(C15*i\_Absorplnuse*(1-d\_ClothAF))+C17)*d\_ConcAS$		
Vapour	0,0138000	0,0002300	$d\_AirCon*d\_BreathRAD*d\_BwAdult$		
Surface deposits (dermal)	0,0004407	0,0000073	$(i\_AppRate/100)*C30*d\_Turf*d\_ReTCAd*d\_ReExpDur*i\_Absorplnuse$		
Entry into treated crops (dermal)	0,0147656	0,0002461	$(d\_TcEntryAd*0.25*d\_DFR*d\_MAF)/1000*MAX(i\_AbsorpProduct,i\_Absorplnuse)$		

3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
<b>1-3 year old child</b>				
Spray drift	0,0012941	0,0001294	$((C20 * i\_Absorplnuse * (1 - d\_ClothAF)) + C22) * d\_ConcAS$	
Vapour	0,0107000	0,0010700	$d\_AirCon * d\_BreathRCh * d\_BwChild$	
Surface deposits				
Dermal	0,0001229	0,0000123	$(i\_AppRate/100) * C30 * d\_Turf * d\_ReTCCh * d\_ReExpDur * MAX(i\_AbsorpProduct, i\_Absorplnuse) * d\_MAF * IF([i\_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1])$	
Hand to mouth	0,0000064	0,0000006	$(i\_AppRate/100) * C30 * d\_Turf * d\_SoExt * d\_AreaHM * d\_ReFreqHM * d\_ReExpDur * i\_AbsorpOrallnuse * d\_MAF$	
Object to mouth	0,0000034	0,0000003	$(i\_AppRate/100) * C30 * d\_DRP * d\_MouthGrass * i\_AbsorpOrallnuse * d\_MAF$	
Entry into treated crops				
Dermal	0,0035319	0,0003532	$(d\_TcEntryMeanCh * 0.25 * d\_DFR * d\_MAF) / 1000 * MAX(i\_AbsorpProduct, i\_Absorplnuse)$	
Hand to mouth			$(i\_AppRate/100) * 1 * d\_Turf * d\_MAF * d\_SoExt * d\_AreaHM * d\_ReFreqHM * d\_ReExpDur * i\_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i\_AppRate/100) * 1 * d\_DRP * d\_MouthGrass * i\_AbsorpOrallnuse * d\_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
<b>Adult</b>				
Spray drift	0,0013229	0,0000220	$((C19 * i\_Absorplnuse * (1 - d\_ClothAF)) + C21) * d\_ConcAS$	
Vapour	0,0138000	0,0002300	$d\_AirCon * d\_BreathRAD * d\_BwAdult$	
Surface deposits (dermal)	0,0003449	0,0000057	$(i\_AppRate/100) * C30 * d\_Turf * d\_ReTCAd * d\_ReExpDur * MAX(i\_AbsorpProduct, i\_Absorplnuse) * d\_MAF * IF([i\_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1])$	
Entry into treated crops (dermal)	0,0117731	0,0001962	$(d\_TcEntryMeanAd * 0.25 * d\_DFR * d\_MAF) / 1000 * MAX(i\_AbsorpProduct, i\_Absorplnuse)$	

**Table A 17: Estimation of longer term bystander/resident exposure towards florasulam according to German bystander and resident model**

Estimation of bystander and resident exposure (adults and children)			
Active substance (a.s.)	florasulam		
Product	FLD-HER 306 SE		
Intended uses	cereals	Field Crops, Tractor Mounted (FCTM)	
Treated area per day (A)	50	ha/d	
Application rate (AR)	0,00375	kg a.s./ha	
Number of applications (NA)	1	1)	
1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).			
Dermal absorption (DA)	70	% (worst case, e.g. during application)	
Inhalation absorption (IA)	100	%	
Oral absorption (OA)	100	%	
Systemic AOEL	0,05	mg/kg bw/d	
Body weight (BW)	60	kg/person (adults)	
	16,15	kg/person (children)	
Distance between application and bystander or resident:			
FCTM:	1	m	
High crops not selected			
		m	
Home & garden not selected			
		m	
Drift deposit (D) for 1 appl. based on appl. technique and distance:		2,77 % (FCTM, 1 m)	
Airborne vapour concentration (AC <sub>v</sub> )		mg/m <sup>3</sup> 2)	
2) 1 µg/m <sup>3</sup> for semivolatile substances, i.e. vapour pressure (20 °C): ≥ 1x10 <sup>-5</sup> - < 5x10 <sup>-3</sup> Pa; 15 µg/m <sup>3</sup> for volatile substances, i.e. vapour pressure (20 °C): ≥ 5x10 <sup>-3</sup> Pa			

### Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	cereals	Drift (D):	2,77	% (FCTM, 1 m)
Application rate (AR):	0,00375 kg a.s./ha	Exposed Body Surface Area (BSA):	1	m <sup>2</sup> (adults)
			0,21	m <sup>2</sup> (children)
Body weight (BW):	60 kg/person (adults)	Specific Inhalation Exposure (I <sub>A</sub> ):	0,001	mg/kg a.s. (6 hours, adults)
	16,15 kg/person (children)		0,00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	70,00 % ('worst case')	Area Treated (A):	50	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100 %	Exposure duration (T):	5	min
AOEL:	0,05 mg/kg bw/d			

Bystander exposure towards florasulam					
Adults			Children		
Bystander: Dermal exposure after application in cereals (via spray drift)					
SDE <sub>B</sub> = (AR x D x BSA x DA) / BW			SDE <sub>B</sub> = (AR x D x BSA x DA) / BW		
(0,375 x 2,77% x 1 x 70%) / 60			(0,375 x 2,77% x 0,21 x 70%) / 16,15		
External exposure	0,0103875	mg/person	External exposure	0,00218138	mg/person
External exposure	0,00017313	mg/kg bw/d	External exposure	0,00013507	mg/kg bw/d
Absorbed dose:	0,0001212	mg/kg bw/d	Absorbed dose:	0,0000945	mg/kg bw/d
Bystander: Inhalation exposure after application in cereals					
SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW			SIE <sub>B</sub> = (I* <sub>A</sub> x AR x A x T x IA) / BW		
(0,001 / 360 x 0,00375 x 50 x 5 x 100%) / 60			(0,001 / 360 x 0,00375 x 50 x 5 x 100%) / 16,15		
External exposure	2,6042E-06	mg/person	External exposure	1,4966E-06	mg/person
External exposure	4,3403E-08	mg/kg bw/d	External exposure	9,2672E-08	mg/kg bw/d
Absorbed dose:	0,0000000	mg/kg bw/d	Absorbed dose:	0,0000001	mg/kg bw/d
Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>			Total systemic exposure: SE <sub>B</sub> = SDE <sub>B</sub> + SIE <sub>B</sub>		
Total systemic exposure (absorbed dose)	0,00727385	mg/person	Total systemic exposure (absorbed dose)	0,00152846	mg/person
Total systemic exposure (absorbed dose)	0,0001212	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0000946	mg/kg bw/d
% of AOEL:	0,24	%	% of AOEL:	0,19	%

## Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

<b>Intended use(s):</b>	cereals	<b>Drift (D):</b>	2,77	% (FCTM, 1 m)
<b>Application rate (AR):</b>	0,00375 kg a.s./ha	<b>Transfer coefficient (TC):</b>	7300	cm <sup>2</sup> /h (adults)
<b>Number of applications (NA):</b>	1		2600	cm <sup>2</sup> /h (children)
<b>Body weight (BW):</b>	60 kg/person (adults)	<b>Turf Transferable Residues (TTR):</b>	5	%
	16,15 kg/person (children)	<b>Exposure Duration (H):</b>	2	h
<b>Dermal absorption (DA):</b>	70,00 % ('worst case')	<b>Airborne Concentration of Vapour (ACV):</b>	none	
<b>Inhalation absorption (IA):</b>	100 %	<b>Inhalation Rate (IR):</b>	16,57	m <sup>3</sup> /d (adults),
<b>Oral absorption (OA)</b>	100 %		8,31	m <sup>3</sup> /d (children)
<b>AOEL</b>	0,05 mg/kg bw/d	<b>Saliva Extraction Factor (SE):</b>	50	%
		<b>Surface Area of Hands (SA):</b>	20	cm <sup>2</sup>
		<b>Frequency of Hand to Mouth (Freq):</b>	20	events/h
		<b>Dislodgeable foliar residues (DFR):</b>	20	%
		<b>Ingestion Rate for Mouthing of Grass/Day (IgR):</b>	25	cm <sup>2</sup> /d

Resident exposure towards florasulam					
Adults			Children		
Residents: Dermal exposure after application in cereals (via deposits caused by spray drift)					
SDE <sub>R</sub> = (AR x NA x D x TTR x TC x H x DA) / BW			SDE <sub>R</sub> = (AR x NA x D x TTR x TC x H x DA) / BW		
(0,0000375 x 1 x 2,77% x 5% x 7300 x 2 x 70%) / 60			(0,0000375 x 1 x 2,77% x 5% x 2600 x 2 x 70%) / 16,15		
External exposure	0,00075829	mg/person	External exposure	0,00027008	mg/person
External exposure	1,2638E-05	mg/kg bw/d	External exposure	1,6723E-05	mg/kg bw/d
Absorbed dose:	0,0000088	mg/kg bw/d	Absorbed dose:	0,0000117	mg/kg bw/d
Residents: Inhalation exposure to vapour					
SIE <sub>R</sub> = (AC <sub>V</sub> x IR x IA) / BW			SIE <sub>R</sub> = (AC <sub>V</sub> x IR x IA) / BW		
(0 x 16,57 x 100%) / 60			(0 x 8,31 x 100%) / 16,15		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		none	Absorbed dose:		none
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE <sub>H</sub> = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0,0000375 x 1 x 2,77% x 5% x 50% x 20 x 20 x 2 x 100%) /		
			External exposure	2,0775E-05	mg/person
			External exposure	1,2864E-06	mg/kg bw/d
			Absorbed dose	0,0000013	mg/kg bw/d
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE <sub>O</sub> = (AR x NA x D x DFR x IgR x OA) / BW		
			(0,0000375 x 1 x 2,77% x 20% x 25 x 100%) / 16,15		
			External exposure	5,1938E-06	mg/person
External exposure	3,2159E-07	mg/kg bw/d			
Absorbed dose	0,0000003	mg/kg bw/d			
Total systemic exposure: SE <sub>R</sub> = SDE <sub>R</sub> + SIE <sub>R</sub>			Total systemic exposure: SE <sub>R</sub> = SDE <sub>R</sub> + SIE <sub>R</sub> + SOE <sub>H</sub> + SOE <sub>O</sub>		
Total systemic exposure (absorbed dose)	0,0005308	mg/person	Total systemic exposure (absorbed dose)	0,00021502	mg/person
Total systemic exposure (absorbed dose)	0,0000088	mg/kg bw/d	Total systemic exposure (absorbed dose)	0,0000133	mg/kg bw/d
% of AOEL:	0,02	%	% of AOEL:	0,03	%

**Table A 18: Estimation of longer term bystander exposure towards florasulam according to EUROPOEM II MODEL bystander exposure**

BYSTANDER EXPOSURE			EUROPOEM II MODEL	
form	FLD-HER 306 SE		Outdoor application	
as	florasulam			
Parameter		Value	Unit	References, comments
SPRAYING Process outdoor				
AR	Application rate	0,00375	kg a.s. / ha	summary of intended uses
SV	Spray volume	200	L / ha	summary of intended uses
Inhalation Exposure			without PPE	
	Default value			
SE	Surrogate Exposure Value	0,03	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation*
RR	Respiratory rate	1,25	m3 / h	default
Inhalation Exposure		0,0007	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
Dermal Exposure				
	Default value			
SE	Surrogate Exposure Value	0,005		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
Dermal Exposure		0,00375	mg a.s./ day	DE = SE xSA X (AR x 100)
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	70	%	
	AOEL	3	mg a.s./ day	based on 60 kg bw
		Without PPE		
Internal exposure		[mg a.s./ day ]		
	Inhalation	0,0007		IE(int) = IE x (IA/100)
	Dermal	0,003		DE(int) = DE x (DA/100)
	Total	0,003		sum
% AOEL				
	Inhalation	0,0		%AOEL = 100 x IE(int) / AOEL
	Dermal	0,1		%AOEL = 100 x DE(int) / AOEL
	Total	0		sum
*	One hour exposure is the default. It is referring to a potential 1 hour exposure, rather than the actual. It is based on the study design, and should not be lowered.			

### A 3.4 Combined exposure calculations for 2,4-D and florasulam

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – vehicle-mounted application	2,4-D	0.2845
	florasulam	0.0074
	<b>Cumulative risk operators (HI)</b>	<b>0.2919</b>



#### **Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)**

Not relevant.