

# REGISTRATION REPORT

## **Part B**

### **Section 6**

#### **Mammalian Toxicology**

Detailed summary of the risk assessment

Product code: GLOB182F

Product name(s): SURRENDER

Chemical active substance:

Fludioxonil, 100 g/L

Interzonal

Zonal Rapporteur Member State: PL

#### **CORE ASSESSMENT**

Applicant: Globachem NV

Date: January 2021

MS Finalisation date: August 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

### Version history

When	What
January 2021	Initial dRR – Globachem NV
August 2021	Initial izRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the izRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are <del>struck through and shaded for transparency</del> .
March 2022	Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the izRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant <del>is struck through and shaded</del> .

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#### Reviewer comments:

This dossier has been prepared to support registration of GLOB182F/Surrender in Poland and zonal registration for which PL was designated zRMS.

GLOB182F/Surrender is a new formulation containing 100 g/L fludioxonil for use as a flowable concentrate (FS) for seed treatment (GAP details see dRR B0).

Product was not a representative formulation reviewed during the Annex I inclusion/active substance renewal and has not previously been evaluated in any EU countries according to the Uniform Principles, thus it is not possible to refer to the DAR conclusion on fludioxonil with regard to the formulation studies. Therefore, relevant data on the plant protection product GLOB182F had to be generated for authorisation purposes.

For the current product registration, APPL provided an assessment of the toxicological potential based on calculation method (ATEmix). ZRMS PL, in accordance with the EC recommendations to avoid tests on animals, for the purposes of hazard classification use the data obtained using the calculation method and do not request for *in vivo* data.

Considering ATEmix/additivity formula and components content GLOB182F/Surrender has a low toxicity in respect to acute oral. Regarding inhalation, dermal toxicity and irritation potential for skin no relevant ingredients were classified for mentioned toxicity. PPP is irritant for eye H318 (based on relevant ingredient content) and skin sensitizer H317 (based on relevant ingredient content).

NDE assessment for operator and workers exposure to the fludioxonil considering all critical use(s) and all tasks identify safe use of the product GLOB182F/Surrender.

GLOB182F is a product for seed treatment and all tasks regarding this type of application (treatment of seeds) occurs indoor in stationary seed treatment facilities, thus there is no risk for exposure of B&R.

## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on GLOB182F \***


Product name and code	GLOB182F
Formulation type	Flowable concentrate for seed treatment [Code: FS]
Active substance(s) (incl. content)	Fludioxonil; 100 g/L
Function	Fungicide
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 Fludioxonil 100 FS 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 GLOB182F according to Regulation (EC) No 1272/2008 as amended**

Hazard class(es), categories:	Skin. Sens. 1 <sup>1)</sup> , H317 Eye Dam. 1, H318
Hazard pictograms or Code(s) for hazard pictogram(s):	
Signal word:	Danger
Hazard statement(s):	H317 May cause and allergic reaction H318 Causes serious eye damage.
Precautionary statement(s):	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/doctor/... P501 Dispose of contents/container to ... <i>Conditions for use ... in accordance with local/regional/national/ international regulation (to be specified).</i> <i>This statement could be partly different in each EU country.</i>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
Hazard determining component(s) for labelling of toxicological properties <sup>1)</sup> :	1,2-benzisothiazol-3(2H)-one; 2-methyl-2H-isothiazol-3-one

<sup>1)</sup> According to the Regulation (EC) No 1272/2008 as amended.

**Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for GLOB182F**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	PPE: Protective clothing and protective gloves against liquid chemicals - relating to classification (H318, H317), and to the exposure estimate for the concentrated product. Personal eye-protection (chemical goggles or face shield) during mixing/loading and handling the contaminated surfaces - relating to classification (H318, H317). Personal eye-protection need not be used during the bagging process.
Workers	Acceptable	PPE: Protective clothing and protective gloves during handling of treated seeds - relating to classification (H317).
Bystanders	Acceptable	None
Residents	Acceptable	None

**Note:** Calculations of operator exposure have been updated by the applicant since the dermal absorption value for the in-use dilution (50%) was incorrectly applied for mixing and loading activities, where operator's exposure to the concentrated product (10% dermal absorption) has to be considered. These results are confirmed by the results of the French SeedTROPEX model (75th percentile). Note that this has no effect on the conclusion, since operators still need to wear protective clothing and protective gloves against liquid chemicals - relating to classification (H318, H317) of the product.

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in <sup>1)</sup> According to the Regulation (EC) No 1272/2008 as amended.

Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents 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, work- er, bystander or resident expo- sure based on [Exposure model]	Acceptability of exposure as- sessment			
			Method / Kind (incl. appli- cation technique )	Max. number (min. interval between appli- cations)  a) per use b) per crop/ season	mL product/ 100kg seeds	Max. application rate (g as/ha)	Seedling rate (kg seeds/ha)			Operator	Worker	Bystander	Residents
1	Sunflower	I (treat- ment seeds) F (sowing)	Seed treatment	a) 1 b) 1	150	1.6875	3.5-11.3	N/A	4-8 L water/ton seeds (incl. product)			*	*
2	Maize	I (treat- ment seeds) F (sowing)	Seed treatment	a) 1 c) 1	50	2.375	24-47.5	N/A	4-8 L water/ton seeds (incl. product)			*	*

NR: Not relevant.

\* GLOB182F is a product for seed treatment and all tasks regarding this type application (treatment of seeds) occurs indoor in stationary seed treatment facilities hence, no exposure is expected for B&R. (for details refer point 6.6.4, p.12 of the dRR)

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

Noticed data gaps are:

Not applicable.

## 6.2 Toxicological Information on Active Substance

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

**Table 6.2-1: Information on active substance**

Fludioxonil	
Common Name	Fludioxonil
CAS-No.	131341-86-1
<b>Classification and proposed labelling</b>	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: / Code for hazard pictogram: / Signal word: / Hazard statement: / Precautionary statement: /
Additional C&L proposal	/
<b>Agreed EU endpoints</b>	
AOEL systemic	0.59 mg/kg bw/d (safety factor of 100)
Reference	EFSA Scientific Report (2007) 110, 1-85

	<b>Fludioxonil</b>
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>	
EFSA Conclusion for active substance	None relevant to seed treatment use.
GLOB182F contains fludioxonil which is listed as a Candidate for Substitution (Regulation (EU) 2015/408).	

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB182F is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB182F**

Type of test, species, model system	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat	<del>Study not necessary;</del> Hazard classification has been based on generic concentration limits ( sum of relevant ingredients). ATEmix-oral > 2000 mg/kg	Yes	None	Theoretical calculations (see part C)
LD <sub>50</sub> dermal, rat	<del>Study not necessary;</del> Hazard classification has been based on generic concentration limits ( sum of relevant ingredients). no relevant ingredients was classified for acute dermal toxicity; (see part C).	Yes	None	Theoretical calculations (see part C)
LC <sub>50</sub> inhalation, rat	<del>Study not necessary;</del> Hazard classification has been based on generic concentration limits ( sum of relevant ingredients). no relevant ingredients was classified for acute inhalation toxicity; (see part C).	Yes	None	Theoretical calculations (see part C)
Skin irritation	<del>Study not necessary;</del> Hazard classification has been based on generic concentration limits ( sum of relevant ingredients). no relevant ingredients was classified for skin corrosion/irritation; (see part C). one ingredient is classified as Skin Corr. 1A but is present below generic concentration limit and is thus not relevant for product classification; (see part C)	Yes	None	Theoretical calculations (see part C)
Eye irritation	<del>Study not necessary;</del> Hazard classification has been based on generic concentration limits ( sum of relevant ingredients). the sum of two three ingredients with H318 is higher than the generic concentration limit (3%)	Yes	Eye Dam. 1, H318	Theoretical calculations (see part C)
Skin sensitisation	<del>Study not necessary;</del> Hazard classification has been based on generic concentration limits ( sum of relevant ingredients). classification based on the specific concentration limit of one co-formulant with Skin Sens. 1A, H317	Yes	Skin Sens. 1A, H317	Theoretical calculations (see part C)
Supplementary studies for combinations of plant protection products	No data – not required	Not applicable		

**Table 6.3-2: Additional toxicological information relevant for classification/labelling of GLOB182F**

	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)	/	/	/	/
Toxicological properties of non-active substance(s) (relevant for classification of product)	1,2-benzisothiazol- 3(2H)-one (CAS No. 2634-33-5, < 0.05% (w/w))*	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin. Sens. 1, H317 (SCL: Skin Sens. 1, H317: C ≥ 0.05 %)	Reg. (EC) No 1272/2008 as amended	Not classified
	2-methyl-2H-isothiazol- 3-one ** (CAS No. 2682-20-4) content 0.01% in PPP	Acute Tox. 2, H330 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 (SCL: Skin Sens. 1A, H317: C ≥ 0.0015 %)	Reg. (EC) No 1272/2008 as amended	Skin Sens. 1A, H317
Further toxicological information	No data – not required			

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

\*\* Regulation (EU) 2018/1480

## 6.4 Toxicological Evaluation of Groundwater Metabolites

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

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in GLOB182F are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in GLOB182F**

	Fludioxonil	
	Value	Reference
Concentrate	10%	EFSA Journal 2017;15(6):4873
Dilution	50%	EFSA Journal 2017;15(6):4873

### 6.5.1 Justification for proposed values - Fludioxonil

No data on dermal absorption for Fludioxonil in GLOB182F 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 GLOB182F**

	Value	Justification for value	Acceptability of justification
Concentrate	10%	default	Justification accepted
Dilution	50%	default	Justification accepted



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

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

Product name and code	GLOB182F
Formulation type	FS
Category	Fungicide
Active substance(s) (incl. content)	<b>Fludioxonil</b> 100 g/L
AOEL systemic	0.59 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	80%
Dermal absorption	Concentrate: 10% Dilution (1:8 ): 50% (Default)

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

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

#### Justification

The critical gap used for the exposure assessment is selected based on the highest application rate (worst-case).

### 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 GLOB182F according to the critical use(s) is presented in Table 6.6-2 and Table 6.6 4. Outcome of the estimation is presented in Table 6.6-3 and Table 6.6-5. Detailed calculations are in Appendix 3. The UK version of the Seed-TROPEX model was used. However, calculations with the French seed TROPEX model have also been added.

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

Critical use(s)	Sunflower (max. 150 mL product/100kg seeds)
Model(s)	SeedTROPEX model (geometric mean values)

**Table 6.6-3: Estimated operator exposure**

		Fludioxonil		
Model data	Dilution	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Continuous flow seed treaters with closed mixing chambers				
Application rate: 0.150 kg a.s./ton seeds				
<b>SEEDTROPEX Model</b> • 10 hours/day of which 1 hour for loading, calibration and cleaning and 8	Undiluted	No PPE	0.864	146.41
		PPE (gloves and protective clothes during all operations)	0.174	29.44

hours for seed bagging • Treatment capacity: 4 ton/hour (32 tons per day) • Packaging: 1 L • 60 kg operator	Dilution 1:8	No PPE	0.444	75.2
		PPE (gloves and protective clothes during all operations)	0.275	46.67

**Table 6.6-4: Estimated operator exposure**

Table 6.5-4: Estimated operator exposure				
			Fludioxonil	
Model data	Dilution	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Continuous flow seed treaters with closed mixing chambers				
Application rate: 0.150 kg a.s./ton seeds				
<b>SEEDTROPEX Model</b> <ul style="list-style-type: none"><li>• 8 hours/day of which 1 hour for loading, calibration and cleaning and 7 hours for seed bagging</li><li>• Treatment capacity: 4 ton/hour (32 tons per day)</li><li>• Packaging: 1 L</li><li>• 60 kg operator</li></ul>	Undiluted	Standard work clothing	0.265	44.944
		Protective gloves during during all phases except bagging	0.111	18.796
	Dilution 1:8	Standard work clothing	0.280	47.506
		Protective gloves during during all phases except bagging	0.117	19.769

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

Critical use(s)	Maize (max. 50 mL product/100kg seeds)
Model(s)	SeedTROPEX model (geometric mean values)

**Table 6.6-5: Estimated operator exposure**

Table 6.3-5: Estimated operator exposure				
			Fludioxonil	
Model data	Dilution	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Continuous flow seed treaters with closed mixing chambers				
Application rate: 0.150 kg a.s./ton seeds				
<b>SEEDTROPEX Model</b>  • 8 hours/day of which 1 hour for loading, calibration and cleaning and 7 hours for seed bagging  • Treatment capacity: 7.5 ton/hour (60 tons per day)	Undiluted	Standard work clothing	0.243	41.183
		Protective gloves during during all phases except bagging	0.091	15.378
	Dilution 1:8	Standard work clothing	0.243	41.183
		Protective gloves during during all phases except bagging	0.091	15.378

<ul style="list-style-type: none"> <li>• Packaging: 1 L</li> <li>• 60 kg operator</li> </ul>				
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Operator exposure was also modelled using the SeedTROPEX model (75th values) for seed treatment and loading and sowing of treated seeds.

The French SeedTROPEX model for seed treatment activities was derived from the original SeedTROPEX database, but adopted the following changes, which were in line with the comments from the Methodology group of the Advisory Committee on Pesticides of the French Ministry of Agriculture.

In the French SeedTROPEX model for seed treatment four different scenarios regarding personal protective equipment (PPE) are considered. In “Scenario 1” no protection is worn during any of the seed treatment activities. “Scenario 2” considers gloves worn during all phases except bagging. For “Scenario 3” gloves are worn during all phases except bagging and respiratory protection worn (level P2 minimum) during the cleaning phase. In “Scenario 4” gloves and non-woven clothing is considered during all phases except gloves during bagging and respiratory protection (level P2 minimum) during the cleaning and bagging phases. A body weight of 70 kg and 60 kg is taken into account.

According to the French Advisory Council on Pesticides for evaluation the 75th percentile of the SeedTROPEX database will be used. The 75th percentile of the exposure data will be compared to the AOEL; this ratio will be used as criterion for a decision of acceptability of the risk.

A summary of the exposure models used for estimation of operator exposure to the active substances during application of GLOB182F according to the critical use(s) is presented in Table 6.6 4. Outcome of the estimation is presented in Table 6.6-4: and Table 6.6-4. Detailed calculations are in Appendix 3.

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

Critical use(s)	Sunflower (max. 150 mL product/100kg seeds)
Model(s)	French SeedTROPEX model (75th percentile)

**Table 6.6-7: Estimated operator exposure**

			Fludioxonil	
Model data	Dilution	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Continuous flow seed treaters with closed mixing chambers				
Application rate: 0.150 kg a.s./ton seeds				
<b>French SEEDTROPEX Model</b> <ul style="list-style-type: none"> <li>• 8 hours/day of which 1 hour, calibration and cleaning and 7 hours for seed bagging</li> <li>• Treatment capacity: 4 ton/hour (32 tons per day)</li> <li>• Packaging: 1 L</li> <li>• 60 kg operator</li> </ul>	Undiluted	Long-sleeved jacket and long trousers as usual work wear	0.2607	44.19
		Long-sleeved jacket and long trousers as usual work wear + Gloves during all phases except bagging	0.1021	17.31
	Dilution 1:8	Long-sleeved jacket and long trousers as usual work wear	0.4532	76.82
		Long-sleeved jacket and long trousers as usual work wear +	0.1846	31.29

		<b>Gloves during all phases except bagging</b>		
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**Table 6.6-8: Exposure models for intended uses**

<b>Critical use(s)</b>	Maize (max. 50 mL product/100kg seeds)
<b>Model(s)</b>	French SeedTROPEX model (75th percentile)

**Table 6.6-9: Estimated operator exposure**

		<b>Fludioxonil</b>		
<b>Model data</b>	<b>Dilution</b>	<b>Level of PPE</b>	<b>Total absorbed dose (mg/kg/day)</b>	<b>% of systemic AOEL</b>
Continuous flow seed treaters with closed mixing chambers				
Application rate: 0.050 kg a.s./ton seeds				
<b>French SEEDTROPEX Model</b> <ul style="list-style-type: none"> <li>8 hours/day of which 1 hour, calibration and cleaning and 7 hours for seed bagging</li> <li>Treatment capacity: 7.5 ton/hour (60 tons per day)</li> <li>Packaging: 1 L</li> <li>60 kg operator</li> </ul>	Undiluted	Long-sleeved jacket and long trousers as usual work wear	0.2081	35.28
		Long-sleeved jacket and long trousers as usual work wear + <b>Gloves during all phases except bagging</b>	0.0838	14.2
	Dilution 1:8	Long-sleeved jacket and long trousers as usual work wear	0.4006	67.90
		Long-sleeved jacket and long trousers as usual work wear + <b>Gloves during all phases except bagging</b>	0.1663	28.18

### **Mobile treaters**

The SeedTROPEX model does not contain data for the assessment of exposure of operators treating seeds on mobile equipment.

For the following reasons exposure to operators treating seed on mobile equipment is considered to be in the same range or less than the exposure to operators working in static plants:

- Treatment on mobile equipment is usually done outside. This will most likely lead to lower levels of dust in the vicinity of the operators compared to working in a closed environment.
- Treatment capacities are estimated to be lower (0.5 to 2 tonnes/hour) on mobile equipment compared to static industrial equipment (estimated to be in the range of 2 to 9 tonnes/hour).
- Exposure time is likely to be shorter than in static plants because part of the working day is used for movement of the treatment equipment to the farms or between farms.

Calculations for industrial seed treatment according to the SeedTROPEX model predict acceptable levels of exposure to fludioxonil for operators wearing a long sleeved work jacket and long trousers. The degree of protection defined is considered to be appropriate for operators working on mobile treatment equipment.

### **On-farm treatment**

The Seed-TROPEX model does not contain data for the assessment of exposure of operators treating seeds using on-farm treatment equipment.

For the following reasons exposure to operators treating seed on-farm is considered to be in the same range or less than the exposure to operators working in static plants:

- Treatment on-farm is usually done outside. This will most likely lead to lower levels of dust in the vicinity of the operators compared to working in a closed environment.
- Treatment capacities are estimated to be lower (0.5 to 2 tonnes/hour) with on-farm equipment compared to static industrial equipment (estimated to be in the range of 2 to 9 tonnes/hour).
- Exposure time is likely to be shorter than in static plants because the operator will only treat sufficient seed for planting on the farm.

Calculations for industrial seed treatment according to the Seed-TROPEX model predict acceptable levels of exposure to fludioxonil for operators wearing a long-sleeved work jacket and long trousers. The degree of protection defined is considered to be appropriate for operators working with on-farm treatment equipment.

### Conclusion

Based on the calculation of operator exposure with the SeedTROPEX model, it is concluded that the risk for the operator using GLOB182F on maize at up to 0.5 L/ton is acceptable with the use of PPE (gloves and protective clothes) for the undiluted product and even without PPE for the dilution, when loading and sowing seeds treated with 1.5 L GLOB182F/ton.

### Conclusion

Based on the calculation of operator exposure with the SeedTROPEX model (geometric mean values), it is concluded that the risk for the operator using GLOB182F on maize and sunflower is acceptable with the use of PPE (gloves and protective clothes) for the undiluted product and even without PPE for the dilution, when loading and sowing seeds treated with 0.5 or 1.5 L GLOB182F/ton.

Based on the calculation of operator exposure with the French SeedTROPEX model (75th percentile), it is concluded that the risk for the operator using GLOB182F on sunflower, at up to 1.5 L/ton, and maize, at up to 0.5 L/ton, is acceptable without the use of PPE normal workwear (Long-sleeved jacket and long trousers as usual work wear) for the undiluted product and the dilution, when loading and sowing seeds treated with GLOB182F.

#### 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 considering 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 10 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB182F according to the critical use. Outcome of the estimation is presented in

Workers other than operators may be exposed only while sowing the treated seeds, when opening sacks containing the treated seeds and when filling the tanks of a sowing machine.

**Table 6.6-5: Estimated worker exposure**

		Fludioxonil	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Preparation and sowing of seeds Maximum seed rate: 47.5 kg seed/ha, 2.375 g a.s./ha Outdoor Work rate: 10 hours/day			
Application rate		0.050 kg a.s./ton seeds	
<b>SEEDTROPEX Model</b> • EADE = 0.730 mg/person/day • EPDE = 1.48 mg/person/day • Inhalation = 0.02 mg/person/day • 60 kg worker	No PPE	0.1267	21.47
	PPE (gloves and protective clothes during all operations)	0.0642	10.88

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

Critical use(s)	Maize and sunflower (max. 150 mL product/100kg seeds)
Model	SeedTROPEX model (geometric mean values)

Workers other than operators may be exposed only while sowing the treated seeds, when opening sacks containing the treated seeds and when filling the tanks of a sowing machine.

**Table 6.6-11: Estimated worker exposure (geometric mean values)**

		Fludioxonil	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Preparation and sowing of seeds Maximum seed rate: 47.5 kg seed/ha, 2.375 g a.s./ha Outdoor Work rate: 8 hours/day			
Application rate	0.050 kg a.s./ton seeds		
<b>SEEDTROPEX Model</b> <ul style="list-style-type: none"> <li>• EADE = 0.730 mg/person/day</li> <li>• EPDE = 1.48 mg/person/day</li> <li>• Inhalation = 0.02 mg/person/day</li> <li>• 60 kg worker</li> </ul>	No PPE	0.101	17.18
	PPE (gloves and protective clothes during all operations)	0.052	8.73

Estimations are done using the French SeedTROPEX model for sowing activities.

In the SeedTROPEX studies the operators wore a long sleeved work jacket and long trousers as usual work wear during all tasks and in addition gloves when handling treated seeds. Thus, in the SeedTROPEX model the estimated actual dermal exposure (EADE) values, therefore, reflect this level of PPE.

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

Critical use(s)	Maize and sunflower (max. 150 mL product/100kg seeds)
Model	French SeedTROPEX model (75th percentile values)

**Table 6.6-13: Estimated worker exposure (75th percentile values)**

		Fludioxonil	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Preparation and sowing of seeds Maximum seed rate: 47.5 kg seed/ha, 2.375 g a.s./ha Outdoor Work rate: 8 hours/day			
Application rate	0.050 kg a.s./ton seeds		
<b>SEEDTROPEX Model</b> <ul style="list-style-type: none"> <li>• EADE = 1.73 mg/person/day</li> <li>• Inhalation = 0.02 mg/person/day</li> <li>• 60 kg worker</li> </ul>	Long-sleeved jacket and long trousers as usual work wear	0.119	20.20

### Conclusion

Based on the calculation of worker exposure with the SeedTROPEX model, it is concluded that there is no unacceptable risk anticipated for workers wearing adequate work clothing (but no PPE) when loading and sowing seeds treated with 1.5L GLOB182F/ton.. Detailed calculations are in Appendix 3.

**Table 6.6-5: Exposure models for intended uses**

Critical use(s)	Maize (max. 150 mL product/100kg seeds)
Model	SeedTROPEX model

Workers other than operators may be exposed only while sowing the treated seeds, when opening sacks containing the treated seeds and when filling the tanks of a sowing machine.

**Table 6.6-5: Estimated worker exposure**

		Fludioxonil	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Preparation and sowing of seeds Maximum seed rate: 47.5 kg seed/ha, 2.375 g a.s./ha Outdoor Work rate: 10 hours/day			
Application rate		0.050 kg a.s./ton seeds	
<b>SEEDTROPEX Model</b> • EADE = 0.730 mg/person/day • EPDE = 1.48 mg/person/day • Inhalation = 0.02 mg/person/day • 60 kg worker	No PPE	0.1267	21.47
	PPE (gloves and protective clothes during all operations)	0.0642	10.88

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

Critical use(s)	Maize and sunflower (max. 150 mL product/100kg seeds)
Model	SeedTROPEX model (geometric mean values)

Workers other than operators may be exposed only while sowing the treated seeds, when opening sacks containing the treated seeds and when filling the tanks of a sowing machine.

**Table 6.6-11: Estimated worker exposure (geometric mean values)**

		Fludioxonil	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Preparation and sowing of seeds Maximum seed rate: 47.5 kg seed/ha, 2.375 g a.s./ha Outdoor Work rate: 8 hours/day			
Application rate		0.050 kg a.s./ton seeds	



<b>SEEDTROPEX Model</b> <ul style="list-style-type: none"> <li>• EADE = 0.730 mg/person/day</li> <li>• EPDE = 1.48 mg/person/day</li> <li>• Inhalation = 0.02 mg/person/day</li> <li>• 60 kg worker</li> </ul>	No PPE	0.101	17.18
	PPE (gloves and protective clothes during all operations)	0.052	8.73

Estimations are done using the French SeedTROPEX model for sowing activities.

In the SeedTROPEX studies the operators wore a long-sleeved work jacket and long trousers as usual work wear during all tasks and in addition gloves when handling treated seeds. Thus, in the SeedTROPEX model the estimated actual dermal exposure (EADE) values, therefore, reflect this level of PPE.

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

Critical use(s)	Maize and sunflower (max. 150 mL product/100kg seeds)
Model	French SeedTROPEX model (75 <sup>th</sup> percentile values)

**Table 6.6-13: Estimated worker exposure (75<sup>th</sup> percentile values)**

		Fludioxonil	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Preparation and sowing of seeds Maximum seed rate: 47.5 kg seed/ha, 2.375 g a.s./ha Outdoor Work rate: 8 hours/day			
Application rate		0.050 kg a.s./ton seeds	
<b>SEEDTROPEX Model</b> <ul style="list-style-type: none"> <li>• EADE = 1.73 mg/person/day</li> <li>• Inhalation = 0.02 mg/person/day</li> <li>• 60 kg worker</li> </ul>	Long-sleeved jacket and long trousers as usual work wear	0.119	20.20

### Conclusion

Based on the calculation of worker exposure with the SeedTROPEX model, it is concluded that there is no unacceptable risk anticipated for workers wearing adequate work clothing (but no PPE) when loading and sowing seeds treated with 1.5L GLOB182F/ton.

### Conclusion

Based on the calculation of worker exposure with the SeedTROPEX model, it is concluded that there is no unacceptable risk anticipated for workers wearing adequate work clothing (but no PPE) when loading and sowing seeds treated with 1.5L GLOB182F/ton.

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

Not required since worker exposure was found to be acceptable without using dislodgeable residue data.

### **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 Bystander and resident exposure (KCP 7.2.2)**

#### **6.6.4.1 Estimation of bystander and resident exposure**

Bystander exposure to GLOB182F was not evaluated as part of the EU review of Fludioxonil. However, a product based on Fludioxonil 25 g/L FS (Celest 025 FS) was one of the lead formulations during the EU review of Fludioxonil. In this review, the bystander exposure to Fludioxonil in a seed treatment product was evaluated. It was concluded that bystander exposure in stationary seed treatment facilities was rare. If an incidental presence of bystanders would occur at a seed treatment facility, it is assumed to be a short duration of exposure and normally lower than that of seed treatment operators who are occupationally exposed longer. Therefore, it was assumed that there would be no risk to persons being incidentally exposed during seed treatment operations with a seed treatment product containing 25 g/L Fludioxonil.

The same conclusion can be made for GLOB182F which contains 100 g/L Fludioxonil. As GLOB182F is a product for seed treatment and treatment of seeds occurs indoor in stationary seed treatment facilities, there is no risk for exposure of residents living in close vicinity of seed treatment facilities.

#### **6.6.4.2 Measurement of bystander and/or resident exposure**

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Fludioxonil will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

### **6.6.5 Combined exposure**

Not relevant. The product contains only one active substance.

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

### 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
-	-	-	-	-	-

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

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

**List of data relied on not submitted by the applicant but necessary for evaluation**

<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

No bridging was necessary.

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

No new study was submitted.

**Reviewer comment:** Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C)

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

No new study was submitted.

**Reviewer comment:** Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C)

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

No new study was submitted.

**Reviewer comment:** Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C)

### A 2.5 Skin irritation (KCP 7.1.4)

No new study was submitted.

**Reviewer comment:** Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C)

### A 2.6 Eye irritation (KCP 7.1.5)

No new study was submitted.

**Reviewer comment:** Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C)

### A 2.7 Skin sensitisation (KCP 7.1.6)

No new study was submitted.

**Reviewer comment:** Hazard assessment and proposed classification of the product is based on content ingredients of the mixture (Additivity formula) (for details see Part C)

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

Not required.

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

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

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

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

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

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

No studies required.

## Appendix 3 Exposure calculations

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

The generic exposure values used for the estimation of the operator exposure for the critical use of GLOB182F on MAize are derived from the SeedTROPEX studies and UK HSE data. They are presented in table A 12 below:

**Table A 1: Task-related generic exposures of seed treatment plant operatives as used in SeedTROPEX (geometric mean values)**

Task		Total potential dermal exposure (mL/operation)*	Estimated actual dermal exposure (mL/operation)*	Potential inhalation exposure (mL/operation)*
Calibration		0.033	0.014	0.001**
Mixing/loading	Fast-couple	0.0052	0.005	0.0001
	Pre-mix	0.0047	0.001	0.0001
Bagging (mg as/h)	Good LEV	1.84	0.698	0.0054***
	Poor LEV	1.84	0.698	0.054***
Cleaning		0.872	0.083	0.016**
* Exposure during bagging in mg/h. ** In the original SeedTROPEX model, these values were incorrect (under estimated). *** These values are based on a combination of SeedTROPEX data and HSE data.				

The assumptions/data utilised in the calculation of operator exposure during seed treatment are summarised in the Table A 2. GLOB182F is packed in 1L, 5L, 10L, 15L, 20L, 200L or 1000L HDPE packaging. The model was run for the 1L packaging which is considered as a worst case since it requires the biggest number of mixing-loading operations. Therefore was considered 1 operation of calibration and cleaning, 48 operations of mixing and loading and 8 hours of bagging per day as the worst case.

**Table A 2: Input parameters considered for the estimation of operator exposure for dilution range 5-20L/ton seeds**

	Fludioxonil	
	Scenario 1 Undiluted	Scenario 2 Dilution 1:8
Concentration active ingredient in the product (g/L)	100	100
Lowest in-use concentration (g/L)	100	50 12.5
Pack size (L)	1	1
Application rate (L/ton)	1.5	1.5
Amount seed treated (tons/h)	4	4
Throughput (tons/day)	32	32
Amount product handled (L/day)	48	48
Worker bodyweight (kg)	60	60
Dermal absorption concentrate (%)	10	10
Dermal absorption dilution (%)	50 10	50
Inhalation absorption (%)	100	100
AOEL (mg/kg bodyweight)	0.59	0.59

The results of the operator exposure are presented in the tables A 3 and 4 for the scenarios 1 (undiluted) and 2 (diluted) respectively.

**Table A 3: Results of the operator exposure for Fludioxonil in scenario 1 (undiluted)**

Task	Potential dermal exposure to fludioxonil (mg as/pers x h or operation)	Estimated actual dermal exposure to fludioxonil (mg as/pers x h or operation)	Inhalation exposure to fludioxonil (mg as/pers x h or operation)	Number of operation or hours	Total potential dermal exposure to fludioxonil (mg as/pers)	Estimated actual dermal exposure to fludioxonil (mg as/pers)	Inhalation exposure to fludioxonil (mg as/pers)	Total potential dermal exposure to fludioxonil (mg as/kg bw)	Estimated actual dermal exposure to fludioxonil (mg as/kg bw)	Inhalation exposure to fludioxonil (mg as/kg bw)
Calibration		3.30	0.100	1	3.30	1.40	0.100	0.05500	0.02333	0.00167
Mixing/loading	Fast-couple	0.52	0.50	48	24.96	24.00	0.480	0.41600	0.40000	0.00800
	Pre-mix	0.47	0.10	48	22.56	4.80	0.480	0.37600	0.08000	0.00800
Bagging	good LEV	1.84	0.70	8	14.72	5.58	0.043	0.24533	0.09307	0.00072
	poor LEV	1.84	0.70	8	14.72	5.58	0.432	0.24533	0.09307	0.00720
		0.00	0.00	8	0.00	0.00	0.000	0.00000	0.00000	0.00000
Cleaning		87.20	8.30	1	87.20	8.30	1.600	1.45333	0.13833	0.02667
Task	Systemic potential exposure to fludioxonil (mg as/kg bw)	Systemic actual dermal exposure to fludioxonil (mg as/kg bw)	Systemic inhalation exposure to fludioxonil (mg as/kg bw)	Total potential systemic exposure to fludioxonil (mg as/kg bw)	Total actual systemic exposure to fludioxonil (mg as/kg bw)	% AOEL (no PPE)	% AOEL (PPE)			
Calibration	0.0275	0.0117	0.0017	0.0292	0.0133	4.94	2.26			
Mixing/loading	Fast-couple	0.0416	0.0400	0.0080	0.0496	0.0480	8.41			
	Pre-mix	0.0376	0.0080	0.0080	0.0456	0.0160	7.73			
Bagging	good LEV	0.0245	0.0093	0.0007	0.0253	0.0100	4.28			
	poor LEV	0.0245	0.0093	0.0072	0.0317	0.0165	5.38			
		0.0000	0.0000	0.0000	0.0000	0.00	0.00			
Cleaning	0.7267	0.0692	0.0267	0.7533	0.0958	127.68	16.24			
Total				0.864	0.174	146.412	29.436			

**Table A 4: Results of the operator exposure for Fludioxonil in scenario 2 (diluted 1:1)**

Task	Potential dermal exposure to fludioxonil (mg as/pers x h or operation)	Estimated actual dermal exposure to fludioxonil (mg as/pers x h or operation)	Inhalation exposure to fludioxonil (mg as/pers x h or operation)	Number of operation or hours	Total potential dermal exposure to fludioxonil (mg as/pers)	Estimated actual dermal exposure to fludioxonil (mg as/pers)	Inhalation exposure to fludioxonil (mg as/pers)	Total potential dermal exposure to fludioxonil (mg as/kg bw)	Estimated actual dermal exposure to fludioxonil (mg as/kg bw)	Inhalation exposure to fludioxonil (mg as/kg bw)
Calibration		1.65	0.70	1	1.65	0.70	0.050	0.02750	0.01167	0.00083
Mixing/loading	Fast-couple	0.52	0.50	48	24.96	24.00	0.480	0.41600	0.40000	0.00800
	Pre-mix	0.47	0.10	48	22.56	4.80	0.480	0.37600	0.08000	0.00800
Bagging	good LEV	1.84	0.70	8	14.72	5.58	0.043	0.24533	0.09307	0.00072
	poor LEV	1.84	0.70	8	14.72	5.58	0.432	0.24533	0.09307	0.00720
		0.00	0.00	8	0.00	0.00	0.000	0.00000	0.00000	0.00000
Cleaning		43.60	4.15	1	43.60	4.15	0.800	0.72667	0.06917	0.01333
Task	Systemic potential exposure to fludioxonil (mg as/kg bw)	Systemic actual dermal exposure to fludioxonil (mg as/kg bw)	Systemic inhalation exposure to fludioxonil (mg as/kg bw)	Total potential systemic exposure to fludioxonil (mg as/kg bw)	Total actual systemic exposure to fludioxonil (mg as/kg bw)	% AOEL (no PPE)	% AOEL (PPE)			
Calibration	0.0138	0.0058	0.0008	0.0146	0.0067	2.47	1.13			
Mixing/loading	Fast-couple	0.2080	0.2000	0.0080	0.2160	0.2080	36.61			
	Pre-mix	0.1880	0.0400	0.0080	0.1960	0.0480	33.22			
Bagging	good LEV	0.1227	0.0465	0.0007	0.1234	0.0473	20.91			
	poor LEV	0.1227	0.0465	0.0072	0.1299	0.0537	22.01			
		0.0000	0.0000	0.0000	0.0000	0.00	0.00			
Cleaning	0.3633	0.0346	0.0133	0.3767	0.0479	63.84	8.12			
Total				0.737	0.316	124.935	53.613			

In all seed treatment related activities, the model calculations indicate that the systemic exposure to Fludioxonil is below the established AOEL of 0.59 mg/kg bw x day, with the use of PPE (gloves and protective clothes) for the undiluted product and for the 1:1 dilution.

According to the model calculations, it can be concluded that the risk for the operator using GLOB182F on maize at up to 0.5 L/ton is acceptable provided the appropriate personal protective equipment is used.

### A 3.2 Worker exposure calculations (KCP 7.2.3.1)

The SeedTROPEX modelling is based on generic exposure figures for dermal and inhalation exposure covering exposure during loading and sowing of treated seed. These generic exposure figures were determined based on studies performed with active substances applied at 370 or 500 g a.s./ton seed and are shown in table A 5. They are expressed in mg a.s./hour and do not take into account the amount of active substance applied to seed. The estimation is based on 10 hours of work for an worker weighing 60kg.

**Table A 5: Generic exposure values for dermal and inhalation exposure during loading and sowing of treated seeds**

Exposition	Possible dermal absorption (mg/person per day) without personal protective equipment	Actual dermal exposure (mg/person per day) with personal protective equipment	Inhalation exposure (mg/person per day) without respiratory protection
Preparation and sowing of seeds – standard values (mg/hour)	1.48	0.73	0.02
10-hour work	14.80	7.30	0.20



Worker exposure following loading and sowing of treated seeds was calculated with and without personal protective equipment and the default dermal absorption values according to the EFSA Guidance 2017 for Fludioxonil. The results are given below:

**Table A 6: Actual dermal exposure to Fludioxonil with PPE**

Route of exposure	Route-specific	Working time	Route-specific exposure	Absorption	Systemic exposure	Systemic exposure	% AOEL
	[mg/person/hr]	[hrs/day]	[mg/person/day]	[%]	[mg/person/day]	[mg/kg bw/day]	
EADE <sup>1)</sup>	0.730	10	7.30	50	3.65		
Inhalation	0.02	10	0.2	100	0.2		
Total systemic dose					3.85	0.064	10.88

1) Estimated actual dermal exposure

**Table A 7: Potential dermal exposure to Fludioxonil without PPE**

Route of exposure	Route-specific	Working time	Route-specific exposure	Absorption	Systemic exposure	Systemic exposure	% AOEL
	[mg/person/hr]	[hrs/day]	[mg/person/day]	[%]	[mg/person/day]	[mg/kg bw/day]	
EPDE <sup>1)</sup>	1.48	10	14.8	50	7.4		
Inhalation	0.02	10	0.2	100	0.2		
Total systemic dose					7.6	0.1267	21.47

1) Estimated potential dermal exposure

### A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

Not relevant.

**Note:** Calculations of operator exposure have been updated by the applicant since the dermal absorption value for the in-use dilution (50%) was incorrectly applied for mixing and loading activities, where operator's exposure to the concentrated product (10% dermal absorption) has to be considered. These results are confirmed by the results of the French SeedTROPEX model (75<sup>th</sup> percentile) provided below.

**Table A 8: Results of the operator exposure for Fludioxonil in scenario 1 (undiluted)**

Task		Exposure (mg/person/day)			Systemic exposure (mg/kg bw/d)		% AOEL (AOEL: 0.59 mg/kg bw x d)	
		Dermal		Inhalative	Potential (no PPE)	Estimated actual (PPE)	Potential (no PPE)	Estimated actual (PPE)
		Potential (no PPE)	Estimated actual (PPE)					
Calibration		3.367	1.429	0.102	0.0073	0.0041	1.24	0.69
Mixing/loading	Fast-couple	25.469	24.490	0.490	0.0506	0.0490	8.58	8.30
	Pre-mix	23.020	4.898	0.490	0.0465	0.0163	7.89	2.77
Bagging	good LEV	14.720	5.584	0.043	0.0253	0.0100	4.28	1.70
	poor LEV	14.720	5.584	0.432	0.0317	0.0165	5.38	2.80
		0.000	0.000	0.000	0.0000	0.0000	0.00	0.00
Cleaning		88.979	8.469	1.633	0.1755	0.0413	29.75	7.00
		Total			0.265	0.111	44.944	18.796

**Table A 9: Results of the operator exposure for Fludioxonil in scenario 2 (diluted 1:8)**

Task		Exposure (mg/person/day)			Systemic exposure (mg/kg bw/d)		% AOEL (AOEL: 0.59 mg/kg bw x d)	
		Dermal		Inhalative	Potential (no PPE)	Estimated actual (PPE)	Potential (no PPE)	Estimated actual (PPE)
		Potential (no PPE)	Estimated actual (PPE)					
Calibration		0.421	0.179	0.013	0.0037	0.0017	0.63	0.29
Mixing/loading	Fast-couple	25.469	24.490	0.490	0.0506	0.0490	8.58	8.30
	Pre-mix	23.020	4.898	0.490	0.0465	0.0163	7.89	2.77
Bagging	good LEV	14.720	5.584	0.043	0.1234	0.0473	20.91	8.01
	poor LEV	14.720	5.584	0.432	0.1299	0.0537	22.01	9.11
		0.000	0.000	0.000	0.0000	0.0000	0.00	0.00
Cleaning		11.122	1.059	0.204	0.0961	0.0122	16.29	2.07
		Total			0.280	0.117	47.506	19.769

**Table A 5: Results of the operator exposure for Fludioxonil in scenario 1 (undiluted)**

Task		Exposure (mg/person/day)		Inhalative	Systemic exposure (mg/kg bw/d)		% AOEL (AOEL: 0.59 mg/kg bw x d)	
		Dermal			Potential (no PPE)	Estimated actual (PPE)	Potential (no PPE)	Estimated actual (PPE)
		Potential (no PPE)	Estimated actual (PPE)					
Calibration		3.379	1.434	0.102	0.0073	0.0041	1.24	0.69
Mixing/loading	Fast-couple	15.974	15.360	0.307	0.0317	0.0307	5.38	5.21
	Pre-mix	14.438	3.072	0.307	0.0292	0.0102	4.95	1.74
Bagging	good LEV	12.880	4.886	0.038	0.0221	0.0088	3.75	1.49
	poor LEV	12.880	4.886	0.378	0.0278	0.0144	4.71	2.45
		0.000	0.000	0.000	0.0000	0.0000	0.00	0.00
Cleaning		89.293	8.499	1.638	0.1761	0.0415	29.85	7.03
Total					0.243	0.091	41.183	15.378

**Table A 6: Results of the operator exposure for Fludioxonil in scenario 2 (diluted 1:8)**

Task		Systemic potential exposure to fludioxonil (mg as/kg bw)	Systemic actual dermal exposure to fludioxonil (mg as/kg bw)	Systemic inhalation exposure to fludioxonil (mg as/kg bw)	Total potential systemic exposure to fludioxonil (mg as/kg bw)	Total actual systemic exposure to fludioxonil (mg as/kg bw)	% AOEL (no PPE)	% AOEL (PPE)
Calibration		0.0035	0.0015	0.0002	0.0037	0.0017	0.63	0.29
Mixing/loading	Fast-couple	0.0266	0.0256	0.0051	0.0317	0.0307	5.38	5.21
	Pre-mix	0.0241	0.0051	0.0051	0.0292	0.0102	4.95	1.74
Bagging	good LEV	0.1073	0.0407	0.0006	0.1080	0.0413	18.30	7.01
	poor LEV	0.1073	0.0407	0.0063	0.1136	0.0470	19.26	7.97
		0.0000	0.0000	0.0000	0.0000	0.0000	0.00	0.00
Cleaning		0.0930	0.0089	0.0034	0.0964	0.0123	16.34	2.08
Total					0.246	0.092	41.616	15.544

In all seed treatment related activities, the model calculations indicate that the systemic exposure to Fludioxonil is below the established AOEL of 0.59 mg/kg bw x day, with the use of PPE (gloves and protective clothes) for the undiluted product and for the 1:8 dilution.

According to the model calculations, it can be concluded that the risk for the operator using GLOB182F on sunflower at up to 1.5 L/ton is acceptable provided the appropriate personal protective equipment is used.

### French SeedTROPEX (75th Percentile)

Operator clothing (Scenario 1): In the Seed-TROPEX studies the operators wore one-layer cotton clothing (long sleeved work jacket and long trousers) as usual work wear during all activities. According to the French Seed-TROPEX model as tier one approach no protection like gloves are worn during calibration, mixing/loading and cleaning.

Operator clothing (Scenario 2): In the Seed-TROPEX studies the operators wore one-layer cotton clothing (long sleeved work jacket and long trousers) as usual work wear during all activities. According to the French Seed-TROPEX model tier 2 approach considers gloves worn during all phases except bagging.

Details of the exposure estimations taking into account the 75<sup>th</sup> are presented in the Tables A7 to A14 below.

**Table A7: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of treated sunflower seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 1 without PPE (Long-sleeved jacket and long trousers as usual work wear) – Undiluted**

Concentration a.s. Product	102.04	g/L					Actual dermal exposure	114.499	mg/day
Dilution factor	1	g/L					Actual inhalation exposure	4.194	mg/day
Dermal absorption concentrate	10.00	%					Sistemic dermal exposure	0.1908	mg/kg bw/day
Dermal absorption dilution	10.00	%					Sistemic inhalation exposure	0.0699	mg/kg bw/day
Inhalation absorption	100	%					Total sistemic exposure	0.2607	mg/kg bw/day
Dose rate	1.5	L/ton seeds					% AOEL	44.19	%
Throughput	32	tons/day							
Pack size	1	L							
AOEL	0.59	mg/kg bw/day							
Weight	60	kg							
<b>CALIBRATION</b>									
Number of operations	1								
Protection gloves	no								
Gloves	0.209	mL/operation	Dermal exposure	0.014	mL/operation	inhalation	0.062	mL/operation	
	21.33	mg/operation		1.429	mg/operation		0.062	mg/operation	
Actual exposure	21.33	mg/day		22.75	mg/day		0.062	mg/day	
Sistemic exposure	0.0355	mg/kg bw/day		0.0379	mg/kg bw/day		0.0010	mg/kg bw/day	
<b>LOADING</b>									
Number of operations	48								
Protection gloves	no								
Gloves	0.0113	mL/operation	Dermal exposure	0.0011	mL/operation	inhalation	0.050	mL/operation	
	1.15	mg/operation		0.112	mg/operation		0.050	mg/operation	
Actual exposure	55.346	mg/day		60.73	mg/day		2.400	mg/day	
Sistemic exposure	0.0922	mg/kg bw/day		0.1012	mg/kg bw/day		0.0400	mg/kg bw/day	
<b>BAGGING</b>									
Number of operations	7								
Protection gloves	no								
Gloves	0.00	mg/h	Dermal exposure	1.14	mg/h	inhalation	0.031	mg/h	
Actual exposure	0.00	mg/day		7.98	mg/day		0.217	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0133	mg/kg bw/day		0.0036	mg/kg bw/day	
<b>CLEANING</b>									
Number of operations	1								
Protection gloves	no								
Gloves	18.5	mg/operation	Dermal exposure	4.53	mg/operation	inhalation	1.515	mg/operation	
Actual exposure	18.5	mg/day		23.03	mg/day		1.515	mg/day	
Sistemic exposure	0.0308	mg/kg bw/day		0.0384	mg/kg bw/day		0.0253	mg/kg bw/day	

Concentration a.s. Product	102.04	g/L		Actual dermal exposure	94.589	mg/day
Dilution factor	8	g/L		Actual inhalation exposure	4.194	mg/day
Dermal absorption concentrate	10.00	%		Sistemic dermal exposure	0.3833	mg/kg bw/day
Dermal absorption dilution	50.00	%		Sistemic inhalation exposure	0.0699	mg/kg bw/day
Inhalation absorption	100	%		Total sistemic exposure	0.4532	mg/kg bw/day
Dose rate	1.5	L/ton seeds		% AOEL	76.82	%
Throughput	32	tons/day				
Pack size	1	L				
AOEL	0.59	mg/kg bw/day				
Weight	60	kg				

		LOADING			
Number of operations	48				
Protection gloves	no				
	Gloves	Dermal exposure		inhalation	
	0.0113	mL/operation	0.0011	mL/operation	0.050
	1.15	mg/operation	0.112	mg/operation	0.050
Actual exposure	55.346	mg/day	60.73	mg/day	2.400
Sistemic exposure	0.0922	mg/kg bw/day	0.1012	mg/kg bw/day	0.0400

		CLEANING				
Number of operations	1					
Protection gloves	no					
Gloves		Dermal exposure		inhalation		
18.5	mg/operation	4.53	mg/operation	1.515	mg/operation	
Actual exposure	18.5	mg/day	23.03	mg/day	1.515	mg/day
Sistemic exposure	0.1542	mg/kg bw/day	0.1919	mg/kg bw/day	0.0253	mg/kg bw/day

**Table A9: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of treated sunflower seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 2 with PPE (gloves during all phases except bagging) – Undiluted**

Concentration a.s. Product	102.04	g/L					Actual dermal exposure	19.326	mg/day
Dilution factor	1	g/L					Actual inhalation exposure	4.194	mg/day
Dermal absorption concentrate	10.00	%					Sistemic dermal exposure	0.0322	mg/kg bw/day
Dermal absorption dilution	10.00	%					Sistemic inhalation exposure	0.0699	mg/kg bw/day
Inhalation absorption	100	%					Total sistemic exposure	0.1021	mg/kg bw/day
Dose rate	1.5	L/ton seeds					% AOEL	17.31	%
Throughput	32	tons/day							
Pack size	1	L							
AOEL	0.59	mg/kg bw/day							
Weight	60	kg							
							</		

**Table A10: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of treated sunflower seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 2 with PPE (gloves during all phases except bagging) – Undiluted**

Concentration a.s. Product	102.04	g/L					Actual dermal exposure	18.076	mg/day
Dilution factor	8	g/L					Actual inhalation exposure	4.194	mg/day
Dermal absorption concentrate	10.00	%					Sistemic dermal exposure	0.1147	mg/kg bw/day
Dermal absorption dilution	50.00	%					Sistemic inhalation exposure	0.0699	mg/kg bw/day
Inhalation absorption	100	%					Total sistemic exposure	0.1846	mg/kg bw/day
Dose rate	1.5	L/ton seeds					% AOEL	31.29	%
Throughput	32	tons/day							
Pack size	1	L							
AOEL	0.59	mg/kg bw/day							
Weight	60	kg							
<b>CALIBRATION</b>									
Number of operations	1								
Protection gloves	yes								
Gloves	0.209	mL/operation	Dermal exposure	0.014	mL/operation	inhalation	0.062	mL/operation	
	2.67	mg/operation		0.179	mg/operation		0.062	mg/operation	
Actual exposure	0.00	mg/day		0.18	mg/day		0.062	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0015	mg/kg bw/day		0.0010	mg/kg bw/day	
<b>LOADING</b>									
Number of operations	48								
Protection gloves	yes								
Gloves	0.0113	mL/operation	Dermal exposure	0.0011	mL/operation	inhalation	0.050	mL/operation	
	1.15	mg/operation		0.112	mg/operation		0.050	mg/operation	
Actual exposure	0.000	mg/day		5.39	mg/day		2.400	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0090	mg/kg bw/day		0.0400	mg/kg bw/day	
<b>BAGGING</b>									
Number of operations	7								
Protection gloves	no								
Gloves	0.00	mg/h	Dermal exposure	1.14	mg/h	inhalation	0.031	mg/h	
Actual exposure	0.00	mg/day		7.98	mg/day		0.217	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0665	mg/kg bw/day		0.0036	mg/kg bw/day	
<b>CLEANING</b>									
Number of operations	1								
Protection gloves	yes								
Gloves	18.5	mg/operation	Dermal exposure	4.53	mg/operation	inhalation	1.515	mg/operation	
Actual exposure	0	mg/day		4.53	mg/day		1.515	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0378	mg/kg bw/day		0.0253	mg/kg bw/day	

**Table A11: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of treated maize seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 1 without PPE (Long-sleeved jacket and long trousers as usual work wear) – Undiluted**

Concentration a.s. Product	102.4	g/L					Actual dermal exposure	91.938	mg/day
Dilution factor	1	g/L					Actual inhalation exposure	3.294	mg/day
Dermal absorption concentrate	10.00	%					Sistemic dermal exposure	0.1532	mg/kg bw/day
Dermal absorption dilution	10.00	%					Sistemic inhalation exposure	0.0549	mg/kg bw/day
Inhalation absorption	100	%					Total sistemic exposure	0.2081	mg/kg bw/day
Dose rate	0.5	L/ton seeds					% AOEL	35.28	%
Throughput	60	tons/day							
Pack size	1	L							
AOEL	0.59	mg/kg bw/day							
Weight	60	kg							
<b>CALIBRATION</b>									
Number of operations	1								
Protection gloves	no								
Gloves	0.209	mL/operation	Dermal exposure	0.014	mL/operation	inhalation	0.062	mL/operation	
	21.40	mg/operation		1.434	mg/operation		0.062	mg/operation	
Actual exposure	21.40	mg/day	22.84	mg/day		0.062	mg/day		
Sistemic exposure	0.0357	mg/kg bw/day	0.0381	mg/kg bw/day		0.0010	mg/kg bw/day		
<b>LOADING</b>									
Number of operations	30								
Protection gloves	no								
Gloves	0.0113	mL/operation	Dermal exposure	0.0011	mL/operation	inhalation	0.050	mL/operation	
	1.16	mg/operation		0.113	mg/operation		0.050	mg/operation	
Actual exposure	34.714	mg/day	38.09	mg/day		1.500	mg/day		
Sistemic exposure	0.0579	mg/kg bw/day	0.0635	mg/kg bw/day		0.0250	mg/kg bw/day		
<b>BAGGING</b>									
Number of operations	7								
Protection gloves	no								
Gloves	0.00	mg/h	Dermal exposure	1.14	mg/h	inhalation	0.031	mg/h	
Actual exposure	0.00	mg/day	7.98	mg/day		0.217	mg/day		
Sistemic exposure	0.0000	mg/kg bw/day	0.0133	mg/kg bw/day		0.0036	mg/kg bw/day		
<b>CLEANING</b>									
Number of operations	1								
Protection gloves	no								
Gloves	18.5	mg/operation	Dermal exposure	4.53	mg/operation	inhalation	1.515	mg/operation	
Actual exposure	18.5	mg/day	23.03	mg/day		1.515	mg/day		
Sistemic exposure	0.0308	mg/kg bw/day	0.0384	mg/kg bw/day		0.0253	mg/kg bw/day		

**Table A12: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of treated maize seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 1 without PPE (Long-sleeved jacket and long trousers as usual work wear) – Undiluted**

Concentration a.s. Product	102.4	g/L					Actual dermal exposure	17.323	mg/day
Dilution factor	1	g/L					Actual inhalation exposure	3.294	mg/day
Dermal absorption concentrate	10.00	%					Sistemic dermal exposure	0.0289	mg/kg bw/day
Dermal absorption dilution	10.00	%					Sistemic inhalation exposure	0.0549	mg/kg bw/day
Inhalation absorption	100	%					Total sistemic exposure	0.0838	mg/kg bw/day
Dose rate	0.5	L/ton seeds					% AOEL	14.20	%
Throughput	60	tons/day							
Pack size	1	L							
AOEL	0.59	mg/kg bw/day							
Weight	60	kg							
<b>CALIBRATION</b>									
Number of operations	1								
Protection gloves	yes								
Gloves	0.209	mL/operation	Dermal exposure	0.014	mL/operation	inhalation	0.062	mL/operation	
	21.40	mg/operation		1.434	mg/operation		0.062	mg/operation	
Actual exposure	0.00	mg/day		1.43	mg/day		0.062	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0024	mg/kg bw/day		0.0010	mg/kg bw/day	
<b>LOADING</b>									
Number of operations	30								
Protection gloves	yes								
Gloves	0.0113	mL/operation	Dermal exposure	0.0011	mL/operation	inhalation	0.050	mL/operation	
	1.16	mg/operation		0.113	mg/operation		0.050	mg/operation	
Actual exposure	0.000	mg/day		3.38	mg/day		1.500	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0056	mg/kg bw/day		0.0250	mg/kg bw/day	
<b>BAGGING</b>									
Number of operations	7								
Protection gloves	no								
Gloves	0.00	mg/h	Dermal exposure	1.14	mg/h	inhalation	0.031	mg/h	
Actual exposure	0.00	mg/day		7.98	mg/day		0.217	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0133	mg/kg bw/day		0.0036	mg/kg bw/day	
<b>CLEANING</b>									
Number of operations	1								
Protection gloves	yes								
Gloves	18.5	mg/operation	Dermal exposure	4.53	mg/operation	inhalation	1.515	mg/operation	
Actual exposure	0	mg/day		4.53	mg/day		1.515	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day		0.0076	mg/kg bw/day		0.0253	mg/kg bw/day	



**Table A13: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of maize treated seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 2 with PPE (gloves during all phases except bagging) – Undiluted**

Concentration a.s. Product	102.4	g/L					Actual dermal exposure	71.957	mg/day
Dilution factor	8	g/L					Actual inhalation exposure	3.294	mg/day
Dermal absorption concentrate	10.00	%					Sistemic dermal exposure	0.3457	mg/kg bw/day
Dermal absorption dilution	50.00	%					Sistemic inhalation exposure	0.0549	mg/kg bw/day
Inhalation absorption	100	%					Total sistemic exposure	0.4006	mg/kg bw/day
Dose rate	0.5	L/ton seeds					% AOEL	67.90	%
Throughput	60	tons/day							
Pack size	1	L							
AOEL	0.59	mg/kg bw/day							
Weight	60	kg							
<b>CALIBRATION</b>									
Number of operations	1								
Protection gloves	no								
Gloves	0.209	mL/operation	Dermal exposure	0.014	mL/operation	inhalation	0.062	mL/operation	
	2.68	mg/operation		0.179	mg/operation		0.062	mg/operation	
Actual exposure	2.68	mg/day	2.85	mg/day	0.062	mg/day			
Sistemic exposure	0.0223	mg/kg bw/day	0.0238	mg/kg bw/day	0.0010	mg/kg bw/day			
<b>LOADING</b>									
Number of operations	30								
Protection gloves	no								
Gloves	0.0113	mL/operation	Dermal exposure	0.0011	mL/operation	inhalation	0.050	mL/operation	
	1.16	mg/operation		0.113	mg/operation		0.050	mg/operation	
Actual exposure	34.714	mg/day	38.09	mg/day	1.500	mg/day			
Sistemic exposure	0.0579	mg/kg bw/day	0.0635	mg/kg bw/day	0.0250	mg/kg bw/day			
<b>BAGGING</b>									
Number of operations	7								
Protection gloves	no								
Gloves	0.00	mg/h	Dermal exposure	1.14	mg/h	inhalation	0.031	mg/h	
Actual exposure	0.00	mg/day	7.98	mg/day	0.217	mg/day			
Sistemic exposure	0.0000	mg/kg bw/day	0.0665	mg/kg bw/day	0.0036	mg/kg bw/day			
<b>CLEANING</b>									
Number of operations	1								
Protection gloves	no								
Gloves	18.5	mg/operation	Dermal exposure	4.53	mg/operation	inhalation	1.515	mg/operation	
Actual exposure	18.5	mg/day	23.03	mg/day	1.515	mg/day			
Sistemic exposure	0.1542	mg/kg bw/day	0.1919	mg/kg bw/day	0.0253	mg/kg bw/day			

**Table A14: Estimation of operator exposure to fludioxonil during equipment calibration, mixing/loading, bagging of maize treated seed and equipment cleaning – Based on French Seed- TROPEX model Scenario 2 with PPE (gloves during all phases except bagging) – Diluted**

Concentration a.s. Product		102.4	g/L	Actual dermal exposure		16.068	mg/day
Dilution factor		8	g/L	Actual inhalation exposure		3.294	mg/day
Dermal absorption concentrate		10.00	%	Sistemic dermal exposure		0.1114	mg/kg bw/day
Dermal absorption dilution		50.00	%	Sistemic inhalation exposure		0.0549	mg/kg bw/day
Inhalation absorption		100	%	Total sistemic exposure		0.1663	mg/kg bw/day
Dose rate		0.5	L/ton seeds	% AOEL		28.18	%
Throughput		60	tons/day				
Pack size		1	L				
AOEL		0.59	mg/kg bw/day				
Weight		60	kg				

CALIBRATION

Number of operations		1					
Protection gloves		yes					
Gloves			Dermal exposure		inhalation		
	0.209	mL/operation	0.014	mL/operation	0.062	mL/operation	
	2.68	mg/operation	0.179	mg/operation	0.062	mg/operation	
Actual exposure	0.00	mg/day	0.18	mg/day	0.062	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day	0.0015	mg/kg bw/day	0.0010	mg/kg bw/day	

LOADING

Number of operations		30					
Protection gloves		yes					
Gloves			Dermal exposure		inhalation		
	0.0113	mL/operation	0.0011	mL/operation	0.050	mL/operation	
	1.16	mg/operation	0.113	mg/operation	0.050	mg/operation	
Actual exposure	0.000	mg/day	3.38	mg/day	1.500	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day	0.0056	mg/kg bw/day	0.0250	mg/kg bw/day	

BAGGING

Number of operations		7					
Protection gloves		no					
Gloves			Dermal exposure		inhalation		
	0.00	mg/h	1.14	mg/h	0.031	mg/h	
Actual exposure	0.00	mg/day	7.98	mg/day	0.217	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day	0.0665	mg/kg bw/day	0.0036	mg/kg bw/day	

CLEANING

Number of operations		1					
Protection gloves		yes					
Gloves			Dermal exposure		inhalation		
	18.5	mg/operation	4.53	mg/operation	1.515	mg/operation	
Actual exposure	0	mg/day	4.53	mg/day	1.515	mg/day	
Sistemic exposure	0.0000	mg/kg bw/day	0.0378	mg/kg bw/day	0.0253	mg/kg bw/day	

**Table A 110: Generic exposure values for dermal and inhalation exposure during loading and sowing of treated seeds (geometric mean values)**

Exposition	Possible dermal absorption (mg/person per day) without personal protective equipment	Actual dermal exposure (mg/person per day) with personal protective equipment	Inhalation exposure (mg/person per day) without respiratory protection
Preparation and sowing of seeds – standard values (mg/hour)	1.48	0.733	0.02
8-hour work	11.84	5.864	0.16

Worker exposure following loading and sowing of treated seeds was calculated with and without personal protective equipment and the default dermal absorption values according to the EFSA Guidance 2017 for Fludioxonil. The results are given below.

**Table A 111: Actual dermal exposure to Fludioxonil with PPE<sup>2)</sup> (geometric mean values)**

Route of exposure	Route specific	Working time	Route specific exposure	Absorption	Systemic exposure	Systemic exposure	% AOEL
	[mg/person/hr]	[hrs/day]	[mg/person/day]	[%]	[mg/person/day]	[mg/kg bw/day]	
EADE <sup>1)</sup>	0.733	8	5.864	50	2.932		
Inhalation	0.02	8	0.16	100	0.16		
Total systemic dose					3.092	0.052	8.73

2) Estimated actual dermal exposure

3) Long-sleeved jacket and long trousers as usual work wear and in addition gloves when handling treated seed

**Table A 112: Potential dermal exposure to Fludioxonil without PPE<sup>2)</sup> (geometric mean values)**

Route of exposure	Route specific	Working time	Route specific exposure	Absorption	Systemic exposure	Systemic exposure	% AOEL
	[mg/person/hr]	[hrs/day]	[mg/person/day]	[%]	[mg/person/day]	[mg/kg bw/day]	
EPDE <sup>1)</sup>	1.48	8	11.84	50	5.92		
Inhalation	0.02	8	0.16	100	0.16		
Total systemic dose					7.6	0.101	17.18

1) Estimated potential dermal exposure

2) Long-sleeved jacket and long trousers as usual work wear

Estimations are done using the French Seed-TROPEX model for sowing activities.

In the Seed-TROPEX studies the operators wore a long-sleeved work jacket and long trousers as usual work wear during all tasks and in addition gloves when handling treated seeds. Thus, in the Seed-TROPEX model the estimated actual dermal exposure (EADE) values reflect this level of PPE. In contrast in the French Seed-TROPEX model the actual dermal exposure corresponds to the contamination of hands not protected by gloves, contamination of the body protected by clothes and contamination of the head. Thus, in the case of the workers who were wearing gloves, the actual dermal contamination was assessed by adding the contamination measured on gloves. The 75<sup>th</sup> percentile exposure values were considered in the French Seed-TROPEX model for exposure evaluation during loading and sowing activities.

**Table A 18: Generic exposure values for dermal and inhalation exposure during loading and sowing of treated seeds (75<sup>th</sup> percentile values)**

Exposition	Actual dermal exposure (mg/person per day) with personal protective equipment	Inhalation exposure (mg/person per day) without respiratory protection
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<b>Preparation and sowing of seeds – standard values (mg/hour)</b>	<b>1.73</b>	<b>0.0288</b>
<b>8-hour work</b>	<b>13.84</b>	<b>0.230</b>

**Table A 19: Potential dermal exposure to Fludioxonil without PPE<sup>2)</sup> (75<sup>th</sup> percentile values)**

Route of exposure	Route specific	Working time	Route specific exposure	Absorption	Systemic exposure	Systemic exposure	% AOEL
	[mg/person/hr]	[hrs/day]	[mg/person/day]	[%]	[mg/person/day]	[mg/kg bw/day]	
<b>EADE<sup>1)</sup></b>	<b>1.73</b>	<b>8</b>	<b>13.84</b>	<b>50</b>	<b>6.92</b>		
<b>Inhalation</b>	<b>0.0288</b>	<b>8</b>	<b>0.230</b>	<b>100</b>	<b>0.2304</b>		
<b>Total systemic dose</b>					<b>7.6</b>	<b>0.119</b>	<b>20.20</b>

1) Estimated actual dermal exposure

2) Long-sleeved jacket and long trousers as usual work wear

### A 3.3.2 Bystander and resident exposure calculations (KCP 7.2.2.1)

Not relevant.

However, as GLOB182F is a product for seed treatment and treatment of seeds occurs indoor in stationary seed treatment facilities, there is no risk for exposure of residents living in close vicinity of seed treatment facilities. However, residents and bystanders can be exposed via dust (attrition) during sowing of the seeds. Therefore, for the sake of completeness, a risk assessment for resident and bystander e.g. considering a default worst case attrition rate during sowing of the treated seed and according to the methods provided on the *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) is provided below.

The assumptions/data utilised in the calculation of operator exposure during seed treatment are summarised in the Table A 19.

**Table A 19: Input parameters considered for the estimation of resident exposure**

<b>Maize/sunflower</b>	<b>Abraded fine dust: Heubach-value (&lt;200µm)</b>	<b>Content of active substance in dust</b>	<b>Max. sowing rate</b>	<b>Worst case attrition rate</b>
<b>Regulatory scenario</b>	[g dust/100.000 seeds and ha]	[% a.s. in dust]	[seeds/ha]	[g a.s./ha]
<b>Realistic worst case</b>	<b>1.50*</b>	<b>70*</b>	<b>225,000**</b>	<b>2.3625</b>

\* Realistic worst-case value for maize and similar seeds, according to the Guidance document for the Authorisation of Plant Protection Products for Seed Treatment (SANCO/10553/2012, draft July 2018\_rev 16).

\*\* Max. sowing rate for GLOB182F (sunflower).

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

	% AOEL				
	Spray drift	Vapour	Surface deposit	Entry into treated crops	Total
<b>Resident adult 75<sup>th</sup> percentile</b>	<b>0.00</b>	<b>0.04</b>	<b>0.00</b>	<b>0.02</b>	<b>-</b>
<b>Resident adult mean</b>	<b>0.00</b>	<b>0.04</b>	<b>0.00</b>	<b>0.01</b>	<b>0.05</b>
<b>Resident child 75<sup>th</sup> percentile</b>	<b>0.00</b>	<b>0.18</b>	<b>0.00</b>	<b>0.03</b>	<b>-</b>
<b>Resident child mean</b>	<b>0.00</b>	<b>0.18</b>	<b>0.00</b>	<b>0.03</b>	<b>0.21</b>