

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: **SNS-F-11**

Product names: **DISFERA90 EC/ LIPOSTAR 90 EC**

Chemical active substance:

difenoconazole, 90 g/L

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT Poland

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: **01/2024**

MS Finalisation date: **07/2024; 10/2024; 11/2024**

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## Version history

When	What
01/2024	Initial dRR
07/2024	ZRMs evaluated dRR submitted by Applicant.
10/2024	The Final Registration Report
11/2024	The final RR after the second round of commenting

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## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on SNS-F-11 \***

Product name and code	SNS-F-11/ DISFERA 90 EC, LIPOSTAR 90 EC
Formulation type	Emulsifiable concentrate [EC]
Active substance(s) (incl. content)	difenoconazole; 90 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 SNS-F-11 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:

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**Table 6.1-2:**                    **Justified proposals for classification and labelling for SNS-F-11 according to Regulation (EC) No 1272/2008**

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Hazard classes, categories	<del>Acute Tox. 4 (o)</del> <b>Acute Tox. 4 (i)</b> <b>Carc. 2, H351</b> <b>Skin Irrit. 2</b> <b>Eye Dam. 1</b>
Hazard pictograms or Code for hazard pictograms	   <b>GHS05   GHS07   GHS08</b>
Signal word	<b>Danger</b>
Hazard statements	<del>H302 Harmful if swallowed.</del> <b>H332 Harmful if inhaled.</b> <b>H351 Suspected of causing cancer</b> <b>H315 Causes skin irritation</b> <b>H318 Causes serious eye damage.</b>

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Precautionary statements	<p><b>Warning section of the label (first page):</b></p> <p><b>P261</b> Avoid breathing dust/fume/gas/mist/vapours/ spray.  <b>P280</b> Wear protective gloves/protective clothing and eye protection/face protection.  <b>P308+P313</b> IF exposed or concerned: Get medical advice/attention.  <b>P305+P351+P338</b> IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  <b>P302 + P352</b> IF ON SKIN: Wash with plenty of water  <b>P304+P340</b> IF INHALED: Remove person to fresh air and keep comfortable for breathing.  <b>P301+P312</b> IF SWALLOWED: Call a POISON CENTRE/ doctor if you feel unwell.</p> <p><b>Other section of the label:</b>  <b>P270</b> Do not eat, drink or smoke when using this product.  <b>P271</b> Use only outdoors or in a well-ventilated area.  <b>P264</b> Wash hands thoroughly after handling.  <b>P405</b> Store locked up.  <b>P362 + P364</b> Take off contaminated clothing and wash it before reuse.  <b>P501</b> Dispose of contents/ container to an approved waste disposal plant.</p> <p>And P280 as follows:  <i>„Stosować rękawice ochronne, odzież ochronną oraz ochronę oczu lub twarzy w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.”</i>  “Wear protective gloves, protective clothing and eye/face shield during mixing/loading and work wear during application”.</p> <p><b>Section First Aid:</b>  <b>P308+P313</b> IF exposed or concerned: Get medical advice/attention</p> <p><b>P305+P351+P338</b> IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  <b>P310</b> Immediately call a POISON CENTER/doctor.</p> <p><b>P302 + P352</b> IF ON SKIN: Wash with plenty of water.  <b>P332 + P313</b> If skin irritation occurs: Get medical advice/ attention.</p> <p><b>P304+P340</b> IF INHALED: Remove person to fresh air and keep comfortable for breathing.  <b>P312</b> Call a POISON CENTRE/doctor if you feel unwell.</p>
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

**Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SNS-F-11**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	AOEM: None OPEX ver 1.0.1: Winter wheat, Winter triticale: None Minor uses according to Article 51: Work wear (arms, body and legs covered) Since SNS-F-11 is classified as Carc.2, H351, Eye Dam. 1, H318 and Skin Irrit. 2, H315, the operator should wear protective clothes, eye protection or face protection and protective gloves when handling the concentrated product.



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	Result	PPE / Risk mitigation measures
Workers	Acceptable	AOEM, OPEX ver 1.0.1: None
Residents	Acceptable	AOEM, OPEX ver 1.0.1: None
Bystanders	Acceptable	AOEM, OPEX ver 1.0.1: None

No unacceptable risk for operators 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.

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use-No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn, G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/syn-ergist (L/ha))  critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***)	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha  a) a.s. 1 b) a.s. 2	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1	Winter wheat (BBCH 33-55)	F	Foliar spray, LCTM	2 (14-21 days)	0.090 kg as/ha	200 – 300	-	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				
2	Winter triticale (BBCH 33-55)	F	Foliar spray, LCTM	2 (14-21 days)	0.090 kg as/ha	200 – 300	-					
3	Winter rape BBCH 32-39 (spring) BBCH 60-65 (spring)	F	Foliar spray, LCTM	1	0.090 kg as/ha  0.1035 kg as/ha	200 – 300	-					
Minor uses according to Article 51												
4	Spring oilseed rape BBCH 32-39 BBCH 60-65	F	Foliar spray, LCTM	1	0.090 kg as/ha 0.1035 kg as/ha	200 – 300	-					
5	Linseed (common flax) BBCH 32-39 BBCH 60-65	F	Foliar spray, LCTM	1	0.090 kg as/ha 0.1035 kg as/ha	200 – 300	-					
6	Poppy seeds BBCH 32-39 BBCH 60-65	F	Foliar spray, LCTM	1	0.090 kg as/ha 0.1035 kg as/ha	200 – 300	-					
7	Mustard seeds BBCH 32-39 BBCH 60-65	F	Foliar spray, LCTM	1	0.090 kg as/ha 0.1035 kg as/ha	200 – 300	-					
8	Gold of pleasure seeds BBCH 32-39	F	Foliar spray, LCTM	1	0.090 kg as/ha	200 – 300	-					

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1	2	3	4	5	6	7	8	9	10
	BBCH 60-65				0.1035 kg as/ha				
9	Sunflower seeds BBCH 32-39 BBCH 60-65	F	Foliar spray, LCTM	1	0.090 kg as/ha 0.1035 kg as/ha	200 – 300	-		
10	Soyabeans (BBCH 32 -65)	F	Foliar spray, LCTM	1	0.1035 kg as/ha	200 – 300	-		

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

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

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

Explanation for column 10 “Acceptability of exposure assessment”

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

## Data gaps

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

### Difenoconazole

No critical areas of concern were identified in the mammalian toxicology section. Two data gaps were identified:

- for an assessment of the toxicological relevance of some impurities;
- to clarify the uncertainties related to the isomer ratio of the tested compound (for which reference values have been derived), the isomer ratio to which the workers will be exposed and the relative toxicity of the different isomers.

(EFSA Journal 2011;9(1):1967)

## 6.2 Toxicological Information on Active Substance(s)

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

**Table 6.2-1: Information on active substance(s)**

	Difenoconazole
Common Name	Difenoconazole
CAS-No.	119446-68-3
<b>Classification and proposed labelling</b>	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<b>Hazard classes, categories:</b> Acute Tox.4 (oral) Eye Irrit. 2 Carc. 2, H351* <b>Code for hazard pictogram:</b> GHS07 <b>Signal word:</b>

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	Difenoconazole
	Warning <b>Hazard statements:</b> H302 Harmful if swallowed. H319 Causes serious eye irritation. <b>Precautionary statements:</b> P264 Wash skin thoroughly after handling. P273 Avoid release to the environment. P280 Wear eye protection/ face protection. P337 + P313 If eye irritation persists: Get medical advice/ attention. P391 Collect spillage. P501 Dispose of contents/ container to an approved waste disposal plant.
Additional C&L proposal	No additional C&L are proposed.
<b>Agreed EU endpoints</b>	
AOEL systemic	0.16 mg/kg bw/d
Reference	EFSA Journal 2011; 9(1):1967 *RAC Opinion, 10 June 2021
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>	
According to Review Report/EFSA Conclusion for active substance	None

### 6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for SNS-F-11 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.

According to Regulation (EC) No 1107/2009 “The use of non-animal test methods and other risk assessment strategies should be promoted”. Animal testing for the purposes of registration procedure should be minimized and tests on vertebrates should be undertaken as a last resort.

To avoid animal testing, skin corrosion/irritation and eye irritation or serious eye damage tests were performed based on alternative *in vitro* methods.

**Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SNS-F-11**

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral (calculation method)		No	<del>Acute Tox 4 (H302)</del>	Calculation method
	Justification presented in Appendix 2			
LD <sub>50</sub> dermal (calculation method)		Yes	-	Calculation method
	Justification presented in Appendix 2			

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LC <sub>50</sub> inhalation (calculation method)		Yes	<b>Acute Tox 4 (H332)</b>	Calculation method
	Justification presented in Appendix 2			
Skin irritation, <i>in vitro</i> / Reconstructed Human Epidermis (OECD 431)	Non-corrosive	Yes	None	Krakowian D.
Skin irritation (calculation method)		Yes	<b>Skin Irrt. 2 (H315)</b>	Calculation method
	Justification presented in Appendix 2			
Eye irritation, <i>in vitro</i> / Reconstructed human Cornea- like Epithelium (RhCE) (OECD 492)	Non-irritant / Irritant	Yes	<b>Eye Dam. 1 (H318)</b>	Krakowian D.
Eye irritation, Isolated Chicken Eye (OECD 438)	Eye damage	Yes		Toczko M.
Skin sensitisation (calculation method)	Non-sensitizing	Yes	-	Calculation method
	Justification presented in Appendix 2			
Supplementary studies for combinations of plant protection products		-		

Formulation does not contain any substances classified as:

- germ cell mutagenic,
- cancerogenic,
- endocrine disruption for human health.

Thus according to points 3.5, 3.6, 3.11 of Regulation (EC) 1272/2008 product SNS-F-11 does not need to be classified in above mentioned categories.

Formulation contains substances classified as:

- respiratory and skin sensitizer,
- reproductive toxic,
- toxic on specific target organs (single exposure),
- toxic on specific target organs (repeat exposure),
- aspiration hazard.

A summary of the toxicological evaluation for SNS-F-11 is described in detail in Appendix 2 (A 2.11).

## 6.4 Toxicological Evaluation of Groundwater Metabolites

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

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## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SNS-F-11 are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in SNS-F-11**

	difenoconazole	
	Value	Reference
Concentrate	25% (default)	Guidance on dermal absorption. <i>EFSA Journal</i> 2017;15(6);4873.
Dilution	70% (default)	

### 6.5.1 Justification for proposed values - difenoconazole

No data on dermal absorption for difenoconazole in SNS-F-11 is available. Justifications for default values according to Guidance on Dermal Absorption (*EFSA Journal* 2017;15(6);4873) are presented in the following table.

Default values of dermal absorption for SNS-F-11 according to Guidance on Dermal Absorption (*EFSA Journal* 2017;15(6);4873) are 25% for concentrate and 70% for dilution. SNS-F-11 is organic solvent formulation - emulsifiable concentrate.

Regarding to Guidance on Dermal Absorption (2017), a default dermal absorption value of:

- 25% may be applied for concentrated products that are organic solvent formulation;
- 70% may be applied for (in use) dilutions of organic solvent formulation.

Based on above, Applicant has proposed for SNS-F-11 a default dermal absorption value of 25% for the concentrate and 70% for the spray solution.

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

	Value	Justification for value	Acceptability of justification
Concentrate	25%	In the absence of any supporting dermal absorption data for SNS-F-11, it is proposed a dermal absorption value of 25% for the concentrate and 70 % in-use dilution, based on Guidance on dermal absorption. <i>EFSA Journal</i> 2017; 15(6);4873.	accepted
Dilution	70%		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	SNS-F-11/ DISFERA 90 EC, LIPOSTAR 90 EC
Formulation type	EC
Category	Fungicide
Active substance	Difenoconazole

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(incl. content)	90 g/L
AOEL systemic	0.16 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 25% (Default) Dilution: 70% (Default)

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

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

### 6.6.2 Operator exposure (KCP 7.2.1)

Comments of zRMS:	<p>The estimations of operator exposure to difenoconazole contained in SNS-F-11 performed by the Applicant are correct.</p> <p><u>Conclusions:</u></p> <p>According to the estimation based on Calcualtor OPEX version v.1.0.1, the use of SNS-F-11 containing difenoconazole (90 g/kg) <b>causes acceptable health risk for:</b></p> <ul style="list-style-type: none"> <li>- <b>unprotected operator (no PPE)</b> (arms, body and legs covered) during mixing/loading and application in the case of tractor mounted boom spray application in winter wheat and winter triticale;</li> <li>- <b>Operator equipped with work wear</b> (arms, body and legs covered) during mixing/loading and application in the case of tractor mounted boom spray application in winter rape, spring oilseed rape, linseed, poppy seeds, mustard seeds, gold of pleasure seeds, sun-flower seeds, soyabeans.</li> </ul> <p>However, taking into account the classification of the product (Carc.2, H251, Eye Dam. 1, H318, Skin Irrit. 2, H315), protective clothing, eye/face protection and protective gloves are mandatory when handling undiluted product.</p> <p>Consequently, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:</p> <p><i>„Stosować rękawice ochronne, odzież ochronną oraz ochronę oczu lub twarzy w trakcie przygotowywania cieczy roboczej oraz odzież roboczą w trakcie wykonywania zabiegu.”</i></p> <p>“Wear protective gloves, protective clothing and eye/face shield during mixing/loading and work wear during application”.</p>
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#### 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 SNS-F-11 according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed

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calculations are in Appendix 3.

No acute AOEL has been set for difenoconazole. Consequently, no acute risk assessment has been provided for this active substance.


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

Critical uses	Winter wheat, Winter triticale (max. 1 L product/ha) Winter rape (max. 1.15 L product/ha) <b>Minor uses according to Article 51</b> Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans (max. 1.15 L product/ha)
Models	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
	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032. OPEX calculator ver. 1.0.1.

**Table 6.6-3: Estimated operator exposure (longer term exposure)**

		Difenoconazole	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
<b>Tractor mounted boom spray application outdoors to low crops</b> <b>Cereals: Winter wheat, winter triticale</b>			
Application rate		0.090 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	No PPE	0.1207	<b>75.4%</b>
	Gloves: M/L and A	0.0566	<b>35.4 %</b>
<b>OPEX</b> calculator ver. 1.0.1	No PPE 	0.1483	<b>92.7 %</b>
	Work wear (arms, body and legs covered): M/L and A 	0.0986	<b>61.6 %</b>
<b>Tractor mounted boom spray application outdoors to low crops</b> <b>Winter rape,</b> <b>Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans</b>			
Application rate		0.1035 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	No PPE	0.1344	<b>84.0 %</b>
	Gloves: M/L and A	0.0631	<b>39.4%</b>
<b>OPEX</b> calculator ver. 1.0.1	No PPE 	0.1632	102 %

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	Work wear (arms, body and legs covered): M/L and A 	0.108	<b>67.7 %</b>
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The exposure to difenoconazole of operator wearing a work clothing (long sleeved shirt, long trousers) but no gloves and applying a product SNS-F-11 on winter rape and cereals using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM and OPEX calculator, is below AOEL.

The application of product SNS-F-11 does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear (arms, body and legs covered) during mixing, loading and application.

Since SNS-F-11 is classified as Eye Dam 1, H318 the operator should wear eye protection or face protection when handling the concentrated product.

### 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)

Comments of zRMS:	<p>The estimations of worker exposure to difenoconazole contained in SNS-F-11 performed by the Applicant are accepted.</p> <p>According to the estimation results, the use of SNS-F-11 containing difenoconazole (90 g/kg) <b>causes acceptable health risk for a unprotected worker</b> assuming 2 hour working day (inspection, irrigation).</p> <p>However, bearing in mind the hygienic rules, the use of protective gloves is recommended when entering treated area.</p> <p>Following sentence is recommended by the evaluator to be placed in the <b>section of precautions for the workers</b>:</p> <p><i>„Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany opryskowi.”</i></p> <p>“Wear protective gloves and work wear when entering treated area.”</p>
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#### 6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure models used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SNS-F-11 according to the critical uses. Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

No acute AOEL has been set for difenoconazole. Consequently, no acute risk assessment has been provided



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for this active substance.

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

Critical uses	Winter wheat, Winter triticale (max. 1 L product/ha) Winter rape (max. 1.15 L product/ha) <b>Minor uses according to Article 51</b> Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans (max. 1.15 L product/ha)
Models	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
	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032. OPEX calculator ver. 1.0.1.

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

		Difenoconazole	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Tractor mounted boom spray application outdoors to low crops</b> <b>Cereals: Winter wheat, winter triticale</b> Inspection, irrigation Outdoor Work rate: 2 hours/day, DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 14 days MAF=1.7			
Number of applications and application rate		2 x 0.090 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential TC: 12500cm <sup>2</sup> /person/h	0.1357	<b>84.8 %</b>
	Work wear (arms, body and legs covered) TC:1400 cm <sup>2</sup> /person/h	0.0152	<b>9.5 %</b>
<b>OPEX calculator ver. 1.0.1</b>	Potential TC: 12500cm <sup>2</sup> /person/h	0.1356	<b>84.7%</b>
	Work wear (arms, body and legs covered) TC:1400 cm <sup>2</sup> /person/h	0.0152	<b>9.5%</b>
	Workwear (arms, body and legs covered) and gloves) TC: 1250 cm <sup>2</sup> /h	0.0136	<b>8.5%</b>
<b>Winter rape,</b> <b>Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans</b> Inspection, irrigation Outdoor Work rate: 2 hours/day, DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 365 days			

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Number of applications and application rate		1 x 0.1035 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Potential TC: 12500cm <sup>2</sup> /person/h	0.0906	<b>56.6 %</b>
	Work wear (arms, body and legs covered) TC:1400 cm <sup>2</sup> /person/h	0.0101	<b>6.3 %</b>
<b>OPEX calculator ver. 1.0.1</b>	Potential TC: 12500cm <sup>2</sup> /person/h	0.0906	<b>56.6%</b>
	Work wear (arms, body and legs covered) TC:1400 cm <sup>2</sup> /person/h	0.0101	<b>6.3%</b>
	Workwear (arms, body and legs covered) and gloves) TC: 1250 cm <sup>2</sup> /h	0.0091	<b>5.7%</b>

Exposure to difenconazole, an active substance of a product SNS-F-11, of a worker not wearing PPE (gloves) but wearing work clothes (long sleeved shirt, long trousers) entering for 2 hours an inspection of a field of winter rape and cereals treated with a product SNS-F-11, calculated with EFSA AOEM and OPEX calculator is below AOEL.

The application of product SNS-F-11 does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice.

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

Not relevant.

#### 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)

Comments of zRMS:	<p>The AAOEL value for difenoconazole is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards the active substance.</p> <p>The results of exposure estimations demonstrate that the use of SNS-F-11 according to the list of intended uses presented in the GAP Table and anticipating the introduction of buffer zone presented (2-3m), <b>cause acceptable health risk for bystander/resident (adult and child).</b></p>
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#### 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 model used for estimation of resident and bystander exposure to difenoconazole. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.**6.6-7 (longer term resident exposure).

Detailed calculations are in Appendix 3.

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

Critical uses	Winter wheat, Winter triticale (max. 1 L product/ha) Winter rape (max. 1.15 L product/ha) <b>Minor uses according to Article 51</b> Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans (max. 1.15 L product/ha)
Models	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
	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032. OPEX calculator ver. 1.0.1.

**Table 6.6-7: Estimated resident exposure (longer term exposure)**

		Difenoconazole	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Cereals: Winter wheat, winter triticale  Buffer zone: 2-3 (m) Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.90 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile)			
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0085	5.29 %
	Vapour (75 <sup>th</sup> perc.)	0.0011	0.67 %
	Deposits (75 <sup>th</sup> perc.)	0.0017	1.07 %
	Re-entry (75 <sup>th</sup> perc.)	0.0183	11.45 %

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	Sum (mean)	0.0216	13.49 %
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0020	1.27%
	Vapour (75 <sup>th</sup> perc.)	0.0002	0.14 %
	Deposits (75 <sup>th</sup> perc.)	0.0007	0.46 %
	Re-entry (75 <sup>th</sup> perc.)	0.0102	6.36 %
	Sum (mean)	0.0099	6.16 %
OPEX calculator ver. 1.0.1			
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.009	5.3%
	Vapour (75 <sup>th</sup> perc.)	0.0008	0.5%
	Deposits (75 <sup>th</sup> perc.)	0.002	1.1 %
	Re-entry (75 <sup>th</sup> perc.)	0.02	11.4 %
	Sum (mean)	0.02	13.3 %
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.002	1.3%
	Vapour (75 <sup>th</sup> perc.)	0.0003	0.2 %
	Deposits (75 <sup>th</sup> perc.)	0.0007	0.5 %
	Re-entry (75 <sup>th</sup> perc.)	0.01	6.3 %
	Sum (mean)	0.01	6.2%
Winter rape, Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold of pleasure seeds, Sunflower seeds, Soyabeans			
Buffer zone: 2-3 (m) Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.1035 kg a.s./ha	
Spray application (AOEM; 75 <sup>th</sup> percentile)			
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0097	6.08 %
	Vapour (75 <sup>th</sup> perc.)	0.0011	0.67%
	Deposits (75 <sup>th</sup> perc.)	0.0011	0.71%
	Re-entry (75 <sup>th</sup> perc.)	0.01222	7.64%
	Sum (mean)	0.0170	10.63%
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0023	1.45%
	Vapour (75 <sup>th</sup> perc.)	0.0002	0.14%
	Deposits (75 <sup>th</sup> perc.)	0.0005	0.31%
	Re-entry (75 <sup>th</sup> perc.)	0.0068	4.25%
	Sum (mean)	0.0071	4.45%
OPEX calculator ver. 1.0.1			
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.01	6.1%
	Vapour (75 <sup>th</sup> perc.)	0.0008	0.5%

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	Deposits (75 <sup>th</sup> perc.)	0.001	0.7%
	Re-entry (75 <sup>th</sup> perc.)	0.01	7.6%
	<b>Sum (mean)</b>	<b>0.02</b>	<b>10.5%</b>
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.002	1.5%
	Vapour (75 <sup>th</sup> perc.)	0.0003	0.2%
	Deposits (75 <sup>th</sup> perc.)	0.0005	0.3%
	Re-entry (75 <sup>th</sup> perc.)	0.007	4.2%
	<b>Sum (mean)</b>	<b>0.007</b>	<b>4.5%</b>

The exposure of residents (adult and child) to difenoconazole, an active substance of a product SNS-F-11, applied on winter rape and cereals treated with this product, using tractor-mounted/trailed boom sprayer with hydraulic nozzles, calculated with the EFSA AOEM and OPEX calculator demonstrates that such an exposure for adult and child resident is below AOEL.

The application of product SNS-F-11 does not pose an unacceptable risk to the health of adult and child residents.

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

#### 6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

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

Tables considered not relevant can be deleted as appropriate.  
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.4	Krakowian D.	2023	SNS-F-11: <i>In vitro</i> Skin Corrosion: Reconstructed Human Epidermis Test Method. Krakowian D., 2023. Study code: SCT-01-23. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	SynthosAgro Sp. z o.o.
KCP 7.1.5	Krakowian D.	2023	SNS-F-11: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage. Krakowian D., 2023. Study code: EIT-01-23. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	SynthosAgro Sp. z o.o.
KCP 7.1.5	Toczko M.	2023	SNS-F-11: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage. Sornat R., 2023, Study code: ICE-02-23. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	SynthosAgro Sp. z o.o.

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

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

The following tables are to be completed by MS

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

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

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

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



## Appendix 2 Detailed evaluation of the studies relied upon

### A 2.1 Statement on bridging possibilities

Comments of zRMS:	The classification of the formulation SNS-F-11 is based on toxicological data of individual ingredients of the mixture (additivity formula) and <i>in vitro</i> data.
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The bridging was not necessary.

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

Comments of zRMS:	<p>There are two ingredients in the product that have been taken into account for the purpose of product classification:</p> <ul style="list-style-type: none"> <li>- Difenconazole: Acute Tox. 4, H302, DL50=1453 mg/kg bw; 8.55%</li> <li>- Component: Acute Tox.4, H302; = ATE =1200 mg/kg bw; 20.2% (acc. to ECHA).</li> </ul> <p><math>100/ATE_{mix}=8.55/1453 + 20.2/1200</math>  <math>ATE_{mix}=4424.7 \text{ mg/kg bw}</math></p> <p><u>Conclusion:</u>          Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to oral acute toxicity.</p>
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### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains:

- one component which is classified as Acute Tox. 3 with hazard statement H301. Its concentration in the product is equal to 0.00001%.
- two components which are classified as Acute Tox. 4 with hazard statement H302. Difenconazole concentration in the product is equal to 8.55% and second one – 20.2%.

Acute oral toxicity value ( $ATE_{mix}$ ) for SNS-F-11 can be estimated according to principles of Regulation (EC) 1272/2008, formula in section 3.1.3.6.1 (additivity formula) as follows:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

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

Therefore,  $ATE_{mix}$  value is equal to:

$$ATE_{mix} = \frac{100}{\frac{0.00001}{100} + \frac{28,75}{500}} = 1\,739.13 \text{ mg/L}$$

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The estimated value  $ATE_{mix}$  of acute oral toxicity for SNS-F-11 is higher than 300 mg/kg bw, but lower than 2000 mg/kg bw. Thus, classification is required according to Regulation (EC) No. 1272/2008. SNS-F-11 can be classified to **category 4 (Acute Tox 4 (H302))**.

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

Comments of zRMS:	Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to dermal acute toxicity.
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#### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 does not contain any component which is classified as acute dermal toxicity, therefore the product will not be classified as acute dermal toxicity.

Therefore, no classification is required according to Regulation (EC) No. 1272/2008.

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

Comments of zRMS:	<p>There is one ingredient in the product that has been taken into account for the purpose of product classification:</p> <ul style="list-style-type: none"> <li>- Component Acute Tox 3, H331, <math>ATE = 3 \text{ mg/L}</math> (Vapours), 20.2% (acc. to ECHA)</li> </ul> <p><u>Conclusion:</u></p> <p>Taking into account the composition of the product, the formulation SNS-F-11 requires classification in regards to inhalation acute toxicity (<b>Acute Tox 4, H332</b>).</p>
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No data on acute inhalation toxicity for difenoconazole in SNS-F-11 is available.

SNS-F-11 contains active substance with a vapour pressure below  $1 \times 10^{-2} \text{ Pa}$  ( $3.32 \times 10^{-8} \text{ Pa}$  at  $25^\circ \text{C}$  (99.0 % purity). Thus, according to the Commission Regulations (EU) No 284/2013, the study of acute inhalation toxicity for SNS-F-11 is not required.

#### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains:

- one component which is classified as Acute Tox. 2 with hazard statement H330. Its concentration in the product is equal to 0.00001%;
- one component which is classified as Acute Tox. 3 with hazard statement H331. Its concentration in the product is equal to 20.2%

Acute inhalation toxicity value ( $ATE_{mix}$ ) for SNS-F-11 can be estimated according to principles of Regulation (EC) 1272/2008, formula in section 3.1.3.6.1 (additivity formula) as follows:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

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

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Therefore, ATE<sub>mix</sub> value is equal to:

$$ATE_{mix} = \frac{100}{\frac{0.00001}{0,5} + \frac{20.2}{3}} = 14.85 \text{ mg/L}$$

## Conclusion

The estimated value ATE<sub>mix</sub> of acute inhalation toxicity for SNS-F-11 is equal to 14.85 mg/l (according to Table 3.1.2; vapours).

The estimated value ATE<sub>mix</sub> of acute inhalation toxicity for SNS-F-11 is higher than 10.0 mg/l, but lower than 20 mg/l. Thus, classification is required according to Regulation (EC) No. 1272/2008. SNS-F-11 can be classified to **category 4 (Acute Tox 4 (H332))**.

## A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	<p>The study (Krakowian D., 2023, code: SCT-01-23) provided by the Applicant is accepted. Acc. to the results of the study, the product SNS-F-11 does not require classification regarding skin corrosion. Since the irritation potential of the product could not be excluded, the calculation method was implemented.</p> <p>There is one component of the product which is classified as Skin Corr 1B with hazard statement H314 (0.00001%). This concentration value is below the concentration limit that triggers classification of the mixture in regards to the skin corrosion</p> <p>Further three components of the product are classified as <b>Skin Irrit. 2</b> with hazard statement <b>H315</b></p> <ul style="list-style-type: none"> <li>-Component 1, 0.09%</li> <li>-Component 2, 0.02%</li> <li>-Component 3, 20.2 %</li> </ul> <p>The sum of concentration values is above the concentration limit that triggers classification of the mixture in regards to the skin irritation.</p> <p><u>Conclusion:</u></p> <p>Taking into account the composition of the product, the formulation SNS-F-11 requires classification in regards to skin irritation (<b>Skin Irrit 2, H315</b>).</p>
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### A 2.5.1

### Study 1

Reference	KCP 7.1.4
Report	DIFLUD 050 FS: <i>In vitro</i> Skin Corrosion: Reconstructed Human Epidermis Test Method. Krakowian D., 2023. Study code: SCT-01-23.
Guideline(s)	OECD 431 (2019)/EU Methods B.40.BIS.
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

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### Materials and methods

<b>Test material (Lot/Batch No.)</b>	SNS-F-11 (Batch No. S/1/210223)
<b>Test sytem</b>	EpiDerm™ tissues (human reconstructed epidermis model)
<b>No. of inserts</b>	2 inserts with tissues of the human skin model EpiDerm
<b>Initial test using one animal</b>	No
<b>Exposure</b>	Topical exposure; 50.0 µL test item are applied without preparation on two tissues.
<b>Exposure time</b>	3 min., 60 min.
<b>Negative control</b>	sterile deionized water
<b>Positive control</b>	8 N potassium hydroxide
<b>Viability Test</b>	MTT Viability Test
<b>Vehicle/Dilution</b>	None
<b>Remarks</b>	None

### Results and discussions

**Table A 1: Tissue viability [%] –3-minute exposure**

	<b>Negative control</b>	<b>Positive control</b>	<b>SNS-F-11</b>
<b>Tissue no. 1 viability</b>	104.7	1.9	99.2
<b>Tissue no. 2 viability</b>	95.3	2.0	96.5
<b>Mean Tissue viability</b>	<b>100.0</b>	<b>1.4</b>	<b>97.9</b>
<b>SD (±)</b>	4.7	0.1	1.3
<b>%CV</b>	4.7	2.6	1.3
<b>Difference between the tissues</b>	9.4	0.1	2.6

**Table A 2: Tissue viability [%] – 1-hour exposure**

	<b>Negative control</b>	<b>Positive control</b>	<b>SNS-F-11</b>
<b>Tissue no. 1 viability</b>	99.7	1.9	96.9
<b>Tissue no. 2 viability</b>	100.3	1.9	80.3
<b>Mean Tissue viability</b>	<b>100.0</b>	<b>1.9</b>	<b>88.6</b>
<b>SD (±)</b>	0.3	0.0	8.3
<b>%CV</b>	0.3	0.2	9.4
<b>Difference between the tissues</b>	0.7	0.0	16.6

### Conclusion

After the 3-minute exposure to the test item, the mean value of relative tissue viability was equal to 97.9 %. After the 1-hour exposure to the test item, the mean value of relative tissue viability was equal to 88.6 %. These values are above the threshold of non-corrosive effects on the skin (viability  $\geq 50$  % after 3-minutes exposure and  $\geq 15$  % after 60-minutes exposure).

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The test item, SNS-F-11, is considered to be **non-corrosive to skin** in the Reconstructed human Epidermis (RhE) Test Method. It can not be classified as category 1 in the UN GHS classification.  
No classification is required according to Regulation (EC) No. 1272/2008.

### A 2.5.2 Calculation method (Regulation (EC) No 1272/2008)

Result of the study presented in point A.2.5.1 (Krakowian D., 2023, Study code: SCT-01-23) does not exclude the irritation potential of tested formulation. Further *in vitro* test was not carried out, thus the additive formula (calculation method) was used to finalize the assessment.

SNS-F-11 contains:

- one component (co-formulant) which is classified as Skin Corr 1B with hazard statement H314. Its concentrations in the product is equal to 0.00001% . This concentration values is below concentration limit that triggers classification of the mixture in regards to the skin corrosion (5%).
- three components (co-formulants) which are classified as Skin Irrit. 2 with hazard statement H315. Their concentrations in the product is equal to 0.09%, 0.02% and 20.2%. The sum of concentration values is above concentration limit (10%) that triggers classification of the mixture in regards to the **skin irritation with hazard statement H315.**

### A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	The study (Krakowian D., 2023, code: EIT-01-23) provided by the Applicant is accepted. Acc. to the results of the study, the product SNS-F-11 requires classification regarding eye corrosion ( <b>Eye Dam. 1, H318</b> ).
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#### A 2.6.1 Study 1

Reference	KCP 7.1.5
Report	SNS-F-11: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage. Krakowian D., 2023. Study code: EIT-01-23.
Guideline(s)	OECD Guideline No. 492 / EU Method B.69.
Deviations	No
GLP	Yes
Acceptability	Yes

#### Materials and methods

Test material (Lot/Batch No.)	SNS-F-11 (Batch No. S/1/210223)
Test sytem	EpiOcular™ tissue construct (cornea epithelial construct (RhCE), nonkeratinized epithelium prepared from normal human keratinocytes)
No. of inserts	2 inserts with tissues
No. of runs	2

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<b>Initial test using one animal</b>	No
<b>Exposure</b>	Topical exposure; 50.0 µL test item are applied without preparation on two tissues.
<b>Exposure time</b>	30±2 minutes
<b>Negative control</b>	sterile deionized water
<b>Positive control</b>	methyl acetate
<b>Viability Test</b>	MTT Viability Test
<b>Vehicle/Dilution</b>	None
<b>Remarks</b>	None

## Results and discussions

**Table A 3: Relative tissue viability [%]**

<b>RUN</b>		<b>Negative control</b>	<b>Positive control</b>	<b>SNS-F-11</b>
<b>1</b>	<b>Tissue no. 1 viability</b>	102.2	27.6	61.6
	<b>Tissue no. 2 viability</b>	97.8	18.9	54.1
	<b>Mean Tissue viability</b>	<b>100.0</b>	<b>23.2</b>	<b>56.2</b>
	<b>SD (±)</b>	2.4	4.4	3.9
	<b>%CV</b>	2.2	18.7	6.5
	<b>Difference between the tissues</b>	4.4	8.7	7.5
<b>2</b>	<b>Tissue no. 1 viability</b>	94.3	21.9	45.7
	<b>Tissue no. 2 viability</b>	105.7	29.7	48.4
	<b>Mean Tissue viability</b>	<b>100.0</b>	<b>25.8</b>	<b>47.1</b>
	<b>SD (±)</b>	5.9	3.9	1.5
	<b>%CV</b>	5.7	15.1	2.9
	<b>Difference between the tissues</b>	11.4	7.8	2.7

## Conclusion

All acceptance criteria (absorbance value for negative control, mean value of relative tissue viability of positive control, viability difference between tissue replicates, compliance with historical data) were within the appropriate range. Therefore, the experiment is considered as valid.

After the treatment with SNS-F-11, the mean value of relative tissue viability was reduced to 56.2% in the first run (NSMTT control subtracted) and reduced to 47.1% in the second run. Both values are below the threshold for non-irritants (>60%).

**SNS-F-11 has not been identified as not requiring classification and labelling** according to UN GHS in the Reconstructed human Cornea-like Epithelium (RhCE) test method. Therefore, further testing with another suitable study (*in vitro*, *in vivo* or *in silico*) may be required to classify SNS-F-11.

### A 2.6.2

### Study 2

Reference

KCP 7.1.5

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Report	SNS-F-11: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage. Toczko M., 2023. Study code: ICE-02-23.
Guideline(s)	OECD Guideline No. 438/EU Method B.48
Deviations	No
GLP	Yes
Acceptability	Yes

## Materials and methods

Test material (Lot/Batch No.)	SNS-F-11 (Batch No. S/1/210223)
Species	Chickens, eyeballs
No. of animals (group size)	9 eyeballs
Initial test using one animal	No
Exposure	0.03 mL (single instillation) for 10 sec.
Irrigation (time point)	10 sec., physiological salt
Post exposure observation period	4 hours
Remarks	None

## Results and discussions

**Table A 4: Eye irritation of SNS-F-11**

Observation after time (min.)	Corneal opacity		Corneal swelling (%)		Fluorescein retention	
	Mean scores	ICE class	Mean scores	ICE class	Mean scores	ICE class
0 min.	0.0	I	0.0	I	0.0	I
30 min.	1.3	II	9.0	I	2.7	IV
75 min.	2.7	IV	13.7	III	-	-
120 min.	2.7	IV	10.5	II	-	-
180 min.	3.0	IV	7.1	II	-	-
240 min.	3.0	IV	5.8	II	-	-

**Table A 5: Eye irritation of SNS-F-11 – Summary of the results**

	Maximal ICE Class			UN GHS Classification
	Fluorescein retention	Corneal opacity	Corneal swelling	
SNS-F-11	IV	IV	III	Category 1
Positive control	IV	IV	IV	Category 1
Negative control	I	I	I	No category

Clinical signs:	Roughness of the corneal surface were observed. Histopathological examinations revealed: erosion, vacuolation, necrosis (all eyeballs) and hyperplasia of epithelium (one eyeball); swelling of cells of stroma (all eyeball); necrosis (two eyeballs) and partial detachment of endothelium (one eyeball).
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## Conclusion

**SNS-F-11 probably cause serious eye damage.** According to UN GHS classification criteria prediction can be made, since the ICE Class combination of the 3 endpoints were: 2 x IV and 1 x III (category 1). On the basis of the results obtained in the course of the histopathological evaluation it can be concluded that the test item had a negative effect on the chicken cornea in the ICE test. The test item can be put into as category 1. Under the experimental conditions, SNS-F-11 is an eye irritant. Thus, be classified as category 2 – **Eye Dam. 1 (H318)**, according to Regulation (EC) No. 1272/2008, Table 3.3.2.

The other additional researches (*in vivo* or *in vitro*) are not necessary for classification of SNS-F-11.

## A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to sensitizing properties.
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### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains one components which is classified as Respiratory sensitizer 1 with hazard statement H334. The concentration of the component in SNS-F-11 is equal to 0.00001%. This concentration is below concentration limit (0.1%) stated in Table 3.4.5 of Regulation 1272/2008.

Thus, no classification is required according to Regulation (EC) No. 1272/2008.

SNS-F-11 contains one component which is classified as Skin Sens. 1 with hazard statement H317. The concentration of the component in SNS-F-11 is equal to 0.00001%. This concentration is below concentration limit (0.1%) stated in Table 3.4.5 of Regulation 1272/2008.

Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

## 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)



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According requirements from Reg. No. 284/2013/WE the study shall be conducted when dermal exposure is a significant exposure route and no acceptable risk is estimated using default absorption value.

Use of plant protection product SNS-F-11 is safe for operator, taking into account proposed dose of product, type of usage, type of personal protective equipment (gloves). Using tractor mounted boom sprayer and maintain general rules of safety and hygiene of working with plant protection products and comply with requirements enclosed in label, risk during employ SNS-F-11 is acceptable, absorbed dose of difenoconazole has safe value, below AOEL for this active ingredients.

According to above there isn't necessity to do tests of dermal absorption for SNS-F-11.

## A 2.11 Other - Toxicological Evaluation

### A 2.11.1 Reproductive toxicity

Comments of zRMS:	<p>There are two ingredients of the product which have been taken into account for the purpose of product classification <b>Repr. 2 H361df</b>:</p> <ul style="list-style-type: none"> <li>- Component 1: 0.09%;</li> <li>- Component 2: 0.00001%.</li> </ul> <p>The sum of concentration values is below the concentration limit that triggers classification of the mixture in regards to the reproduction toxicity.</p> <p><u>Conclusion:</u>          Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to reproduction toxicity.</p>
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#### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains two components which are classified as Repr. 2 with hazard statement H3361d,f. Their concentrations in the product is equal to 0.09% (H361d) and 0.00001% (H361f). The sum of concentration values is below concentration limit (3%) stated in Table 3.7.2 of Regulation 1272/2008.

Thus, no classification is required according to Regulation (EC) No. 1272/2008.

### A 2.11.2 Specific target organ toxicity — single exposure

Comments of zRMS:	<p>There are three ingredients of the product which have been taken into account for the purpose of product classification <b>STOT SE 3</b>:</p> <ul style="list-style-type: none"> <li>- Component 1: 0.09% STOT SE 3, H336;</li> <li>- Component 2: 0.02% STOT SE 3, H336;</li> <li>- Component 3: 0.00001% STOT SE 3, H335 - Specific Concentration limits <math>5 \% \leq C &lt; 5 \%</math> (acc. to ECHA).</li> </ul> <p>The sum of concentration values of component 1 and 2 is below the concentration limit that triggers classification of the mixture in regards to the specific target organ toxicity single exposure.</p> <p>Concentration value of component 3 is below the Specific Concentration limits.</p>
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	<u>Conclusion:</u> Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to specific target organ toxicity in case of single exposure.
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#### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains:

- two components which are classified as STOT SE 3 with hazard statement H336 (nervous system). Their concentrations in the product is equal to 0.09% and 0.02%. The sum of concentration values is below concentration limit (20%) stated Regulation 1272/2008.
- one component which is classified as STOT SE 3 with hazard statement H335. Its concentration in the product is equal to 0.00001%. This concentration is below specific concentration limit:  $0.5\% \leq C < 5\%$ .

Thus, no classification is required according to Regulation (EC) No. 1272/2008.

#### A 2.11.3 Specific target organ toxicity — repeated exposure

Comments of zRMS:	There is one ingredient of the product which has been taken into account for the purpose of product classification STOT RE 2, H373:  - Component 1: 0.09% STOT RE 2; H373  Concentration value is below the concentration limit that triggers classification of the mixture in regards to the specific target organ toxicity in case of repeated exposure.  <u>Conclusion:</u> Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to specific target organ toxicity in case of repeated exposure.
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#### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains:

- one component which is classified as STOT RE 2 with hazard statement H373. Its concentration in the product is equal to 0.09%. This concentration is below specific concentration limit 20%.

Thus, no classification is required according to Regulation (EC) No. 1272/2008.

#### A 2.11.4 Aspiration hazard

Comments of zRMS:	There are two ingredients of the product which have been taken into account for the purpose of product classification Asp. Tox. 1, H304:  - Component 1: 0.09%; - Component 2: 0.02%.  The sum of concentration values is below the concentration limit that triggers classification of the mixture in regards to the aspiration toxicity.  <u>Conclusion:</u> Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to the aspiration toxicity.
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Comments of zRMS:	<p><b>A.2.11.5 Carcinogenicity</b></p> <p>There is one ingredient of the product which has been taken into account for the purpose of product classification Carc.2, H351:</p> <p>- difenoconazole: 8.11%</p> <p>Concentration value is above (<math>\geq 1,0</math> %) the concentration limit that triggers classification of the mixture in regards to the carcinogenicity.</p> <p><u>Conclusion:</u></p> <p>Taking into account the composition of the product, the formulation SNS-F-11 does not require classification in regards to specific target organ toxicity in case of repeated exposure.</p>
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#### Calculation method (Regulation (EC) No 1272/2008)

SNS-F-11 contains two components which are classified as Asp. Tox.1 with hazard statement H304. Their concentrations in the product is equal to 0.09% and 0.02%. The sum of concentration values is below concentration limit (10%) stated Regulation 1272/2008.

Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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## Appendix 3 Exposure calculations

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

#### A 3.1.1 Calculations for difenoconazole

#### Cereals: Winter wheat, winter triticale

**Table A 6: Input parameters considered for the estimation of operator exposure**

Formulation type	EC		Crop type	Cereals
Application rate (AR)	0.090	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	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.16	mg/kg bw/d	Water soluble bag	No

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**Table A 7: Estimation of longer term operator exposure towards active substance according to EFSA guidance**





**Operator exposure for SNS-F-11 outdoor spray applications**

Operator exposure for one 1:12 outdoor spray application					
Application rate of active substance		0,09 kg a.s./ha		<i>i_AppRate</i>	
Assumed area treated		50 ha/day		<i>d_AreaTreated</i>	
Amount of active substance applied		4,5 kg a.s./day		<i>i_AmountAS</i>	
Dermal absorption of the product		25,00%		<i>i_AbsorpProduct</i>	
Dermal absorption of in-use dilution		70,00%		<i>i_AbsorInuse</i>	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	15460	57406	AOEM	
	Body	10268	111494	AOEM	
	Head	233	1281	AOEM	
	Protected hands (gloves)	92	891	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	90	658	AOEM	
	Protected head (hood and face shield)	4	72	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	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	667	6896	AOEM	
	Body	373	1924	AOEM	
	Head	18	53	AOEM	
	Protected hands (gloves)	96	3972	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	10	25	AOEM	
	Inhalation	2	7	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	Yes		vehicle mounted upward spraying only	

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	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	7,2393212	3,3971155
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1206554	0,0566186
% of RVNAS	75,41%	35,39%

**Table A 8:** Estimation of longer term operator exposure towards difenoconazole according to OPEX calculator ver. 1.0.1.

		Short term exposure	
Mixing/loading Application		Difenoconazole (% AOEL) Normal & vehicle-mounted	
		92.7	
		61.6	
Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Number of applications and application rate: 2 x 0.09 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %			
Difenoconazole	M/L: Workwear App: Workwear	0.1	61.6

**Winter rape,  
 Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold  
 of pleasure seeds, Sunflower seeds, Soyabeans**

**Table A 9:** Input parameters considered for the estimation of operator exposure

Formulation type	EC		Crop type	Oilseeds
Application rate (AR)	0.1035	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	Yes
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.16	mg/kg bw/d	Water soluble bag	No

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**Table A 10: Estimation of longer term operator exposure towards active substance according to EFSA guidance**

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**Operator exposure for SNS-F-11 outdoor spray applications**

Application rate of active substance	0,1035 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	5,175 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70,00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 <sup>th</sup> centile	95 <sup>th</sup> centile		
	Hands	17217	64006	AOEM	
	Body	11328	116115	AOEM	
	Head	268	1473	AOEM	
	Protected hands (gloves)	100	1025	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	102	757	AOEM	
	Protected head (hood and face shield)	4	83	AOEM	
	Inhalation	6	30	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	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	768	7639	AOEM	
	Body	429	2212	AOEM	
	Head	20	61	AOEM	
	Protected hands (gloves)	103	4037	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	12	29	AOEM	
	Inhalation	2	7	AOEM	
	<b>Protective Equipment</b>	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	Yes		vehicle mounted upward spraying only	





	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	8,0636553	3,7845762
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1343943	0,0630763
% of RVNAS	84,00%	39,42%



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**Table A 11:** Estimation of longer term operator exposure towards difenoconazole according to OPEX calculator ver. 1.0.1.

*Short term exposure*

Mixing/loading	Application	Difenoconazole (% AOEL) Normal & vehicle-mounted
		102
		67.7

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Difenoconazole	Number of applications and application rate: 1 x 0.1035 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.1	67.7

## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for difenoconazole

#### Cereals: Winter wheat, winter triticale

**Table A 12:** Input parameters considered for the estimation of worker exposure

Intended use(s)	cereals		Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	0.090	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	14	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)	1.7		TC dermal (work wear)	1400	cm <sup>2</sup> /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	-	cm <sup>2</sup> /h
AOEL	0.16	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

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**Table A 13: Estimation of longer term worker exposure towards active substance according to EFSA guidance**

Worker exposure from residues on foliage for SNS-F-11			
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	0,09 kg a.s./ha		
Number of applications	2		
Interval between multiple applications	14 days		
Half-life of active substance	30 days		
Multiple application factor	1,7		
Dermal absorption of the product	25,00%		
Dermal absorption of the in-use dilution	70,00%		
Dislodgeable foliar residue ( $i\_AppRate * i\_DFR$ )	0,27 $\mu\text{g a.s./cm}^2$		
Working hours	2 hr		
Dermal transfer coefficient - Total potential exposure	12500 $\text{cm}^2/\text{hr}$		
Dermal transfer coefficient - arms, body and legs covered	1400 $\text{cm}^2/\text{hr}$		
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment $\text{cm}^2/\text{hr}$		
Inhalation transfer coefficient for automated applications	NA $\text{ha/hr} * 10^{(-3)}$		
Inhalation transfer coefficient for cutting ornamentals	NA $\text{ha/hr} * 10^{(-3)}$		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA $\text{ha/hr} * 10^{(-3)}$		
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	8,1441736	0,9121474	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1357362	0,0152025	
% of RVNAS	84,84%	9,50%	
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	8,1441736	0,1357362	
Dermal - Work wear - arms, body and legs covered	0,9121474	0,0152025	
Dermal - Working wear and gloves	no TC available for this assessment		
Inhalation			

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**Table A 14: Estimation of longer term worker exposure towards difenoconazole according to OPEX calculator ver. 1.0.1.**

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	8.1	0.9	0.8	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	8.1	0.9	0.8	NA
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.02	0.01	NA
	% of AOEL	84.7	9.5	8.5	NA

**Winter rape,  
Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold  
of pleasure seeds, Sunflower seeds, Soyabeans**

**Table A 15: Input parameters considered for the estimation of worker exposure**

Intended use(s)	Oilseeds		Dislodgeable foliar residue (DFR)	3	µg/cm <sup>2</sup> /kg a.s./ha
Application rate (AR)	0.1035	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	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)	-		TC dermal (work wear)	1400	cm <sup>2</sup> /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	1250	cm <sup>2</sup> /h
AOEL	0.16	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 <sup>-3</sup>
AAOEL		mg/kg bw/d			

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**Table A 16: Estimation of longer term worker exposure towards active substance according to EFSA guidance**

Worker exposure from residues on foliage for SNS-F-11			
Crop type	Oilseeds		
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	0,1035 kg a.s./ha		
Number of applications	1		
Interval between multiple applications	365 days		
Half-life of active substance	30 days		
Multiple application factor	1,0		
Dermal absorption of the product	25,00%		
Dermal absorption of the in-use dilution	70,00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3105 µg a.s./cm²		
Working hours	2 hr		
Dermal transfer coefficient - Total potential exposure	12500 cm²/hr		
Dermal transfer coefficient - arms, body and legs covered	1400 cm²/hr		
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm²/hr		
Inhalation transfer coefficient for automated applications	NA ha/hr*10^(-3)		
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10^(-3)		
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10^(-3)		
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5,4337500	0,6085800	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0905625	0,0101430	
% of RVNAS	56,60%	6,34%	
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	5,4337500	0,0905625	
Dermal - Work wear - arms, body and legs covered	0,6085800	0,0101430	
Dermal - Working wear and gloves	no TC available for this assessment		
Inhalation			

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**Table A 17: Estimation of longer term worker exposure towards difenoconazole according to OPEX calculator ver. 1.0.1.**

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	5.4	0.6	0.5	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	5.4	0.6	0.5	NA
	Total systemic exposure [mg/kg bw per day]	0.09	0.01	0.009	NA
	% of AOEL	56.6	6.3	5.7	NA

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

**A 3.3.1 Calculations for difenoconazole**

**Cereals: Winter wheat, winter triticale**

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**Table A 18: Input parameters considered for the estimation of longer term resident exposure**

Bystander exposure for SNS-F-11			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		<i>i_AppEquip</i>
Formulation type	soluble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0,09 kg a.s./ha		<i>i_AppRate</i>
Buffer strip	2-3 m		<i>i_Buffer</i>
Concentration of active substance (in-use dilution for liquid applications)	0,45 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 ( $i\_AppRate * i\_DFR$ )	0,27 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>
Bystander dermal spray drift exposure - adult	1,21 ml spray dilution/person		
Bystander dermal spray drift exposure - child	0,74 ml spray dilution/person		
Bystander inhal. spray drift exposure - adult	0,00050 ml spray dilution/person		
Bystander inhal. spray drift exposure - child	0,00112 ml spray dilution/person		
Exposure duration	2 hours		<i>d_ByExpDur</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> /kg bw/day		<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /kg bw/day		<i>d_BreathRCh</i>
Drift percentage on surface (90th percentile)	8,50%		
Turf transferable residues percentage	5,00%		<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	14500 cm <sup>2</sup> /hour		<i>d_ByTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	5200 cm <sup>2</sup> /hour		<i>d_ByTCCh</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	20 events/hour		<i>d_ByFreqHM</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 - adult	7500 cm <sup>2</sup> /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops - child	2250 cm <sup>2</sup> /h		<i>d_TcEntryCh</i>

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**Table A 19: Estimation of longer term resident exposure towards difenoconazole according to EFSA guidance**

<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)	0,0845631	0,0107000	0,0170702	0,1832439	0,2158748
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0084563	0,0010700	0,0017070	0,0183244	0,0215875
% of RVNAS	5,29%	0,67%	1,07%	11,45%	13,49%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1214460	0,0138000	0,0443912	0,6108130	0,5910102
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0020241	0,0002300	0,0007399	0,0101802	0,0098502
% of RVNAS	1,27%	0,14%	0,46%	6,36%	6,16%
<b>2. Resident exposure 75th Percentile</b>			<b>3. Summing of exposure pathways mean</b>		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]		Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
<b>1-3 year old child</b>			<b>1-3 year old child</b>		
Spray drift	0,0845631	0,0084563	Spray drift	0,0465705	0,0046571
Vapour	0,0107000	0,0010700	Vapour	0,0107000	0,0010700
Surface deposits			Surface deposits		
Dermal	0,0158106	0,0015811	Dermal	0,0115756	0,0011576
Hand to mouth	0,0008253	0,0000825	Hand to mouth	0,0006042	0,0000604
Object to mouth	0,0004344	0,0000434	Object to mouth	0,0003180	0,0000318
Entry into treated crops			Entry into treated crops		
Dermal	0,1832439	0,0183244	Dermal	0,1461065	0,0146106
Hand to mouth			Hand to mouth		
Object to mouth			Object to mouth		
<b>Adult</b>			<b>Adult</b>		
Spray drift	0,1214460	0,0020241	Spray drift	0,0576879	0,0009615
Vapour	0,0138000	0,0002300	Vapour	0,0138000	0,0002300
Surface deposits (dermal)	0,0443912	0,0007399	Surface deposits (dermal)	0,0325007	0,0005417
Entry into treated crops (dermal)	0,6108130	0,0101802	Entry into treated crops (dermal)	0,4870216	0,0081170

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**Table A 20: Estimation of longer term resident exposure towards difenoconazole according to OPEX calculator ver. 1.0.1.**

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 14 days Minimum volume of water: 200 l			
Number of applications and application rate: 2 x 0.09 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
<b>Difenoconazole</b>			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.009	5.3
	Vapour (75th perc.)	0.0008	0.5
	Deposits (75th perc.)	0.002	1.1
	Re-entry (75th perc.)	0.02	11.4
	Sum (mean)	0.02	13.3
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	1.3
	Vapour (75th perc.)	0.0003	0.2
	Deposits (75th perc.)	0.0007	0.5
	Re-entry (75th perc.)	0.01	6.3
	Sum (mean)	0.01	6.2

**Winter rape,  
 Spring oilseed rape, Linseed (common flax), Poppy seeds, Mustard seeds, Gold  
 of pleasure seeds, Sunflower seeds, Soyabeans**



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**Table A 21: Input parameters considered for the estimation of longer term resident exposure**

Resident exposure for SNS-F-11	
Croptype	Cereals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0,09 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,45 g a.s./l
Dermal absorption of product	25,00%
Dermal absorption of in-use dilution	70,00%
Oral absorption	100,00%
Dislodgeable foliar residue ( $i\_AppRate * i\_DFR$ )	0,27 $\mu\text{g a.s./cm}^2$
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure Pa of $<5*10^{-3}\text{Pa}$
Concentration in air	0,001 $\text{mg/m}^3$
Resident dermal spray drift exposure 75th percentile	0,47 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile	0,327 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile	0,00010 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile	0,00022 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person
Exposure duration dermal	2 hours
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0,25 hours
Light clothing adjustment factor	18,0%
Breathing rate adult	0,23 $\text{m}^3/\text{day/kg}$
Breathing rate child (1-3 year old)	1,07 $\text{m}^3/\text{day/kg}$
Drift percentage on surface (75th percentile)	5,60%
Drift percentage on surface (mean)	4,10%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 $\text{cm}^2/\text{hour}$
Transfer coeff. of surface deposits-child (1-3 year old)	2600 $\text{cm}^2/\text{hour}$
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 $\text{cm}^2$
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 $\text{cm}^2$
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile)	7500 $\text{cm}^2/\text{h}$
Transfer coefficient for entry into treated crops (75th percentile)	2250 $\text{cm}^2/\text{h}$
Transfer coefficient for entry into treated crops (mean)	5980 $\text{cm}^2/\text{h}$
Transfer coefficient for entry into treated crops (mean)	1794 $\text{cm}^2/\text{h}$

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**Table A 22: Estimation of longer term resident exposure towards difenoconazole according to EFSA guidance**

<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)	0,0972476	0,0107000	0,0113891	0,1222594	0,1700760
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0097248	0,0010700	0,0011389	0,0122259	0,0170076
% of RVNAS	6,08%	0,67%	0,71%	7,64%	10,63%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1396629	0,0138000	0,0296176	0,4075313	0,4267636
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0023277	0,0002300	0,0004936	0,0067922	0,0071127
% of RVNAS	1,45%	0,14%	0,31%	4,25%	4,45%

<b>2. Resident exposure 75th Percentile</b>		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
<b>1-3 year old child</b>		
Spray drift	0,0972476	0,0097248
Vapour	0,0107000	0,0010700
Surface deposits		
Dermal	0,0105487	0,0010549
Hand to mouth	0,0005506	0,0000551
Object to mouth	0,0002898	0,0000290
Entry into treated crops		
Dermal	0,1222594	0,0122259
Hand to mouth		
Object to mouth		
<b>Adult</b>		
Spray drift	0,1396629	0,0023277
Vapour	0,0138000	0,0002300
Surface deposits (dermal)	0,0296176	0,0004936
Entry into treated crops (dermal)	0,4075313	0,0067922

<b>3. Summing of exposure pathways mean</b>		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
<b>1-3 year old child</b>		
Spray drift	0,0535561	0,0053556
Vapour	0,0107000	0,0010700
Surface deposits		
Dermal	0,0077232	0,0007723
Hand to mouth	0,0004031	0,0000403
Object to mouth	0,0002122	0,0000212
Entry into treated crops		
Dermal	0,0974815	0,0097481
Hand to mouth		
Object to mouth		
<b>Adult</b>		
Spray drift	0,0663411	0,0011057
Vapour	0,0138000	0,0002300
Surface deposits (dermal)	0,0216843	0,0003614
Entry into treated crops (dermal)	0,3249383	0,0054156

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**Table A 23: Estimation of longer term resident exposure towards difenoconazole according to OPEX calculator ver. 1.0.1.**

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 200 l			
Number of applications and application rate: 1 x 0.1035 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm <sup>2</sup> foliage per kg a.s./ha DT50: 30 days			
<b>Difenoconazole</b>			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.01	6.1
	Vapour (75th perc.)	0.0008	0.5
	Deposits (75th perc.)	0.001	0.7
	Re-entry (75th perc.)	0.01	7.6
	Sum (mean)	0.02	10.5
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	1.5
	Vapour (75th perc.)	0.0003	0.2
	Deposits (75th perc.)	0.0005	0.3
	Re-entry (75th perc.)	0.007	4.2
	Sum (mean)	0.007	4.5

#### 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)