

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: GLOB1911F

Product name(s): **CURRANDO/ SUBIGON/ COLLECTOR**

Chemical active substance:

Difenoconazole, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: August 2020

MS Finalisation date: May 2021

Revision date: October 2021

Version history

When	What
August 2020	Version submitted by the applicant
May 2021	Version evaluated by zRMS
September 2021	Version supplemented by the applicant taking into account comments of MSs
October 2021	Version revised to take into account comments of MSs

Table of Contents

6	Mammalian Toxicology (KCP 7).....	5
6.1	Summary	5
6.2	Toxicological Information on Active Substance(s)	7
6.3	Toxicological Evaluation of Plant Protection Product.....	7
6.4	Toxicological Evaluation of Groundwater Metabolites.....	9
6.5	Dermal Absorption (KCP 7.3)	9
6.5.1	Justification for proposed values - Difenconazole.....	9
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2).....	9
6.6.1	Selection of critical use(s) and justification	10
6.6.2	Operator exposure (KCP 7.2.1)	10
6.6.2.1	Estimation of operator exposure	10
6.6.3	Measurement of operator exposure.....	11
6.6.4	Worker exposure (KCP 7.2.3)	11
6.6.4.1	Estimation of worker exposure	11
6.6.4.2	Refinement of generic DFR value (KCP 7.2).....	15
6.6.4.3	Measurement of worker exposure.....	15
6.6.5	Bystander and resident exposure (KCP 7.2.2)	16
6.6.5.1	Estimation of bystander and resident exposure	16
6.6.5.2	Measurement of bystander and/or resident exposure.....	17
6.6.6	Combined exposure	18
Appendix 1	Lists of data considered in support of the evaluation.....	19
Appendix 2	Detailed evaluation of the studies relied upon.....	21
A 2.1	Statement on bridging possibilities	21
A 2.2	Acute oral toxicity (KCP 7.1.1)	21
A 2.3	Acute percutaneous (dermal) toxicity (KCP 7.1.2)	21
A 2.4	Acute inhalation toxicity (KCP 7.1.3)	21
A 2.5	Skin irritation (KCP 7.1.4).....	21
A 2.6	Eye irritation (KCP 7.1.5).....	21
A 2.7	Skin sensitisation (KCP 7.1.6).....	21
A 2.8	Supplementary studies for combinations of plant protection products (KCP 7.1.7)	21
A 2.9	Data on co-formulants (KCP 7.4)	21
A 2.9.1	Material safety data sheet for each co- formulants.....	21
A 2.9.2	Available toxicological data for each co-formulant.....	22
A 2.10	Studies on dermal absorption (KCP 7.3)	22
A 2.11	Other/Special Studies	22
Appendix 3	Exposure calculations	23
A 3.1	Operator exposure calculations (KCP 7.2.1.1)	23
A 3.2	Worker exposure calculations (KCP 7.2.3.1)	26
A 3.3	Bystander and resident exposure calculations (KCP 7.2.2.1).....	31

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)	35
-------------------	--	-----------

No exposure and/or DFR studies were required, since the risk was acceptable based on standard model calculations.	35
---	-----------

This part of dRR of the product CURRANDO/ SUBIGON/ COLLECTOR has been evaluated based on request of Ministry of Agriculture and Rural Development in Poland expressed in a letter of 27 July 2020 with a case mark KS.rs.8208.1.11.2020.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on GLOB1911F *

Product name and code	GLOB1911F/Currando/ Subigon/ Collector
Formulation type	Suspension concentrate [SC]
Active substance(s) (incl. content)	Difenoconazole; 500 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 GLOB1911F 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 GLOB1911F according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Eye Irrit. 2
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07
Signal word:	Warning
Hazard statement(s):	H319 Causes serious eye irritation
Precautionary statement(s):	P264 Wash hands and face thoroughly after handling P280 Wear protective gloves/protective clothing /eye protection/face protection P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] EUH208 — Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for GLOB1911F

	Result	PPE / Risk mitigation measures
Operators	Acceptable	no PPE: Operator wearing work wear (arms, body and legs covered) but no gloves. Personal eye protection need to be used – relating to classification (H319).
Workers	Acceptable	no PPE: Worker wearing work wear (arms, body and legs covered) but no gloves
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. But specific PPE is necessary with respect to the classification of the PPP (Eye Irrit. 2, H319).

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. safener/ 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. applica- tion technique ***	Max. number (min. interval between applica- tions) a) per use b) per crop/ season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Operator	Worker	Bystander	Residents
1	Potato (BBCH 40-99)	F	Normal downward spraying, LCTM	a) 1-4 b) 1-4	a) 0.125 b) 0.500	100-400	14					
2, 3	Sugar beet/ fodder beet (after BBCH 31 till 49)	F	Normal downward spraying, LCTM	a) 1-2 b) 1-2	a) 0.125 b) 0.250	100-400	21					
4, 5, 6	Oilseed rape (winter and spring) (BBCH 19-69)	F	Normal downward spraying, LCTM	a) 1-2 b) 1-2	a) 0.125 b) 0.250	100-400	56					

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

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

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

Explanation for column 10 “Acceptability of exposure assessment”

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

Data gaps

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

Noticed data gaps are: None

6.2 Toxicological Information on Active Substance(s)

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

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

	Difenoconazole
Common Name	Difenoconazole
CAS-No.	119446-68-3
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Acute Tox. (Oral) 4, Aquatic Acute 1, Aquatic Chronic 1 Code(s) for hazard pictogram(s): GHS07, GHS09 Signal word: Warning Hazard statement(s): H302, H400, H410 Precautionary statement(s): P264, P270, P273, P280, P301+P312, P330, P302+P352, P312, P322, P363, P391, P501
Additional C&L proposal	Please insert proposal for additional C&L if no (sufficient) harmonized classification is available
Agreed EU endpoints	
AOEL systemic	0.16 mg/kg bw/d (safety factor of 100)
Reference	Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole EFSA Conclusion 2011 (EFSA Journal 2011;9(1):1967) SANCO/830/08 – rev. 27 September 2011; 13 December 2013 and 18 May 2020
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report for active substance	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB1911F is given in the following tables.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB1911F

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	Study not necessary	Yes	Acute Tox. 4, H302 None None	Theoretical calculations (see part C)
LD ₅₀ dermal, rat	Study not necessary	Yes	None	Theoretical calculations (see part C)
LC ₅₀ inhalation, rat	Study not necessary	Yes	None	Theoretical calculations (see part C)
Skin irritation	Study not necessary	Yes	None	Theoretical calculations (see part C)
Eye irritation	Study not necessary	Yes	Eye Irrit. 2, H319	Theoretical calculations (see part C)
Skin sensitisation	Study not necessary	Yes	None EUH 208 (see part C)	Theoretical calculations (see part C)
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of GLOB1911F

	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)	See part C	Eye Dam. 1, H318	See part C	Eye Irrit. 2, H319
Toxicological properties of non-active substance(s) (relevant for classification of product)	1,2- benzisothiazol-3(2H)-one (CAS 2634-33-5, < 0.05% (w/w))* Content 0.03% in PPP	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
Further toxicological	No data – not required			

	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)
information				

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

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 GLOB1911F are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in GLOB1911F

	Difenoconazole	
	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 - Difenoconazole

No data on dermal absorption for Difenoconazole in GLOB1911F 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 Difenoconazole

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	default	EFSA Journal 2017;15(6):4873
Dilution	50 %	default	EFSA Journal 2017;15(6):4873

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	GLOB1911F/Currando/ Subigon/ Collector
Formulation type	SC

Category	Fungicide
Container size(s), short description	250, 500 ml and 1, 2, 3, 5, 10, 15, 20 litre containers HDPE, HDPE/PA, HDPE/F, HDPE/EVOH For mor information see dRR Part B, Section 1, 2 and 4
Active substance(s) (incl. content)	Difenoconazole 500 g/L
AOEL systemic	0.16 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 10 % Dilution: 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 zone is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of GLOB1911F according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

The intended use oilseed rape belongs to crop type ‘Oilseeds’ and intended uses sugar beet and potato belong to crop type ‘Root and tuber vegetables’ Therefore risk assessment were performed for these two crop types at the highest application rate of 2 x 0.25L/ha (interval of 14 days) and 4 x 0.25L/ha (interval of 10 days).

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Potato (max. 4 x 0.25L product/ha, interval 10d) Sugar beet (max. 2 x 0.25L product/ha, interval 14d), is covered by Potato which belongs to the same crop type ‘Root and tuber vegetables’. Oilseed rape (max. 2 x 0.25L product/ha, interval 14d)
Model(s)	AOEM model (Version 30 March 2015)

Table 6.6-3: Estimated operator exposure

		Difenoconazole	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Crop type: Oilseeds			
Tractor mounted boom spray application outdoors to low crops			

Application rate		2 x 0.125 kg a.s./ha, interval 14d	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	No PPE*	0.0421209	26.33
Crop type: Root and tuber vegetables			
Tractor mounted boom spray application outdoors to low crops			
Application rate		4 x 0.125 kg a.s./ha, interval 10d	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	No PPE*	0.0421209	26.33

*no PPE: Operator wearing work wear (arms, body and legs covered) but no gloves

Conclusion

According to the model calculations, it can be concluded that the risk for the operator using GLOB1911F according to the proposed GAP is acceptable without the use of personal protective equipment (only work wear with arms, body and legs covered). Detailed calculations can be found in Appendix 3.

6.6.3 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.

zRMS:

The exposure to difenoconazole of operator wearing the adequate work clothing (with arms, body and legs covered) and applying the product Glob1911f / Currando/ Subigon/ Collector on oilseeds or sugar beet or potato at dose 0.125 kg a.s./ha (0.25L product/ha), using tractor-mounted/trailed boom sprayer with hydraulic nozzles, calculated with the EFSA AOEM amounted to 26.33 % of AOEL of difenoconazole. It is thus concluded that the application of product Glob1911f / Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of operator wearing the adequate work clothing (with arms, body and legs covered) for its intended use and dose within good agricultural practice.

Noting that the product is classified Eye Irrit. 2 to protect eye operators should wear protective goggles or face protection.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB1911F according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

The green highlighted information below was added by the applicant after commenting to satisfy a re-

quest from some Member States to implement a new scenario for worker exposure in sugar beets (the removal of bolting beets). The calculation is based on the EFSA AOEM model (so using the formulas from the EFSA AOEM) but substituting the standard input values from the EFSA AOEM by the ones given by the Member States for removal of bolting beets based on data presented in a published study (Baumann J, Anft T, Doughty KJ and Kuster CJ, 2019. Exposure to pesticide residues during manual removal of bolting sugar beets: determination of transfer coefficients for worker risk assessment. Journal of Consumer Protection and Food Safety 2019; 14, 283-286. According to the applicant, this worker exposure scenario (manual removal of bolting sugar beets) is not yet agreed in the EU as it isn't part of the EFSA AOEM model which is the only agreed model for calculation of exposure to operators/workers/residents/bystanders at the moment. It is therefore not relevant for use on the zonal level.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Potato (max. 4 x 0.25L product/ha, interval 10d) Sugar beet (max. 2 x 0.25L product/ha, interval 14d), is covered by Potato which belongs to the same crop type 'Root and tuber vegetables'. Oilseed rape (max. 2 x 0.25L product/ha, interval 14d) Removal of bolting beets (max. 4 x 0.125 kg a.s./ha, interval 10d)
Model(s)	AOEM model (Version 30 March 2015)

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
Crop type: Oilseeds			
Tractor mounted boom spray application outdoors to low crops Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days (default) DFR: 3 µg active substance/cm ² of foliage/kg a.s. applied/ha (default) Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.125 kg a.s./ha, interval 14d	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.1346590	84.16
	No PPE*: Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0150818	9.43
Crop type: Root and tuber vegetables			
Tractor mounted boom spray application outdoors to low crops Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days (default) DFR: 3 µg active substance/cm ² of foliage/kg a.s. applied/ha 0.375 µg/cm ² /kg a.s./ha (default) Interval between treatments: 10 days			
Number of applications and application rate		4 x 0.125 kg a.s./ha, interval 10d	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.2284110	142.76
	No PPE*: Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0255820	15.99
Tractor mounted boom spray application outdoors to low crops Removal of bolting beets Outdoor Work rate: 8 hours/day, Interval between treatments: 10 days DT ₅₀ : 30 days (default) DFR: 3 µg active substance/cm ² of foliage/kg a.s. applied/ha (default)			
Number of applications and application rate		4 x 0.125 kg a.s./ha, interval 10d	
Body weight: 60 kg	Potential TC: 18600 cm ² /person/h	0.7905	494.06
	Work wear (arms, body and legs covered) TC: 4400 cm ² /person/h	0.187	116.88
	Work wear (arms, body and legs covered) + gloves TC: 430 cm ² /person/h	0.018275	11.42
Crop type: Root and tuber vegetables			

EUROPOEM II model Inspection Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		4 x 0.125 kg a.s./ha, interval 10d	
	Potential TC: - cm ² /person/h	n.a.	n.a.
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.105	66
	Work wear (arms, body and legs covered) and gloves TC: - cm ² /person/h The use of gloves will result extra reduction factor of 5	0.021	13

*no PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves

During the commenting period, a comment was made by some Member States that removal of bolting beets is a relevant worker task that needs to be considered in the risk assessment of plant protection products intended to be applied in sugar beets. Depending on the climatic conditions and the variety of the seeds two types, genetic bolters and annual bolters, can occur in sugar beet fields. If they are not removed before the seeds get mature they can cause economic damage by impacting the yield and by contaminating the fields with weed beet in the next years. Bolting beet removal takes place either between June and July (annual bolters) or between August and September (genetic bolters) but not before BBCH 39. This is done mainly by hand in case of an occurrence of <500 bolting beets/ha. In case of a higher occurrence of >500 bolting beets/ha mechanical or chemical treatments are preferred. As the application of GLOB1911F is intended to be made between BBCH 31 and 49, the removal of bolting beets needs to be considered.

The removal of bolting beets is not covered by the current “Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products” (EFSA, 2014). So far, only a re-entry for inspection tasks for up to 2 hours is considered for the risk assessment of plant protection products for field crops, including sugar beet (EFSA, 2014). However, it is expected that the assumed working rate of 2 hours per day will be exceeded when removing bolting beets manually. In addition, the transfer coefficients, which are being used to estimate the exposure of the worker during inspection activities in field crops, are not appropriate for this task.

In addition to an increased work rate of 8h, the following TC values for the manual removal of bolting beets are suggested:

- Potential: 18600 cm²/h
- Work wear: 4400 cm²/h
- Work wear + gloves: 430 cm²/h

These figures are based on data presented in a published study (Baumann J, Anft T, Doughty KJ and Kuster CJ, 2019. Exposure to pesticide residues during manual removal of bolting sugar beets: determination of transfer coefficients for worker risk assessment. Journal of Consumer Protection and Food Safety 2019; 14, 283-286).

Worker exposure from the removal of bolting beets was calculated for the intended dose rate of 2x 0.25 L/ha and 14d application interval in sugar beets. After an application with this dose rate, work wear and gloves are necessary to get an acceptable safe risk for the worker when removing bolting beets.

Conclusion

Based on the calculation of worker exposure with the AOEM model, it is concluded that there is no unacceptable risk anticipated for workers wearing adequate work clothing (work wear – arms, body and legs covered but no PPE) when re-entering the field treated with GLOB1911F according to the proposed GAP.

For the worker entering treated sugar beet fields, a distinction needs to be made based on the task that needs to be performed:

- crop inspection: risk acceptable without PPE and no specific re-entry period
- removal of bolting beets (0.25 L/ha): risk acceptable with PPE (gloves)

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Refinement of the generic Dislodgeable Foliar Residues (DFR) was not necessary since the risk to workers was acceptable based on the standard values.

6.6.4.3 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.

zRMS:

The exposure to difenoconazole of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of oilseeds treated with the product Glob1911f / Currando/ Subigon/ Collector treated 2 times at a dose of 0.125 kg a.s./ha with interval 14d or a field of root and tuber vegetables treated 4 times at a dose of 0.125 kg a.s./ha with interval 10d, as foreseen in GAP, calculated with the EFSA AOEM amounted respectively to 9.43 % of AOEL or 15.99 % of AOEL, therefore the application of product Glob1911f / Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of worker wearing adequate work clothing for its intended use within good agricultural practice.

The exposure to difenoconazole of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of root and tuber vegetables treated 4 times at a dose of 0.125 kg a.s./ha with interval 10d, as foreseen in GAP, calculated with EUROPOEM II amounted respectively to 66 % of AOEL, but for worker wearing additionally protective gloves amounted to 13 % of AOEL. Thus, according to exposure estimated with EUROPOEM II the application of product Glob1911f / Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of worker wearing adequate work clothing and protective gloves for its intended use within good agricultural practice.

The exposure to difenoconazole of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 8 hours for removal of bolting beets a field of beets treated with the product Glob1911f / Currando/ Subigon/ Collector 4 times at a dose of 0.125 kg a.s./ha, interval 10d as foreseen in GAP, calculated with the EFSA AOEM using acceptable input data, amounted respectively to 116.88 % of AOEL thus is posing an unacceptable health risk. However, when worker is wearing additionally protective gloves the exposure is equal 13% of AOEL, thus is not causing an unacceptable risk.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident 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(s) used for estimation of bystander and resident exposure to Difenoconazole. Outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure) . Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Potato (max. 4 x 0.25L product/ha, interval 10d) Sugar beet (max. 2 x 0.25L product/ha, interval 14d), is covered by Potato which belongs to the same crop type 'Root and tuber vegetables'. Oilseed rape (max. 2 x 0.25L product/ha, interval 14d)
Model(s)	AOEM model (Version 30 March 2015)

Table 6.6-7: Estimated bystander and resident exposure

		Difenoconazole	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Crop type: Oilseeds			
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg active substance/cm ² of foliage/kg a.s. applied/ha 0.375 µg/cm ² /kg a.s./ha (default) Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.125 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0167863	10.49%
	Vapour (75 th perc.)	0.0010700	0.67%
	Deposits (75 th perc.)	0.0017435	1.09%
	Re-entry (75 th perc.)	0.0181790	11.36%
	Sum (mean)	0.0260874	16.30%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0040167	2.51%
	Vapour (75 th perc.)	0.0002300	0.14%
	Deposits (75 th perc.)	0.0007340	0.46%
	Re-entry (75 th perc.)	0.0100994	6.31%
	Sum (mean)	0.0107282	6.71%

Crop type: Root and tuber vegetables			
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg active substance/cm ² of foliage/kg a.s. applied/ha 0.375 µg/cm ² /kg a.s./ha (default) Interval between treatments: 10 days			
Number of applications and application rate		4 x 0.125 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0167863	10.49%
	Vapour (75 th perc.)	0.0010700	0.67%
	Deposits (75 th perc.)	0.0029573	1.85%
	Re-entry (75 th perc.)	0.0308355	19.27%
	Sum (mean)	0.0370676	23.17%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0040167	2.51%
	Vapour (75 th perc.)	0.0002300	0.14%
	Deposits (75 th perc.)	0.0012450	0.78%
	Re-entry (75 th perc.)	0.0171308	10.71%
	Sum (mean)	0.0167087	10.44%

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

zRMS:

The exposure of residents (adult and child) to difenoconazole, an active substance of a product Glob1911f /Currando/ Subigon/ Collector, applied on oilseeds 2 times at a dose of 0.125 kg a.s./ha with interval 14d or on a field of root and tuber vegetables treated 4 times at a dose of 0.125 kg a.s./ha with interval 10d, as foreseen in GAP, using tractor-mounted/trailed boom sprayer with hydraulic nozzles, calculated with the EFSA AOEM demonstrates that such an exposure for child and adult resident is equal respectively to 16.30% - 23.17% (child) and 6.71% - 10.44% (adult) of AOEL for difenoconazole, thus the application of product Glob1911f /Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of child and adult residents. Thus it is concluded that the application of product Glob1911f /Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of adult and child resident due to its intended use within good agricultural practice.

No bystander acute exposure estimation is required since no acute acceptable operator exposure value (AAOEL) has been set for difenoconazole, the active substance of a product Glob1911f /Currando/ Subigon/ Collector. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to difenoconazole as a result of application of Glob1911f /Currando/ Subigon/ Collector with accordance with intended use within good agricultural practice.

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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

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

The following tables are to be completed by MS

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

No bridging was necessary.

A 2.2 Acute oral toxicity (KCP 7.1.1)

No new study was submitted.

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

No new study was submitted.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No new study was submitted.

A 2.5 Skin irritation (KCP 7.1.4)

No new study was submitted.

A 2.6 Eye irritation (KCP 7.1.5)

No new study was submitted.

A 2.7 Skin sensitisation (KCP 7.1.6)

No new study was submitted.

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 new study was submitted.

A 2.11 Other/Special Studies

Not required.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

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

Crop type: Oilseeds – Oilseed rape (2 x 0.125 kg a.s./ha, interval 14 days)

Operator exposure for GLOB1911F outdoor spray applications					
Application rate of active substance	0.125 kg a.s./ha			<i>i_AppRate</i>	
Assumed area treated	50 ha/day			<i>d_AreaTreated</i>	
Amount of active substance applied	6.25 kg a.s./day			<i>i_AmountAS</i>	
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>	
Dermal absorption of in-use dilution	50.00%			<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 th centile	95 th centile		
	Hands	19909	74139	AOEM	
	Body	12935	122660	AOEM	
	Head	324	1778	AOEM	
	Protected hands (gloves)	113	1238	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	121	914	AOEM	
	Protected head (hood and face shield)	5	101	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	927	8771	AOEM	
	Body	518	2672	AOEM	
	Head	24	74	AOEM	
	Protected hands (gloves)	115	4127	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	35	AOEM	
	Inhalation	3	8	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Crop type: Root and tuber vegetables – Potato (4 x 0.125 kg a.s./ha, interval 10 days)

Operator exposure for GLOB1911F outdoor spray applications

Application rate of active substance		0.125 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied		6.25 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product		10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution		50.00%	<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 th centile	95 th centile		
	Hands	19909	74139	AOEM	
	Body	12935	122660	AOEM	
	Head	324	1778	AOEM	
	Protected hands (gloves)	113	1238	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	121	914	AOEM	
	Protected head (hood and face shield)	5	101	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	927	8771	AOEM	
	Body	518	2672	AOEM	
	Head	24	74	AOEM	
	Protected hands (gloves)	115	4127	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	35	AOEM	
	Inhalation	3	8	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Crop type: Root and tuber vegetables – Sugar beet (3 x 0.125 kg a.s./ha, interval 14 days)

The toxicological risk assessment for the use in sugar/fodder beet is performed with a worst-case envelope of maximum 3 applications and covers the intended use of maximum 2 applications.

Operator exposure for GLOB1911F outdoor spray applications

Application rate of active substance	0.125 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	6.25 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Outdoor soluble concentrates, emulsifiable concentrate, etc. Downward spraying, vehicle-mounted

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	19909	74139	AOEM	
	Body	12935	122660	AOEM	
	Head	324	1778	AOEM	
	Protected hands (gloves)	113	1238	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	121	914	AOEM	
	Protected head (hood and face shield)	5	101	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	927	8771	AOEM	
	Body	518	2672	AOEM	
	Head	24	74	AOEM	
	Protected hands (gloves)	115	4127	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	14	35	AOEM	
	Inhalation	3	8	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 2: Estimation of longer term operator exposure towards Difenconazole according to EFSA guidance

Crop type: Oilseeds – Oilseed rape (2 x 0.125 kg a.s./ha, interval 14 days)

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.0607789	2.5272518	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0676796	0.0421209	
% of RVNAS	42.30%	26.33%	

Crop type: Root and tuber vegetables – Potato (4 x 0.125 kg a.s./ha, interval 10 days)

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.0607789	2.5272518	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0676796	0.0421209	
% of RVNAS	42.30%	26.33%	

Crop type: Root and tuber vegetables – Sugar beet (3 x 0.125 kg a.s./ha, interval 14 days)

The toxicological risk assessment for the use in sugar/fodder beet is performed with a worst-case envelope of maximum 3 applications and covers the intended use of maximum 2 applications.

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.0607789	2.5272518	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0676796	0.0421209	
% of RVNAS	42.30%	26.33%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

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

Crop type: Oilseeds – Oilseed rape (2 x 0.125 kg a.s./ha, interval 14 days)

Worker exposure from residues on foliage for GLOB1911F		
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	0.125 kg a.s./ha	i_AppRate
Number of applications	2	i_AppNo
Interval between multiple applications	14 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	1.7	d_MAF
Dermal absorption of the product	10.00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%	i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.375 µg a.s./cm ²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³	d_InhalTcSort

Crop type: Root and tuber vegetables – Potato (4 x 0.125 kg a.s./ha, interval 10 days)

Worker exposure from residues on foliage for GLOB1911F		
Crop type	Root and tuber vegetables	
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	0.125 kg a.s./ha	i_AppRate
Number of applications	4	i_AppNo
Interval between multiple applications	10 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	2.9	d_MAF
Dermal absorption of the product	10.00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%	i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.375 µg a.s./cm ²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³	d_InhalTcSort

Crop type: Root and tuber vegetables – Sugar beet (3 x 0.125 kg a.s./ha, interval 14 days)

The toxicological risk assessment for the use in sugar/fodder beet is performed with a worst-case envelope of maximum 3 applications and covers the intended use of maximum 2 applications.

Worker exposure from residues on foliage for GLOB1911F		
Crop type	Root and tuber vegetables	
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	0.125 kg a.s./ha	i_AppRate
Number of applications	3	i_AppNo
Interval between multiple applications	14 days	i_AppInt
Half-life of active substance	30 days	d_HalfLifeAS
Multiple application factor	2.2	d_MAF
Dermal absorption of the product	10.00%	i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%	i_AbsorpInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.375 µg a.s./cm ²	d_DFR
Working hours	2 hr	d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm ² /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁴ (-3)	d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁴ (-3)	d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁴ (-3)	d_InhalTcSort

Table A 4: Estimation of longer term worker exposure towards Difenconazole according to EFSA guidance

Crop type: Oilseeds – Oilseed rape (2 x 0.125 kg a.s./ha, interval 14 days)

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	8.0795373	0.9049082	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1346590	0.0150818		
% of RVNAS	84.16%	9.43%		

Crop type: Root and tuber vegetables – Potato (4 x 0.125 kg a.s./ha, interval 10 days)

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	13.7046612	1.5349221	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.2284110	0.0255820		
% of RVNAS	142.76%	15.99%		

Crop type: Root and tuber vegetables – Sugar beet (3 x 0.125 kg a.s./ha, interval 14 days)

The toxicological risk assessment for the use in sugar/fodder beet is performed with a worst-case envelope of maximum 3 applications and covers the intended use of maximum 2 applications.

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	10.5341329	1.1798229	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1755689	0.0196637		
% of RVNAS	109.73%	12.29%		

Table A5 Estimation of worker exposure towards active substance according to EU-ROPEM II

WORKER EXPOSURE			EUROPOEM II MODEL	
form	Currando S.C.		Re-entry in the field	
a.s.	Difenoconazole			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0,125	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				w ithout PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,14	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
	Dermal Exposure	1,05	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	10	%	
	PPE-factor dermal	5		gloves*
	AOEL	0,16	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,105	0,021	DE(int) = DE x (DA/100)
	Total	0,105	0,021	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	66	13	%AOEL = 100 x DE(int) / AOEL
	Total	66	13	sum

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

Table A6. Estimation of exposure to active substance of worker removing for 8 hour bolt-ing beets

Worker exposure - potential	
DFR ($\mu\text{g ai/cm}^2$ foliage)	3
TC ($\text{cm}^2/\text{person/h}$) (potential exposure)	18600
T (h)	8
Dosis (kg as/ha)	0,125
MAF	1,7
Dermal absorption (%)	50
PDE (mg a.s./d)	94,860
Systemic exposure (mg a.s./d)	47,43
Worker exposure (mg a.s./kg bw x d)	0,7905
AOEL	0,16
% AOEL	494,06
Worker exposure - workwear	
DFR ($\mu\text{g ai/cm}^2$ foliage)	3
TC ($\text{cm}^2/\text{person/h}$) (Work wear (arms, body and legs covered))	4400
T (h)	8
Dosis (kg as/ha)	0,125
MAF	1,7
Dermal absorption (%)	50
PDE (mg a.s./d)	22,440
Systemic exposure (mg a.s./d)	11,22
Worker exposure (mg a.s./kg bw x d)	0,187
AOEL	0,16
% AOEL	116,88
Worker exposure - workwear and gloves	
DFR ($\mu\text{g ai/cm}^2$ foliage)	3
TC ($\text{cm}^2/\text{person/h}$) (Work wear (arms, body and legs covered) and gloves)	430
T (h)	8
Dosis (kg as/ha)	0,125
MAF	1,7
Dermal absorption (%)	50
PDE (mg a.s./d)	2,193
Systemic exposure (mg a.s./d)	1,0965
Worker exposure (mg a.s./kg bw x d)	0,018275
AOEL	0,16
% AOEL	11,42

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

Table A 5: Input parameters considered for the estimation of longer term resident exposure

Crop type: Oilseeds – Oilseed rape (2 x 0.125 kg a.s./ha, interval 14 days)

Resident exposure for GLOB1911F			
Croptype	Oilseeds		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		<i>i_FormVal</i>
Buffer strip	2-3 m		<i>i_Buffer</i>
Application rate of the product	0.125 kg a.s./ha		<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	1.25 g a.s./l		<i>d_ConcAS</i>
Dermal absorption of product	10.00%		<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%		<i>i_Absorpinuse</i>
Oral absorption	100.00%		<i>i_AbsorpOrallinuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.375 µg a.s./cm ²		<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	Pa	<i>i_Volat</i>
Concentration in air	0.001 mg/m ³		<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person		
Exposure duration dermal	2 hours		<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours		<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours		<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%		<i>d_ClothAF</i>
Breathing rate adult	0.23 m ³ /day/kg		<i>d_BreathRAD</i>
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg		<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5.60%		
Drift percentage on surface (mean)	4.10%		
Turf transferable residues percentage	5.00%		<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm ² /hour		<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour		<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%		<i>d_SolExt</i>
Surface area of hands mouthed	20 cm ²		<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour		<i>d_ReFreqHM</i>
Ingestion rate for mouthings of grass per day	25 cm ²		<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%		<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h		<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h		<i>d_TcEntryCh</i>

Crop type: Root and tuber vegetables – Potato (4 x 0.125 kg a.s./ha, interval 10 days)

Resident exposure for GLOB1911F			
Croptype	Root and tuber vegetables		
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	0.125 kg a.s./ha		
Concentration of active substance (in-use dilution for liquid applications)	1.25 g a.s./l		
Dermal absorption of product	10.00%		
Dermal absorption of in-use dilution	50.00%		
Oral absorption	100.00%		
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.375 µg a.s./cm ²		
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa		
Concentration in air	0.001 mg/m ³		
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person		
Exposure duration dermal	2 hours		
Exposure duration inhalation	24 hours		
Exposure duration entry into treated crops	0.25 hours		
Light clothing adjustment factor	18.0%		
Breathing rate adult	0.23 m ³ /day/kg		
Breathing rate child (1-3 year old)	1.07 m ³ /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 cm ² /hour		
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour		
Saliva extraction percentage	50.00%		
Surface area of hands mouthed	20 cm ²		
Frequency of hand to mouth activity	9.5 events/hour		
Ingestion rate for mouthing of grass per day	25 cm ²		
Dislodgeable residues percentage transferability for object to mouth	20.00%		
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h		
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h		
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h		
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h		

Crop type: Root and tuber vegetables – Sugar beet (3 x 0.125 kg a.s./ha, interval 14 days)

The toxicological risk assessment for the use in sugar/fodder beet is performed with a worst-case envelope of maximum 3 applications and covers the intended use of maximum 2 applications.

Resident exposure for GLOB1911F		
Croptype	Root and tuber vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	i_FormVal
Buffer strip	2-3 m	i_Buffer
Application rate of the product	0.125 kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	1.25 g a.s./l	d_ConcAS
Dermal absorption of product	10.00%	i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%	i_AbsorpInuse
Oral absorption	100.00%	i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.375 µg a.s./cm ²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	i_Volat
Concentration in air	0.001 mg/m ³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person	
Exposure duration dermal	2 hours	d_ReExpDur
Exposure duration inhalation	24 hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%	d_ClothAF
Breathing rate adult	0.23 m ³ /day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1.07 m ³ /day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour	d_ReTCCh
Saliva extraction percentage	50.00%	d_SalExt
Surface area of hands mouthed	20 cm ²	d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour	d_ReFreqHM
Ingestion rate for mouthings of grass per day	25 cm ²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%	d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h	d_TcEntryCh

Table A 6: Estimation of longer-term resident exposure towards Difenoconazole according to EFSA guidance

Crop type: Oilseeds – Oilseed rape (2 x 0.125 kg a.s./ha, interval 14 days)

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1678625	0.0107000	0.0174346	0.1817896	0.2608740
Total systemic exposure per kg body weight	0.0167863	0.0010700	0.0017435	0.0181790	0.0260874
% of RVNAS	10.49%	0.67%	1.09%	11.36%	16.30%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2410000	0.0138000	0.0440389	0.6059653	0.6436913
Total systemic exposure per kg body weight	0.0040167	0.0002300	0.0007340	0.0100994	0.0107282
% of RVNAS	2.51%	0.14%	0.46%	6.31%	6.71%

Crop type: Root and tuber vegetables – Potato (4 x 0.125 kg a.s./ha, interval 10 days)

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1678625	0.0107000	0.0295728	0.3083549	0.3706757
Total systemic exposure per kg body weight	0.0167863	0.0010700	0.0029573	0.0308355	0.0370676
% of RVNAS	10.49%	0.67%	1.85%	19.27%	23.17%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2410000	0.0138000	0.0746995	1.0278496	1.0025217
Total systemic exposure per kg body weight	0.0040167	0.0002300	0.0012450	0.0171308	0.0167087
% of RVNAS	2.51%	0.14%	0.78%	10.71%	10.44%

Crop type: Root and tuber vegetables – Sugar beet (3 x 0.125 kg a.s./ha, interval 14 days)

The toxicological risk assessment for the use in sugar/fodder beet is performed with a worst-case envelope of maximum 3 applications and covers the intended use of maximum 2 applications.

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1678625	0.0107000	0.0227313	0.2370180	0.3087874
Total systemic exposure per kg body weight	0.0167863	0.0010700	0.0022731	0.0237018	0.0308787
% of RVNAS	10.49%	0.67%	1.42%	14.81%	19.30%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2410000	0.0138000	0.0574180	0.7900600	0.8002716
Total systemic exposure per kg body weight	0.0040167	0.0002300	0.0009570	0.0131677	0.0133379
% of RVNAS	2.51%	0.14%	0.60%	8.23%	8.34%

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)

No exposure and/or DFR studies were required, since the risk was acceptable based on standard model calculations.