

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: GLOB2021dF

Product name: PIRLANKO

Chemical active substances:

Prothioconazole, 156 g/L

Boscalid, 156 g/L

Central Zone

Zonal Rapporteur Member State:

Poland

CORE ASSESSMENT

(authorization)

Applicant: GLOBACHEM NV

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When	What
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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on GLOB2021dF *

Product name and code	GLOB2021dF
Formulation type	Suspension concentrate [SC]
Active substances (incl. content)	Boscalid: 156 g/L Prothioconazole: 156 g/L
Function	Fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substances	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of GLOB2021dF 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 GLOB2021dF according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Eye Damage 1
Hazard pictograms or Code for hazard pictogram	GHS05
Signal word	Danger
Hazard statement	H318 – Causes serious eye damage
Precautionary statements	P280 – Wear protective gloves, 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 P310 – Immediately call a POISON CENTER or doctor
Additional labelling phrases	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH208] To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains: Alcohols, C11-14-iso-, C13-rich, ethoxylated

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GLOB2021dF

	Result	PPE / Risk mitigation measures
Operators	Acceptable	M/L: Workwear + gloves (resulting from exposure assessment), + eye protection or face protection (due to the fact that the product is classified as Eye Dam. 1 H318). Application: Workwear (resulting from exposure assessment), + eye protection or face protection (due to the fact that the product is

	Result	PPE / Risk mitigation measures
		classified as Eye Dam. 1 H318).
Workers	Acceptable	Workwear (resulting from exposure assessment)
Residents	Acceptable	None
Bystanders	Acceptable	None

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (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) Boscalid b) Prothioconazole	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Winter oilseed rape (BBCH 14-59)	F	Spraying, LCTM	a) 2 (21) b) 2	a) 0.125 b) 0.125	2100 - 300	N/A	1 application in autumn and 1 application in spring.				
1	Winter & spring oilseed rape (BBCH 21-59)	F	Spraying, LCTM	a) 2 (21) b) 2	a) 0.125 b) 0.125	2100 - 300	N/A	2 applications in spring				
2	Winter & spring oilseed rape (BBCH 60-69)	F	Spraying LCTM	a) 2 (21) b) 2	a) 0.125 b) 0.125	2100 - 300	N/A	/				
3-16	Cereals, winter & spring	F	Spraying LCTM	a) 2 (21) b) 2	a) 0.125 b) 0.125	2100 - 300	N/A	/				

* 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:

- data gap 1
- data gap 2

- data gap 3

6.2 Toxicological Information on Active Substances

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1 – 6.2-3.

Table 6.2-1: Information on Boscalid

	Boscalid
Common Name	Boscalid
CAS-No.	188425-85-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	No classification of toxicological relevance.
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.1 mg/kg bw/d (corrected for 44% oral absorption)
Reference	EFSA, 2008 SANCO/3919/2007 – Rev 5, 21.01.2008
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Conclusion for Boscalid	None

Table 6.2-2: Information on Prothioconazole

	Prothioconazole
Common Name	Prothioconazole
CAS-No.	178928-70-6
Index number	613-337-00-9
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	No classification of toxicological relevance.
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	Prothioconazole: 0.2 mg/kg bw/d Prothioconazole-desthio : 0.01 mg/kg bw/d
Reference	EFSA, 2007 EFSA Scientific Report (2007) 106, 1-9
Conditions to take into account/critical areas of concern with regard to toxicology	
According to EFSA Conclusion for Prothioconazole	None. The metabolite prothioconazole-desthio is more toxic than Prothioconazole in the rat and rabbit developmental studies (the classification Repro cat 2, H361d was proposed)

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB2021dF is given in the following tables. Full summary of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

The plant protection product GLOB2021dF is a mixture containing two active substances. The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity. Therefore, combined toxicity with dose additivity is assumed as worst case. Reference is made to point 6.6.5 for the calculation of the combined exposure whereby as a worst case approach, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. The individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL. The Hazard Index (HI) is the sum of the individual HQs

Comments of zRMS:	GLOB2021dF was not a representative formulation reviewed during the Annex I inclusion/active substances renewal and was not previously evaluated in any EU countries. For the product registration no experimental acute toxicity data were submitted. The applicant declared that an assessment of acute toxicity including irritancy and skin sensitisation properties of GLOB2021dF have been conducted by based on the alternative method (additivity approach/calculation) according to the Regulation (EC) 1272/2008. However, the applicant did not take into account all relevant ingredients. The product GLOB2021dF contains 1,2-Benzisothiazol-3(2H)-one in concentration triggering EUH208 labelling ($C \geq 0,05\%$). zRMS proposal of classification and labelling for GLOB2021dF according to the Regulation (EC) 1272/2008 is presented below. In order to avoid tests on animals, the use of alternative method (additivity approach/calculation) for the purposes of hazard classification is preferred. The product GLOB2021dF does not contain any relevant ingredient that is classified in the following classes: acute toxicity (oral, dermal, inhalation), skin irritation, STOT SE, STOT RE, carcinogenicity, mutagenicity, reprotoxicity. The product contains Alcohols, C11-14-iso-, C13-rich, ethoxylated that is classified as Eye Dam. 1 H318 in concentration triggering classification Eye Dam. 1, H318 for the product ($C \geq 3\%$). The product GLOB2021dF contains 1,2-Benzisothiazol-3(2H)-one in concentration that does not trigger classification as Skin Sens. (SCL $\geq 0,5\%$), but triggers EUH208 labelling of the product ($C \geq 0,05\%$) according to section 2.8 of Annex II to CLP Regulation. Required supplemental hazard information assigned to plant protection products subject to 1107/2009/EC is EUH401 - To avoid risks to human health and the environment, comply with the instructions for use. According to article 18(3) b) of Regulation (EC) 1272/2008 the identity of all substances in the mixture that contribute to the classification of the mixture should be included on the label. Classification for health hazard Eye Dam. 1 H318 Labelling for health hazard Pictograms: GHS05 Signal word: Danger Hazard statements: H318 – Causes serious eye damage Precautionary statements: P280 – Wear 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 P310 – Immediately call a POISON CENTER or doctor EU specific hazard statements: EUH208 - Contains 1,2-Benzisothiazol-3(2H)-one. May produce an allergic reaction. EUH401 - To avoid risks to human health and the environment, comply with the instructions for use. Contains: Alcohols, C11-14-iso-, C13-rich, ethoxylated
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	The applicant provided exposure assessment for operator, worker, bystander and resident using EFSA online calculator v 1.0.1. (OPEX). Operator exposure in the most worst-case scenario (with assumed 50% conversion from prothioconazole to prothioconazole-desthio and 10% default dermal absorption during M/L) was provided by the applicant. A more realistic scenario considering that prothioconazole-desthio is not present during M/L and considering a 50% conversion during application is also provided by the applicant. For the metabolite Prothioconazole-desthio the dermal absorption rates were used in calculations (except worst case scenario) based on an in vitro dermal absorption study with Prothioconazole-desthio formulated as GLOB2021dF performed according to EFSA Guidance on Dermal Absorption (2017). However, in accordance with the EFSA Guidance on Dermal Absorption (2017), standard deviation and the multiplication factor should be added to the mean absorption. Thus zRMS has revised output of the dermal absorption study. Since it resulted in higher value dermal absorption, the evaluator has revised exposure assessment using EFSA online calculator v 1.0.1. (OPEX).
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Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB2021dF

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 / No / Supplementary	None	Theoretical calculations (see part C)
LD ₅₀ dermal, rat	Study not necessary	Yes / No / Supplementary	None	Theoretical calculations (see part C)
LC ₅₀ inhalation, rat	Study not necessary	Yes / No / Supplementary	None	Theoretical calculations (see part C)
Skin irritation	Study not necessary	Yes / No / Supplementary	None	Theoretical calculations (see part C)
Eye irritation	Study not necessary	Yes / No / Supplementary	Eye Dam. 1, H318	Theoretical calculations (see part C)
Skin sensitisation	Study not necessary	Yes / No / Supplementary	None	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 GLOB2021dF

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification and labelling of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Boscalid	/	/	/
	Prothioconazole	/	/	/
Toxicological properties of non-active substance(s) (relevant for classification of product)	Genapol X060 Alcohols, C11-14- iso-, C13-rich, ethoxylated	Eye irritant Dam. 1 H318 (C≥3 %)	MSDS	Eye Dam. 1 H318 cat. 1
	Proxel GXL 1,2-Benzisothiazol- 3(2H)-one	Skin sensitizing. Eye irritant Skin Sens. 1 H317 C≥0,05 % C≥0.036 %***	MSDS and Reg. 1272/2008	H318 cat. 1 EUH208
Further toxicological information	No data – not required			

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

** Material safety data sheet by the applicant

*** Regulation (EU) 2024/197, mandatory SCL from 1 September 2025.

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 boscalid and prothioconazole, and the metabolite prothioconazole-desthio in GLOB2021dF are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances and relevant metabolite in GLOB2021dF

Boscalid		
	Value	Reference
Concentrate	10 %	Default value
Dilution	50 %	Default value
Prothioconazole		
	Value	Reference
Concentrate	10 %	Default value
Dilution	50 %	Default value

Prothioconazole-desthio (M04)		
	Value	Reference
Concentrate	Not relevant / 10%*	
Dilution 50% conversion	10.3315%	KCP 7.3-01, Di Donato, M., 2023
Dilution 100% conversion	5.917.7%	
Dilution 0% conversion	50 %	Default value

* Prothioconazole-desthio is only present in trace amounts in the formulation and is not formed in the spray solution. Therefore exposure during mixing and loading is not regarded as relevant. However, as a worst-case approach, calculations assuming a conversion of 50% and 100% during mixing and loading are included as well.

6.5.1 Justification for proposed values

Proposed dermal absorption rates for prothioconazole are the default values in line with the current EFSA guidance document on dermal absorption (EFSA Journal 2017; 15(6):4873).

Table 6.5-2: Default dermal absorption rates

	Value		Justification for value	Acceptability of justification
	Boscalid	Prothioconazole		
Concentrate	10%	10%	EFSA Journal 2017; 15(6):4873 A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed.	Acceptable
Dilution	50%	50%	EFSA Journal 2017; 15(6):4873 A default dermal absorption value of 50% may be applied for (in use) dilutions that are water-based/dispersed.	Acceptable

For the metabolite Prothioconazole-desthio the dermal absorption rates are based on an *in vitro* dermal absorption study with Prothioconazole-desthio formulated as GLOB2021dF. Two different dilutions were tested for Prothioconazole-desthio, i.e. 0.189 g Prothioconazole-desthio/L and 0.377 g Prothioconazole-desthio/L corresponding to a 50% and 100% photolytic degradation of the active substance Prothioconazole in the highest in use field dilution, i.e. 0.8 L concentrate/ha in 300 L water, according to a dilution rate of 1:500. This way the realistic situation where prothioconazole is degraded to the metabolite is simulated, with both the situation where all a.i. is converted and thus 100% Prothioconazole-desthio is present and no parent is left, as well as the situation where only half the conversion has taken place and 50% of Prothioconazole-desthio together with 50% of the parent is present. For the subsequent risk assessments the dermal absorption value with the corresponding conversion rate is used.

The study results are summarized in the following table. Full summaries of studies on the dermal absorption of Prothioconazole-desthio have not previously been evaluated within an EU peer review process and are described in detail in Appendix 2.

Table 6.5-4: Summary of the results of submitted dermal absorption studies for Prothioconazole-desthio

Test	Concentrate	Spray dilution 1 50% conversion*	Spray dilution 2 100% conversion**	Spray dilution 3 0% conversion***	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference
<i>In vitro</i> dermal absorption on human skin with [¹⁴ C]-prothioconazole-desthio formulated as GLOB2021dF	Not relevant	- 0.141g [¹⁴ C]-prothioconazole-desthio/L dilution ratio 1:500 - 0.156g prothioconazole/L - 0.312g boscalid/L	- 0.282 g [¹⁴ C]-prothioconazole-desthio/L dilution ratio 1:500 - 0.312g boscalid/L	Not tested Default dermal absorption: 50% (Cfr. EFSA GD on dermal absorption, 2017)	GLOB2021dF spiked with radioactive labelled [¹⁴ C]prothioconazole-desthio	acceptable	The study is performed on the same product as the registration is sought to.	acceptable	KCP 7.3-01, Di Donato, M., 2023 - IES Study number: 20230017 Not reviewed at EU level

* 50% conversion: this dilution corresponds to 50% photolysis degradation of prothioconazole into prothioconazole-desthio

** 100% conversion: this dilution corresponds to 100% photolysis degradation of prothioconazole into prothioconazole-desthio

*** 0% conversion: this dilution corresponds to 0% photolysis degradation of prothioconazole into prothioconazole-desthio

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	GLOB2021dF		
Formulation type	SC		
Category	Fungicide		
Container size(s), short description	0.100, 0.150, 0.250, 0.500, 1, 2, 3, 5, 10, 15, 20 L HDPE, HDPE/PA, HDPE/F, HDPE/EVOH		
Active substance(s) (incl. content)	Boscalid 156 g/L	Prothioconazole 156 g/L	Prothioconazole-desthio
AOEL systemic	0.1 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
Inhalation absorption	100%	100 %	100 %
Oral absorption	44%	100 %	100 %
Dermal absorption	Concentrate: 10% Dilution: 50%	Concentrate: 10% Dilution: 50 %	Concentrate: not relevant / 10% Dilution 50% conversion: 10.33% Dilution 100% conversion: 5.91%

For the metabolite Prothioconazole-desthio, two separate types of simulations are carried out: the first simulation assumes a 100% conversion of the parent into the metabolite (1), while the second simulation assumes a 50% conversion of the parent into Prothioconazole-desthio (2). The application rate of the metabolite is calculated correspondingly as follows:

Application rate M04 = application rate of Prothioconazole x Mw M04/Mw Parent x conversion rate (%)

Thus, the application rate of M04 is

- (1) Oilseed rape: $125 \text{ g a.s./ha} \times 312.2 \text{ g/mol} / 344.3 \text{ g/mol} \times 1 = 113.35 \text{ g met./ha}$
Cereals: $125 \text{ g a.s./ha} \times 312.2 \text{ g/mol} / 344.3 \text{ g/mol} \times 1 = 113.35 \text{ g met./ha}$
- (2) Oilseed rape: $125 \text{ g a.s./ha} \times 312.2 \text{ g/mol} / 344.3 \text{ g/mol} \times 0.5 = 56.67 \text{ g met./ha}$
Cereals: $125 \text{ g a.s./ha} \times 312.2 \text{ g/mol} / 344.3 \text{ g/mol} \times 0.5 = 56.67 \text{ g met./ha}$

For both simulations the dermal absorption value corresponding to the conversion rate assumed is used: 5.91% for the first simulation assuming a 100% conversion and 10.33% for the second simulation assuming a 50% conversion.

Outcome of the estimations are presented in Table 6.6-3 to 5. Detailed calculations are in Appendix 3.

6.6.1 Selection of critical use(s) and justification

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

Justification

All uses applied for are in oilseed rape and cereals with for both crops a maximum number of two applications. Therefore all those crops are simulated with two applications and the shortest application interval possible, the lowest water volume and the highest dose rate as a worst case approach.

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 GLOB2021dF according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Combined exposure to Boscalid, Prothioconazole and Prothioconazole-desthio is calculated in Annex point 6.6.5. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target toxicity.

Table 6.6-2: Exposure models for intended uses

Critical uses	Oilseed rape and cereals (max. 0.8 L/product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 calculator version: 1.0.0

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

Model data	Level of PPE	Boscalid		Prothioconazole		Prothioconazole-desthio	
		Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops							
1) 0% conversion from prothioconazole to prothioconazole-desthio							
Application rate		0.125 kg a.s./ha		0.125 kg a.s./ha		0 kg a.s./ha	
Spray application outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Potential	0.08	80.2	0.08	40.1	/	/
	Work wear (arms, body and legs covered)	0.05	52.8	0.05	26.4	/	/
2) 100% conversion from prothioconazole to prothioconazole-desthio							
Application rate		0.125 kg a.s./ha		0 kg a.s./ha		0.113 kg a.s./ha	
Spray application outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Potential	0.08	80.2	/	/	0.002	21
	Work wear (arms, body and legs covered)	0.05	52.8	/	/	0.001	14.3
3) 50% conversion from prothioconazole to prothioconazole-desthio (assuming 10% dermal absorption during M/L)							
Application rate		0.125 kg a.s./ha		0.0625 kg a.s./ha		0.0567 kg a.s./ha	
Spray application outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Potential	0.08	80.2	0.05	24.3	0.04	410
	Work wear (arms, body and legs covered)	0.05	52.8	0.03	16.3	0.03	277
	Work wear (arms, body and legs covered) + gloves M/L	0.01	9.3	0.005	2.4	0.001	14.8
4) 50% conversion from prothioconazole to prothioconazole-desthio (without assuming dermal absorption during M/L)							
Application rate		0.125 kg a.s./ha		0.0625 kg a.s./ha		0.0567 kg a.s./ha	
Spray application	Potential	0.08	80.2	0.05	24.3	0.001	12.5

outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered)	0.05	52.8	0.03	16.3	0.001	8.6
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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 workwear and gloves as personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.2	The applicant presented calculations for the application of GLOB2021dF on field crops: covering all uses from critical GAP table.			
	The applicant provided exposure assessment for operator in the most worst-case scenario with assumed 50% conversion from prothioconazole to prothioconazole-desthio and 10% default dermal absorption during M/L. A more realistic scenario considering that prothioconazole-desthio is not present during M/L and considering a 50% conversion during application is also provided by the applicant using dermal absorption from experimental data. The exposure calculations were conducted by the applicant using the EFSA online calculator 2022 v 1.0.0. (OPEX). The evaluator has revised the exposure calculations using higher value for dermal absorption (15% instead of 10.33%) for the metabolite Prothioconazole-desthio obtained from in vitro dermal absorption study according to EFSA Guidance on Dermal Absorption (2017).			
	The calculations for more realistic scenario (prothioconazole-desthio is not present during M/L and 50% conversion to prothioconazole-desthio during application):			
	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			
	Boscalid	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
		M/L: Workwear	0.056	52.856
		App: Workwear		
Prothioconazole	Number of applications and application rate: 2 x 0.0624 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %			
	M/L: Workwear	0.05	26.4	
	App: Workwear	0.03	16.317.1	
Prothioconazole-desthio	Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 15 %			
	M/L: Workwear	0.001	12	
	App: Workwear			
Combined exposure		Hazard index		
	M/L: Workwear	0.9		
	App: Workwear	0.89		

Agreed endpoint 6.6.2	Operator exposure after the most worst-case scenario (with a 50% conversion from prothioconazole to prothioconazole-desthio, assuming a 10% dermal absorption during M/L) was acceptable when workwear + gloves during M/L were worn. Risk of operator exposure during application of Pirlanko (GLOB2021dF) is acceptable under conditions of intended use when the workwear is worn. Due to the fact that the product GLOB2021dF is classified as Eye Dam. 1 H318, the operator should wear eye protection or face protection during mixing/loading and application operations.
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6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB2021dF according to the critical uses. Outcome of the estimation is presented in Table 6.6-6 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical uses	Oilseed rape and cereals (max. 0.8 L/product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 calculator version: 1.0.0

Table 6.6-6: Estimated worker exposure (Longer term exposure)

Model data	Level of PPE	Boscalid		Prothioconazole		Prothioconazole-desthio	
		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 15d (covering 21d)							
1) 0% conversion from prothioconazole to prothioconazole-desthio							
Application rate		2 x 0.125 kg a.s./ha		2 x 0.125 kg a.s./ha		2 x 0 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.1	133	0.1	66.7	/	/
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.01	14.9	0.01	7.5	/	/
2) 100% conversion from prothioconazole to prothioconazole-desthio							
Application rate		2 x 0.125 kg a.s./ha		2 x 0 kg a.s./ha		2 x 0.113 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.1	133	/	/	0.01	107
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.01	14.9	/	/	0.001	12
3) 50% conversion from prothioconazole to prothioconazole-desthio							
Application rate		2 x 0.125 kg a.s./ha		2 x 0.0625 kg a.s./ha		2 x 0.0567 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.1	133	0.07	33.3	0.01	125
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.01	14.9	0.007	3.7	0.001	14

6.6.3.2 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.

6.6.3.3 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 consideration of workwear and gloves as personal protective equipment (PPE), a study to provide measurements of worker exposure was not necessary and was therefore not performed.

Comments of zRMS study comment 6.6.3	The applicant presented calculations for the application GLOB2021dF covering all uses from critical GAP table.			
	The applicant provided exposure assessment for worker in the most worst-case scenario (with assumed 100% conversion from prothioconazole to prothioconazole-desthio). A more realistic scenario considering that prothioconazole-desthio is not present during M/L and considering a 50% conversion during application is also provided by the applicant.			
	The exposure calculations were conducted by the applicant using the EFSA online calculator 2022 v 1.0.0. (OPEX). The evaluator has revised the exposure calculations using higher value for dermal absorption (15% instead of 10.33%) for the metabolite Prothioconazole-desthio obtained from vitro dermal absorption study according to EFSA Guidance on Dermal Absorption (2017).			
	The revised calculations for more realistic scenario (prothioconazole-desthio is not present during M/L and 50% conversion to prothioconazole-desthio during application):			
	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
	Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 15 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
	Boscalid Number of applications & application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
	Potential	0.1	133	13
	Workwear	0.01	14.9	0
	Workwear and gloves	0.01	13.3	0
	Hands covered, no workwear			
	Prothioconazole Number of applications & application rate: 2 x 0.0624 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
	Potential	0.07	33.3	0
	Workwear	0.007	3.7	0
	Workwear and gloves	0.007	3.3	0
	Hands covered, no workwear			
	Prothioconazole-desthio Number of applications & application rate: 2 x 0.056584 kg a.s./ha Dermal absorption: 15 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
	Potential	0.02	181	26
	Workwear	0.002	20.3	0

	Workwear and gloves	0.002	18.1	0
	Combined		Hazard index	
	potential		3.5	54
	Workwear		0.4	0
	Workwear and gloves		0.3	0
	Hands covered, no workwear			0
Agreed endpoint 6.6.3	Worker exposure during re-entry activities on area treated with Pirlanko (GLOB2021dF) after the most worst-case scenario (with a 100% conversion from prothioconazole to prothioconazole-desthio) and revised more realistic scenario (50% conversion during application) is acceptable when workwear is worn.			

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-7 shows the exposure model used for estimation of resident and bystander exposure to Boscalid, Prothioconazole and Prothioconazole-desthio. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure models for intended uses

Critical uses	Oilseed rape and cereals (max. 0.8 L/product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 calculator version: 1.0.0

Table 6.6-8: Estimated resident exposure (longer term exposure)

Model data	Boscalid		Prothioconazole		Prothioconazole-desthio	
	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
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/cm ² /kg a.s./ha Interval between treatments: 15d (covering 21d)						
1) 0% conversion from prothioconazole to prothioconazole-desthio						
Number of applications and application rate	2 x 0.125 kg a.s./ha		2 x 0.125 kg a.s./ha		2 x 0 kg a.s./ha	

Resident child Body weight: 10 kg	Drift (75 th perc.)	0.02	16.9	0.02	8.5	/	/
	Vapour (75 th perc.)	8e-05	0.08	5e-05	0.02	/	/
	Deposits (75 th perc.)	0.002	1.6	0.002	0.9	/	/
	Re-entry (75 th perc.)	0.02	18	0.02	9	/	/
	Sum (mean)	0.02	24.9	0.02	12.4	/	/
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.004	4	0.004	2	/	/
	Vapour (75 th perc.)	3e-05	0.03	2e-05	0.008	/	/
	Deposits (75 th perc.)	0.0007	0.7	0.0007	0.4	/	/
	Re-entry (75 th perc.)	0.01	10	0.01	5	/	/
	Sum (mean)	0.01	10.4	0.01	5.2	/	/
2) 100% conversion from prothioconazole to prothioconazole-desthio							
Number of applications and application rate		2 x 0.125 kg a.s./ha		2 x 0 kg a.s./ha		2 x 0.113 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.02	16.9	/	/	0.001	13.6
	Vapour (75 th perc.)	8e-05	0.08	/	/	4e-05	0.4
	Deposits (75 th perc.)	0.002	1.6	/	/	0.0002	2
	Re-entry (75 th perc.)	0.02	18	/	/	0.001	14.4
	Sum (mean)	0.02	24.9	/	/	0.002	20.8
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.004	4	/	/	0.0003	3.2
	Vapour (75 th perc.)	3e-05	0.03	/	/	1e-05	0.1
	Deposits (75 th perc.)	0.0007	0.7	/	/	6e-05	0.6
	Re-entry (75 th perc.)	0.01	10	/	/	0.0008	8
	Sum (mean)	0.01	10.4	/	/	0.0008	8.5
3) 50% conversion from prothioconazole to prothioconazole-desthio							
Number of applications and application rate		2 x 0.125 kg a.s./ha		2 x 0.0625 kg a.s./ha		2 x 0.0567 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.02	16.9	0.008	4.2	0.002	15.9
	Vapour (75 th perc.)	8e-05	0.08	5e-05	0.02	4e-05	0.4
	Deposits (75 th perc.)	0.002	1.6	0.0009	0.4	0.0002	2.2
	Re-entry (75 th perc.)	0.02	18	0.009	4.5	0.002	16.9
	Sum (mean)	0.02	24.9	0.01	6.2	0.002	24.2
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.004	4	0.002	1	0.0004	3.8
	Vapour (75 th perc.)	3e-05	0.03	2e-05	0.008	1e-05	0.1
	Deposits (75 th perc.)	0.0007	0.7	0.0004	0.2	7e-05	0.7
	Re-entry (75 th perc.)	0.01	10	0.005	2.5	0.0009	9.4
	Sum (mean)	0.01	10.4	0.005	2.6	0.001	9.9

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

Comments of zRMS study comment 6.6.4	The applicant presented calculations for the application GLOB2021dF covering all uses from critical GAP table.			
	The applicant provided exposure assessment for resident and bystander in the most worst-case scenario (with assumed 100% conversion from prothioconazole to prothioconazole-desthio). A more realistic scenario considering 50% conversion of prothioconazole-desthio during application is also provided by the applicant.			
	The exposure calculations were conducted by the applicant using the EFSA online calculator 2022 v 1.0.0. (OPEX). The evaluator has revised the exposure calculations using higher value for dermal absorption (15% instead of 10.33%) for the metabolite Prothioconazole-desthio in vitro dermal absorption study according to EFSA Guidance on Dermal Absorption (2017).			
	The revised calculations for more realistic scenario (50% conversion to prothioconazole-desthio during application):			
	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: 15 days Minimum volume of water: 100 l			
	Boscalid	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days		
	Resident child Body weight: 10 kg	Drift (75th perc.)	0.02	16.9
		Vapour (75th perc.)	0.0008	0.8
		Deposits (75th perc.)	0.002	1.7
		Re-entry (75th perc.)	0.02	18
		Sum (mean)	0.03	25.6
	Resident adult Body weight: 60 kg	Drift (75th perc.)	0.004	4
		Vapour (75th perc.)	0.0003	0.3
		Deposits (75th perc.)	0.0007	0.7
		Re-entry (75th perc.)	0.01	10
		Sum (mean)	0.01	10.7
	Prothioconazole	Number of applications and application rate: 2 x 0.0624 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days		
	Resident child Body weight: 10 kg	Drift (75th perc.)	0.008	4.2
		Vapour (75th perc.)	0.0008	0.4
		Deposits (75th perc.)	0.0009	0.4
		Re-entry (75th perc.)	0.009	4.5
		Sum (mean)	0.01	6.6
		Drift (75th perc.)	0.002	1

	Resident adult Body weight: 60 kg	Vapour (75th perc.)	0.0003	0.1
		Deposits (75th perc.)	0.0004	0.2
		Re-entry (75th perc.)	0.005	2.5
		Sum (mean)	0.005	2.7
	Prothioconazole-desthio Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption: 15 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			
	Resident child Body weight: 10 kg	Drift (75th perc.)	0.002	23.1
		Vapour (75th perc.)	0.0008	8
		Deposits (75th perc.)	0.0003	2.9
		Re-entry (75th perc.)	0.002	24.5
		Sum (mean)	0.004	42.2
	Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0005	5.5
		Vapour (75th perc.)	0.0003	2.7
		Deposits (75th perc.)	0.0001	1
		Re-entry (75th perc.)	0.001	13.6
		Sum (mean)	0.002	16.8
	Combined exposure			Hazard index
	Resident child Body weight: 10 kg	Drift (75th perc.)		0.4
		Vapour (75th perc.)		0.09
		Deposits (75th perc.)		0.05
		Re-entry (75th perc.)		0.5
		Sum (mean)		0.7
	Resident adult Body weight: 60 kg	Drift (75th perc.)		0.1
		Vapour (75th perc.)		0.03
		Deposits (75th perc.)		0.02
		Re-entry (75th perc.)		0.3
		Sum (mean)		0.3
Agreed endpoint 6.6.4	Resident exposure (covering bystander) after the most worst-case scenario (with a 100% conversion from prothioconazole to prothioconazole-desthio) and revised more realistic scenario (50% conversion during application) was acceptable.			

6.6.5 Combined exposure

The product is a mixture of two active substances.

6.6.5.1 Exposure assessment of Boscalid, Prothioconazole and Prothioconazole-desthio in GLOB2021dF

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

predicted exposure as % of systemic AOEL from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-9: Risk assessment to operators from combined exposure (longer term exposure)

Active ingredient		Application scenario			
		Boscalid	Prothioconazole	Prothioconazole-desthio	Cumulative risk (HI)
Operators					
Tractor mounted - No PPE - 0% Conversion		0.528	0.264	0	0.792
Tractor mounted - No PPE - 100% Conversion		0.528	0	0.143	0.671
Tractor mounted – Gloves M/L - 50% Conversion – 10% dermal absorption		0.093	0.024	0.148	0.265
Tractor mounted - No PPE - 50% Conversion – no dermal absorption		0.528	0.163	0.086	0.777
Workers					
Inspection, irrigation – 0% Conversion		0.149	0.075	0	0.224
Inspection, irrigation – 100% Conversion		0.149	0	0.120	0.269
Inspection, irrigation – 50% Conversion		0.149	0.037	0.140	0.326
Residents					
Child – 0% Conversion	Drift	0.169	0.085	0	0.25
	Vapour	0.0008	0.0002	0	0.001
	Deposits	0.016	0.009	0	0.03
	Re-entry	0.18	0.09	0	0.27
	Sum of all pathways	0.249	0.124	0	0.37
Adult – 0% Conversion	Drift	0.04	0.02	0	0.06
	Vapour	0.0003	0.00008	0	0.0004
	Deposits	0.007	0.004	0	0.01
	Re-entry	0.10	0.05	0	0.15
	Sum of all pathways	0.104	0.052	0	0.16
Child – 100% Conversion	Drift	0.169	0	0.136	0.31
	Vapour	0.0008	0	0.004	0.005
	Deposits	0.016	0	0.02	0.04
	Re-entry	0.18	0	0.144	0.32
	Sum of all pathways	0.249	0	0.208	0.46
Adult – 100% Conversion	Drift	0.04	0	0.032	0.07
	Vapour	0.0003	0	0.001	0.001
	Deposits	0.007	0	0.006	0.01
	Re-entry	0.10	0	0.08	0.18
	Sum of all pathways	0.104	0	0.085	0.19
Child – 50% Conversion	Drift	0.169	0.042	0.159	0.37
	Vapour	0.0008	0.0002	0.004	0.01
	Deposits	0.016	0.004	0.022	0.04
	Re-entry	0.18	0.045	0.169	0.39
	Sum of all pathways	0.249	0.062	0.242	0.55
Adult – 50% Conversion	Drift	0.04	0.01	0.038	0.09
	Vapour	0.0003	0.00008	0.001	0.001

Active ingredient	Application scenario			
	Boscalid	Prothioconazole	Prothioconazole-desthio	Cumulative risk (HI)
	Estimated exposure / AOEL (HQ)			
	Deposits	0.007	0.002	0.007
Re-entry	0.10	0.025	0.094	0.22
Sum of all pathways	0.104	0.026	0.099	0.23

The Hazard Index is < 1. Thus, combined exposure to all active substances in GLOB2021dF is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

Comments of zRMS Study comment 6.6.5	According to revised EFSA OPEX calculations for the most worst-case scenario for operator (with assumed 50% conversion from prothioconazole to prothioconazole-desthio and 10% default dermal absorption during M/L) it can be concluded that the risk of operator exposure during mixing & loading is acceptable under conditions of intended use when the workwear and gloves are worn. Risk of operator exposure during application is acceptable under conditions of intended use when the workwear is worn. According to revised EFSA OPEX calculations for more realistic scenario (prothioconazole-desthio is not present during M/L and 50% conversion to prothioconazole-desthio during application) it can be concluded that the risk of operator exposure during mixing & loading and application using the tractor-mounted on field is acceptable under conditions of intended use when the workwear (long sleeved shirt, long trousers) is worn.		
	zRMS calculations for operator:		
	Combined exposure		Hazard index
	M/L: Workwear App: Workwear		0.8
	Taking into account that the metabolite can be present even at concentrated product this worst case approach should be taken into account as well. Thus use of gloves is recommended for operator during mixing & loading.		
	As regards risk of worker exposure during re-entry activities on area treated with GLOB2021dF it can be concluded that in the most worst-case scenario (with assumed 100% conversion from prothioconazole to prothioconazole-desthio) and in a revised more realistic scenario (considering 50% conversion during application) risk is acceptable under conditions of intended use when the workwear (long sleeved shirt, long trousers) is worn.		
	zRMS calculations for worker:		
	Combined	Hazard index	Re-entry restriction [days]
	potential	3.5	54
	Workwear	0.4	0
	Workwear and gloves	0.3	0
	Hands covered, no workwear		0
	According to calculations in the most worst-case scenario (with assumed 100% conversion from prothioconazole to prothioconazole-desthio) and in a revised more		

	realistic scenario considering 50% conversion during application, it can be concluded that risk for resident (child and adult) and bystander after application of GLOB2021dF is acceptable. zRMS calculations for resident and bystander:		
	Combined exposure		Hazard index
	Resident child Body weight: 10 kg	Drift (75th perc.)	0.4
		Vapour (75th perc.)	0.09
		Deposits (75th perc.)	0.05
		Re-entry (75th perc.)	0.5
		Sum (mean)	0.7
	Resident adult Body weight: 60 kg	Drift (75th perc.)	0.1
		Vapour (75th perc.)	0.03
		Deposits (75th perc.)	0.02
		Re-entry (75th perc.)	0.3
		Sum (mean)	0.3
zRMS agreed endpoints 6.6.5	According to EFSA OPEX calculations of combined exposure it can be concluded that the risk of operator exposure during mixing & loading is acceptable under conditions of intended use when the workwear and gloves are worn. Risk of operator exposure during application is acceptable under conditions of intended use when the workwear is worn. Due to the fact that the product GLOB2021dF is classified as Eye Dam. 1 H318, the operator should wear eye protection or face protection during mixing/loading and application operations. As regards risk of worker exposure during re-entry activities on area treated with GLOB2021dF, according to EFSA OPEX calculations, it can be concluded that risk is acceptable under conditions of intended use when the workwear (long sleeved shirt, long trousers) is worn. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. The exposure assessment for residents also covers bystander exposure. According to calculations, it can be concluded that there is no unacceptable risk to any resident (child and adult) and bystander after application of GLOB2021dF.		

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 7.3	Di Donato M.	2023	Prothioconazole-desthio – In vitro percutaneous penetration of [14C]Prothioconazole-desthio formulated as GLOB2002F through Human Skin Membranes 20230017 IES GLP Unpublished	N	Globachem NV

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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	Y/N	Owner

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
			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Studies on dermal absorption (KCP 7.3)

A 2.1.1 Study 1 – Prothioconazole-desthio, a prothioconazole metabolite in GLOB2021dF

Comments of zRMS:	In vitro dermal absorption study with Prothioconazole-desthio formulated as GLOB2021dF performed according to GLP, OECD 428 and EFSA Guidance on Dermal Absorption (2017). The study is acceptable. However, in accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and according to Table 1 of EFSA Guidance it is equal to 0.67 (for 11 replicates used in submitted study). Thus zRMS has revised output of the dermal absorption study. Total absorption is 15% and 7.7% for spray dilution with 50% and 100% conversion of prothioconazole to prothioconazole-desthio respectively.
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Reference	KCP 7.3-01
Report	Prothioconazole-dezthio – <i>In vitro</i> percutaneous penetration of [14C]Prothioconazole-desthio formulated as GLOB2021dF through Human Skin Membranes, Di Donato M., 2023, 20230017
Guideline(s)	Yes; OECD 428, EC No 440/2008
Deviations	No
GLP	Yes
Acceptability	Yes/No/Supplementary

Summary

Test material	Name (Lot/Batch No.)	Prothioconazole-desthio
	Specific activity	5.52 MBq/mg
	Radiochemical purity	99.75%
Product	Name (Lot/Batch No.)	GLOB2021dF
	Company code	GLOB2021dF
	Concentration a.s.	Boscalid 156 g/L Prothioconazole 156 g/L
	Formulation type	SC
Blank product	Name (Lot/Batch No.)	GLOB2021dF Blank FOP6075-1)
	Concentration a.s.	Boscalid 156 g/L Prothioconazole 0 g/L

The percutaneous penetration of Prothioconazole-desthio, i.e. 2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazole-1-yl)propan-2-ol, a degradation product of the fungicide Prothioconazole, formulated as GLOB2021dF, was investigated in vitro using split-thickness skin membranes from human skin.

The skin membranes were set up in flow-through diffusion cells and formulated [¹⁴C]Prothioconazole-desthio was applied onto the skin membranes at two nominal dose levels of 0.189 g/L and 0.377 g Prothioconazole-desthio/L. The dose levels represent 50 % and 100 % photolysis degradation of Prothioconazole in the highest in use field dilution, i.e. 0.8 L product/ha in 300 L water, corresponding to 0.416 g Prothioconazole/L.

The exposure of the test item was performed under non-occluded conditions over an exposure time of 6 hours. Thereafter, the remaining test item was removed by washing the skin membranes with a mild soap solution. Further penetration of the remaining test item after removal was measured for additional 18 hours. At end of experiment, i.e. 24 hours after application, an additional skin membrane wash was performed. Test item remaining in/on the application site was removed by tape stripping of the application site until the epidermis was removed. During the experimental period, the receptor fluid (phosphate physiological buffered saline with the addition of 5 % (w/v) Volpo N20) was collected in hourly intervals between 0-6 hours and thereafter in 2 hours intervals until the end of the experiments.

Dose Level	Species	Conc. [mg/cm ³]	Appl. Dose [µg/cm ²]	Number of Replicates	Number of Donors	Collection period [h]
Low Dose (A1)	Human	0.152	1.52	11	7	0-24 h
Low Dose (B1)		0.370	3.70	11	6	

After application of [¹⁴C]Prothioconazole-desthio the penetration of radioactivity through the skin membrane was moderate for both low dose applications independent on their composition. Within 6 hours of exposure 6.41 % and 2.95% of the dose penetrated through the human skin membrane into the receptor fluid for formulation A1 and B1, respectively. The flux within the first 6 hours was calculated to 0.0256 and 0.0330 µg·cm⁻²·h⁻¹ for formulation A1 and B1, respectively. Within 24 hours a total amount of 10.07% and 5.40% of the applied radioactivity penetrated through the human skin membranes for formulation A1 and B1, respectively.

The majority of radioactivity could be removed from the application site by skin membrane wash, accounting for 69.15 % (A1) and 58.30 % (B1). An additional amount of 12.17 % and 18.74 % could be removed by the second skin membrane wash at 24 hours. In total, 81.43% and 77.22 % of the dose could be recovered in skin membrane wash at 6 and 24 hours and in donor cell wash for formulation A1 and B1, respectively (dislodged dose).

After the washing procedure, 6.92% (A1) and 13.88% (B1) were recovered in the first tow tape strips and a further 2.09% and 5.38%, respectively were recovered in tape strips 3-10. After tape stripping, the amounts of test item remaining in the skin membrane were determined to be 0.19% for the low dose and 0.44% of the high dose.

The amounts of dose recovered in the receptor fluids, skin membrane wash, tape strips, skin membranes, donor and receptor cell washes are summarized in the following table.

[% of Dose]				
Formulation	A1		B1	
Dose applied [µg·cm ⁻²]	1.52		3.70	
	Mean	SD	Mean	SD
Receptor Fluid				
0- 6 h	6.41	3.74	2.95	1.76
6-12 h	2.50	1.77	1.40	0.82
0-12 h	8.91	5.27	4.35	2.06
12-24 h	1.16	0.99	1.05	0.83

Receptor Cell Rinse	0.06	0.04	0.06	0.05
Subtotal	10.13	6.12	5.47	2.52
Skin Membrane	0.19	0.16	0.44	0.31
Absorption (incl. Tape Strip 3-10)	10.33 (12.42)	6.26 (6.31)	5.91 (11.29)	2.71 (7.17)
Membrane Wash 6 h	69.15	7.42	58.30	14.83
Membrane Wash 24 h	12.17	3.13	18.74	6.64
Donor-Cell Wash	0.12	0.04	0.18	0.07
Dislodged Dose	81.43	6.31	77.22	10.85
Tape Strip 1	5.32	3.57	9.18	3.62
Tape Strip 2	1.60	0.91	4.70	3.20
Subtotal	6.92	4.20	13.88	4.11
Tape Strip 3	0.65	0.45	1.79	2.20
Tape Strip 4	0.57	0.56	1.11	1.60
Tape Strip 5	0.31	0.37	0.86	1.68
Tape Strip 6	0.25	0.37	0.43	0.83
Tape Strip 7	0.20	0.32	0.62	1.45
Tape Strip 8	0.10	0.21	0.28	0.80
Tape Strip 9	< 0.01	< 0.01	0.14	0.41
Tape Strip 10	< 0.01	< 0.01	0.15	0.45
Subtotal	2.09	1.21	5.38	6.22
Tape Strips	9.01	4.92	19.25	9.42
Absorption $t_{0.5}$	86 %	8 %	78 %	10 %
Recovery	100.77	2.65	102.38	3.15

Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at $t_{0.5}$]	Yes [86 ± 8]	Yes [78 ± 10]
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	10.33 ± 6.26	5.91 ± 2.71
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) ²	N/A	N/A
Absorption estimate normalised ¹	10.33 ± 0.67 × 6.26	5.91 ± 0.67 × 2.71
Relevant absorption estimate	14.52	7.7257
Total absorption²	15	7.7

¹ In accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and is given in Table 1 of EFSA Guidance.

² Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

The average of total recovery for the performed experiments was found at 100.77 % and 102.38% of the applied doses for dose formulation A1 and B1, respectively.

Conclusion/endpoint:

The dermal penetration of Prothioconazole-desthio formulated as GLOB2021dF through human skin membrane was calculated based on the amount penetrated through the skin membrane and recovered in receptor fluid and receptor cell rinse and the amount recovered in the remaining skin membrane after tape stripping. The dermal penetration estimates to be used for risk assessment were set at 10.33% and 5.91% for the 1:500 spray dilution with 50% and 100% conversion of prothioconazole to prothioconazole-desthio respectively.

Appendix 3 Exposure calculations

A 3.1 Information on product and active substances

Table A 1: 0% conversion to prothioconazole-desthio

Product name	GLOB2021dF
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156
AOEL [mg/kg bw/day]	0.1
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	44
Dermal absorption [%] (concentrate)	10
Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	156
AOEL [mg/kg bw/day]	0.2
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10

Table A 2: 100% conversion to prothioconazole-desthio

Product name	GLOB2021dF
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156
AOEL [mg/kg bw/day]	0.1
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	44
Dermal absorption [%] (concentrate)	10
Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	141.46
AOEL [mg/kg bw/day]	0.01
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	0
Dermal absorption [%] (dilution) 0.282 [g a.s./l or kg]	5.91

Table A 3: 50% conversion to prothioconazole-desthio (assuming 10% dermal absorption during M/L)

Product name	GLOB2021dF
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156
AOEL [mg/kg bw/day]	0.1
AAOEL [mg/kg bw]	

Inhalation absorption [%]	100
Oral absorption [%]	44
Dermal absorption [%] (concentrate)	10
Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	78
AOEL [mg/kg bw/day]	0.2
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10
Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	70.73
AOEL [mg/kg bw/day]	0.01
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10
Dermal absorption [%] (dilution) 0.141 [g a.s./l or kg]	10.33

Table A 4: 50% conversion to prothioconazole-desthio (without assuming dermal absorption during M/L)

Product name	GLOB2021dF
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156
AOEL [mg/kg bw/day]	0.1
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100

Oral absorption [%]	44
Dermal absorption [%] (concentrate)	10
Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	70.73
AOEL [mg/kg bw/day]	0.01
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	0
Dermal absorption [%] (dilution) 0.141 [g a.s./l or kg]	10.33
Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	78
AOEL [mg/kg bw/day]	0.2
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10

Table A 5: Assessed use

Use	Crops	Max. application rate of the product [l or kg/ha]	Unit	Max. no. of applications	Interval between multiple applications [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/outdoor	Application method	Type of cultivation	Application technique	Buffer strip [m]	Drift reduction [%]
Use 1	Field crops	0.8	l/ha	2	15	100	300	Outdoor	Downward spraying	Normal	Vehicle-mounted	2-3	0

A 3.2 Operator exposure calculations (KCP 7.2.1.1)

A 3.2.1 Calculations for boscalid, prothioconazole (no conversion to prothioconazole-desthio) and combined exposure according to EFSA guidance (including input parameters)

Mixing/loading	Application	Boscalid (% AOEL) Normal & vehicle-mounted	Prothioconazole (% AOEL)	Combined (hazard index)
		80.2	40.1	1.2
		52.8	26.4	0.792

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			
Boscalid	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.05	52.8
Prothioconazole	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.05	26.4
Combined exposure			Hazard index
			M/L: Workwear App: Workwear
			0.8

Boscalid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	43.7	43.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
Mixing and loading (µg/kg bw per day)	Body exposure	0.3	0.3
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.7	0.7
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.1	0.1
	<i>Hand protection</i>	<i>None</i>	<i>None</i>
Application (µg/kg bw per day)	Hands exposure	7.7	7.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.2	0.2
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.04	0.04
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.05
	% of AOEL	52.8	52.8

Prothioconazole , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	156	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.2		
AAOEL [mg/kg bw]			

Prothioconazole , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	<i>Hand protection</i>	<i>None</i>	<i>None</i>

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hands exposure	43.7	43.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.3	0.3
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.7	0.7
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.1	0.1
	<i>Hand protection</i>	<i>None</i>	<i>None</i>
Application (µg/kg bw per day)	Hands exposure	7.7	7.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.2	0.2
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.04	0.04
	<i>Hand protection</i>	<i>None</i>	<i>None</i>
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.05
	% of AOEL	26.4	26.4

A 3.2.2 Calculations for boscalid, prothioconazole, prothioconazole-desthio (50% conversion, 10% dermal absorption during M/L) and combined exposure according to EFSA guidance (including input parameters)

Mixing/loading	Application	Boscalid (% AOEL) Normal & vehicle-mounted	Prothioconazole (% AOEL)	Desthio (% AOEL)	Combined (hazard index)
		80.2	24.3	410	5.14
		52.8	16.3	277	3.46
		9.3	2.4	14.8	0.265

Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile
Crop density: Normal

Boscalid	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %			
	M/L: Workwear	0.05	52.8	
	App: Workwear			
Prothioconazole	Number of applications and application rate: 2 x 0.0624 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %			
	M/L: Workwear	0.03	16.3	
	App: Workwear			
Desthio	Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 10.33 %			
	M/L: Workwear + Protected hands	0.001	14.8	
	App: Workwear			
Combined exposure				Hazard index
M/L: Workwear + Protected hands				0.3
App: Workwear				

Boscalid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	43.7	43.7
	Body protection	Workwear	Workwear
	Body exposure	0.3	0.3
	Head protection	None	None
	Head exposure	0.7	0.7
	Inhalation protection	None	None
	Inhalation exposure	0.1	0.1
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	7.7	7.7

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.2	0.2
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.04	0.04
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.05
	% of AOEL	52.8	52.8

Prothioconazole , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	78	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.2		
AAOEL [mg/kg bw]			

Prothioconazole , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	28.1	28.1
	Body protection	Workwear	Workwear
	Body exposure	0.2	0.2
	Head protection	None	None
	Head exposure	0.3	0.3
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	3.8	3.8
	Body protection	Workwear	Workwear
	Body exposure	0.06	0.06
	Head protection	None	None
	Head exposure	0.1	0.1
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.03	0.03
	% of AOEL	16.3	16.3

Desthio , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	70.73	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted

Dermal absorption [%] (dilution)	10.33	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.01		
AAOEL [mg/kg bw]			

Desthio , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	Protected hands
	Hands exposure	26.4	0.2
	Body protection	Workwear	Workwear
	Body exposure	0.2	0.2
	Head protection	None	None
	Head exposure	0.3	0.3
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	0.7	0.7
	Body protection	Workwear	Workwear
	Body exposure	0.01	0.01
	Head protection	None	None
	Head exposure	0.02	0.02
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.03	0.001
	% of AOEL	277	14.8

A 3.2.3 Calculations for boscalid, prothioconazole, prothioconazole-desthio (50% conversion, without dermal absorption during M/L) and combined exposure according to EFSA guidance (including input parameters)

Mixing/loading	Application	Boscalid (% AOEL) Normal & vehicle-mounted	Desthio (% AOEL)	Prothioconazole (% AOEL)	Combined (hazard index)
		80.2	12.5	24.3	1.17
		52.8	8.6	16.3	0.777

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			
Boscalid	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.05	52.8
Desthio	Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 10.33 %		
	M/L: Workwear App: Workwear	0.0009	8.6
Prothioconazole	Number of applications and application rate: 2 x 0.0624 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.03	16.3
Combined exposure			Hazard index

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
	M/L: Workwear App: Workwear		0.8

Boscalid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	Hand protection	None	None
	Hands exposure	43.7	43.7
Mixing and loading (µg/kg bw per day)	Body protection	Workwear	Workwear
	Body exposure	0.3	0.3
	Head protection	None	None

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Application (µg/kg bw per day)	Head exposure	0.7	0.7
	Inhalation protection	None	None
	Inhalation exposure	0.1	0.1
	Hand protection	None	None
	Hands exposure	7.7	7.7
	Body protection	Workwear	Workwear
	Body exposure	0.1	0.1
	Head protection	None	None
	Head exposure	0.2	0.2
	Inhalation protection	None	None
	Inhalation exposure	0.04	0.04
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.05
	% of AOEL	52.8	52.8

Desthio , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	70.73	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	10.33	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.01		

AAOEL [mg/kg bw]

Desthio , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0	0
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0	0
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0	0
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.7	0.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.01	0.01
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.02	0.02
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.0009	0.0009
	% of AOEL	8.6	8.6

Prothioconazole , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	78	Crops	Field crops

Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.2		
AAOEL [mg/kg bw]			

Prothioconazole , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	28.1	28.1
	Body protection	Workwear	Workwear
	Body exposure	0.2	0.2
	Head protection	None	None
	Head exposure	0.3	0.3
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	3.8	3.8
	Body protection	Workwear	Workwear
	Body exposure	0.06	0.06
	Head protection	None	None
	Head exposure	0.1	0.1
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Total	Total systemic exposure [mg/kg bw per day]	0.03	0.03
	% of AOEL	16.3	16.3

A 3.2.4 Calculations for boscalid, prothioconazole, prothioconazole-desthio (100% conversion) and combined exposure according to EFSA guidance (including input parameters)

Mixing/loading	Application	Boscalid (% AOEL) Normal & vehicle-mounted	Desthio (% AOEL)	Combined (hazard index)
		80.2	21	1.01
		52.8	14.3	0.671

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			
Boscalid	Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.05	52.8
Desthio	Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 8.83679745493107 %		
	M/L: Workwear App: Workwear	0.001	14.3
Combined exposure			Hazard index
			0.7

Boscalid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	43.7	43.7
	Body protection	Workwear	Workwear
	Body exposure	0.3	0.3
	Head protection	None	None
	Head exposure	0.7	0.7
	Inhalation protection	None	None
	Inhalation exposure	0.1	0.1
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	7.7	7.7
	Body protection	Workwear	Workwear

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.2	0.2
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.04	0.04
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.05
	% of AOEL	52.8	52.8

Desthio , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	141.46	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	8.83679745493107	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.01		
AAOEL [mg/kg bw]			

Desthio , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	<i>Hand protection</i>	<i>None</i>	<i>None</i>

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hands exposure	0	0
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0	0
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0	0
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.1	0.1
	<i>Hand protection</i>	<i>None</i>	<i>None</i>
Application (µg/kg bw per day)	Hands exposure	1.2	1.2
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.02	0.02
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.03	0.03
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.04	0.04
	<i>Hand protection</i>	<i>None</i>	<i>None</i>
Total	Total systemic exposure [mg/kg bw per day]	0.001	0.001
	% of AOEL	14.3	14.3

A 3.3 Worker exposure calculations (KCP 7.2.3.1)

A 3.3.1 Calculations for boscalid, prothioconazole (no conversion to prothioconazole-desthio) and combined exposure according to EFSA guidance (including input parameters)

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 15 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Boscalid			
Potential	0.1	133	13
Workwear	0.01	14.9	0
Workwear and gloves	0.01	13.3	0
Hands covered, no workwear			
Number of applications & application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Prothioconazole			
Potential	0.1	66.7	0
Workwear	0.01	7.5	0
Workwear and gloves	0.01	6.7	0

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Hands covered, no workwear			
Combined		Hazard index	
potential		2	31
Workwear		0.2	0
Workwear and gloves		0.2	0
Hands covered, no workwear			0

Boscalid , Input data

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.8	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	2	DT50 foliar worker [days]	30
Interval between multiple applications [days]	15		
Multiple application factor	1.71		
Body weight (kg)	60		
Name of active substance	Boscalid		
Dermal absorption [%] (dilution)	50		

Inhalation absorption [%]	100
Time [hours per day]	2

Boscalid , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	8	0.9	0.8	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	8	0.9	0.8	NA
	Total systemic exposure [mg/kg bw per day]	0.1	0.01	0.01	NA
	% of AOEL	133	14.9	13.3	NA

Prothioconazole , Input data

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.2
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.8	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	2	DT50 foliar worker [days]	30
Interval between multiple applications [days]	15		
Multiple application factor	1.71		
Body weight (kg)	60		

Name of active substance	Prothioconazole
Dermal absorption [%] (dilution)	50
Inhalation absorption [%]	100
Time [hours per day]	2

Prothioconazole , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	8	0.9	0.8	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	8	0.9	0.8	NA
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.01	0.01	NA
	% of AOEL	66.7	7.5	6.7	NA

A 3.3.2 Calculations for boscalid, prothioconazole, prothioconazole-desthio (50% conversion) and combined exposure according to EFSA guidance (including input parameters)

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 15 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Potential	0.1	133	13
Workwear	0.01	14.9	0
Workwear and gloves	0.01	13.3	0
Hands covered, no workwear			
Number of applications & application rate: 2 x 0.056584 kg a.s./ha Dermal absorption: 10.33 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Desthio			
Potential	0.01	125	10
Workwear	0.001	14	0
Workwear and gloves	0.001	12.5	0
Hands covered, no workwear			
Number of applications & application rate: 2 x 0.0624 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Prothioconazole			
Potential	0.07	33.3	0
Workwear	0.007	3.7	0

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Workwear and gloves	0.007	3.3	0
Hands covered, no workwear			
Combined		Hazard index	
potential		3.8	47
Workwear		0.4	0
Workwear and gloves		0.4	0
Hands covered, no workwear			0

Boscalid , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	156	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	Hand protection	None	None

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hands exposure	43.7	43.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.3	0.3
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.7	0.7
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.1	0.1
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	7.7	7.7
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.1	0.1
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.2	0.2
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.04	0.04
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.05
	% of AOEL	52.8	52.8

Desthio , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Desthio
Concentration of active substance [g a.s./l or kg]	70.73	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	10.33	Indoor/outdoor	Outdoor

Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.01		
AAOEL [mg/kg bw]			

Desthio , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	0	0
	Body protection	Workwear	Workwear
	Body exposure	0	0
	Head protection	None	None
	Head exposure	0	0
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	0.7	0.7
	Body protection	Workwear	Workwear
	Body exposure	0.01	0.01
	Head protection	None	None
	Head exposure	0.02	0.02
	Inhalation protection	None	None
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.0009	0.0009
	% of AOEL	8.6	8.6

Prothioconazole , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	78	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.2		
AAOEL [mg/kg bw]			

Prothioconazole , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	28.1	28.1
	Body protection	Workwear	Workwear
	Body exposure	0.2	0.2
	Head protection	None	None
	Head exposure	0.3	0.3
	Inhalation protection	None	None
	Inhalation exposure	0.08	0.08
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	3.8	3.8
	Body protection	Workwear	Workwear

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
	Body exposure	0.06	0.06
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.1	0.1
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.03	0.03
Total	Total systemic exposure [mg/kg bw per day]	0.03	0.03
	% of AOEL	16.3	16.3

A 3.3.3 Calculations for boscalid, prothioconazole, prothioconazole-desthio (100% conversion) and combined exposure according to EFSA guidance (including input parameters)

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 15 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Potential	0.1	133	13
Workwear	0.01	14.9	0
Workwear and gloves	0.01	13.3	0
Hands covered, no workwear			
Number of applications & application rate: 2 x 0.056584 kg a.s./ha Dermal absorption: 8.83679745493107 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Desthio			
Potential	0.01	107	3
Workwear	0.001	12	0
Workwear and gloves	0.001	10.7	0
Hands covered, no workwear			
Combined		Hazard index	
potential		2.4	38
Workwear		0.3	0
Workwear and gloves		0.2	0
Hands covered, no workwear			0

Boscalid , Input data

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.8	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	2	DT50 foliar worker [days]	30
Interval between multiple applications [days]	15		
Multiple application factor	1.71		
Body weight (kg)	60		
Name of active substance	Boscalid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Boscalid , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	8	0.9	0.8	NA

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	8	0.9	0.8	NA
	Total systemic exposure [mg/kg bw per day]	0.1	0.01	0.01	NA
	% of AOEL	133	14.9	13.3	NA

Desthio , Input data

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.01
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	0.8	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	2	DT50 foliar worker [days]	30
Interval between multiple applications [days]	15		
Multiple application factor	1.71		
Body weight (kg)	60		
Name of active substance	Desthio		
Dermal absorption [%] (dilution)	8.83679745493107		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Desthio , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	0.6	0.07	0.06	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
Total	Total systemic exposure [mg a.s. per day]	0.6	0.07	0.06	NA
	Total systemic exposure [mg/kg bw per day]	0.01	0.001	0.001	NA
	% of AOEL	107	12	10.7	NA

A 3.4 Resident and bystander exposure calculations (KCP 7.2.3.1)

A 3.4.1 Calculations for boscalid, prothioconazole (no conversion to prothioconazole-desthio) and combined exposure according to EFSA guidance (including input parameters)

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: 15 days Minimum volume of water: 100 l				
Boscalid		Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Resident child Body weight: 10 kg	Drift (75th perc.)	0.02	16.9	
	Vapour (75th perc.)	8e-05	0.08	
	Deposits (75th perc.)	0.002	1.6	
	Re-entry (75th perc.)	0.02	18	
	Sum (mean)	0.02	24.9	
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.004	4	
	Vapour (75th perc.)	3e-05	0.03	
	Deposits (75th perc.)	0.0007	0.7	
	Re-entry (75th perc.)	0.01	10	
	Sum (mean)	0.01	10.4	
Prothioconazole		Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
		Drift (75th perc.)	0.02	8.5

Model data		Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident child Body weight: 10 kg		Vapour (75th perc.)	5e-05	0.02
		Deposits (75th perc.)	0.002	0.9
		Re-entry (75th perc.)	0.02	9
		Sum (mean)	0.02	12.4
Resident adult Body weight: 60 kg		Drift (75th perc.)	0.004	2
		Vapour (75th perc.)	2e-05	0.008
		Deposits (75th perc.)	0.0007	0.4
		Re-entry (75th perc.)	0.01	5
		Sum (mean)	0.01	5.2
Combined exposure				Hazard index
Resident child Body weight: 10 kg		Drift (75th perc.)		0.3
		Vapour (75th perc.)		0.001
		Deposits (75th perc.)		0.02
		Re-entry (75th perc.)		0.3
		Sum (mean)		0.4
Resident adult Body weight: 60 kg		Drift (75th perc.)		0.06
		Vapour (75th perc.)		0.0003
		Deposits (75th perc.)		0.01
		Re-entry (75th perc.)		0.2
		Sum (mean)		0.2

A 3.4.2 Calculations for boscalid, prothioconazole, prothioconazole-desthio (50% conversion) and combined exposure according to EFSA guidance (including input parameters)

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: 15 days Minimum volume of water: 100 l			
Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.02	16.9
	Vapour (75th perc.)	8e-05	0.08
	Deposits (75th perc.)	0.002	1.6
	Re-entry (75th perc.)	0.02	18
	Sum (mean)	0.02	24.9
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.004	4
	Vapour (75th perc.)	3e-05	0.03
	Deposits (75th perc.)	0.0007	0.7
	Re-entry (75th perc.)	0.01	10
	Sum (mean)	0.01	10.4
Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption: 10.33 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Desthio			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.002	15.9
	Vapour (75th perc.)	4e-05	0.4
	Deposits (75th perc.)	0.0002	2.2
	Re-entry (75th perc.)	0.002	16.9
	Sum (mean)	0.002	24.2

Model data		Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident adult Body weight: 60 kg		Drift (75th perc.)	0.0004	3.8
		Vapour (75th perc.)	1e-05	0.1
		Deposits (75th perc.)	7e-05	0.7
		Re-entry (75th perc.)	0.0009	9.4
		Sum (mean)	0.001	9.9
Prothioconazole		Number of applications and application rate: 2 x 0.0624 kg a.s./ha		
		Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Resident child Body weight: 10 kg		Drift (75th perc.)	0.008	4.2
		Vapour (75th perc.)	5e-05	0.02
		Deposits (75th perc.)	0.0009	0.4
		Re-entry (75th perc.)	0.009	4.5
		Sum (mean)	0.01	6.2
Resident adult Body weight: 60 kg		Drift (75th perc.)	0.002	1
		Vapour (75th perc.)	2e-05	0.008
		Deposits (75th perc.)	0.0004	0.2
		Re-entry (75th perc.)	0.005	2.5
		Sum (mean)	0.005	2.6
Combined exposure				Hazard index
Resident child Body weight: 10 kg		Drift (75th perc.)		0.4
		Vapour (75th perc.)		0.005
		Deposits (75th perc.)		0.04
		Re-entry (75th perc.)		0.4
		Sum (mean)		0.6
Resident adult Body weight: 60 kg		Drift (75th perc.)		0.09
		Vapour (75th perc.)		0.002
		Deposits (75th perc.)		0.02

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
	Re-entry (75th perc.)		0.2
	Sum (mean)		0.2

A 3.4.3 Calculations for boscalid, prothioconazole, prothioconazole-desthio (100% conversion) and combined exposure according to EFSA guidance (including input parameters)

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: 15 days Minimum volume of water: 100 l
Boscalid				Number of applications and application rate: 2 x 0.1248 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)		0.02	16.9
	Vapour (75th perc.)		8e-05	0.08
	Deposits (75th perc.)		0.002	1.6
	Re-entry (75th perc.)		0.02	18
	Sum (mean)		0.02	24.9
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.004	4
	Vapour (75th perc.)		3e-05	0.03
	Deposits (75th perc.)		0.0007	0.7
	Re-entry (75th perc.)		0.01	10
	Sum (mean)		0.01	10.4
Desthio				Number of applications and application rate: 2 x 0.056584 kg a.s./ha Dermal absorption: 8.83679745493107 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days
Resident child Body weight: 10 kg	Drift (75th perc.)		0.001	13.6
	Vapour (75th perc.)		4e-05	0.4
	Deposits (75th perc.)		0.0002	2
	Re-entry (75th perc.)		0.001	14.4

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Resident adult Body weight: 60 kg	Sum (mean)	0.002	20.8
	Drift (75th perc.)	0.0003	3.2
	Vapour (75th perc.)	1e-05	0.1
	Deposits (75th perc.)	6e-05	0.6
	Re-entry (75th perc.)	0.0008	8
	Sum (mean)	0.0008	8.5
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.3
	Vapour (75th perc.)		0.005
	Deposits (75th perc.)		0.04
	Re-entry (75th perc.)		0.3
	Sum (mean)		0.5
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.07
	Vapour (75th perc.)		0.002
	Deposits (75th perc.)		0.01
	Re-entry (75th perc.)		0.2
	Sum (mean)		0.2

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.