

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: Protiokonazol 300 EC

Product name(s): HERA 300 EC

Chemical active substance:

prothioconazole, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

v.2

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on Protiokonazol 300 EC *

Product name and code	Protiokonazol 300 EC
Formulation type	Emulsifiable concentrate [Code: EC]
Active substance (incl. content)	prothioconazole; 300 g/L
Function	fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of Protiokonazol 300 EC 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 Protiokonazol 300 EC according to Regulation (EC) No 1272/2008



Hazard class(es), categories	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335
Hazard pictograms or Code(s) for hazard pictogram(s)	  GHS05 GHS07
Signal word	Danger
Hazard statement(s)	H315 - Causes skin irritation. H318 - Causes serious eye damage. H335 - May cause respiratory irritation.
Precautionary statement(s)	P261 - Avoid breathing dust/vapours/ spray. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352 - IF ON SKIN: Wash with plenty of water with soap. P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor. P332 + P313 - If skin irritation occurs: Get medical advice/ attention. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for Protiokonazol 300 EC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Workwear (arms, body and legs covered) and gloves during mixing/loading and during application.
Workers	Acceptable	Workwear (arms, body and legs covered) and gloves when inspecting the treated crops.
Residents	Acceptable	Buffer zone of at least 5 m away from residential buildings/habitats and bystanders with 50% drift reduction should be used.
Bystanders	Acceptable	

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 situa- tion (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safen- er/synergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure assess- ment			
			Method / Kind (incl. applica- tion technique ***)	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	Max. applica- tion rate kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Cereals Winter wheat (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35	Exposure based on EFSA model AOEM (Agricul- tural Operator Exposure Model [Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015] and EFSA Journal 2022;20(1):7032				
2	Cereals Spring wheat, (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35					
3	Cereals Winter triticale (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35					
4	Cereals Spring triticale (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35					
5	Cereals Spring barley (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35					
6	Cereals Winter barley (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35					
7	Cereals Rye (BBCH 29-65)	F	Spraying, LCTM	a) 1 b) 2 (14)	a) 0.195 b) 0.390	100 -400	35					
8	Oilseeds Winter oilseed rape (BBCH 13-19)	F	Spraying, LCTM	a) 1 b) 1	a) 0.180 b) 0.180	100 -400	56					
9	Oilseeds Winter oilseed rape	F	Spraying, LCTM	a) 1 b) 2 (21)	a) 0.180 b) 0.360	100 -400	56					

1	2	3	4	5	6	7	8	9	10
	(BBCH 61-72)								
10	Oilseeds Spring oilseed rape (BBCH 16-69)	F	Spraying, LCTM	a) 1 b) 2 (14-21)	a) 0.180 b) 0.360	100 -400	56		

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

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

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

Explanation for column 10 "Acceptability of exposure assessment"

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

Data gaps

DN/A

6.2 Toxicological Information on Active Substance(s)

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

Table 6.2-1: Information on active substance

Prothioconazole	
Common Name	prothioconazole
CAS-No.	178928-70-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Reg. 1272/2008 (Harmonised C&L (18ATP)): <u>Hazard classes (s), categories:</u> Aquatic Acute 1 Aquatic Chronic 1 <u>Code(s) for hazard pictogram(s):</u> GHS09 <u>Signal word:</u> Warning <u>Hazard statement(s):</u> H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects. <u>Precautionary statement(s):</u> -
Additional C&L proposal	NR
Agreed EU endpoints	
AOEL systemic	0.2 mg/kg bw/d (prothioconazole) 0.01 mg/kg bw/d (prothioconazole-desthio) - metabolite*
Reference	EFSA Scientific Report (2007) 106, 1-98
Conditions to take into account/critical areas of concern with regard to toxicology	
EFSA Conclusion for active substance	None

* According to the EFSA conclusion (EFSA Scientific Report 2007; 106, 1-98) the metabolite prothioconazole-desthio (M04) is considered more toxic than the parent. Therefore, a detailed risk assessment for all population groups is required also for this metabolite.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for Protiokonazol 300 EC is given in the following tables.

No studies are submitted with this application. Classification is based on composition of the product. According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction. For more details, please refer to dRR Part C.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Protiokonazol 300 EC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat Reg. 1272/2008	Not relevant (based on composition – calculation method)	Yes	None	dRR Part C
LD ₅₀ dermal, rat Reg. 1272/2008	Not relevant (based on composition – calculation method)	Yes	None	dRR Part C
LC ₅₀ inhalation, rat Reg. 1272/2008	ATE _{mix-inhal} > 5 mg/L (dust and mist) (based on composition – calculation method)	Yes	None	dRR Part C
Skin irritation Reg. 1272/2008	Skin irritant (based on composition – calculation method)	Yes	Skin Irrit. 2, H315	dRR Part C
Eye irritation Reg. 1272/2008	Eye damaging (based on composition – calculation method)	Yes	Eye Dam. 1, H318	dRR Part C
Skin sensitisation Reg. 1272/2008	Not relevant (based on composition – calculation method)	Yes	None	dRR Part C
Supplementary studies for combinations of plant protection products	-	-	-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of Protiokonazol 300 EC

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Prothioconazole (ca. 29% (w/w))	Not classified for human health hazards	Reg. 1272/2008 (Harmonised C&L (18ATP))	-
Toxicological properties of non-active substance(s) (relevant for classification of product)	N,N-dimethyl fatty acid amide (ca. 29% (w/w))	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335	Reg. 1272/2008	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335
Further toxicological information	No data – not required	-	-	-

6.4 Toxicological Evaluation of Groundwater Metabolites

Metabolites of prothioconazole are predicted to occur in groundwater at concentration below 0.1 µg/L (see dRR Part B8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 - rev.10 is therefore not required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in Protiokonazol 300 EC are presented in the following table.

According to the EFSA conclusion (EFSA Scientific Report 2007; 106, 1-98) the metabolite prothioconazole-desthio (M04) is considered more toxic than the parent. Therefore, a detailed risk assessment for all population groups is required also for this metabolite.

For prothioconazole-desthio dermal absorption value is relevant only for diluted formulation. The concentrated formulation does not contain prothioconazole-desthio. The conversion occurs with varying intensity during drying process of water diluted solutions of prothioconazole on surfaces.

Table 6.5-1: Dermal absorption rates for active substances in Protiokonazol 300 EC

Prothioconazole		
	Value	Reference
Concentrate	25 %	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption and SANTE/2018/10591 rev.1 of 24 October 2018.
Dilution	70 %	
Prothioconazole-desthio (M04)		
	Value	Reference
Option I		
Concentrate	20 % *	No dermal absorption studies were performed and submitted with the representative formulation. Hence, for M04, a 20% dermal value has been derived from a dermal absorption study in monkeys EFSA Scientific Report (2007).
Dilution	20 %	
Option II		
Concentrate	25 % *	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption and SANTE/2018/10591 rev.1 of 24 October 2018.
Dilution	70 %	

* Diluted prothioconazole can degrade to the metabolite prothioconazole-desthio. Formation of prothioconazole-desthio is not expected in the concentrate, thus the dermal absorption of prothioconazole-desthio from concentrate was not considered and a dermal absorption value of 0% was applied to remove this from calculation.

6.5.1 Justification for proposed values - prothioconazole

No data on dermal absorption for prothioconazole in Protiokonazol 300 EC is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 rev.1 of 24 October 2018 (a corrigendum (minor modification) on EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for prothioconazole

	Value	Justification for value	Acceptability of justification
Concentrate	25 %	According to EFSA Journal 2017;15(6):4873 a default dermal absorption value of 25% may be applied for concentrated products that are organic solvent-formulated ^(a) or in other ^(b) types of formulations. According to SANTE/2018/10591 rev.1 of 24 October 2018 a "concentrate" when the active substance is present in the plant protection product at a concentration higher than 50 g/L (or 50g/Kg or 5%).	Yes
Dilution	70 %	According to EFSA Journal 2017;15(6):4873 a default dermal absorption value of 70% may be applied for (in use) dilutions of organic solvent-formulated ^(a) or in other ^(b) types of formulations According to SANTE/2018/10591 rev.1 of 24 October 2018 a "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%).	Yes

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

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

6.5.2 Justification for proposed values – prothioconazole-desthio (M04)

Option I:

According to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole, a dermal absorption study in rhesus monkeys using an SC formulation containing M04, a 20% dermal absorption was considered appropriate for use in operator, worker and resident exposure calculations.

Table 6.5-3: Default dermal absorption rates for prothioconazole-desthio

	Value	Justification for value	Acceptability of justification
Concentrate	20 %*	No dermal absorption studies were performed and submitted with the representative formulation.	Yes
Dilution	20 %	Hence, for M04, a 20% dermal value has been derived from a dermal absorption study in monkeys EFSA Scientific Report (2007).	Yes

* Diluted prothioconazole can degrade to the metabolite prothioconazole-desthio. Formation of prothioconazole-desthio is not expected in the concentrate, thus the dermal absorption of prothioconazole-desthio from concentrate was not considered and a dermal absorption value of 0% was applied to remove this from calculation.

Option II:

No data on dermal absorption for prothioconazole in Protiokonazol 300 EC is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 rev.1 of 24 October 2018 (a corrigendum (minor modification) on EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-4: Default dermal absorption rates for prothioconazole-desthio

	Value	Justification for value	Acceptability of justification
Concentrate	25 %*	According to EFSA Journal 2017;15(6):4873 a default dermal absorption value of 25% may be applied for concentrated products that are organic solvent-formulated ^(a) or in other ^(b) types of formulations. According to SANTE/2018/10591 rev.1 of 24 October 2018 a "concentrate" when the active substance is present in the plant protection product at a concentration higher than 50 g/L (or 50g/Kg or 5%).	Yes
Dilution	70 %	According to EFSA Journal 2017;15(6):4873 a default dermal absorption value of 70% may be applied for (in use) dilutions of organic solvent-formulated ^(a) or in other ^(b) types of formulations According to SANTE/2018/10591 rev.1 of 24 October 2018 a "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%).	Yes

* Diluted prothioconazole can degrade to the metabolite prothioconazole-desthio. Formation of prothioconazole-desthio is not expected in the concentrate, thus the dermal absorption of prothioconazole-desthio from concentrate was not considered and a dermal absorption value of 0% was applied to remove this from calculation.

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	Protiokonazol 300 EC		
Formulation type	EC		
Category	Fungicide		
Container size(s), short description	250mL, 0.5L, 1L, 2L, 5L, 10L, 20L bottles, canisters HDPE, HDPE/PA (COEX), fHDPE and 220L, 1000L drums and containers HDPE professional		
Active substance (incl. content)	Prothioconazole 300 g/L	Prothioconazole-desthio 272.1 g/L	
AOEL systemic	0.2 mg/kg bw/d	0.01 mg/kg bw/d	
Inhalation absorption	100 %	100%	
Oral absorption	100 %	100%	
Dermal absorption	Concentrate: 25 % Dilution: 70 % (Default)	Option I: Concentrate: 0% Dilution: 20% (EFSA Scientific Report 2007; 106, 1-98)	Option II: Concentrate: 0 % Dilution: 70 % (Default)

For the exposure assessment to prothioconazole-desthio a total conversion of prothioconazole to prothioconazole-desthio was assumed. To calculate the amount of prothioconazole-desthio a conversion factor of 0.907 was applied (based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio).

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4.

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 Protiokonazol 300 EC according to the critical use is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 and Table 6.6-2 (longer term exposure). Detailed calculations are in Appendix 3.

None AAOEL was allocated for prothioconazole and its metabolite, prothioconazole-desthio. Therefore, estimates of the acute exposure to operators has not been conducted.

Table 6.6-2: Exposure models for intended uses

Critical uses	Cereals (max. 0.65 L product/ha) Oilseeds (max. 0.6 L product/ha)
Model	EFSA model AOEM (Agricultural Operator Exposure Model [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015] EFSA model AOEM (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

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

Prothioconazole			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted			
Application rate		0.195 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg OPEX version: 30/03/2015	Potential exposure	0.2195287	109.76
	Work wear (arms, body and legs covered) M/L and A	0.1374243	68.71
	Work wear (arms, body and legs covered) M/L and A +	0.0060677	3.03

	gloves		
Spray application (AOEM; 95 th percentile) Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential exposure	0.3	128
	M/L: Workwear App: Workwear	0.2	83.3
	M/L: Workwear + gloves App: Workwear	0.02	10.9
Oilseeds Outdoor Downward spraying Vehicle-mounted Application rate 0.180 kg a.s./ha			
Spray application (AOEM; 75 th percentile) Body weight: 60 kg <i>OPEX version: 30/03/2015</i>	Potential exposure	0.2062919	103.15
	Work wear (arms, body and legs covered) M/L and A	0.1288731	64.44
	Work wear (arms, body and legs covered) M/L and A + gloves	0.0056908	2.85
Spray application (AOEM; 95 th percentile) Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential exposure	0.2	121
	M/L: Workwear App: Workwear	0.2	78.9
	M/L: Workwear + gloves App: Workwear	0.02	10.1

Table 6.6-4: Estimated operator exposure (longer term exposure) – prothioconazole-desthio

Prothioconazole-desthio			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Option I: Cereals Outdoor Downward spraying Vehicle-mounted Dermal absorption of in-use dilution: 20%			
Application rate		0.177 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg <i>OPEX version: 30/03/2015</i>	Potential exposure	0.0071072	71.07
	Work wear (arms, body and legs covered) M/L and A	0.0047278	47.28
	Work wear (arms, body and legs covered) M/L and A + gloves	0.0008138	8.14
Spray application (AOEM; 95 th percentile) Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential exposure	0.007	71
	M/L: Workwear App: Workwear	0.004	47.2
	M/L: Workwear + gloves	0.004	47.2

	App: Workwear		
Option II: Cereals Outdoor Downward spraying Vehicle-mounted Dermal absorption of in-use dilution: 70%			
Application rate		0.177 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg OPEX version: 30/03/2015	Potential exposure	0.0244514	244.51
	Work wear (arms, body and legs covered) M/L and A	0.0161235	161.23
	Work wear (arms, body and legs covered) M/L and A + gloves	0.0024246	24.25
Spray application (AOEM; 95 th percentile) Body weight: 60 kg OPEX version: 1.0.1	Potential exposure	0.02	244
	M/L: Workwear App: Workwear	0.02	161
	M/L: Workwear + gloves App: Workwear + gloves	0.002	24.2
Option I: Oilseeds Outdoor Downward spraying Vehicle-mounted Dermal absorption of in-use dilution: 20%			
Application rate		0.163 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg OPEX version: 30/03/2015	Potential exposure	0.0065535	65.54
	Work wear (arms, body and legs covered) M/L and A	0.0043623	43.62
	Work wear (arms, body and legs covered) M/L and A + gloves	0.0007742	7.74
Spray application (AOEM; 95 th percentile) Body weight: 60 kg OPEX version: 1.0.1	Potential exposure	0.007	65.5
	M/L: Workwear App: Workwear	0.004	43.6
	M/L: Workwear + gloves App: Workwear	0.004	43.6
Option II: Oilseeds Outdoor Downward spraying Vehicle-mounted Dermal absorption of in-use dilution: 70%			
Application rate		0.163 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.0225259	225.26
	Work wear (arms, body and legs covered) M/L and A	0.0148567	148.57

OPEX version: 30/03/2015	Work wear (arms, body and legs covered) M/L and A + gloves	0.0022948	22.98
Spray application (AOEM; 95 th percentile) Body weight: 60 kg OPEX version: 1.0.1	Potential exposure	0.02	225
	M/L: Workwear App: Workwear	0.015	148
	M/L: Workwear + gloves App: Workwear + gloves	0.002	23

Conclusion

According to the model calculations, it can be concluded that the risk for the operator using Protiokonazol 300 EC on intended uses presented in GAP table is acceptable if operator is equipped with work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application.

ACCEPTED

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-6 shows the exposure models used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with Protiokonazol 300 EC according to the critical use. Outcome of the estimation is presented in Table 6.6-7 and Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

None AAOEL was allocated for prothioconazole and its metabolite, prothioconazole-desthio. Therefore, estimates of the acute exposure to workers has not been conducted.

According to EFSA Scientific Report (2007) 106, 1-98:

- the default DFR value is unrealistic even for the worst case scenario,
- the residue decline studies in DAR UK, 2004 (Section B7) are available (conducted in accordance with the supported GAP), their results suggest significantly lower DFR value.

Regarding above estimations (**Option II**) of worker exposure to metabolite prothioconazole-desthio were carried out using DFR value of $1\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$ and 70% dermal absorption value of in-use dilution.

Table 6.6-6: Exposure models for intended uses

Critical uses	Cereals (max. 0.65 L product/ha) Oilseeds (max. 0.6 L product/ha)
Model	EFSA model AOEM (Agricultural Operator Exposure Model [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015] EFSA model AOEM (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

Table 6.6-7: Estimated worker exposure (long term exposure) - prothioconazole

Prothioconazole			
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 $\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$ Interval between treatments: 14			
EFSA model AOEM			
Number of applications and application rate		2 x 0.195 kg a.s./ha	
Body weight: 60 kg OPEX version: 30/03/2015	Potential TC: 12500 cm ² /person/h	0.2940952	147.05
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0329387	16.47
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-

<p>Body weight: 60 kg</p> <p>OPEX version: 1.0.1</p>	<p>Potential</p> <p>TC: 12500 cm²/person/h</p>	0.3	147
	<p>Work wear (arms, body and legs covered)</p> <p>TC: 1400 cm²/person/h</p>	0.03	16.4
	<p>Work wear (arms, body and legs covered) and gloves</p> <p>TC: 1250 cm²/person/h</p>	0.03	14.7
<p>Oilseeds</p> <p>Outdoor</p> <p>Downward spraying</p> <p>Vehicle-mounted</p> <p>Inspection, irrigation</p> <p>Work rate: 2 hours/day</p> <p>DT₅₀: 30 days</p> <p>DFR: 3 µg/cm²/kg a.s./ha</p> <p>Interval between treatments: 21</p>			
EFSA model AOEM			
Number of applications and application rate		2 x 0.180 kg a.s./ha	
<p>Body weight: 60 kg</p> <p>OPEX version: 30/03/2015</p>	<p>Potential</p> <p>TC: 12500 cm²/person/h</p>	0.2544526	127.23
	<p>Work wear (arms, body and legs covered)</p> <p>TC: 1400 cm²/person/h</p>	0.0284987	14.25
	<p>Work wear (arms, body and legs covered) and gloves</p> <p>TC: not available</p>	-	-
<p>Body weight: 60 kg</p> <p>OPEX version: 1.0.1</p>	<p>Potential</p> <p>TC: 12500 cm²/person/h</p>	0.3	128
	<p>Work wear (arms, body and legs covered)</p> <p>TC: 1400 cm²/person/h</p>	0.03	14.3
	<p>Work wear (arms, body and legs covered) and gloves</p> <p>TC: 1250 cm²/person/h</p>	0.03	12.8

Table 6.6-7: Estimated worker exposure (long term exposure) - prothioconazole-desthio

Prothioconazole-desthio			
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<p>Option I:</p> <p>Cereals</p> <p>Outdoor</p> <p>Downward spraying</p> <p>Vehicle-mounted</p> <p>Inspection, irrigation</p> <p>Work rate: 2 hours/day</p> <p>DT₅₀: 30 days</p> <p>DFR: 3 µg/cm²/kg a.s./ha</p> <p>Interval between treatments: 14</p>			

Dermal absorption of in-use dilution: 20%			
EFSA model AOEM			
Number of applications and application rate		2 x 0.177 kg a.s./ha	
Body weight: 60 kg <i>OPEX version: 30/03/2015</i>	Potential TC: 12500 cm ² /person/h	0.0762708	762.71
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0085423	85.42
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential TC: 12500 cm ² /person/h	0.08	761
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.009	85.2
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.008	76.1
Option II: Cereals Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 14 Dermal absorption of in-use dilution: 70%			
EFSA model AOEM			
Number of applications and application rate		2 x 0.177 kg a.s./ha	
Body weight: 60 kg <i>OPEX version: 30/03/2015</i>	Potential TC: 12500 cm ² /person/h	0.0889826	889.83
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0099661	99.66
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential TC: 12500 cm ² /person/h	0.09	887
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.01	99.4
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.009	88.7
Option I: Oilseeds			

Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 21 Dermal absorption of in-use dilution: 20%			
EFSA model AOEM			
Number of applications and application rate		2 x 0.163 kg a.s./ha	
Body weight: 60 kg <i>OPEX version:</i> 30/03/2015	Potential TC: 12500 cm ² /person/h	0.0658346	658.35
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0073735	73.73
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential TC: 12500 cm ² /person/h	0.07	661
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.007	74.1
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.007	66.1
Option II: Oilseeds Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 21 Dermal absorption of in-use dilution: 70%			
EFSA model AOEM			
Number of applications and application rate		2 x 0.163 kg a.s./ha	
Body weight: 60 kg <i>OPEX version:</i> 30/03/2015	Potential TC: 12500 cm ² /person/h	0.0768070	768.07
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0086024	86.02
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential TC: 12500 cm ² /person/h	0.08	771
	Work wear (arms, body and	0.009	86.4

	legs covered) TC: 1400 cm ² /person/h		
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.008	77.1

Refinement calculations for prothioconazole-desthio - 45 % conversion

A 45 % conversion of prothioconazole to prothioconazole-desthio can be considered as tier 2 refinement. Such approach was agreed by experts at the TC for prothioconazole (September 2020).

Regarding above the total amount of prothioconazole to be applied, as described in the GAP:

- 0.195 kg would correspond to 0.177 kg for cereals of prothioconazole-desthio which would be transformed into 0.0796 kg for cereals of prothioconazole-desthio (45%). The refinement calculation is presented below.
- 0.180 kg would correspond to 0.163 kg for oilseeds of prothioconazole-desthio which would be transformed into 0.0735 kg for oilseeds of prothioconazole-desthio (45%). The refinement calculation is presented below.

Table 6.6-8: Estimated worker exposure (long term exposure) - prothioconazole-desthio

Prothioconazole-desthio			
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 14 Dermal absorption of in-use dilution: 70%			
EFSA model AOEM			
Number of applications and application rate		2 x 0.0796 kg a.s./ha	
Body weight: 60 kg <i>OPEX version:</i> <i>30/03/2015</i>	Potential TC: 12500 cm ² /person/h	0.0400171	400.17
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0044819	44.82
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential TC: 12500 cm ² /person/h	0.04	400
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.004	44.8

	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.004	40
Oilseeds Outdoor Downward spraying Vehicle-mounted Inspection, irrigation Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 21 Dermal absorption of in-use dilution: 70%			
EFSA model AOEM			
Number of applications and application rate		2 x 0.0735 kg a.s./ha	
Body weight: 60 kg <i>OPEX version: 30/03/2015</i>	Potential TC: 12500 cm ² /person/h	0.0346338	346.34
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0038790	38.79
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential TC: 12500 cm ² /person/h	0.03	347
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.004	38.9
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.003	34.7

Conclusion

The results of the exposure estimations show that the use of Protiokonazol 300 EC according to the list of intended uses presented in GAP Table, causes no health risk for the worker if the workwear (arms, body and legs covered) is used.

Taking into account hygienic rules, it is recommended that a worker inspecting treated area was dressed properly (long trousers, long-sleeve shirt) and equipped with protective gloves. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

ACCEPTED

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

According to EFSA Scientific Report (2007) 106, 1-98:

- the default DFR value is unrealistic even for the worst case scenario
- the residue decline studies in DAR UK, 2004 are available (conducted in accordance with the supported GAP), their results suggest significantly lower DFR value.

Regarding above estimations (*Option II*) of worker exposure to metabolite prothioconazole-desthio were carried out using DFR value of $1\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$ and 70% dermal absorption value of in-use dilution.

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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 6.6-8 shows the exposure model used for estimation of resident and bystander exposure to prothioconazole. The outcome of the estimation is presented in **Błąd! Nie można odnaleźć źródła odwołania.9**, **Błąd! Nie można odnaleźć źródła odwołania.10** and **Błąd! Nie można odnaleźć źródła odwołania.11** (longer term resident exposure). Detailed calculations are in Appendix 3.

None AAOEL was allocated for prothioconazole and its metabolite, prothioconazole-desthio. Therefore, estimates of the acute exposure to bystanders has not been conducted.

Table 6.6-8: Exposure models for intended uses

Critical use	Cereals (max. 0.65 L product/ha)
Model	EFSA model AOEM (Agricultural Operator Exposure Model [Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874; calculator version: 30/03/2015] EFSA model AOEM (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

Table 6.6-9: Estimated resident exposure (longer term exposure) - prothioconazole

Prothioconazole		
Model data	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: $3\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$ Interval between treatments: 14		

Number of applications and application rate		2 x 0.195 kg a.s./ha	
Resident child Body weight: 10 kg <i>OPEX version:</i> <i>30/03/2015</i>	Drift (75 th perc.)	0.0366440	18.32
	Vapour (75 th perc.)	0.0010700	0.54
	Deposits (75 th perc.)	0.0036985	1.85
	Re-entry (75 th perc.)	0.0397028	19.85
	Sum (mean)	0.0556148	27.81
Resident adult Body weight: 60 kg <i>OPEX version:</i> <i>30/03/2015</i>	Drift (75 th perc.)	0.0087711	4.39
	Vapour (75 th perc.)	0.0002300	0.12
	Deposits (75 th perc.)	0.0016030	0.80
	Re-entry (75 th perc.)	0.0220571	11.03
	Sum (mean)	0.0231569	11.58
Resident child Body weight: 10 kg <i>OPEX version: 1.0.1</i>	Drift (75 th perc.)	0.04	18.5
	Vapour (75 th perc.)	0.0008	0.4
	Deposits (75 th perc.)	0.004	1.8
	Re-entry (75 th perc.)	0.04	19.8
	Sum (mean)	0.06	27.6
Resident adult Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Drift (75 th perc.)	0.009	4.4
	Vapour (75 th perc.)	0.0003	0.1
	Deposits (75 th perc.)	0.002	0.8
	Re-entry (75 th perc.)	0.02	11
	Sum (mean)	0.02	11.5

Table 6.6-10: Estimated resident exposure (longer term exposure) - prothioconazole-desthio

Prothioconazole-desthio			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Option I: Cereals Outdoor Downward spraying Vehicle-mounted Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 14 Dermal absorption of in-use dilution: 20%			
Number of applications and application rate		2 x 0.177 kg a.s./ha	
Resident child Body weight: 10 kg <i>OPEX version:</i>	Drift (75 th perc.)	0.0095311	95.31
	Vapour (75 th perc.)	0.0010700	10.70
	Deposits (75 th perc.)	0.0011361	11.36

30/03/2015	Re-entry (75 th perc.)	0.0034322	34.32
	Sum (mean)	0.0098935	98.94
Resident adult Body weight: 60 kg OPEX version: 30/03/2015	Drift (75 th perc.)	0.0022768	22.77
	Vapour (75 th perc.)	0.0002300	2.30
	Deposits (75 th perc.)	0.0004157	4.16
	Re-entry (75 th perc.)	0.0019068	19.07
	Sum (mean)	0.0031371	31.37
Resident child Body weight: 10 kg OPEX version: 1.0.1	Drift (75 th perc.)	0.01	96
	Vapour (75 th perc.)	0.0008	8
	Deposits (75 th perc.)	0.001	11.3
	Re-entry (75 th perc.)	0.01	103
	Sum (mean)	0.02	151
Resident adult Body weight: 60 kg OPEX version: 1.0.1	Drift (75 th perc.)	0.002	22.8
	Vapour (75 th perc.)	0.0003	2.7
	Deposits (75 th perc.)	0.0004	4.1
	Re-entry (75 th perc.)	0.006	57
	Sum (mean)	0.006	61.9
Option II: Cereals Outdoor Downward spraying Vehicle-mounted Buffer zone: 10 (m) Drift reduction technology: yes DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 14 Dermal absorption of in-use dilution: 70%			
Number of applications and application rate		2 x 0.177 kg a.s./ha	
Resident child Body weight: 10 kg OPEX version: 30/03/2015	Drift (75 th perc.)	0.0091375	91.38
	Vapour (75 th perc.)	0.0010700	10.70
	Deposits (75 th perc.)	0.0003897	3.90
	Re-entry (75 th perc.)	0.0120127	120.13
	Sum (mean)	0.0160375	160.37
Resident adult Body weight: 60 kg OPEX version: 30/03/2015	Drift (75 th perc.)	0.0017272	12.27
	Vapour (75 th perc.)	0.0002300	2.30
	Deposits (75 th perc.)	0.0001689	1.69
	Re-entry (75 th perc.)	0.0066737	66.74
	Sum (mean)	0.0066111	66.11
Resident child Body weight: 10 kg OPEX version: 1.0.1	Drift (75 th perc.)	0.009	91.5
	Vapour (75 th perc.)	0.0008	8
	Deposits (75 th perc.)	0.0004	3.9

	Re-entry (75 th perc.)	0.01	120
	Sum (mean)	0.02	157
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.002	16.9
	Vapour (75 th perc.)	0.0003	2.7
OPEX version: 1.0.1	Deposits (75 th perc.)	0.0002	1.7
	Re-entry (75 th perc.)	0.007	66.5
	Sum (mean)	0.007	66.4

Since an unacceptable risk has been identified for a child resident (in **Option II**) even when risk mitigation measures have been considered (drift-reduction (50%) and 10 m buffer strip), below is proposed refined calculation that demonstrate an acceptable risk for resident, based on more realistic endpoints.

Refinement calculations for prothioconazole-desthio - 45 % conversion

A 45 % conversion of prothioconazole to prothioconazole-desthio can be considered as tier 2 refinement. Such approach was agreed by experts at the TC for prothioconazole (September 2020).

Regarding above the total amount of prothioconazole to be applied, 0.195 kg as described in the GAP, would correspond to 0.177 kg for cereals of prothioconazole-desthio which would be transformed into 0.0796 kg for cereals of prothioconazole-desthio (45%). The refinement calculation is presented below.

Table 6.6-11: Estimated resident exposure (longer term exposure) - prothioconazole-desthio (refinement calculation)

Prothioconazole-desthio			
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals Outdoor Downward spraying Vehicle-mounted Buffer zone: 5 (m) Drift reduction technology: yes DT ₅₀ : 30 days DFR: 1 µg/cm ² /kg a.s./ha Interval between treatments: 14 Dermal absorption of in-use dilution: 70%			
Number of applications and application rate		2 x 0.0796 kg a.s./ha	
Resident child Body weight: 10 kg OPEX version: 30/03/2015	Drift (75 th perc.)	0.0049756	49.76
	Vapour (75 th perc.)	0.0010700	10.70
	Deposits (75 th perc.)	0.0003100	3.10
	Re-entry (75 th perc.)	0.0054023	54.02
	Sum (mean)	0.0083671	83.67
Resident adult Body weight: 60 kg OPEX version: 30/03/2015	Drift (75 th perc.)	0.0009067	9.07
	Vapour (75 th perc.)	0.0002300	2.30
	Deposits (75 th perc.)	0.0001344	1.34
	Re-entry (75 th perc.)	0.0030013	30.01
	Sum (mean)	0.0031962	31.96
Resident child	Drift (75 th perc.)	0.005	50.4

Body weight: 10 kg OPEX version: 1.0.1	Vapour (75 th perc.)	0.0008	8
	Deposits (75 th perc.)	0.0003	3.1
	Re-entry (75 th perc.)	0.005	54
	Sum (mean)	0.008	81
Resident adult Body weight: 60 kg OPEX version: 1.0.1	Drift (75 th perc.)	0.0009	9.2
	Vapour (75 th perc.)	0.0003	2.7
	Deposits (75 th perc.)	0.0001	1.3
	Re-entry (75 th perc.)	0.003	30
	Sum (mean)	0.003	32.3

Conclusion

The reference value acutely toxic active substance (RVAAS, AAOEL) for prothioconazole and its metabolite, prothioconazole-desthio is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

Regarding above calculations and bystander and resident safety, additional risk mitigation measures should be applied as below:

During spraying, a buffer zone of at least 5 m away from residential buildings/habitats and bystanders with 50% drift reduction should be used.

ACCEPTED

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

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

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

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

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not relevant.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Protiokonazol 300 EC does not contain co-formulants classified for acute oral toxicity and does not need to be classified in this category
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No studies submitted with this application. Classification based on composition of the product. According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details, please refer to Part C.

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

Comments of zRMS:	Protiokonazol 300 EC does not contain co-formulants classified for acute dermal toxicity and does not need to be classified in this category
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No studies submitted with this application. Classification based on composition of the product. According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details, please refer to Part C.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	ATE mix = 129 for acute inhalation toxicity, which is above 5.0, therefore product Protiokonazol 300 EC should not be classify in this category.
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No studies submitted with this application. Classification based on composition of the product. According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details, please refer to Part C.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	$\Sigma\%$ Skin irritation (Category 2) is above 29%, which is above 10%, therefore Protiokonazol 300 EC should be classified as Skin Irrit. 2, H315 - Causes skin irritation.
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No studies submitted with this application. Classification based on composition of the product. According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details, please refer to Part C.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	$\Sigma\%$ Skin corrosion Sub-Category 1A, 1B, 1C or Category 1 + Serious eye damage (Category 1) is above 29%, which is above 3%, therefore Protiokonazol 300 EC should be classified as Eye Dam. 1, H318 - Causes serious eye damage.
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No studies submitted with this application. Classification based on composition of the product. According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details, please refer to Part C.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	According to the Regulation EC No. 1272/2008, HERA is not classified. No signal word or hazard statement is required for this hazard.
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of Protiokonazol 300 EC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

For more details, please refer to Part C.

Specific target organ toxicity – single exposure (STOT SE)

$\Sigma\%$ Category 3, Respiratory Tract Irritation is above 20%, therefore Protiokonazol 300 EC should be classified as STOT SE 3, H335 - May cause respiratory irritation.

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

Not relevant. No new/additional supplementary studies were submitted.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission.

sion (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

No studies submitted with this application.

A 2.11 Other/Special Studies

No studies submitted with this application.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for prothioconazole

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

Formulation type	EC		Crop type	Cereals
Application rate (AR)	0.195	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.2	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

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

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance		0,195 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied		9,75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product		25,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution		70,00%	<i>i_AbsorInuse</i>
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application		Outdoor	
Application method		Downward spraying	
Application equipment		Vehicle-mounted	
Season		not relevant	
Mixing and loading	Exposure values	µg exposure/day mixed and loaded	
		75 th centile	95 th centile
	Hands	28037	104815
	Body	17682	139575
	Head	506	2774
	Protected hands (gloves)	152	1931
	Protected body (workwear or protective garment and sturdy footwear)	179	1426
	Protected head (hood and face shield)	8	157
	Inhalation	7	30
	Protective Equipment	Select for inclusion	
	Gloves	No	
	Clothing	Work wear - arms, body and legs covered	
	Head and respiratory PPE	None	
	Water soluble bag	No	
Application	Exposure values	µg exposure/day applied	
		75 th centile	95 th centile
	Hands	1446	12148
	Body	809	4168
	Head	38	115
	Protected hands (gloves)	146	4347
	Protected body (workwear or protective garment and sturdy footwear)	22	54
	Inhalation	3	11
	Protective Equipment	Select for inclusion	
	Gloves	No	
	Clothing	Work wear - arms, body and legs covered	
	Head and respiratory PPE	None	
	Closed cab	No	
		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	13,1717191	8,2454596	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2195287	0,1374243	
% of RVNAS	109,76%	68,71%	

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance		0,195 kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied		9,75 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product		25,00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution		70,00%	<i>i_AbsorInuse</i>		
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
		OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted			
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28037	104815	AOEM	
	Body	17682	139575	AOEM	
	Head	506	2774	AOEM	
	Protected hands (gloves)	152	1931	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	179	1426	AOEM	
	Protected head (hood and face shield)	8	157	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1446	12148	AOEM	
	Body	809	4168	AOEM	
	Head	38	115	AOEM	
	Protected hands (gloves)	146	4347	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	22	54	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	13,1717191	0,3640615	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2195287	0,0060677	
% of RVNAS	109,76%	3,03%	

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

Formulation type	EC		Crop type	Oilseeds
Application rate (AR)	0.180	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.2	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

Table A 4: Estimation of longer term operator exposure towards prothioconazole according to EFSA guidance

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Operator: Exposure for Vehicle-mounted, 500 kg outdoor spray applications					
Application rate of active substance		0,18 kg a.s./ha		i_AppRate	
Assumed area treated		50 ha/day		d_AreaTreated	
Amount of active substance applied		9 kg a.s./day		i_AmountAS	
Dermal absorption of the product		25,00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		70,00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	26361	98482	AOEM	
	Body	16715	136367	AOEM	
	Head	467	2561	AOEM	
	Protected hands (gloves)	144	1783	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	167	1316	AOEM	
	Protected head (hood and face shield)	7	145	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1335	11457	AOEM	
	Body	746	3848	AOEM	
	Head	35	106	AOEM	
	Protected hands (gloves)	140	4306	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	50	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	
	1. Total				
		Without RPE/PPE		With RPE/PPE	
Longer term					
Total systemic exposure from mixing, loading and application (mg a.s./day)		12,3775142		7,7323859	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)		0,2062919		0,1288731	
% of RVNAS		103,15%		64,44%	

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance	0,18 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	9 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	25,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70,00%	<i>i_AbsorpInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	26361	98482	AOEM	
	Body	16715	136367	AOEM	
	Head	467	2561	AOEM	
	Protected hands (gloves)	144	1783	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	167	1316	AOEM	
	Protected head (hood and face shield)	7	145	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1335	11457	AOEM	
	Body	746	3848	AOEM	
	Head	35	106	AOEM	
	Protected hands (gloves)	140	4306	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	50	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	12,3775142	0,3414496	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,2062919	0,0056908	
% of RVNAS	103,15%	2,85%	

A 3.1.2 Calculations for prothioconazole-desthio

Option I

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

Formulation type	EC		Crop type	Cereals
Application rate (AR)	0.177	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0	% (concentr.)	Indoor/outdoor	Outdoor
	20	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.01	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

Table A 6: Estimation of longer term operator exposure towards prothioconazole according to EFSA guidance

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Operator exposure for: Atrazine: 0.00					
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1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,4264315	0,2836673	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0071072	0,0047278	
% of RVNAS	71,07%	47,28%	

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance	0,177 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	8,85 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	0,00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	20,00%	<i>i_AbsorpInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	26022	97201	AOEM	
	Body	16518	135703	AOEM	
	Head	459	2518	AOEM	
	Protected hands (gloves)	142	1753	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	164	1294	AOEM	
	Protected head (hood and face shield)	7	143	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1313	11316	AOEM	
	Body	734	3784	AOEM	
	Head	35	105	AOEM	
	Protected hands (gloves)	138	4298	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	49	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,4264315	0,0488290	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0071072	0,0008138	
% of RVNAS	71,07%	8,14%	

Table A 7: Input parameters considered for the estimation of operator exposure

Formulation type	EC		Crop type	Oilseeds
Application rate (AR)	0.163	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0	% (concentr.)	Indoor/outdoor	Outdoor
	20	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.01	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

Table A 8: Estimation of longer term operator exposure towards prothioconazole according to EFSA guidance

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance 0,163 kg a.s./ha <i>i_AppRate</i> Assumed area treated 50 ha/day <i>d_AreaTreated</i> Amount of active substance applied 8,15 kg a.s./day <i>i_AmountAS</i> Dermal absorption of the product 0,00% <i>i_AbsorpProduct</i> Dermal absorption of in-use dilution 20,00% <i>i_AbsorInuse</i> Formulation type Soluble concentrates, emulsifiable concentrate, etc. Indoor or Outdoor application Outdoor Application method Downward spraying Application equipment Vehicle-mounted Season not relevant					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	24423	91161	AOEM	
	Body	15589	132493	AOEM	
	Head	423	2319	AOEM	
	Protected hands (gloves)	135	1614	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	153	1192	AOEM	
	Protected head (hood and face shield)	7	131	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1209	10654	AOEM	
	Body	676	3484	AOEM	
	Head	32	96	AOEM	
	Protected hands (gloves)	132	4257	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	19	45	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,3932104	0,2617384	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0065535	0,0043623	
% of RVNAS	65,54%	43,62%	

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance	0,163 kg a.s./ha	i_AppRate			
Assumed area treated	50 ha/day	d_AreaTreated			
Amount of active substance applied	8,15 kg a.s./day	i_AmountAS			
Dermal absorption of the product	0,00%	i_AbsorpProduct			
Dermal absorption of in-use dilution	20,00%	i_AbsorInuse			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	24423	91161	AOEM	
	Body	15589	132493	AOEM	
	Head	423	2319	AOEM	
	Protected hands (gloves)	135	1614	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	153	1192	AOEM	
	Protected head (hood and face shield)	7	131	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application					
	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1209	10654	AOEM	
	Body	676	3484	AOEM	
	Head	32	96	AOEM	
	Protected hands (gloves)	132	4257	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	19	45	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,3932104	0,0464534	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0065535	0,0007742	
% of RVNAS	65,54%	7,74%	

Option II

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

Formulation type	EC		Crop type	Cereals
Application rate (AR)	0.177	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.01	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

Table A 10: Estimation of longer term operator exposure towards prothioconazole according to EFSA guidance

Operator exposure for Protiokonazol 300 EC outdoor spray applications				
Application rate of active substance	0,177 kg a.s./ha	<i>i_AppRate</i>		
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>		
Amount of active substance applied	8,85 kg a.s./day	<i>i_AmountAS</i>		
Dermal absorption of the product	0,00%	<i>i_AbsorpProduct</i>		
Dermal absorption of in-use dilution	70,00%	<i>i_AbsorInuse</i>		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Season	not relevant			
	OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted			
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference
		75 th centile	95 th centile	Comment
	Hands	26022	97201	AOEM
	Body	16518	135703	AOEM
	Head	459	2518	AOEM
	Protected hands (gloves)	142	1753	AOEM
	Protected body (workwear or protective garment and sturdy footwear)	164	1294	AOEM
	Protected head (hood and face shield)	7	143	AOEM
	Inhalation	7	30	AOEM
	Protective Equipment	Select for inclusion		Penetration factor
	Gloves	No		Inhalation Protection factor
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model
	Head and respiratory PPE	None		1
	Water soluble bag	No		1
Application	Exposure values	µg exposure/day applied		Reference
		75 th centile	95 th centile	Comment
	Hands	1313	11316	AOEM
	Body	734	3784	AOEM
	Head	35	105	AOEM
	Protected hands (gloves)	138	4298	AOEM
	Protected body (workwear or protective garment and sturdy footwear)	20	49	AOEM
	Inhalation	3	10	AOEM
	Protective Equipment	Select for inclusion		Penetration factor
	Gloves	No		Inhalation Protection factor
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model
	Head and respiratory PPE	None		1
	Closed cab	No		vehicle mounted upward spraying only

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,4670841	0,9674097	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0244514	0,0161235	
% of RVNAS	244,51%	161,23%	

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance	0,177 kg a.s./ha	i_AppRate			
Assumed area treated	50 ha/day	d_AreaTreated			
Amount of active substance applied	8,85 kg a.s./day	i_AmountAS			
Dermal absorption of the product	0,00%	i_AbsorpProduct			
Dermal absorption of in-use dilution	70,00%	i_AbsorpInuse			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	26022	97201	AOEM	
	Body	16518	135703	AOEM	
	Head	459	2518	AOEM	
	Protected hands (gloves)	142	1753	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	164	1294	AOEM	
	Protected head (hood and face shield)	7	143	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1313	11316	AOEM	
	Body	734	3784	AOEM	
	Head	35	105	AOEM	
	Protected hands (gloves)	138	4298	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	49	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,4670841	0,1454755	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0244514	0,0024246	
% of RVNAS	244,51%	24,25%	

Table A 11: Input parameters considered for the estimation of operator exposure

Formulation type	EC		Crop type	Oilseeds
Application rate (AR)	0.163	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.01	mg/kg bw/d	Water soluble bag	No
AAOEL	-	mg/kg bw/d	-	-

Table A 12: Estimation of longer term operator exposure towards prothioconazole according to EFSA guidance

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Operator: Exposure for: Vehicle-mounted, 500 kg outdoor spray applications					
Application rate of active substance		0,163 kg a.s./ha		i_AppRate	
Assumed area treated		50 ha/day		d_AreaTreated	
Amount of active substance applied		8,15 kg a.s./day		i_AmountAS	
Dermal absorption of the product		0,00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		70,00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	24423	91161	AOEM	
	Body	15589	132493	AOEM	
	Head	423	2319	AOEM	
	Protected hands (gloves)	135	1614	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	153	1192	AOEM	
	Protected head (hood and face shield)	7	131	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1209	10654	AOEM	
	Body	676	3484	AOEM	
	Head	32	96	AOEM	
	Protected hands (gloves)	132	4257	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	19	45	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	
	1. Total				
		Without RPE/PPE		With RPE/PPE	
Longer term					
Total systemic exposure from mixing, loading and application (mg a.s./day)		1,3515515		0,8913994	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)		0,0225259		0,0148567	
% of RVNAS		225,26%		148,57%	

Operator exposure for Protiokonazol 300 EC outdoor spray applications

Application rate of active substance	0,163 kg a.s./ha	i_AppRate		
Assumed area treated	50 ha/day	d_AreaTreated		
Amount of active substance applied	8,15 kg a.s./day	i_AmountAS		
Dermal absorption of the product	0,00%	i_AbsorpProduct		
Dermal absorption of in-use dilution	70,00%	i_AbsorpInuse		
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Season	not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted				
Mixing and loading	Exposure values	µg exposure/day mixed and loaded	Reference	Comment
		75 th centile95 th centile		
	Hands	2442391161	AOEM	
	Body	15589132493	AOEM	
	Head	4232319	AOEM	
	Protected hands (gloves)	1351614	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1531192	AOEM	
	Protected head (hood and face shield)	7131	AOEM	
	Inhalation	730	AOEM	
	Protective Equipment	Select for inclusion	Penetration factor	Inhalation Protection factor
	Gloves	Yes	Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered	Incl. in AOEM model	
Head and respiratory PPE	None	1	1	
Water soluble bag	No	1		
Application	Exposure values	µg exposure/day applied	Reference	Comment
		75 th centile95 th centile		
	Hands	120910654	AOEM	
	Body	6763484	AOEM	
	Head	3296	AOEM	
	Protected hands (gloves)	1324257	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1945	AOEM	
	Inhalation	310	AOEM	
	Protective Equipment	Select for inclusion	Penetration factor	
	Gloves	Yes	Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered	Incl. in AOEM model	
	Head and respiratory PPE	None	1	1
	Closed cab	No	vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,3515515	0,1379021	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0225259	0,0022984	
% of RVNAS	225,26%	22,98%	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for prothioconazole

Table A 13: Input parameters considered for the estimation of worker exposure

Intended use	cereals, inspection/irrigation, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.195 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	NR days	Work rate per day (WR)	2	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR	TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.2 mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	- mg/kg bw/d	-	-	-

Table A 14: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,195 kg a.s./ha			<i>i_AppRate</i>
Number of applications	2			<i>i_AppNo</i>
Interval between multiple applications	14 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1,7			<i>d_MAF</i>
Dermal absorption of the product	25,00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	70,00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,585 µg a.s./cm ²			<i>d_DFR</i>
Working hours	2 hr			<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr			<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr			<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}			<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	17,6457094	1,9763195	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2940952	0,0329387		
% of RVNAS	147,05%	16,47%		

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

Intended use	oilseeds, inspection/irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.180	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	NR	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d	-	-	-

Table A 16: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,18	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	21	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1,6			d_MAF
Dermal absorption of the product	25,00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	70,00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,54	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm ² /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	15,2671574	1,7099216	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2544526	0,0284987		
% of RVNAS	127,23%	14,25%		

A 3.2.2 Calculations for prothioconazole-desthio

Option I

Table A 17: Input parameters considered for the estimation of worker exposure

Intended use	cereals, inspection/irrigation, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.177 kg a.s./ha	Dermal absorption (DA)	20	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	NR days	Work rate per day (WR)	2	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR	TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.01 mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	- mg/kg bw/d	-	-	-

Table A 18: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,177	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1,7			d_MAF
Dermal absorption of the product	0,00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	20,00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,531	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4,5762499	0,5125400	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0762708	0,0085423		
% of RVNAS	762.71%	85.42%		

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

Intended use	oilseeds, inspection/irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.163	kg a.s./ha	Dermal absorption (DA)	20	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	NR	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.01	mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d	-	-	-

Table A 20: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,163	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	21	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1,6			d_MAF
Dermal absorption of the product	0,00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	20,00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,489	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm ² /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	3,9500740	0,4424083	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0658346	0,0073735		
% of RVNAS	658,35%	73,73%		

Option II

Table A 21: Input parameters considered for the estimation of worker exposure

Intended use	cereals, inspection/irrigation, outdoor	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s./ha
Application rate (AR)	0.177 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	NR days	Work rate per day (WR)	2	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR	TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.01 mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	- mg/kg bw/d	-	-	-

Table A 22: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,177 kg a.s./ha		i_AppRate	
Number of applications	2		i_AppNo	
Interval between multiple applications	14 days		i_AppInt	
Half-life of active substance	30 days		d_HalfLifeAS	
Multiple application factor	1,7		d_MAF	
Dermal absorption of the product	0,00%		i_AbsorpProduct	
Dermal absorption of the in-use dilution	70,00%		i_Absorplnuse	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,177 µg a.s./cm ²		d_DFR	
Working hours	2 hr		d_WorkHr	
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr		d_DermTcUCV	
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr		d_DermTcCV1	
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm ² /hr		d_DermTcCV2	
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}		d_InhalTcAut	
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}		d_InhalTcCut	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}		d_InhalTcSort	
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	5,3389582	0,5979633	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0889826	0,0099661		
% of RVNAS	889,83%	99,66%		

Table A 23: Input parameters considered for the estimation of worker exposure

Intended use	oilseeds, inspection/irrigation, outdoor		Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s./ha
Application rate (AR)	0.163	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	NR	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.01	mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d	-	-	-

Table A 24: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,163	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	21	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1,6			d_MAF
Dermal absorption of the product	0,00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	70,00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,163	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm ² /hr	d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4,6084197	0,5161430	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0768070	0,0086024		
% of RVNAS	768,07%	86,02%		

Refinement calculations for prothioconazole-desthio - 45 % conversion

Table A 25: Input parameters considered for the estimation of worker exposure

Intended use	cereals, inspection/irrigation, outdoor	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0796 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	NR days	Work rate per day (WR)	2	h/d
Half-life of active substance	30 days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR	TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.01 mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	- mg/kg bw/d	-	-	-

Table A 26: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,0796	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1,7			d_MAF
Dermal absorption of the product	0,00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	70,00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0796	µg a.s./cm²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm²/hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm²/hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm²/hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	2,4010230	0,2689146	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0400171	0,0044819		
% of RVNAS	400,17%	44,82%		
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	2,4010230	0,0400171	d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorplnuse	
Dermal - Work wear - arms, body and legs covered	0,2689146	0,0044819	d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Dermal - Working wear and gloves	no TC available for this assessment		d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Inhalation				Na for outdoor activities

Table A 27: Input parameters considered for the estimation of worker exposure

Intended use	oilseeds, inspection/irrigation, outdoor		Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0735	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	NR	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	NR		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	NR	cm ² /h
AOEL	0.01	mg/kg bw/d	Task specific factor inhalation	NR	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d	-	-	-

Table A 28: Estimation of acute worker exposure towards active substance according to EFSA guidance

Worker exposure from residues on foliage for Protiokonazol 300 EC				
Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0,0735	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	21	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1,6			d_MAF
Dermal absorption of the product	0,00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	70,00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0735	µg a.s./cm²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm²/hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm²/hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm²/hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	2,0780298	0,2327393	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0346338	0,0038790		
% of RVNAS	346,34%	38,79%		
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	2,0780298	0,0346338	d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_Absorplnuse	
Dermal - Work wear - arms, body and legs covered	0,2327393	0,0038790	d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Dermal - Working wear and gloves	no TC available for this assessment		d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorplnuse	
Inhalation				Na for outdoor activities

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for prothioconazole

Table A 29: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Protiokonazol 300 EC			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		<i>i_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		<i>i_FormVal</i>
Buffer strip	2-3 m		<i>i_Buffer</i>
Application rate of the product	0,195 kg a.s./ha		<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	1,95 g a.s./l		<i>d_ConcAS</i>
Dermal absorption of product	25,00%		<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	70,00%		<i>i_Absorpinuse</i>
Oral absorption	100,00%		<i>i_AbsorpOrallnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0,585 µg a.s./cm ²		<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa		<i>i_Volat</i>
Concentration in air	0,001 mg/m ³		<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0,47 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person		
Exposure duration dermal	2 hours		<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours		<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0,25 hours		<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18,0%		<i>d_ClothAF</i>
Breathing rate adult	0,23 m ³ /day/kg		<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg		<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm ² /hour		<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour		<i>d_ReTCCh</i>
Saliva extraction percentage	50,00%		<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²		<i>d_AreaHM</i>
Frequency of hand to mouth activity	9,5 events/hour		<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm ²		<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20,00%		<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h		<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h		<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h		<i>d_TcEntryCh</i>

Table A 30: Estimation of longer term resident exposure towards prothioconazole according to EFSA guidance

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,3664401	0,0107000	0,0369854	0,3970285	0,5561481
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0366440	0,0010700	0,0036985	0,0397028	0,0556148
% of RVNAS	18,32%	0,54%	1,85%	19,85%	27,81%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,5262660	0,0138000	0,0961809	1,3234282	1,3894124
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0087711	0,0002300	0,0016030	0,0220571	0,0231569
% of RVNAS	4,39%	0,12%	0,80%	11,03%	11,58%

2. Resident exposure 75th Percentile				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,3664401	0,0366440	$((C16 * i_Absorplnuse * (1 - d_ClothAF)) + C18) * d_ConcAS$	
Vapour	0,0107000	0,0010700	$d_AirCon * d_BreathRCh * d_BwChild$	
Surface deposits				
Dermal	0,0342562	0,0034256	$(i_AppRate/100) * C29 * d_Turf * d_ReTCCh * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorplnuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1))$	
Hand to mouth	0,0017881	0,0001788	$(i_AppRate/100) * C29 * d_Turf * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse * d_MAF$	
Object to mouth	0,0009411	0,0000941	$(i_AppRate/100) * C29 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	
Entry into treated crops				
Dermal	0,3970285	0,0397028	$(d_TcEntryCh * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	
Hand to mouth			$(i_AppRate/100) * d_Turf * d_MAF * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_AppRate/100) * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,5262660	0,0087711	$((C15 * i_Absorplnuse * (1 - d_ClothAF)) + C17) * d_ConcAS$	
Vapour	0,0138000	0,0002300	$d_AirCon * d_BreathRAD * d_BwAdult$	
Surface deposits (dermal)	0,0961809	0,0016030	$(i_AppRate/100) * C30 * d_Turf * d_ReTCAd * d_ReExpDur * i_Absorplnuse$	
Entry into treated crops (dermal)	1,3234282	0,0220571	$(d_TcEntryAd * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	
3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,2018055	0,0201806	$((C20 * i_Absorplnuse * (1 - d_ClothAF)) + C22) * d_ConcAS$	
Vapour	0,0107000	0,0010700	$d_AirCon * d_BreathRCh * d_BwChild$	
Surface deposits				
Dermal	0,0250804	0,0025080	$(i_AppRate/100) * C30 * d_Turf * d_ReTCCh * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorplnuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1))$	
Hand to mouth	0,0013091	0,0001309	$(i_AppRate/100) * C30 * d_Turf * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse * d_MAF$	
Object to mouth	0,0006890	0,0000689	$(i_AppRate/100) * C30 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	
Entry into treated crops				
Dermal	0,3165640	0,0316564	$(d_TcEntryMeanCh * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	
Hand to mouth			$(i_AppRate/100) * i * d_Turf * d_MAF * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_AppRate/100) * i * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,2499809	0,0041663	$((C19 * i_Absorplnuse * (1 - d_ClothAF)) + C21) * d_ConcAS$	
Vapour	0,0138000	0,0002300	$d_AirCon * d_BreathRAD * d_BwAdult$	
Surface deposits (dermal)	0,0704181	0,0011736	$(i_AppRate/100) * C30 * d_Turf * d_ReTCAd * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorplnuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1))$	
Entry into treated crops (dermal)	1,0552134	0,0175869	$(d_TcEntryMeanAd * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	

A 3.3.2 Calculations for prothioconazole-desthio

Option I

Table A 31: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Protiokonazol 300 EC			
Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		i_FormVal
Buffer strip	2-3 m		i_Buffer
Application rate of the product	0,177 kg a.s./ha		i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	1,77 g a.s./l		d_ConcAS
Dermal absorption of product	0,00%		i_AbsorpProduct
Dermal absorption of in-use dilution	20,00%		i_AbsorpInuse
Oral absorption	100,00%		i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,177 µg a.s./cm ²		d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	Pa	i_Volat
Concentration in air	0,001 mg/m ³		d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,47 ml spray dilution/person		
Resident dermal spray drift exposure 75th percentile - child	0,327 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - adult	0,00010 ml spray dilution/person		
Resident inhal. spray drift exposure 75th percentile - child	0,00022 ml spray dilution/person		
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person		
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person		
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person		
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person		
Exposure duration dermal	2 hours		d_ReExpDur
Exposure duration inhalation	24 hours		d_ReExpDurlnhal
Exposure duration entry into treated crops	0,25 hours		d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%		d_ClothAF
Breathing rate adult	0,23 m ³ /day/kg		d_BreathRAD
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg		d_BreathRCh
Drift percentage on surface (75th percentile)	5,60%		
Drift percentage on surface (mean)	4,10%		
Turf transferable residues percentage	5,00%		d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour		d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour		d_ReTCCh
Saliva extraction percentage	50,00%		d_SalExt
Surface area of hands mouthed	20 cm ²		d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour		d_RefreqHM
Ingestion rate for mouthing of grass per day	25 cm ²		d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h		d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h		d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h		d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h		d_TcEntryCh

Table A 32: Estimation of longer term resident exposure towards prothioconazole according to EFSA guidance

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0953110	0,0107000	0,0113613	0,0343219	0,0989354
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0095311	0,0010700	0,0011361	0,0034322	0,0098935
% of RVNAS	95,31%	10,70%	11,36%	34,32%	98,94%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1366086	0,0138000	0,0249436	0,1144062	0,1882262
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0022768	0,0002300	0,0004157	0,0019068	0,0031371
% of RVNAS	22,77%	2,30%	4,16%	19,07%	31,37%

2. Resident exposure 75th Percentile				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0953110	0,0095311	$((C16 * i_Absorpinuse * (1 - d_ClothAF)) + C18) * d_ConcAS$	
Vapour	0,0107000	0,0010700	$d_AirCon * d_BreathRCh * d_BwChild$	
Surface deposits				
Dermal	0,0088840	0,0008884	$(i_AppRate/100) * C29 * d_Turf * d_ReTCCh * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorpinuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	
Hand to mouth	0,0016230	0,0001623	$(i_AppRate/100) * C29 * d_Turf * d_SalExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse * d_MAF$	
Object to mouth	0,0008542	0,0000854	$(i_AppRate/100) * C29 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	
Entry into treated crops				
Dermal	0,0343219	0,0034322	$(d_TcEntryCh * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorpinuse)$	
Hand to mouth			$(i_AppRate/100) * d_Turf * d_MAF * d_SalExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_AppRate/100) * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,1366086	0,0022768	$(C15 * i_Absorpinuse * (1 - d_ClothAF)) + C17) * d_ConcAS$	
Vapour	0,0138000	0,0002300	$d_AirCon * d_BreathRAD * d_BwAdult$	
Surface deposits (dermal)	0,0249436	0,0004157	$(i_AppRate/100) * C30 * d_Turf * d_ReTCAd * d_ReExpDur * i_Absorpinuse$	
Entry into treated crops (dermal)	0,1144062	0,0019068	$(d_TcEntryAd * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorpinuse)$	
3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0525513	0,0052551	$((C20 * i_Absorpinuse * (1 - d_ClothAF)) + C22) * d_ConcAS$	
Vapour	0,0107000	0,0010700	$d_AirCon * d_BreathRCh * d_BwChild$	
Surface deposits				
Dermal	0,0065044	0,0006504	$(i_AppRate/100) * C30 * d_Turf * d_ReTCCh * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorpinuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	
Hand to mouth	0,0011883	0,0001188	$(i_AppRate/100) * C30 * d_Turf * d_SalExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse * d_MAF$	
Object to mouth	0,0006254	0,0000625	$(i_AppRate/100) * C30 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	
Entry into treated crops				
Dermal	0,0273660	0,0027366	$(d_TcEntryMeanCh * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorpinuse)$	
Hand to mouth			$(i_AppRate/100) * i_1 * d_Turf * d_MAF * d_SalExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_AppRate/100) * i_1 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0649440	0,0010824	$((C19 * i_Absorpinuse * (1 - d_ClothAF)) + C21) * d_ConcAS$	
Vapour	0,0138000	0,0002300	$d_AirCon * d_BreathRAD * d_BwAdult$	
Surface deposits (dermal)	0,0182623	0,0003044	$(i_AppRate/100) * C30 * d_Turf * d_ReTCAd * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorpinuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	
Entry into treated crops (dermal)	0,0912199	0,0015203	$(d_TcEntryMeanAd * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorpinuse)$	

Option II

Table A 33: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Protiokonazol 300 EC		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	i_FormVal
Buffer strip	10 m	i_Buffer
Application rate of the product	0,177 kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	1,77 g a.s./l	d_ConcAS
Dermal absorption of product	0,00%	i_AbsorpProduct
Dermal absorption of in-use dilution	70,00%	i_Absorpinuse
Oral absorption	100,00%	i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,177 µg a.s./cm ²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa Pa	i_Volat
Concentration in air	0,001 mg/m ³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,20385 ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,17965 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00013 ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,10973 ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,1 ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00007 ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00011 ml spray dilution/person	
Exposure duration dermal	2 hours	d_ReExpDur
Exposure duration inhalation	24 hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25 hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%	d_ClothAF
Breathing rate adult	0,23 m ³ /day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	1,30%	
Drift percentage on surface (mean)	1,00%	
Turf transferable residues percentage	5,00%	d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour	d_ReTCCh
Saliva extraction percentage	50,00%	d_SalExt
Surface area of hands mouthed	20 cm ²	d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm ²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%	d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h	d_TcEntryCh

Table A 34: Estimation of longer term resident exposure towards prothioconazole according to EFSA guidance

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0913755	0,0107000	0,0038967	0,1201266	0,1603747
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0091375	0,0010700	0,0003897	0,0120127	0,0160375
% of RVNAS	91,38%	10,70%	3,90%	120,13%	160,37%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1036334	0,0138000	0,0101333	0,4004219	0,3966683
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0017272	0,0002300	0,0001689	0,0066737	0,0066111
% of RVNAS	17,27%	2,30%	1,69%	66,74%	66,11%

2. Resident exposure 75th Percentile				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0913755	0,0091375	$((C16 * i_{AbsorpInuse} * (1 - d_{ClothAF})) + C18) * d_{ConcAS}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0107000	0,0010700	$d_{AirCon} * d_{BreathRCh} * d_{BwChild}$	
Surface deposits				
Dermal	0,0036091	0,0003609	$(i_{AppRate}/100) * C29 * d_{Turf} * d_{ReTCCh} * d_{ReExpDur} * MAX(i_{AbsorpProduct}, i_{AbsorpInuse}) * d_{MAF} * IF(i_{AppEquip} = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Hand to mouth	0,0001884	0,0000188	$(i_{AppRate}/100) * C29 * d_{Turf} * d_{SalExt} * d_{AreaHM} * d_{ReFreqHM} * d_{ReExpDur} * i_{AbsorpOrallInuse} * d_{MAF}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Object to mouth	0,0000992	0,0000099	$(i_{AppRate}/100) * C29 * d_{DRP} * d_{MouthGrass} * i_{AbsorpOrallInuse} * d_{MAF}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops				
Dermal	0,1201266	0,0120127	$(d_{TcEntryCh} * 0.25 * d_{DFR} * d_{MAF}) / 1000 * MAX(i_{AbsorpProduct}, i_{AbsorpInuse})$	
Hand to mouth			$(i_{AppRate}/100) * d_{Turf} * d_{MAF} * d_{SalExt} * d_{AreaHM} * d_{ReFreqHM} * d_{ReExpDur} * i_{AbsorpOrallInuse}$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_{AppRate}/100) * d_{DRP} * d_{MouthGrass} * i_{AbsorpOrallInuse} * d_{MAF}$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,1036334	0,0017272	$(C15 * i_{AbsorpInuse} * (1 - d_{ClothAF})) + C17) * d_{ConcAS}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0138000	0,0002300	$d_{AirCon} * d_{BreathRAD} * d_{BwAdult}$	
Surface deposits (dermal)	0,0101333	0,0001689	$(i_{AppRate}/100) * C30 * d_{Turf} * d_{ReTCAd} * d_{ReExpDur} * i_{AbsorpInuse}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops (dermal)	0,4004219	0,0066737	$(d_{TcEntryAd} * 0.25 * d_{DFR} * d_{MAF}) / 1000 * MAX(i_{AbsorpProduct}, i_{AbsorpInuse})$	
3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0508964	0,0050896	$((C20 * i_{AbsorpInuse} * (1 - d_{ClothAF})) + C22) * d_{ConcAS}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0107000	0,0010700	$d_{AirCon} * d_{BreathRCh} * d_{BwChild}$	
Surface deposits				
Dermal	0,0027763	0,0002776	$(i_{AppRate}/100) * C30 * d_{Turf} * d_{ReTCCh} * d_{ReExpDur} * MAX(i_{AbsorpProduct}, i_{AbsorpInuse}) * d_{MAF} * IF(i_{AppEquip} = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Hand to mouth	0,0001449	0,0000145	$(i_{AppRate}/100) * C30 * d_{Turf} * d_{SalExt} * d_{AreaHM} * d_{ReFreqHM} * d_{ReExpDur} * i_{AbsorpOrallInuse} * d_{MAF}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Object to mouth	0,0000763	0,0000076	$(i_{AppRate}/100) * C30 * d_{DRP} * d_{MouthGrass} * i_{AbsorpOrallInuse} * d_{MAF}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops				
Dermal	0,0957809	0,0095781	$(d_{TcEntryMeanCh} * 0.25 * d_{DFR} * d_{MAF}) / 1000 * MAX(i_{AbsorpProduct}, i_{AbsorpInuse})$	
Hand to mouth			$(i_{AppRate}/100) * i_{d_{Turf}} * d_{MAF} * d_{SalExt} * d_{AreaHM} * d_{ReFreqHM} * d_{ReExpDur} * i_{AbsorpOrallInuse}$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_{AppRate}/100) * i_{d_{DRP}} * d_{MouthGrass} * i_{AbsorpOrallInuse} * d_{MAF}$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0558037	0,0009301	$((C19 * i_{AbsorpInuse} * (1 - d_{ClothAF})) + C21) * d_{ConcAS}$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0138000	0,0002300	$d_{AirCon} * d_{BreathRAD} * d_{BwAdult}$	
Surface deposits (dermal)	0,0077949	0,0001299	$(i_{AppRate}/100) * C30 * d_{Turf} * d_{ReTCAd} * d_{ReExpDur} * MAX(i_{AbsorpProduct}, i_{AbsorpInuse}) * d_{MAF} * IF(i_{AppEquip} = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops (dermal)	0,3192697	0,0053212	$(d_{TcEntryMeanAd} * 0.25 * d_{DFR} * d_{MAF}) / 1000 * MAX(i_{AbsorpProduct}, i_{AbsorpInuse})$	

Refinement calculations for prothioconazole-desthio - 45 % conversion

Table A 35: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for Protiokonazol 300 EC		
Croptype	Cereals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted-Drift Reduction	i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	i_FormVal
Buffer strip	5 m	i_Buffer
Application rate of the product	0,0796 kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,796 g a.s./l	d_ConcAS
Dermal absorption of product	0,00%	i_AbsorpProduct
Dermal absorption of in-use dilution	70,00%	i_Absorpinuse
Oral absorption	100,00%	i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0796 µg a.s./cm ²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	i_Volat
Concentration in air	0,001 mg/m ³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0,23798 ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0,2175 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0,00017 ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0,12278 ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0,12 ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0,00008 ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0,00014 ml spray dilution/person	
Exposure duration dermal	2 hours	d_ReExpDur
Exposure duration inhalation	24 hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0,25 hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%	d_ClothAF
Breathing rate adult	0,23 m ³ /day/kg	d_BreathRAD
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	2,30%	
Drift percentage on surface (mean)	1,80%	
Turf transferable residues percentage	5,00%	d_Turf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour	d_ReTCCCh
Saliva extraction percentage	50,00%	d_SalExt
Surface area of hands mouthed	20 cm ²	d_AreaHM
Frequency of hand to mouth activity	9,5 events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm ²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20,00%	d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm ² /h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h	d_TcEntryCh

Table A 36: Estimation of longer term resident exposure towards prothioconazole according to EFSA guidance

1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0497560	0,0107000	0,0031004	0,0540230	0,0836707
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0049756	0,0010700	0,0003100	0,0054023	0,0083671
% of RVNAS	49,76%	10,70%	3,10%	54,02%	83,67%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0544028	0,0138000	0,0080626	0,1800767	0,1917722
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0009067	0,0002300	0,0001344	0,0030013	0,0031962
% of RVNAS	9,07%	2,30%	1,34%	30,01%	31,96%

2. Resident exposure 75th Percentile				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0497560	0,0049756	$((C16 * i_Absorplnuse * (1 - d_ClothAF)) + C18) * d_ConcAS$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0107000	0,0010700	$d_AirCon * d_BreathRCh * d_BwChild$	
Surface deposits				
Dermal	0,0028716	0,0002872	$(i_AppRate/100) * C29 * d_Turf * d_ReTCCh * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorplnuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Hand to mouth	0,0001499	0,0000150	$(i_AppRate/100) * C29 * d_Turf * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse * d_MAF$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Object to mouth	0,0000789	0,0000079	$(i_AppRate/100) * C29 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops				
Dermal	0,0540230	0,0054023	$(d_TcEntryCh * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	
Hand to mouth			$(i_AppRate/100) * d_Turf * d_MAF * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_AppRate/100) * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0544028	0,0009067	$((C15 * i_Absorplnuse * (1 - d_ClothAF)) + C17) * d_ConcAS$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0138000	0,0002300	$d_AirCon * d_BreathRAD * d_BwAdult$	
Surface deposits (dermal)	0,0080626	0,0001344	$(i_AppRate/100) * C30 * d_Turf * d_ReTCAd * d_ReExpDur * i_Absorplnuse$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops (dermal)	0,1800767	0,0030013	$(d_TcEntryAd * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	
3. Summing of exposure pathways mean				
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]	Formula	Comments
1-3 year old child				
Spray drift	0,0274700	0,0027470	$((C20 * i_Absorplnuse * (1 - d_ClothAF)) + C22) * d_ConcAS$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0107000	0,0010700	$d_AirCon * d_BreathRCh * d_BwChild$	
Surface deposits				
Dermal	0,0022474	0,0002247	$(i_AppRate/100) * C30 * d_Turf * d_ReTCCh * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorplnuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Hand to mouth	0,0001173	0,0000117	$(i_AppRate/100) * C30 * d_Turf * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse * d_MAF$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Object to mouth	0,0000617	0,0000062	$(i_AppRate/100) * C30 * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops				
Dermal	0,0430744	0,0043074	$(d_TcEntryMeanCh * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	
Hand to mouth			$(i_AppRate/100) * i_Turf * d_MAF * d_SolExt * d_AreaHM * d_ReFreqHM * d_ReExpDur * i_AbsorpOrallnuse$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Object to mouth			$(i_AppRate/100) * i_Turf * d_DRP * d_MouthGrass * i_AbsorpOrallnuse * d_MAF$	Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.
Adult				
Spray drift	0,0280812	0,0004680	$((C19 * i_Absorplnuse * (1 - d_ClothAF)) + C21) * d_ConcAS$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Vapour	0,0138000	0,0002300	$d_AirCon * d_BreathRAD * d_BwAdult$	
Surface deposits (dermal)	0,0063099	0,0001052	$(i_AppRate/100) * C30 * d_Turf * d_ReTCAd * d_ReExpDur * MAX(i_AbsorpProduct, i_Absorplnuse) * d_MAF * IF(i_AppEquip = "Vehicle-mounted-Drift Reduction", 0.5, 1)$	Since drift reducing nozzles are selected a 50% reduction factor has been applied
Entry into treated crops (dermal)	0,1435812	0,0023930	$(d_TcEntryMeanAd * 0.25 * d_DFR * d_MAF) / 1000 * MAX(i_AbsorpProduct, i_Absorplnuse)$	







AOEM EFSA 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) OPEX version: 1.0.1

Information on product and active substance(s)

Product name	Protiokonazol 300 EC
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Prothioconazole
Concentration of active substance [g a.s./l or kg]	300
AOEL [mg/kg bw/day]	0.2
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	25
Name of active substance	Prothioconazole-desthio
Concentration of active substance [g a.s./l or kg]	272.1
AOEL [mg/kg bw/day]	0.01
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	0







Operator

Use 1 : Field crops - cereals

Mixing/loading	Application	Prothioconazole (% AOEL)	Prothioconazole- desthio (% AOEL)
		Normal & vehicle-mounted	
		128	71
		83.3	47.2
		10.9	47.2

Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted







Model data	Level of PPE	Total ab- sorbed dose [mg/kg bw per day]	% of sys- temic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Prothioconazole	Number of applications and application rate: 2 x 0.195 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.2	83.3
	Number of applications and application rate: 2 x 0.176865 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 20 %		
Prothioconazole-desthio	M/L: Workwear App: Workwear	0.005	47.2

		Prothioconazole (% AOEL)	Prothioconazole- desthio (% AOEL)
Mixing/loading	Application	Normal & vehicle-mounted	
		128	244
		83.3	161
		3.4	24.2

Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted







Model data	Level of PPE	Total ab- sorbed dose [mg/kg bw per day]	% of sys- temic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Prothioconazole	Number of applications and application rate: 2 x 0.195 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.2	83.3
Prothioconazole-desthio	Number of applications and application rate: 2 x 0.176865 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear + Protected hands App: Workwear + Protected hands	0.002	24.2

Use 2 : Field crops - oilseeds

Mixing/loading	Application	Prothioconazole (% AOEL)	Prothioconazole- desthio (% AOEL)
		Normal & vehicle-mounted	
		121	65.6
		78.9	43.6
		10.1	43.6

Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

Model data	Level of PPE	Total ab- sorbed dose [mg/kg bw per day]	% of sys- temic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Prothioconazole	Number of applications and application rate: 2 x 0.18 kg a.s./ha Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.2	78.9
Prothioconazole-desthio	Number of applications and application rate: 2 x 0.16326 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 20 %		
	M/L: Workwear App: Workwear	0.004	43.6

Mixing/loading	Application	Prothioconazole (% AOEL)	Prothioconazole- desthio (% AOEL)
		121	225
		78.9	148
		3.2	23

Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

Model data	Level of PPE	Total ab- sorbed dose [mg/kg bw per day]	% of sys- temic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Prothioconazole	Number of applications and application rate: 2 x 0.18 kg a.s./ha		
	Dermal absorption (concentrate): 25 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear App: Workwear	0.2	78.9
Prothioconazole-desthio	Number of applications and application rate: 2 x 0.16326 kg a.s./ha		
	Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 70 %		
	M/L: Workwear + Protected hands App: Workwear + Protected hands	0.002	23

Worker

Use 1 : Field crops – cereals

Scenario 1 : Outdoor, normal

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: 14 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 0.195 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.3	147	17
Workwear	0.03	16.4	0
Workwear and gloves	0.03	14.7	0
Number of applications & application rate: 2 x 0.176865 kg a.s./ha Dermal absorption: 20 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.08	761	88
Workwear	0.009	85.2	0
Workwear and gloves	0.008	76.1	0

Use 1 : Field crops – cereals

Scenario 1 : Outdoor, normal

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: 14 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 0.176865 kg a.s./ha Dermal absorption: 70 % DFR: 1 µg/cm ² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Potential	0.09	887	95
Workwear	0.01	99.4	0
Workwear and gloves	0.009	88.7	0

Use 1 : Field crops – cereals

Scenario 1 : Outdoor, normal

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: 14 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: 1 x 0.0797253 kg a.s./ha Dermal absorption: 70 % DFR: 1 µg/cm ² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Potential	0.04	400	60
Workwear	0.004	44.8	0
Workwear and gloves	0.004	4	0

Use 2 : Field crops – oilseeds

Scenario 1 : Outdoor, normal

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: 21 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 0.18 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.3	128	11
Workwear	0.03	14.3	0
Workwear and gloves	0.03	12.8	0
Hands covered, no workwear			
Number of applications & application rate: 2 x 0.16326 kg a.s./ha Dermal absorption: 20 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.07	661	82
Workwear	0.007	74.1	0
Workwear and gloves	0.007	66.1	0

Use 2 : Field crops – oilseeds

Scenario 1 : Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Number of applications & application rate: 2 x 0.16326 kg a.s./ha Dermal absorption: 70 % DFR: 1 µg/cm ² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Prothioconazole-desthio (refined dfr)			
Potential	0.08	771	89
Workwear	0.009	86.4	0
Workwear and gloves	0.008	77.1	0

Use 2 : Field crops – oilseeds

Scenario 1 : Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Prothioconazole-desthio (re- fined dfr)	Inspection, irrigation / Outdoor		
	Work rate: 2 hours/day		
	Interval: 21 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: 1 x 0.073467 kg a.s./ha		
	Dermal absorption: 70 %		
	DFR: 1 µg/cm ² foliage per kg a.s./ha		
	DT50 Foliar: 30 days		
	DT50 Air: 30 days		
	DT50 Soil: 30 days		
Potential	0.03	347	54
Workwear	0.004	38.9	0
Workwear and gloves	0.003	34.7	0

Resident

Use 1 : Field crops – cereals

Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 14 days Minimum volume of water: 100 l			
Number of applications and application rate: 2 x 0.195 kg a.s./ha Dermal absorption: 70 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Prothioconazole	Drift (75th perc.)	0.04	18.5
	Vapour (75th perc.)	0.0008	0.4
	Deposits (75th perc.)	0.004	1.8
	Re-entry (75th perc.)	0.04	19.8
	Sum (mean)	0.06	27.6
Resident child Body weight: 10 kg	Drift (75th perc.)	0.009	4.4
	Vapour (75th perc.)	0.0003	0.1
	Deposits (75th perc.)	0.002	0.8
	Re-entry (75th perc.)	0.02	11
	Sum (mean)	0.02	11.5
Number of applications and application rate: 2 x 0.176865 kg a.s./ha Dermal absorption: 20 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Prothioconazole- desthio	Drift (75th perc.)	0.01	96
	Vapour (75th perc.)	0.0008	8
	Deposits (75th perc.)	0.001	11.3
	Re-entry (75th perc.)	0.01	103
	Sum (mean)	0.02	151
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	22.8
	Vapour (75th perc.)	0.0003	2.7
	Deposits (75th perc.)	0.0004	4.1
	Re-entry (75th perc.)	0.006	57
	Sum (mean)	0.006	61.9

Use 1 : Field crops – cereals

Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 10 m Drift reduction technology: 50 % Interval between treatments: 14 days Minimum volume of water: 100 l			
Prothioconazole- desthio (refined dfr)	Number of applications and application rate: 2 x 0.176865 kg a.s./ha		
	Dermal absorption: 70 %		
	DFR: 1 µg/cm ² foliage per kg a.s./ha		
	DT50: 30 days		
	Drift (75th perc.)	0.009	91.5
Resident child Body weight: 10 kg	Vapour (75th perc.)	0.0008	8
	Deposits (75th perc.)	0.0004	3.9
	Re-entry (75th perc.)	0.01	120
	Sum (mean)	0.02	157
	Drift (75th perc.)	0.002	16.9
Resident adult Body weight: 60 kg	Vapour (75th perc.)	0.0003	2.7
	Deposits (75th perc.)	0.0002	1.7
	Re-entry (75th perc.)	0.007	66.5
	Sum (mean)	0.007	66.4
	Drift (75th perc.)	0.002	16.9

Use 1 : Field crops – cereals

Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 5 m Drift reduction technology: 50 % Interval between treatments: 14 days Minimum volume of water: 100 l			
Prothioconazole- desthio (refined dfr)	Number of applications and application rate: 1 x 0. 0797253 kg a.s./ha		
	Dermal absorption: 70 %		
	DFR: 1 µg/cm² foliage per kg a.s./ha		
	DT50: 30 days		
	Drift (75th perc.)	0.005	50.4
Resident child Body weight: 10 kg	Vapour (75th perc.)	0.0008	8
	Deposits (75th perc.)	0.0003	3.1
	Re-entry (75th perc.)	0.005	54
	Sum (mean)	0.008	81
	Drift (75th perc.)	0.0009	9.2
Resident adult Body weight: 60 kg	Vapour (75th perc.)	0.0003	2.7
	Deposits (75th perc.)	0.0001	1.3
	Re-entry (75th perc.)	0.003	30
	Sum (mean)	0.003	32.3
	Drift (75th perc.)	0.0009	9.2

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)

Please refer to point 6.6.3.2.