

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SIP 41061

Product name: SIP 41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization of use)

Applicant: Sipcam Oxon S.p.A.

Submission date: April 2022

MS Finalisation date: January 2023; June 2023; July 2023

Version history

When	What
January 2023	Initial zRMS assessment
June 2023	RR update following commenting phase.
July 2023	Estimation after updated use (Cucurbit, handheld, greenhouse)

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SIP 41061 *

Product name and code	SIP 41061
Formulation type	SC
Active substance(s) (incl. content)	Prothioconazole 400 g/L
Function	fungicide
Product already evaluated as the ‘representative formulation’ during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of SIP 41061 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 SIP 41061 according to Regulation (EC) No 1272/2008

Hazard class(es), categories	-
Hazard pictograms or Code(s) for hazard pictogram(s)	-
Signal word	-
Hazard statement(s)	-
Precautionary statement(s)	-
Additional labelling phrases	EUH208 “Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction”)

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SIP 41061

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Field Crops: Work wear during mixing/loading and application Orchard in field: Work wear during mixing/loading and application, gloves during application Orchard manual, hand-held application, upwards: Work wear during mixing/loading and application.
Workers	Acceptable	Field Crops: Work wear (arms, body and legs covered) Sugar beet, bolting: Work wear (arms, body and legs covered) and gloves Stone fruits: Work wear (arms, body and legs covered) Pome fruits: Work wear (arms, body and legs covered) and gloves

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	Result	PPE / Risk mitigation measures
Residents	Acceptable	Cereals 300L water min or DRT or 5 m buffer zone Cucurbits, handheld, greenhouse 300 L water min
Bystanders	Acceptable	None

Choose one of the following options:

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

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

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

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safen- er/synergist (L/ha)) critical gap for operator, work- er, resident or bystander expo- sure based on [Exposure mod- el]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion technique ***	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1-2	Cereals (Wheat (Soft, Durum), Triticale, Rye Barley	F	Spraying, LCTM	2 (14)	a) 0.200	200-600	21	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				
3	Oilseed Rape	F	Spraying, LCTM	2 (14)	a) 0.180	200-600	50	EFSA Journal 2014;12(10):3874				
4	Sugar beet	F	Spraying, LCTM	2 (14)	a) 0.160	200-600	28	EFSA Journal 2014;12(10):3874				
5	Cucurbits edible peel	G	Spraying HH	3 (10)	a) 0.120	200-600	10	ECPA/Croplife model for Operator, EFSA model for worker and resident				
6a,b	Pome fruits (Apple, Quince, Medlar)	F	Spraying HCTM	2 (7-9)	a) 0.120	500-1500	14	EFSA Journal 2014;12(10):3874				
7	Stone fruits (Peach, Nectarin, Plum, Apricot, Cherry)	F	Spraying HCTM	2 (7)	a) 0.160	500-1500	3	EFSA Journal 2014;12(10):3874				
8	Carrot (other	F	Spraying,	a) 2 (21)	a) 0.200	500-1000	21	EFSA Journal				

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1	2	3	4	5	6	7	8	9	10
	roots and tubers vegetables)		LCTM			1500		2014;12(10):3874	

* 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

N/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(s)

	Prothioconazole	Prothioconazole-desthio
Common Name	Prothioconazole	Prothioconazole-desthio
CAS-No.	178928-70-6	120983-64-4
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Acute 1, Aquatic Chronic 1 Code for hazard pictogram: GHS09 Signal word: Wng Hazard statement(s): H400, H410	Hazard classes (s) Aquatic Chronic 1 Code for hazard pictogram: GHS09 Signal word: Wng Hazard statement(s): H410
Additional C&L proposal	-	-
Agreed EU endpoints		
AOEL systemic	0.2 mg/kg bw/d (corrected for 100% oral absorption)	0.01 mg/kg bw/d (corrected for 100% oral absorption)
Reference	EFSA (2007) 106, 1-98, Conclusion on the peer review of prothioconazole Committee for RAC Assessment RAC Adopted 15 March 2019 Official Journal of the European Union COMMISSION DELEGATED REGULATION (EU) 2021/849, of 11 March 2021	EFSA (2007) 106, 1-98, Conclusion on the peer review of prothioconazole

	Prothioconazole	Prothioconazole-desthio
	<p>Note: REGULATIONS COMMISSION IMPLEMENTING REGULATION (EU) 2022/708 of 5 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances: prothioconazole The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows (16) in the sixth column, expiration of approval, of row 168, Prothioconazole, the date is replaced by ‘31 July 2023 :</p>	
Conditions to take into account/critical areas of concern with regard to toxicology		
According to Review Report/EFSA Conclusion for active substance	operator safety in spray applications. Conditions of use shall include adequate protective measures,	The metabolite prothioconazole-desthio is more toxic than prothioconazole in the rat and rabbit developmental studies (the classification Repro cat 2, R61 is proposed)

6.3 Toxicological Evaluation of Plant Protection Product

No toxicological studies have been conducted with SIP 41061.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SIP 41061

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	na	Yes	None	Calculation-Please refer to dRR part C
LD ₅₀ dermal, rat	na	Yes	None	Calculation-Please refer to dRR part C
LC ₅₀ inhalation, rat	na	Yes	None	Calculation-Please refer to dRR part C
	or e.g. Not submitted, not necessary. Justification presented in Appendix 2) Regulation 1272/2008; Annex I point 3.1.3.6.2.2			
Skin irritation,	na	Yes	None	Calculation-Please refer to

				dRR part C
Eye irritation,	na	Yes	None	Calculation- Please refer to dRR part C
Skin sensitisation	na	Yes	None	Calculation- Please refer to dRR part C
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SIP 41061

	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 (35.13% (w/w))	none	Reg. 1272/2008 / MSDS** / EFSA conclusion	none
Toxicological properties of non-active substance(s) (relevant for classification of product)	Please refer to dRR part C	Please refer to dRR part C	Reg. 1272/2008 / MSDS** / EFSA conclusion	None (EUH208 “Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction”)
Further toxicological information	No data – not required			

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

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

Diluted prothioconazole can degrade to the metabolite prothioconazole-desthio on clothing, certain plant surfaces or on skin during the drying process. Since prothioconazole-desthio is a developmental toxicant, it was agreed with the RMS for Annex I approval of prothioconazole that non-dietary risk assessments for prothioconazole-desthio would also be provided.

A summary of the dermal absorption rates for the active substances in SIP41061 are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SIP41061

	Prothioconazole		Prothioconazole-desthio	
	Value	Reference	Value	Reference
Concentrate	0.08%	New study reported in Appendix 2	-	-
Dilution 0.27 mg/ml (1:1500)	14%	New study reported in Appendix 2		
Dilution 0.08 mg/ml (1:5000)	19%	New study reported in Appendix 2	16%	New study reported in Appendix 2
Dilution 0.08 mg/ml dried residue (1:5000)			3.5%	New study reported in Appendix 2

6.5.1 Justification for proposed values – Prothioconazole and Prothioconazole-desthio

Proposed dermal absorption rates for Prothioconazole are based on dermal absorption studies on SIP 41061. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of Prothioconazole and Prothioconazole -desthio in SIP 41061 that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for Prothioconazole and Prothioconazole-desthio

Test	Concentrate	Spray dilution	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	0.08%	1:1500 14% 1:5000 19%	SIP 41061	Yes	Not required	Justification accepted. Endpoint can be used for current product .	Spa S., 2021, Report No 20287173
In vitro (human)		1:5000 16% 1:5000 dried residue 3.5%	SIP 41061	Yes	Not required	Justification accepted. Endpoint can be used for current product.	Spa S., 2021, Report No 20309159

* indicates that a study was reviewed at EU level

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Risk assessment for Prothioconazole in SIP 41061 is provided. Diluted prothioconazole can degrade to the metabolite prothioconazole-desthio on clothing, certain plant surfaces or on skin during the drying process.

Since prothioconazole-desthio is a suspected developmental toxicant, it was agreed with the RMS for Annex I approval of prothioconazole that non-dietary risk assessments for prothioconazole-desthio would also be provided. This will only be relevant where diluted prothioconazole is involved. The assessment has been conducted for Prothioconazole and its metabolite Prothioconazole-desthio considering 100% of each one separately.

Assuming 100% conversion of prothioconazole to prothioconazole-desthio and taking into account the molar ratio of prothioconazole-desthio to prothioconazole ($312.2/344.3 = 0.907$), prothioconazole-desthio rates have been recalculated appropriately for the assessment

This approach is very conservative and extremely worst case as a complete transformation of prothioconazole into prothioconazole-desthio does not occur within the timeframe considered for activities according to the proposed cGAP. It should also be considered that in the RAR of the ongoing review of Prothioconazole, updated and more favourable endpoints based on available data have been considered for both active ingredient and metabolite. With the updated endpoints mitigations due to the worst-case assessment for 100% prothioconazole-desthio would not be needed.

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

Product name and code	SIP 41061	
Formulation type	SC	
Category	Fungicide	
Active substance(s) (incl. content)	Prothioconazole 400 g/L	Prothioconazole-desthio
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: 0.08% Dilution: 14% (0.27 g/L) Dilution: 19% (0.08 g/L) (Based on product)	Concentrate: - Dilution: 16% (0.08 g/L) (Based on product)

6.6.1 Selection of critical use(s) and justification

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

Justification

Cereals: Highest application rate and worst-case interval for field crops Covers sugar beet, oilseed rape and carrot for most scenarios)

Sugar beet: bolting only, as specific re-entry activity

Oilseed Rape: resident

Carrot: resident

Cucurbits: fruiting vegetables scenario, indoor.

Orchard: Stone fruit worst case for dose rate for operator; stone and apple fruit different refinement for re-entry activities RA

6.6.2 Operator exposure (KCP 7.2.1)

As no harmonised approach on the setting of acute reference values for non-dietary human exposure is available, and no AAOEL has been established for Prothioconazole, no acute exposure calculations are necessary.

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 SIP 41061 according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (acute exposure) and Table 6.6-4 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Wheat, Barley (field crops, max. 0.5 L product/ha) Stone fruits (orchard, max 0.4 L product/ha) Cucurbits (fruiting vegetables, greenhouse, max 0.2 0.3 L product/ha)
Model(s)	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

Table 6.6-3: Estimated operator exposure (acute exposure)

Not required, see above

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

		Prothioconazole		Prothioconazole-desthio	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (wheat, barley)					
Application rate		0.2 kg a.s./ha		0.181 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0042	2.09	0.0039	39
	Work wear (arms, body and legs covered) M/L and A + type of PPE/RPE				
Tractor mounted spray application outdoors to high crops (stone fruits)					
Application rate		0.16 kg a.s./ha		0.145 kg a.s./ha	
Spray application (AOEM; 75 th percentile)	Work wear (arms, body and legs covered) M/L and A	0.0201	10.06	0.0157	156.6

Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + gloves A			0.0064	64.39
Manual, hand-held sprayer, upwards spraying outdoors to high crops (stone fruits)					
Application rate		0.16 kg a.s./ha		0.145 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0106	5.32	0.0086	86.04
	Work wear (arms, body and legs covered) M/L and A + gloves A				
Manual, hand-held sprayer, upwards spraying (cucurbits) greenhouse (ECPA/CropLife model)					
Application rate		0.12 kg a.s./ha		0.109 kg a.s./ha	
Spray application (ECPA/CropLife; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.14182	70.9	0.10985	1098.5
	Work wear (arms, body and legs covered) M/L and A + gloves, impervious coverall, mask FFP2 A			0.007733	77.3
Manual, hand-held sprayer, upwards spraying (cucurbits) greenhouse (Dutch model)					
Application rate		0.12 kg a.s./ha		0.109 kg a.s./ha	
Spray application Dutch Model Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	4.6800	33	3.5970	514
	Work wear (arms, body and legs covered) M/L and A + gloves, impervious coverall, mask			0.4033	58

Based on the above calculations, for both prothioconazole and its metabolite prothioconazole-desthio, the operator exposure for the intended GAP uses of SIP 41061 is below the limit of 100% AOEL if the following PPEs are taken into account:

Field Crops (max. 2 x 0.5 l product/ha at 14 days interval)

- Tractor-mounted boom sprayer, downwards

⇒ Work wear during mixing/loading and application

Orchard (max. 2 x 0.4 l product/ha at 7days interval)

Tractor-mounted airblast sprayer, upwards

⇒ Work wear during mixing/loading and application, gloves during application

- Manual, hand-held application, upwards

⇒ Work wear during mixing/loading and application.

Tractor mounted spray application outdoors to high crops (stone fruits)

⇒ Work wear (arms, body and legs covered) M/L and A + gloves A

Cucurbits greenhouse (max. 3x 0.3 kg product/ha at 10 days interval)

⇒ **Cucurbits greenhouse (max. 3x 0.3 kg product/ha at 10 days interval)**

Manual, hand-held application (ECPA/CropLife model)

⇒ Work wear during mixing/loading and application, gloves, impervious coverall, mask FFP2 during application.

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)

As no harmonised approach on the setting of acute reference values for non-dietary human exposure is available, and no AAOEL has been established for Prothioconazole, no acute exposure calculations are necessary.

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SIP 41061 according to the critical use(s). Outcome of the estimation is presented in Table 6.6-6 (acute exposure) and Table 6.6-7 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 0.5 L product/ha, interval 14 days) Cucurbits indoor and outdoor (max 3 x 0.3 L product/ha, interval 10 days) Sugar beet (bolting only, max 2 x 0.4 product/ha, interval 14 days) Stone trees (max 2 x 0.4 L product/ha, interval 7 days) Apple trees (max 2 x 0.3 L product/ha, interval 7 days)
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

Table 6.6-6: Estimated worker exposure (acute exposure)

Not required, see above

Table 6.6-7: Estimated worker exposure (longer term exposure)

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		Prothioconazole		Prothioconazole-desthio	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, Inspection Outdoor Body weight: 60 kg Work rate: 2 hours/day, DT ₅₀ :30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha		2 x 0.181 kg a.s./ha	
EFSA model	Potential TC: 12500 cm ² /person/h	0.0603	30.16	0.0624	623.96
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0068	3.38	0.0070	69.88
	Work wear (arms, body and legs covered) and gloves TC: n.a. cm ² /person/h				
Cucurbits, Reaching, picking Indoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 x 0.12 kg a.s./ha		3 x 0.109 kg a.s./ha	
EFSA model	Potential TC: 5800 cm ² /person/h	0.1282	64.10	0.0981	980.63
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0553	27.63	0.0423	422.69
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0128	6.41	0.0098	98.06
Sugar beet, bolting Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.16 kg a.s./ha		2 x 0.145 kg a.s./ha	
EFSA model TC values	Potential TC: 18600 cm ² /person/h	0.32829	164.2	0.29751	2975

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Baumann J., 2019 ¹	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.07943	39.71	0.07198	720
	Work wear (arms, body and legs covered) and gloves TC: 430 cm ² /person/h	0.00759	3.79	0.00688	68.78
Stone fruits, Reaching, picking Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days Prothioconazole 5.3 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.5 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.160 kg a.s./ha		2 x 0.145 kg a.s./ha	
EFSA model	Potential TC: 22500 cm ² /person/h	0.5063	253.2	0.0487	487.31
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.1013	50.63	0.0097	97.46
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0506	25.32	0.0049	48.73
Pome fruits, Reaching, picking Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days Prothioconazole 8 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 1.2 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.120 kg a.s./ha		2 x 0.109 kg a.s./ha	
EFSA model	Potential TC: 22500 cm ² /person/h	0.3798	189.88	0.0970	970
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0760	37.98	0.0194	194
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0380	18.99	0.0097	97

Based on a comment from cMS Germany, an alternative risk assessment for Prothioconazole-desthio, based on a DFR value calculated as mean from all worst case samples across available DFR studies on pome and stone fruits (see Appendix 5 for calculation) and standard DT50=30d is provided below for stone fruits (covers pome fruits since lower dose rate)

¹ Baumann J, Anft T, Doughty KJ and Kuster CJ, 2019. Exposure to pesticide residues during manual removal of bolting sugar beets: determination of transfer coefficients for worker risk assessment. Journal of Consumer Protection and Food Safety 2019; 14, 283-286).

Stone fruits, Reaching, picking – covers Pome fruits Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 0.65 µg/cm ² /kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate			2 x 0.145 kg a.s./ha		
EFSA model	Potential TC: 22500 cm ² /person/h			0.0837	837.24
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h			0.0167	167.45
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h			0.0084	83.72

Based on these calculations also re-entry in stone fruits would require gloves.

Based on the above calculations, the worker exposure for the intended GAP uses of SIP 41061 is below the limit of 100% AOEL if the following label mitigations are taken into account:

Field Crops (max. 2 x 0.5 l product/ha at 14 days interval)

⇒ Work wear (arms, body and legs covered)

Sugar beet, bolting (max. 2 x 0.4 l product/ha at 14 days interval))

⇒ Work wear (arms, body and legs covered) and gloves

Cucurbits greenhouse (max. 3x 0.3 l product/ha at 10 days interval)

⇒ Work wear (arms, body and legs covered) and gloves

Stone fruits (max. 2 x 0.4 l product/ha at 7 days interval)

⇒ Work wear (arms, body and legs covered)

Pome fruits (max. 2 x 0.3 l product/ha at 7 days interval)

⇒ Work wear (arms, body and legs covered) and gloves

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

A refinement of the generic DFR values was obtained for leaves from stone and pome fruit trees, treated with SIP 41061 and then analysed for both prothioconazole and prothioconazole-desthio.

Due to the low reliability of field fortification samples for prothioconazole, probably linked to the low concentration level of the samples, only information regarding desethyl-prothioconazole has been considered to obtain specific DFR and DT50 values for re-entry risk assessment.

More details for each study can be found in Appendix 2 to this section.

The DFR values were overall consistent among the available studies, and consistent with similar data obtained from maize leaves and reported in Prothioconazole RAR (DFR after 2 applications with 14 days interval around 0.6 µg/cm²/kg a.i./ha). Prothioconazole-desthio appeared immediately after application, demonstrating fast conversion from prothioconazole in diluted solutions, as expected. DFR values are always much lower than the default value of 3 µg/cm²/kg a.s./ha, and similarly, DT 50 values demonstrate that for prothioconazole and prothioconazole-desthio the default value of 30 days is greatly overestimated.

Details of the available studies can be found in Appendix 4 to this document.

Stone fruits

Two trials conducted on two representative trees of the group, in S-EU countries are available. The **worst case mean values** will be considered to select the appropriate DFR values to refine re-entry risk assessment.

Sample	Prothioconazole - desthio	
	mean value $\mu\text{g}/\text{cm}^2/\text{kg a.i./ha}$	
	<i>I/PR21/PE03</i>	<i>S/PR21/PL01</i>
S1 - 0 DAA1	0.240625	0.24375
S3 - 0 DAA2	0.150625	0.325833333
S5 - 2 DAA2	0.18625	0.48125
S6 - 3 DAA2	0.114375	0.493333333
S7 - 7 DAA2	0.058125	0.324166667
DT50 (days)	2.594	5.218

The following worst-case values will be used for risk assessment for re-entry in stone fruits orchards.

DFR 0.5 $\mu\text{g}/\text{cm}^2/\text{kg a.i./ha}$
DT50 5.3 days

Pome fruits

Four trials conducted in S-EU and C-EU countries are available

Sample	Prothioconazole - desthio			
	mean value $\mu\text{g}/\text{cm}^2/\text{kg a.i./ha}$			
	<i>I/PR21/AP05</i>	<i>CHR-21-51470 FR01</i>	<i>CHR-21-51470 PL02</i>	<i>CHR-21-51470 PL03</i>
S1 - 0 DAA1	0.360833333	0.264166667	0.411666667	0.5325
S3 - 0 DAA2	0.44	0.515833333	0.530833333	1.17
S5 - 2 DAA2	0.366666667	0.58	0.574166667	0.686666667
S6 - 3 DAA2	0.175	0.433333333	0.464166667	0.765
S7 - 7 DAA2	0.144166667	0.3025	0.296666667	0.848333333
DT50 (days)	3.505	3.694	3.366	8.010

The following worst-case values will be used for risk assessment for re-entry in apple fruits orchards

DFR 1.2 $\mu\text{g}/\text{cm}^2/\text{kg a.i./ha}$
DT50 8 days

Moreover, these values are considered sufficiently protective, after evaluation of all available data, to refine other crops values, and to demonstrate that for prothioconazole-desthio the default values of DFR= 3 $\mu\text{g}/\text{cm}^2/\text{kg a.i./ha}$ and DT50=30 days constitute an unreasonable worst case.

Additional evaluations after public commenting phase are reported in Appendix 5

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 and

re-entry intervals, 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

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

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

Table 6.6-8 shows the exposure model(s) used for estimation of resident and bystander exposure to Prothioconazole and Prothioconazole-desthio. The outcome of the estimation is presented in

Tractor mounted boom spray application outdoors to low crops-cereals					
Buffer zone: 5 m					
Drift reduction technology: no					
DT ₅₀ : 30 days					
DFR: 3 µg/cm ² /kg a.s./ha					
Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha 200 L		2 x 0.181 kg a.s./ha 200 L	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0026	25.98
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0004	4.03
	Re-entry (75 th perc.)			0.0084	84.23
	Sum (mean)			0.0095	95.3
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0005	4.72
	Vapour (75 th perc.)			0.0002	2.30
	Deposits (75 th perc.)			0.0001	1.40
	Re-entry (75 th perc.)			0.0047	46.80
	Sum (mean)			0.0043	43.15

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops – Oilseed rape (covers also sugar beet)					

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Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.18 kg a.s./ha, 200 L water		2 x 0.163 kg a.s./ha, 200 L water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0034	1.70	0.0035	35.14
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0009	0.44	0.0009	8.83
	Re-entry (75 th perc.)	0.0073	3.66	0.0076	75.86
	Sum (mean)	0.0094	4.72	0.0097	97.03
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0008	0.41	0.0008	8.39
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0003	0.15	0.0003	3.06
	Re-entry (75 th perc.)	0.0041	2.04	0.0042	42.14
	Sum (mean)	0.0041	2.04	0.0042	42.13

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops - carrot Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 21 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha, 500 l water		2 x 0.183 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0015	0.76	0.0016	15.61
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0009	0.46	0.0009	9.19
	Re-entry (75 th perc.)	0.0076	3.82	0.0079	78.95
	Sum (mean)	0.0087	4.33	0.0089	88.99
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0004	0.18	0.0004	3.73
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0003	0.15	0.0003	3.19
	Re-entry (75 th perc.)	0.0042	2.12	0.0044	43.86
	Sum (mean)	0.0040	2.00	0.0041	41.38

For cucurbits grown indoor, it is considered that the calculations provided by AOEM model for outdoor scenarios, excluding the component from re-entry represent a worst-case risk assessment.

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		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held application, indoor - cucurbits Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 x 0.12 kg a.s./ha, 200 l water		3 x 0.109 kg a.s./ha, 200 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0159	7.94	0.0122	121.67
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0004	0.21	0.0003	3.41
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)	0.0193	9.65	0.00935	93.46
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0088	4.40	0.0067	67.29
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0002	0.08	0.0001	1.18
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)	0.0102	5.12	0.0047	47.24
		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held application, outdoor/indoor - Cucurbits Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate				3 x 0.109 kg a.s./ha, 300 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0081	81.11
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0003	3.41
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)			0.00668	66.76
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0002	2.30
	Vapour (75 th perc.)			0.0001	1.18
	Deposits (75 th perc.)			0.0040	39.63

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	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)			0.003257	32.57

*re-entry not relevant for indoor application

Upon request of NL during the commenting phase, the most relevant calculations according to Lee side turbulence model have been added below for information only. The most relevant scenario (scenario 3, high volume) is demonstrated as safe. These calculations represent a local approach (to be considered in the NL addendum), focused on acute exposure, which is not relevant for Prothioconazole containing products and an extreme worst case and should only be considered as supporting information. As reported in the instructions to the model:

"It should be noted that the Lee Side Turbulence model is a generic model, with many limitations and a limited validation. It overestimates the exposure during and after a crop treatment, but seems to reflect a more realistic exposure for fogging techniques."

Detailed calculations have been included in the updated NL addendum.

Lee Turbulence Model (NL)						
Test item	Prothioconazole				Prothioconazole-desthio	
AOEL (mg/kg bw/d)	0.2				0.01	
Results						
				%AOEL		%AOEL
Scenario 1 (volatility >10 mPa):	0.184	-	ug/kg bw/day	92.23487	0.168	1675.600137
Scenario 2 (LMV):	0.257	-	ug/kg bw/day	128.4054	0.233	2332.69823
Scenario 3 (high volume):	0.007		ug/kg bw/day	3.617054	0.007	65.70980929
Scenario 4 (low volume):	0.014	-	ug/kg bw/day	7.234107	0.013	131.4196186
Scenario 5 (volatility <0.01 mPa):	0.036	-	ug/kg bw/day	18.08527	0.033	328.5490464

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 5.3 days Prothioconazole-desthio					

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DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.5 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.16 kg a.s./ha, 500 l water		2 x 0.145 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0085	4.24	0.0065	64.74
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0030	1.49	0.0018	17.99
	Re-entry (75 th perc.)	0.0095	4.75	0.0009	9.14
	Sum (mean)	0.0164	8.21	0.0074	73.92
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0047	2.34	0.0036	35.80
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0011	0.54	0.0006	6.24
	Re-entry (75 th perc.)	0.0053	2.64	0.0005	5.08
	Sum (mean)	0.0083	4.15	0.0034	34.39

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted spray application outdoors to high crops (Pome Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 8 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 1.2 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.12 kg a.s./ha, 500 l water		2 x 0.109 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0064	3.18	0.0049	48.67
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0022	1.12	0.0015	14.92
	Re-entry (75 th perc.)	0.0071	3.56	0.0018	18.19
	Sum (mean)	0.0126	6.2	0.0068	68.29
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0035	1.76	0.0027	26.91
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0008	0.41	0.0005	5.18
	Re-entry (75 th perc.)	0.0040	1.98	0.0010	10.11
	Sum (mean)	0.0063	3.14	0.0032	31.79

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		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 5.3 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.5 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.16 kg a.s./ha, 500 l water		2 x 0.145 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0085	4.24	0.0065	64.74
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0030	1.49	0.0018	17.99
	Re-entry (75 th perc.)	0.0095	4.75	0.0009	9.14
	Sum (mean)	0.0164	8.21	0.0074	73.92
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0047	2.34	0.0036	35.80
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0011	0.54	0.0006	6.24
	Re-entry (75 th perc.)	0.0053	2.64	0.0005	5.08
	Sum (mean)	0.0083	4.15	0.0034	34.39

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Pome Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 8 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 1.2 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.12 kg a.s./ha, 500 l water		2 x 0.109 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0064	3.18	0.0049	48.67
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0022	1.12	0.0015	14.92
	Re-entry (75 th perc.)	0.0071	3.56	0.0018	18.19
	Sum (mean)	0.0126	6.29	0.0068	68.29
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0035	1.76	0.0027	26.91
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0008	0.41	0.0005	5.18
	Re-entry (75 th perc.)	0.0040	1.98	0.0010	10.11

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	Sum (mean)	0.0063	3.14	0.0032	31.79
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Based on a comment from cMS Germany, an alternative risk assessment for Prothioconazole-desthio, based on a DFR value calculated as mean from all worst case samples across available DFR studies on pome and stone fruits (see Appendix 5 for calculation) and standard DT50=30d is provided below for stone fruits (covers pome fruits since lower dose rate). The results are in line with the previous calculations and the risk is safe.

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 0.65 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate				2 x 0.145 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0065	64.74
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0024	23.77
	Re-entry (75 th perc.)			0.0016	15.70
	Sum (mean)			0.0083	83.43
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0036	35.80
	Vapour (75 th perc.)			0.0002	2.30
	Deposits (75 th perc.)			0.0008	8.25
	Re-entry (75 th perc.)			0.0009	8.72
	Sum (mean)			0.0039	38.78

Based on the above calculations, the resident exposure for the intended GAP uses of SIP 41061 is generally below the limit of 100% AOEL. In the following situations the indicated label mitigations should be considered:

Cereals (max. 2 x 0.5 l product/ha at 14 days interval)

⇒ 300L water min or DRT or 5 m buffer zone

(longer term resident exposure) and Table 6.6-9 (acute bystander exposure). Detailed calculations are in Appendix 3.

Table 6.6-8: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 0.5 L product/ha, interval 14 days) Oilseed rape (max. 2 x 0.45 L product/ha, interval 14 days)
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	Carrot (max. 2 x 0.5 L product/ha, interval 21 days) Cucurbits indoor (max 3 x 0.3 L product/ha, interval 10 days) Stone trees (max 2 x 0.4 L product/ha, interval 7 days) Apple trees (max 2 x 0.3 L product/ha, interval 7 days)
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

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

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops - Cereals Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha 200L		2 x 0.181 kg a.s./ha 200L	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0038	1.89	0.0039	39.03
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0010	0.49	0.0010	9.80
	Re-entry (75 th perc.)	0.0081	4.07	0.0084	84.23
	Sum (mean)	0.0104	5.18	0.0107	106.56
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0009	0.45	0.0009	9.32
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0003	0.16	0.0003	3.40
	Re-entry (75 th perc.)	0.0045	2.26	0.0047	46.80
	Sum (mean)	0.0045	2.25	0.0047	46.53
Tractor mounted boom spray application outdoors to low crops - Cereals Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha 200L		2 x 0.181 kg a.s./ha 300L	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0026	26.02
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0010	9.80
	Re-entry (75 th perc.)			0.0084	84.23
	Sum (mean)			0.0099	99.39
Resident adult	Drift (75 th perc.)			0.0006	6.21

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Body weight: 60 kg	Vapour (75 th perc.)			0.0002	2.30
	Deposits (75 th perc.)			0.0003	3.40
	Re-entry (75 th perc.)			0.0047	46.80
	Sum (mean)			0.0045	45.06
Tractor mounted boom spray application outdoors to low crops-cereals Buffer zone: 2-3 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha 200 L		2 x 0.181 kg a.s./ha 200 L	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0020	19.51
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0005	4.90
	Re-entry (75 th perc.)			0.0084	84.23
	Sum (mean)			0.0092	92.21
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0005	4.66
	Vapour (75 th perc.)			0.0002	2.30
	Deposits (75 th perc.)			0.0002	1.70
	Re-entry (75 th perc.)			0.0047	46.80
	Sum (mean)			0.0043	43.07
Tractor mounted boom spray application outdoors to low crops-cereals Buffer zone: 5 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha 200 L		2 x 0.181 kg a.s./ha 200 L	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0026	25.98
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0004	4.03
	Re-entry (75 th perc.)			0.0084	84.23
	Sum (mean)			0.0095	95.3
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0005	4.72
	Vapour (75 th perc.)			0.0002	2.30
	Deposits (75 th perc.)			0.0001	1.40
	Re-entry (75 th perc.)			0.0047	46.80
	Sum (mean)			0.0043	43.15

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		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops – Oilseed rape (covers also sugar beet) Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.18 kg a.s./ha, 200 L water		2 x 0.163 kg a.s./ha, 200 L water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0034	1.70	0.0035	35.14
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0009	0.44	0.0009	8.83
	Re-entry (75 th perc.)	0.0073	3.66	0.0076	75.86
	Sum (mean)	0.0094	4.72	0.0097	97.03
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0008	0.41	0.0008	8.39
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0003	0.15	0.0003	3.06
	Re-entry (75 th perc.)	0.0041	2.04	0.0042	42.14
	Sum (mean)	0.0041	2.04	0.0042	42.13

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops - carrot Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 21 days					
Number of applications and application rate		2 x 0.2 kg a.s./ha, 500 l water		2 x 0.183 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0015	0.76	0.0016	15.61
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0009	0.46	0.0009	9.19
	Re-entry (75 th perc.)	0.0076	3.82	0.0079	78.95
	Sum (mean)	0.0087	4.33	0.0089	88.99
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0004	0.18	0.0004	3.73
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0003	0.15	0.0003	3.19
	Re-entry (75 th perc.)	0.0042	2.12	0.0044	43.86

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	Sum (mean)	0.0040	2.00	0.0041	41.38
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For cucurbits grown indoor, it is considered that the calculations provided by AOEM model for outdoor scenarios, excluding the component from re-entry represent a worst-case risk assessment.

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held application, indoor - cucurbits Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 x 0.12 kg a.s./ha, 200 l water		3 x 0.109 kg a.s./ha, 200 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0159	7.94	0.0122	121.67
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0004	0.21	0.0003	3.41
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)	0.0193	9.65	0.00935	93.46
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0088	4.40	0.0067	67.29
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0002	0.08	0.0001	1.18
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)	0.0102	5.12	0.0047	47.24
		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held application, outdoor/indoor - Cucurbits Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate				3 x 0.109 kg a.s./ha, 300 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0081	81.11
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0003	3.41
	Re-entry (75 th perc.)*				
	Sum (mean) no re-			0.00668	66.76

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	entry (indoor)				
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0002	2.30
	Vapour (75 th perc.)			0.0001	1.18
	Deposits (75 th perc.)			0.0040	39.63
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)			0.003257	32.57

*re-entry not relevant for indoor application

Upon request of NL during the commenting phase, the most relevant calculations according to Lee side turbulence model have been added below for information only. The most relevant scenario (scenario 3, high volume) is demonstrated as safe. These calculations represent a local approach (to be considered in the NL addendum), focused on acute exposure, which is not relevant for Prothioconazole containing products and an extreme worst case and should only be considered as supporting information. As reported in the instructions to the model:

"It should be noted that the Lee Side Turbulence model is a generic model, with many limitations and a limited validation. It overestimates the exposure during and after a crop treatment, but seems to reflect a more realistic exposure for fogging techniques."

Detailed calculations have been included in the updated NL addendum.

Lee Turbulence Model (NL)						
Test item	Prothioconazole				Prothioconazole-desthio	
AOEL (mg/kg bw/d)	0.2				0.01	
Results						
				%AOEL		%AOEL
Scenario 1 (volatility >10 mPa):	0.184	-	ug/kg bw/day	92.23487	0.168	1675.600137
Scenario 2 (LMV):	0.257	-	ug/kg bw/day	128.4054	0.233	2332.69823
Scenario 3 (high volume):	0.007	-	ug/kg bw/day	3.617054	0.007	65.70980929
Scenario 4 (low volume):	0.014	-	ug/kg bw/day	7.234107	0.013	131.4196186
Scenario 5 (volatility <0.01 mPa):	0.036	-	ug/kg bw/day	18.08527	0.033	328.5490464

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		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 5.3 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.5 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.16 kg a.s./ha, 500 l water		2 x 0.145 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0085	4.24	0.0065	64.74
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0030	1.49	0.0018	17.99
	Re-entry (75 th perc.)	0.0095	4.75	0.0009	9.14
	Sum (mean)	0.0164	8.21	0.0074	73.92
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0047	2.34	0.0036	35.80
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0011	0.54	0.0006	6.24
	Re-entry (75 th perc.)	0.0053	2.64	0.0005	5.08
	Sum (mean)	0.0083	4.15	0.0034	34.39

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted spray application outdoors to high crops (Pome Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 8 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 1.2 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.12 kg a.s./ha, 500 l water		2 x 0.109 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0064	3.18	0.0049	48.67
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0022	1.12	0.0015	14.92
	Re-entry (75 th perc.)	0.0071	3.56	0.0018	18.19
	Sum (mean)	0.0126	6.2	0.0068	68.29
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0035	1.76	0.0027	26.91
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0008	0.41	0.0005	5.18

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	Re-entry (75 th perc.)	0.0040	1.98	0.0010	10.11
	Sum (mean)	0.0063	3.14	0.0032	31.79

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 5.3 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.5 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.16 kg a.s./ha, 500 l water		2 x 0.145 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0085	4.24	0.0065	64.74
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0030	1.49	0.0018	17.99
	Re-entry (75 th perc.)	0.0095	4.75	0.0009	9.14
	Sum (mean)	0.0164	8.21	0.0074	73.92
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0047	2.34	0.0036	35.80
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0011	0.54	0.0006	6.24
	Re-entry (75 th perc.)	0.0053	2.64	0.0005	5.08
	Sum (mean)	0.0083	4.15	0.0034	34.39

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Pome Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 8 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 1.2 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.12 kg a.s./ha, 500 l water		2 x 0.109 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0064	3.18	0.0049	48.67
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0022	1.12	0.0015	14.92
	Re-entry (75 th perc.)	0.0071	3.56	0.0018	18.19
	Sum (mean)	0.0126	6.29	0.0068	68.29

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Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0035	1.76	0.0027	26.91
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0008	0.41	0.0005	5.18
	Re-entry (75 th perc.)	0.0040	1.98	0.0010	10.11
	Sum (mean)	0.0063	3.14	0.0032	31.79

Based on a comment from cMS Germany, an alternative risk assessment for Prothioconazole-desthio, based on a DFR value calculated as mean from all worst case samples across available DFR studies on pome and stone fruits (see Appendix 5 for calculation) and standard DT50=30d is provided below for stone fruits (covers pome fruits since lower dose rate). The results are in line with the previous calculations and the risk is safe.

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 0.65 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate				2 x 0.145 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)			0.0065	64.74
	Vapour (75 th perc.)			0.0011	10.70
	Deposits (75 th perc.)			0.0024	23.77
	Re-entry (75 th perc.)			0.0016	15.70
	Sum (mean)			0.0083	83.43
Resident adult Body weight: 60 kg	Drift (75 th perc.)			0.0036	35.80
	Vapour (75 th perc.)			0.0002	2.30
	Deposits (75 th perc.)			0.0008	8.25
	Re-entry (75 th perc.)			0.0009	8.72
	Sum (mean)			0.0039	38.78

Based on the above calculations, the resident exposure for the intended GAP uses of SIP 41061 is generally below the limit of 100% AOEL. In the following situations the indicated label mitigations should be considered:

Cereals (max. 2 x 0.5 l product/ha at 14 days interval)

⇒ 300L water min or DRT or 5 m buffer zone

Cucurbits, handheld, greenhouse (max. 3x 0.3 l product/ha at 10 days inter-

val)

⇒ 300 L water min

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 or prothioconazole-desithio 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. As 100% conversion is assumed in the exposure assessment, there is no need to calculate combined exposure to these two substances

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2/01	Desiante A.	2022	Determination of dislodgeable foliar residues of prothioconazole and prothioconazole – desthio in raw agricultural commodity peach following two applications of SIP 41061 (prothioconazole 400 g/l SC). (Southern Europe, 1 trial, year 2021) Report No BIU-011-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished	N	Sipcam Oxon S.p.A.
KCP 7.2/02	Desiante A.	2022	Determination of dislodgeable foliar residues of prothioconazole and prothioconazole – desthio in raw agricultural commodity plum following two applications of SIP 41061 (prothioconazole 400 g/l SC). (Southern Europe, 1 trial, year 2021) Report No RAU-022-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished	N	Sipcam Oxon S.p.A.
KCP 7.2/03	Desiante A.	2022	Determination of dislodgeable foliar residues of prothioconazole and prothioconazole – desthio in raw agricultural commodity apple following two applications of SIP 41061 (prothioconazole 400 g/l SC). (Southern Europe, 1 trial, year 2021) Report No BIU-027-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished	N	Sipcam Oxon S.p.A.
KCP 7.2/04	Casalinovo L.	2022	Determination of dislodgeable foliar residues of prothioconazole and Prothio-conazole-desthio in raw agricultural commodity apple following two applica-tions of SIP41061 (prothioconazole 400 g/l SC)	N	Sipcam Oxon S.p.A.

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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
			(Southern and Central Europe, 3 trial, year 2021) Report No RAU-023-21 Research Center BioSphereS by Biotechnologie BT GLP Unpublished		
KCP 7.3/01	Spa S.	2021	The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole in a Concentrate Formulation and Two In-Use Dilutions through Human Split-Thickness Skin. Report No 20287173 Charles River Laboratories GLP Unpublished	N	Sipcam Oxon S.p.A.
KCP 7.3/02	Spa S.	2021	The In Vitro Percutaneous Absorption of radiolabelled Prothioconazoledesthio in an In-Use Dilution and from a Transferred Dried Surface Residue hereof through Human Split-Thickness Skin Report No 20309159 Charles River Laboratories GLP Unpublished	N	Sipcam Oxon S.p.A.

The following tables are to be completed by MS

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List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

No bridging necessary, no Acute tox study conducted

Comments of zRMS:	N/A
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Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	According to Regulation EC 1272/2008, SIP 41061 should not be classified for the acute oral toxicity.
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No acute oral toxicity study has been performed with the formulation SIP 41061; however, additional information relating to the available toxicological data is detailed in the Part C (confidential information).

Overall, according to Regulation EC 1272/2008, SIP 41061 should not be classified for the acute oral toxicity.

A 2.2 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	According to Regulation EC 1272/2008, SIP 41061 should not be classified for the acute dermal toxicity.
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No acute dermal toxicity study has been performed with the formulation SIP 41061; however, additional information relating to the available toxicological data is detailed in the Part C (confidential information).

Overall, according to Regulation EC 1272/2008, SIP 41061 should not be classified for the acute dermal toxicity.

A 2.3 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	According to Regulation EC 1272/2008, SIP 41061 should not be classified for the acute inhalation toxicity.
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No acute inhalation toxicity study has been performed with the formulation SIP 41061; however, additional information relating to the available toxicological data is detailed in the Part C (confidential information).

Overall, according to Regulation EC 1272/2008, SIP 41061 should not be classified for the acute inhalation

toxicity.

A 2.4 Skin irritation (KCP 7.1.4)

Comments of zRMS:	According to Regulation EC 1272/2008, SIP 41061 should not be classified for skin irritation
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No skin irritation study has been performed with the formulation SIP 41061; however, additional information relating to the available toxicological data is detailed in the Part C (confidential information).

Overall, according to Regulation EC 1272/2008, SIP 41061 should not be classified for skin irritation.

A 2.5 Eye irritation (KCP 7.1.5)

Comments of zRMS:	According to Regulation EC 1272/2008, SIP 41061 should not be classified for eye irritation
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No eye irritation study has been performed with the formulation SIP 41061; however, additional information relating to the available toxicological data is detailed in the Part C (confidential information).

Overall, according to Regulation EC 1272/2008, SIP 41061 should not be classified for eye irritation.

A 2.6 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	According to Regulation EC 1272/2008, SIP 41061 should not be classified for skin sensitization with EUH208 "Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction"
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No skin sensitization study has been performed with the formulation SIP 41061; however, additional information relating to the available toxicological data is detailed in the Part C (confidential information).

Overall, according to Regulation EC 1272/2008, SIP 41061 should not be classified for skin sensitization. but should be phrase EUH208 "Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction"

According to Regulation EC 1272/2008, SIP 41061 should not be classified for skin sensitization, however the product should be labelled with EUH208 "Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction"

A 2.7 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

none

A 2.8 Data on co-formulants (KCP 7.4)

A 2.8.1 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 2.8.2 Available toxicological data for each co-formulant

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

A 2.9 Studies on dermal absorption (KCP 7.3)

In vitro dermal absorption human skin

Comments of zRMS:	<p>After correction for variability, the calculated dermal absorption value Prothioconazole for test preparation 1 (concentrate) is 0.08%</p> <p>test preparation 2 (spray dilution I) 13.7% 14%</p> <p>test preparation 3 (spray dilution II) 18.6% 19%</p>
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Reference	KCP 7.3/01
Report	The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole in a Concentrate Formulation and Two In-Use Dilutions through Human Split-Thickness Skin. Spa S., 2021, Report No 20287173
Guideline(s)	Yes, OECD 428 (2004) OECD 28 (2004) OECD 156 (2011) SANCO/222/2000 rev. 7 (2004) EFSA (2017) Guidance on Dermal Absorption
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	NR

Materials and methods

Test material	Name (Lot/Batch No.)	[triazole-U-14C]Prothioconazole (Batch (Lot) No: 12204DZA001-1)
Radiolabelled Test Item	Test preparation	radioformulation
	Specific activity	1891 MBq/mmol (= 5.47 MBq/mg)
	Radiochemical purity	98.1%

4.1.2.1. Non-Radiolabelled Test item	Name (Lot/Batch No.)	Prothioconazole (Batch (Lot) Number: 22410A)
	Company code	
	Purity	99.5%
Blank product	Name (Lot/Batch No.)	SIP 41061 blank formulation (Batch (Lot) No: 21/0078)
	Concentration a.s.	400 g/L (SC) not relevant

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.5 mL/h
	Exposed skin area	0.64 cm ²
	Cover	open
Membrane	Skin type	dermatomed
	Skin thickness range	200-400 µm
	Skin donors age	16-55
	Skin donors sex	f
	Location	breast/abdomen
	Source	ex vivo
	Integrity test	permeation of tritiated water
Receptor	Receptor medium	phosphate buffered saline (PBS) containing polyoxyethylene 20 oleyl ether (6%, w/v), sodium azide (0.01%, w/v), streptomycin (0.1 mg/mL) and penicillin G (100 units/mL).
	Solubility in receptor medium	y
Sample Time	Exposure time	8h
	Observation time	24h
Sampling	Sample intervals	Fractions of the receptor fluid collected at 0-1, 1-2, followed by 2-h intervals until 24 h after dosing.
Washing		post exposure
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks:		

Tested doses	Concentrate	Spray dilution 1	Spray dilution 2
Target concentration [mg/ml]	400	0.27	0.08
No. of donors	4	4	4
No of cells used/valid cells*	8/8	8/8	6/8*

* The mass balance of two samples was outside the 100 ± 10% range and these samples were therefore excluded from the calculations of the mean.

Results and discussions

The results of the *in vitro* percutaneous penetrations are summarized in the following table.

Table A 1: In-vitro dermal penetration of active substance 1 formulated as product code/name through human skin - Recovery data

Dose group	High dose	Mid dose	Low dose
	(Formulation concentrate)	(Spray dilution 1:1500)	(Spray dilution 1:5000)
Target concentration [mg/mL]	400	0.27	0.08
	Recovery [%]	Recovery [%]	Recovery [%]

	Mean	S.D.	Mean	S.D.	Mean	S.D.
Dislodgeable dose						
Skin washing after 8 h	97.9	1.5	82.2	6.8	8.35	6.5
Donor chamber wash	0.15	0.06	1.22	2.28	0.63	0.32
Dose associated to skin						
Stratum Corneum 1-2	0.014	0.017	4.0	3.73	3.51	2.88
Stratum Corneum 3-last	0.01	0.02	8.69	2.45	9.79	7.30
Unexposed skin	0.004	0.004	0.014	0.021	0.018	0.013
Absorbed dose						
Receptor fluid	0.019	0.004	2.14	0.82	0.80	0.13
Receptor chamber wash	0.005	0.005	0.08	0.14	0.03	0.01
Total recovery¹	98.1	1.5	98.7	1.2	98.6	6.0
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}]	No [59% ±7]		No [78% ±6]		No [72% ±3]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	0.06	0.03	11.3	2.8	10.9	7.7
If yes: Absorption estimates = absorbed dose + skin preparation	-	-	-	-	-	-
Absorption estimate normalised ³	-		-		-	
Relevant absorption estimate ⁴	0.0852		13.652		18.6	
Absorption estimates used for risk assessment⁵	0.08		14		19	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study. Finally, the skin preparation is also considered potentially absorbable.

³ According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

⁴ In accordance with the EFSA Guidance on Dermal Absorption, 1*k standard deviation was added to the mean% dermal penetration in cases where the standard deviation was ≥ 25% of the mean value with k=0.84 for n=8 and k=1 for n=6.

⁵ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

The mean radiochemical purity was > 97% in all formulations tested. The results of the radiochemical purity assessment confirmed that the test item was stable upon dosing of the test preparations.

The maximum absorption rate (flux) into the receptor fluid was 0.0798 µg.equiv./cm²/h (Cell 9, test preparation 1), which corresponds to (0.0798 µg × 0.64)/(1 h × 1.5 mL/h) = 0.034 µg/mL. Therefore, the solubility of the test item in the receptor fluid was demonstrated to be adequate and not rate limiting to the absorption process.

For all test preparations, the integrity of the reported skin samples was within the acceptability criteria, i.e., absorption ≤ 1.6% of applied dose of tritiated water for the human skin.

Remarks

The mass balance of two samples in the low dose set was outside the 100 ± 10% range and these samples were therefore excluded from the calculations of the mean.

Conclusion/endpoint:

The absorption of [¹⁴C]PTZ into the receptor fluid within the first half of the study duration was <75% for all three test preparations. Therefore, the dermal absorption value for risk assessment is calculated from the po-

tentially absorbable dose (i.e. total absorbed + exposed skin + stratum corneum, without the first two tape-strips) as defined by the EFSA Guidance on dermal absorption (2017). After correction for variability, the calculated dermal absorption value for test preparation 1 (concentrate) is 0.08% (i.e. $0.06 + (0.84 \times 0.03)$), for test preparation 2 (spray dilution I) 13.7% (i.e. $11.3 + (0.84 \times 2.8)$) and for test preparation 3 (spray dilution II) 18.6% (i.e. $10.9 + (1 \times 7.7)$).

Comments of zRMS:	<p>The calculated dermal absorption values for PTZ-desthio for test preparation is</p> <p>1 (spray dilution) is 16.1% 16%</p> <p>2 (dry residue) is 3.54% 3.5%</p>
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Reference	KCP 7.3/02
Report	The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole-desthio in an In-Use Dilution and from a Transferred Dried Surface Residue hereof through Human Split-Thickness Skin. Spa S., 2021, Report No 20309159
Guideline(s)	Yes, OECD 428 (2004) OECD 28 (2004) OECD 156 (2011) SANCO/222/2000 rev. 7 (2004) EFSA (2017) Guidance on Dermal Absorption
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	NR

Materials and methods

Test material	Name (Lot/Batch No.)	[triazole-U- ¹⁴ C]Prothioconazole-desthio (Batch (Lot) No: 12203DZA001-3)
Radiolabelled Test Item	Test preparation	radioformulation
	Specific activity	1950 MBq/mmol (= 6.21 MBq/mg)
	Radiochemical purity	98.9%
4.1.2.1. Non-Radiolabelled Test item	Name (Lot/Batch No.)	Prothioconazole-desthio (Batch (Lot) Number: FCC3159872)
	Company code	-
	Purity	97%
Blank product	Name (Lot/Batch No.)	SIP 41061 blank formulation (Batch (Lot) No:

		21/0078)
	Concentration a.s.	400 g/L (SC)
Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.5 mL/h
	Exposed skin area	0.64 cm ²
	Cover	open
Membrane	Skin type	dermatomed
	Skin thickness range	200-400 µm
	Skin donors age	16-55
	Skin donors sex	f
	Location	breast/abdomen
	Source	ex vivo
	Integrity test	permeation of tritiated water
Receptor	Receptor medium	phosphate buffered saline (PBS) containing polyoxyethylene 20 oleyl ether (6%, w/v), sodium azide (0.01%, w/v), streptomycin (0.1 mg/mL) and penicillin G (100 units/mL).
	Solubility in receptor medium	y
Sample Time	Exposure time	8h
	Observation time	24h
Sampling	Sample intervals	Fractions of the receptor fluid collected at 0-1, 1-2, followed by 2-h intervals until 24 h after dosing.
Washing		post exposure
Final Procedure	Tape stripping	y
	TS 1-2 analysed separately	y
Remarks:		

Tested doses	Spray dilution 1	Dried residue*
Target concentration	0.07 mg/ml	0.7 µg/cm ²
No. of donors	4	4
No of cells used/valid cells	8/8	8/8*

* To refine the exposure to prothioconazole-desthio derived by re-entry in the field one section of the study has been performed with the formulated product at its highest in-field dilution administered as dried residue. This dose level reflects potential exposure to a dried surface residue, as can be found on foliage as a consequence of using the (diluted) test item. For re-entry workers, exposure to a dried surface residue occurs post-application during re-entry tasks such as crop maintenance, crop inspection and hand harvesting.

Results and discussions

Table A 2: In-vitro dermal penetration of active substance 1 formulated as product code/name through human skin - Recovery data

Dose group	Low dose (Spray dilution 1:5000)		Low dose-dried (Spray dilution 1:5000)	
	Mean	S.D.	Mean	S.D.
Target concentration	0.07 mg/ml		0.7 µg/cm ²	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin washing after 8 h	84.5	4.4	96.5	2.5

Donor chamber wash	0.86	0.28	0.27	0.12
Dose associated to skin				
Stratum Corneum 1-2	0.35	0.28	0.25	0.37
Stratum Corneum 3-last	0.78	0.63	0.48	0.59
Unexposed skin	0.0015	0.007	0.0095	0.0098
Absorbed dose				
Receptor fluid	12.6	3.9	2.31	1.13
Receptor chamber wash	0.057	0.029	0.064	0.032
Total recovery¹	99.4	1.8	100	2.0
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}]	Yes [96.1% ±2.1]		Yes [83.6% ±6.9]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	-	-	-	-
If yes: Absorption estimates = absorbed dose + skin preparation	12.9	3.8	2.51	1.23
Absorption estimate normalised ³	-		-	
Relevant absorption estimate ⁴	16.1		3.54	
Absorption estimates used for risk assessment⁵	16		3.5	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study. Finally, the skin preparation is also considered potentially absorbable.

³ According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.

⁴ In accordance with the EFSA Guidance on Dermal Absorption, 1*k standard deviation was added to the mean% dermal penetration in cases where the standard deviation was ≥ 25% of the mean value with k=0.84 for n=8.

⁵ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

The mean radiochemical purity was > 99% in all formulations tested. The results of the radiochemical purity assessment confirmed that the test item was stable upon dosing of the test preparations.

The maximum absorption rate (flux) into the receptor fluid was 0.061 µg.equiv./cm²/h (Cell 10, test preparation 1), which corresponds to (0.061 µg×0.64)/(1 h×1.5 mL/h) = 0.026 µg/mL. Therefore, the solubility of the test item in the receptor fluid was demonstrated to be adequate and not rate-limiting to the absorption process.

For all test preparations, the integrity of the reported skin samples was within the acceptability criteria, i.e., absorption ≤1.6% of applied dose of tritiated water for the human skin.

Remarks

none.

Conclusion/endpoint:

The absorption of [¹⁴C]PTZ-desthio into the receptor fluid within the first half of the study duration on human skin was >75%, for both test preparations. Therefore, for risk assessment the dermal absorption values can be calculated from the dermal delivery (i.e. total absorbed + exposed skin without tape-strips) as defined by the EFSA Guidance on dermal absorption (2017). After correction for variability, the calculated dermal absorption values for PTZ-desthio for test preparation 1 (spray dilution) and 2 (dry residue) are 16.1% (i.e. 12.9 + (0.84 × 3.8)) and 3.54 % (i.e. 2.51 + (0.84 × 1.23)), respectively.

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A 2.10 Other/Special Studies

none

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Prothioconazole

Cereals

Tractor mounted, downward spraying

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

Formulation type	SC		Crop type	Cereals
Application rate (AR)	0.2	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.08	% (concentr.)	Indoor/outdoor	Outdoor
	14	% (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 acute operator exposure towards active substance according to EFSA guidance

Not relevant

Table A 5: Estimation of longer term operator exposure towards Prothioconazole according to EFSA guidance

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0063	% of AOEL	3.15%	
	Acute systemic exposure mg/kg bw/day	0.0432	% of AAOEL		
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0042	% of AOEL	2.09%	
	Acute systemic exposure mg/kg bw/day	0.0315	% of AAOEL		

Orchard

- Tractor-mounted airblast sprayer, upwards

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

Formulation type	SC		Crop type	Orchards-stone fruits
Application rate (AR)	0.16	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.08	% (concentr.)	Indoor/outdoor	Outdoor
	19	% (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 7: Estimation of acute operator exposure towards active substance according to EFSA guidance

Not relevant

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

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0643	% of AOEL	32.13%	
	Acute systemic exposure mg/kg bw/day	0.3323	% of AAOEL		
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0201	% of AOEL	10.06%	
	Acute systemic exposure mg/kg bw/day	0.0718	% of AAOEL		

- Manual, hand-held application, upwards

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

Formulation type	SC		Crop type	Orchards-stone fruits
Application rate (AR)	0.16	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Hand-held
Dermal absorption (DA)	0.08	% (concentr.)	Indoor/outdoor	Outdoor
	19	% (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 10: Estimation of acute operator exposure towards active substance according to EFSA guidance

Not relevant

Table A 11: Estimation of longer term operator exposure towards Prothioconazole according to EFSA guidance

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.1889	% of AOEL	94.46%	
	Acute systemic exposure mg/kg bw/day	0.5895	% of AAOEL		
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0106	% of AOEL	5.32%	
	Acute systemic exposure mg/kg bw/day	0.0312	% of AAOEL		

Cucurbits

- Manual, hand-held application, upwards, greenhouse

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Data entry screen & summary calculation sheet				GREENHOUSE MODEL v_2.1	
Product:	SIP 41061	75th percentile			
Formulation:	Liquid				
Body weight [kg]:	60				
Active substance(s):	Prothio-desthio	Substance 2	Substance 3	Substance 4	Add substance
Concentration [g/l or kg]	400	0	0	0	
Inhalation absorption [%]	100	0	0	0	
Dermal absorption [%]					Remove substance
Concentration	0.001	0.0	0.0	0.0	
Dilution:	16.0	0.0	0.0	0.0	
AOEL [mg/kg bw/day]	0.01	0.0	0.0	0.0	
Scenario 1: High crop, standard					
Application rate [l or kg product/ha]:	0.3				
Dose [kg a.s./ha]:	0.12	0.0	0.0	0.0	Add application scenario
Work rate [ha/day]:	8.00				
PPE during application:					
PPE during mix/loading:	Respiration: None	Respiration: Mask FFP2			
Hands: None	Hands: Gloves				Remove application scenario
Head: None	Head: None				
Body: Impervious clothing					
Summary					
Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model					
75th percentile					
Active substance	Protection	Systemic exposure [mg/kg]	AOEL [mg/kg bw/day]	% of AOEL	
High crop, standard					
Prothio-desthio	None	0.12112	0.01	1211.2	
	With	0.008526		85.3	

Dutch Model

OPERATOR EXPOSURE		DUTCH GREENHOUSE MODEL		
form	SIP 41061	Application including mixing and loading		
a.s.	Prothioconazole			
Parameter	Value	Unit	References, comments	
MANUAL SPRAYING in greenhouses				
AR Application rate	0.12	kg a.s./ha	summary of intended uses	
A Area treated	1	ha/ day	Dutch model	
Inhalation Exposure				
without PPE				
SV Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)	
Inhalation Exposure (without PPE)	0.12	mg a.s./ day	IE = SV x AR x A	
Inhalation Exposure (with PPE)				
with PPE				
PPE-factor	2		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)	

Inhalation Exposure (with PPE)	0.06	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
Dermal Exposure			without PPE
SV Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure	24	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)			with PPE
PPE-factor	10		Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)	2.4	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure			
IA Inhalation Absorption	100	%	
DA Dermal Absorption	19	%	
AOEL	14	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s. / day]	[mg a.s. / day]	
Inhalation	0.1200	0.0600	IE(int) = IE x (IA/100)
Dermal	4.5600	0.4560	DE(int) = DE x (DA/100)
Total	4.6800	0.5160	sum
% AOEL			
Inhalation	1	0	%AOEL = 100 x IE(int) / AOEL
Dermal	33	3	%AOEL = 100 x DE(int) / AOEL
Total	33	4	sum

A 3.1.2 Calculations for prothioconazole-desthio

Cereals

Tractor mounted, downward spraying

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

Formulation type	SC		Crop type	Cereals
Application rate (AR)	0.181	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	-	% (concentr.)	Indoor/outdoor	Outdoor
	16	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.02	mg/kg bw/d	Water soluble bag	No
AAOEL		mg/kg bw/d		

Table A 13: Estimation of acute operator exposure towards active substance according to EFSA guidance

Not relevant

Table A 14: Estimation of longer-term operator exposure towards Prothioconazole-desthio according to EFSA guidance

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0058	% of AOEL	58.46	
	Acute systemic exposure mg/kg bw/day	0.0420	% of AAOEL		
Mixing and Loading		nr	Clothing = Work wear - arms, body and legs covered	nr	nr
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0039	% of AOEL	39.00	
	Acute systemic exposure mg/kg bw/day	0.0318	% of AAOEL		

Orchard

- Tractor-mounted airblast sprayer, upwards

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

Formulation type	SC		Crop type	Orchards-stone fruits
Application rate (AR)	0.145	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	-	% (concentr.)	Indoor/outdoor	Outdoor
	16	% (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 16: Estimation of acute operator exposure towards active substance according to EFSA guidance

Not relevant

Table A 17: Estimation of longer term operator exposure towards Prothioconazole-desthio according to EFSA guidance

Operator Model	Mixing, loading and application AOEM
----------------	--------------------------------------

Potential exposure	Longer term systemic exposure mg/kg bw/day	0.0493	% of AOEL	492.85%
	Acute systemic exposure mg/kg bw/day	0.2529	% of AAOEL	
Mixing and Loading	nr	Clothing = Work wear - arms, body and legs covered	nr	nr
Application	Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0064	% of AOEL	64.39%
	Acute systemic exposure mg/kg bw/day	0.0344	% of AAOEL	

- Manual, hand-held application, upwards

Table A 18: Input parameters considered for the estimation of operator exposure

Formulation type	SC		Crop type	Orchards-stone fruits
Application rate (AR)	0.145	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Hand-held
Dermal absorption (DA)	-	% (concentr.)	Indoor/outdoor	Outdoor
	16	% (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 19: Estimation of acute operator exposure towards active substance according to EFSA guidance

Not relevant

Table A 20: Estimation of longer term operator exposure towards Prothioconazole-desethio according to EFSA guidance

Operator Model		Mixing, loading and application AOEM		
Potential exposure	Longer term systemic exposure mg/kg bw/day	0.1564	% of AOEL	1563.54
	Acute systemic exposure mg/kg bw/day	0.4942	% of AAOEL	
Mixing and Loading	Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No	Clothing = Work wear - arms, body and	RPE = None	Closed cabin = No

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		legs covered		
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day	0.0091	% of AOEL	90.84%
	Acute systemic exposure mg/kg bw/day	0.0265	% of AAOEL	

Cucurbits

- Manual, hand-held application, upwards, greenhouse

Data entry screen & summary calculation sheet
GREENHOUSE MODEL v.2.1

Product:	SIP 41061	75th percentile		
Formulation:	Liquid			
Body weight [kg]:	60			
Active substance(s):	Prothio-desthio	Substance 2	Substance 3	Substance 4
Concentration [g/l or kg]	363	0	0	0
Inhalation absorption [%]	100	0	0	0
Dermal absorption [%]				
Concentration	0.001	0.0	0.0	0.0
Dilution:	16.0	0.0	0.0	0.0
AOEL [mg/kg bw/day]	0.01	0.0	0.0	0.0

Scenario 1: High crop, standard

Application rate [l or kg product/ha]:	0.3			
Dose [kg a.s./ha]:	0.1088	0.0	0.0	0.0
Work rate [ha/day]:	8.00			

PPE during application:

Respiration	Mask FFP2
Hands:	Gloves
Head:	None
Body:	Impervious clothing

Summary
Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model
75th percentile

Active substance	Protection	Systemic exposure [mg/kg]	AOEL [mg/kg bw/day]	% of AOEL
High crop, standard				
Prothio-desthio	None	0.10985	0.01	1098.5
	With	0.007733		77.3

Dutch Model

OPERATOR EXPOSURE

form SIP 41061
a.s. Prothioconazole-desthio

DUTCH GREENHOUSE MODEL

Application including mixing and loading

Parameter	Value	Unit	References, comments
MANUAL SPRAYING in greenhouses			

AR	Application rate	0.109	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure			without PPE	
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		0.109	mg a.s./ day	IE = SV x AR x A
Inhalation Exposure (with PPE)			with PPE	
	PPE-factor	2	Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)	
Inhalation Exposure (with PPE)		0.0545	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
Dermal Exposure			without PPE	
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure		21.8	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)			with PPE	
	PPE-factor	10	Gloves + coverall: 10 (Dutch model)	
Dermal Exposure (with PPE)		2.18	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	16	%	
	AOEL	0.7	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
		[mg a.s. / day]	[mg a.s. / day]	
Internal exposure				
	Inhalation	0.1090	0.0545	IE(int) = IE x (IA/100)
	Dermal	3.4880	0.3488	DE(int) = DE x (DA/100)
	Total	3.5970	0.4033	sum
% AOEL				
	Inhalation	16	8	%AOEL = 100 x IE(int) / AOEL
	Dermal	498	50	%AOEL = 100 x DE(int) / AOEL
	Total	514	58	sum

A 3.2 Worker exposure calculations (KCP 7.2.3.1)**A 3.2.1 Calculations for Prothioconazole****Cereals**

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

Intended use(s)	Cereals, inspection, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.2	kg a.s./ha	Dermal absorption (DA)	14	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	14	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1.7		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)		cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 22: Estimation of longer term worker exposure towards Prothioconazole according to EFSA guidance

1. Total		
	Potential exposure	Work wear - arms, body and legs covered
Total systemic exposure (mg a.s./day)	3.6196327	0.4053989
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0603272	0.0067566
% of AOEL	30.16%	3.38%
2. Details		
	Systemic exposure	
	[mg a.s. /day]	[mg a.s./kg bw/day]
Dermal - Potential	3.6196327	0.0603272
Dermal - Work wear - arms, body and legs covered	0.4053989	0.0067566
Dermal - Working wear and gloves	no TC available for this assessment	

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

Intended use(s)	Fruiting vegetables, reaching/picking, indoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.12	kg a.s./ha	Dermal absorption (DA)	19	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

AAOEL	-	mg/kg bw/d			
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Table A 24: Estimation of longer term worker exposure towards Prothioconazole according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	7.6921185	3.3155683	0.7692118
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1282020	0.0552595	0.0128202
% of AOEL	64.10%	27.63%	6.41%
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	7.6921185	0.1282020	
Dermal - Work wear - arms, body and legs covered	3.3155683	0.0552595	
Dermal - Working wear and gloves	0.7692118	0.0128202	

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

Intended use(s)	Sugar beet, bolting, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.16	kg a.s./ha	Dermal absorption (DA)	19	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	14	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	18600	cm ² /h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	4500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	430	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 26: Estimation of longer term worker exposure towards Prothioconazole according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves

Total systemic exposure per kg body weight (mg/kg bw/day)	0.32829	0.07943	0.00759
% of AOEL	164.2%	39.71%	3.79%

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

Intended use(s)	Orchards, reaching/picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm²/kg a.s./ha
Application rate (AR)	0.16	kg a.s./ha	Dermal absorption (DA)	19	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	22500	cm²/h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	4500	cm²/h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm²/h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 28: Estimation of longer term worker exposure towards Prothioconazole according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	30.3805521	6.0761104	3.0380552
Total systemic exposure per kg body weight (mg/kg bw/day)	0.5063425	0.1012685	0.0506343
% of AOEL	253.17%	50.63%	25.32%
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	30.3805521	0.5063425	
Dermal - Work wear - arms, body and legs covered	6.0761104	0.1012685	
Dermal - Working wear and gloves	3.0380552	0.0506343	

Pome fruits

Table A 29: Input parameters considered for the estimation of worker exposure

Intended use(s)	Orchards, reaching/picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.12	kg a.s./ha	Dermal absorption (DA)	19	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	22500	cm ² /h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	4500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 30: Estimation of longer term worker exposure towards Prothioconazole according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	22.7854141	4.5570828	2.2785414
Total systemic exposure per kg body weight (mg/kg bw/day)	0.3797569	0.0759514	0.0379757
% of AOEL	189.88%	37.98%	18.99%
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	22.7854141	0.3797569	
Dermal - Work wear - arms, body and legs covered	4.5570828	0.0759514	
Dermal - Working wear and gloves	2.2785414	0.0379757	

A 3.2.2 Calculations for Prothioconazole-desthio**Cereals****Table A 31: Input parameters considered for the estimation of worker exposure**

Intended use(s)	Cereals, inspection, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.181	kg a.s./ha	Dermal absorption (DA)	16	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%

Interval between applications	14	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1.7		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)		cm ² /h
AOEL	0.01	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 32: Estimation of longer term worker exposure towards Prothioconazole-desthio according to EFSA guidance

1. Total		
	Potential exposure	Work wear - arms, body and legs covered
Total systemic exposure (mg a.s./day)	3.7437344	0.4192983
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0623956	0.0069883
% of AOEL	623.96	69.88
2. Details		
	Systemic exposure	
	[mg a.s. /day]	[mg a.s./kg bw/day]
Dermal - Potential	3.7437344	0.0623956
Dermal - Work wear - arms, body and legs covered	0.4192983	0.0069883
Dermal - Working wear and gloves	no TC available for this assessment	

Cucurbits

Table A 33: Input parameters considered for the estimation of worker exposure

Intended use(s)	Fruiting vegetables, reaching/picking, outdoor/indoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.109	kg a.s./ha	Dermal absorption (DA)	16	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.01	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 34: Estimation of longer term worker exposure towards Prothioconazole-desthio according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5.8837959	2.5361189	0.5883796
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0980633	0.0422686	0.0098063
% of AOEL	980.63%	422.69%	98.06%
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	5.8837959	0.0980633	
Dermal - Work wear - arms, body and legs covered	2.5361189	0.0422686	
Dermal - Working wear and gloves	0.5883796	0.0098063	

Sugar beet**Table A 35: Input parameters considered for the estimation of worker exposure**

Intended use(s)	Sugar beet, bolting, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.16	kg a.s./ha	Dermal absorption (DA)	16	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	14	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	18600	cm ² /h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	4500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	430	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 36: Estimation of longer term worker exposure towards Prothioconazole according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure per kg body weight (mg/kg bw/day)	0.29751	0.07198	0.00688
% of AOEL	2975	720	68.78

Stone fruits**Table A 37: Input parameters considered for the estimation of worker exposure**

Intended use(s)	Orchards, reaching/picking, outdoor	Dislodgeable foliar residue (DFR)	0.5	µg/cm ² /kg a.s./ha
Application rate (AR)	0.145 kg a.s./ha	Dermal absorption (DA)	16	% (worst case)
Number of applications (NA)	2	Inhalation absorption (IA)	100	%
Interval between applications	7 days	Work rate per day (WR)	8	h/d
Half-life of active substance	5.3 days	TC dermal (potential)	22500	cm ² /h
Multiple application factor (MAF)	2.4	TC dermal (work wear)	4500	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	2250	cm ² /h
AOEL	0.2 mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d		

Table A 38: Estimation of longer term worker exposure towards Prothioconazole-desthio according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	2.9238796	0.5847759	0.2923880
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0487313	0.0097463	0.0048731
% of AOEL	487.31%	97.46%	48.73%
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	2.9238796	0.0487313	
Dermal - Work wear - arms, body and legs covered	0.5847759	0.0097463	
Dermal - Working wear and gloves	0.2923880	0.0048731	

Pome fruits**Table A 39: Input parameters considered for the estimation of worker exposure**

Intended use(s)	Orchards, reaching/picking, outdoor	Dislodgeable foliar residue (DFR)	1.2	µg/cm ² /kg a.s./ha
Application rate (AR)	0.109 kg a.s./ha	Dermal absorption (DA)	16	% (worst case)
Number of applications (NA)	2	Inhalation absorption (IA)	100	%
Interval between applications	7 days	Work rate per day (WR)	8	h/d

Half-life of active substance	8	days	TC dermal (potential)	22500	cm ² /h
Multiple application factor (MAF)	2.4		TC dermal (work wear)	4500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 40: Estimation of longer term worker exposure towards Prothioconazole-desthio according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5.8210331	1.1642066	0.5821033
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0970172	0.0194034	0.0097017
% of AOEL	970.17	194.03	97.02
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	5.8210331	0.0970172	
Dermal - Work wear - arms, body and legs covered	1.1642066	0.0194034	
Dermal - Working wear and gloves	0.5821033	0.0097017	

Stone fruits (additional, DFR 0.65 µg/cm²/kg a.s./ha, covers Pome fruits)**Table A 41: Input parameters considered for the estimation of worker exposure**

Intended use(s)	Orchards, reaching/picking, outdoor		Dislodgeable foliar residue (DFR)	0.65	µg/cm ² /kg a.s./ha
Application rate (AR)	0.145	kg a.s./ha	Dermal absorption (DA)	16	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	8	days	TC dermal (potential)	22500	cm ² /h
Multiple application factor (MAF)	1.9		TC dermal (work wear)	4500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	2250	cm ² /h
AOEL	0.2	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³
AAOEL	-	mg/kg bw/d			

Table A 42: Estimation of longer term worker exposure towards Prothioconazole-desthio according to EFSA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5.0234509	1.0046902	0.5023451
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0837242	0.0167448	0.0083724
% of AOEL	837.24%	167.45%	83.72%
2. Details			
	Systemic exposure		
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	5.0234509	0.0837242	
Dermal - Work wear - arms, body and legs covered	1.0046902	0.0167448	
Dermal - Working wear and gloves	0.5023451	0.0083724	

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1) -Prothioconazole Cereals

Table A 43: Input parameters considered for the estimation of longer-term resident exposure

Intended use(s)	Tractor mounted boom spray application outdoors to low crops - Cereals		Drift reduction (DR)	0	%
Application rate (AR)	0.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.6	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.1	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			

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Part B – Section 6 - Core Assessment

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Dermal absorption (DA)	14%	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 44: 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)	0.0377596	0.0107000	0.0098261	0.0814417	0.1036643
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0037760	0.0010700	0.0009826	0.0081442	0.0103664
% of RVNAS	1.89%	0.54%	0.49%	4.07%	5.18%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0540560	0.0138000	0.0197294	0.2714725	0.2704098
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0009009	0.0002300	0.0003288	0.0045245	0.0045068
% of RVNAS	0.45%	0.12%	0.16%	2.26%	2.25%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0377596	0.0037760
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0070269	0.0007027
Hand to mouth	0.0018339	0.0001834
Object to mouth	0.0009652	0.0000965
Entry into treated crops		
Dermal	0.0814417	0.0081442
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0540560	0.0009009
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0197294	0.0003288
Entry into treated crops (dermal)	0.2714725	0.0045245

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0208340	0.0020834
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0051447	0.0005145
Hand to mouth	0.0013427	0.0001343
Object to mouth	0.0007067	0.0000707
Entry into treated crops		
Dermal	0.0649362	0.0064936
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0257111	0.0004285
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0144447	0.0002407
Entry into treated crops (dermal)	0.2164540	0.0036076

Oilseed rape**Table A 45: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops – Oilseed rape		Drift reduction (DR)	0	%
Application rate (AR)	0.18	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	5	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			

Dermal absorption (DA)	14	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 46: 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)	0.0339836	0.0107000	0.0088435	0.0732976	0.0943679
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0033984	0.0010700	0.0008843	0.0073298	0.0094368
% of RVNAS	1.70%	0.54%	0.44%	3.66%	4.72%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0486504	0.0138000	0.0177565	0.2443252	0.2447489
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0008108	0.0002300	0.0002959	0.0040721	0.0040791
% of RVNAS	0.41%	0.12%	0.15%	2.04%	2.04%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0339836	0.0033984
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0063242	0.0006324
Hand to mouth	0.0016506	0.0001651
Object to mouth	0.0008687	0.0000869
Entry into treated crops		
Dermal	0.0732976	0.0073298
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0486504	0.0008108
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0177565	0.0002959
Entry into treated crops (dermal)	0.2443252	0.0040721

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0187506	0.0018751
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0046302	0.0004630
Hand to mouth	0.0012084	0.0001208
Object to mouth	0.0006360	0.0000636
Entry into treated crops		
Dermal	0.0584426	0.0058443
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0231400	0.0003857
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0130003	0.0002167
Entry into treated crops (dermal)	0.1948086	0.0032468

Carrot**Table A 47: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops – Carrot		Drift reduction (DR)	0	%
Application rate (AR)	0.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	21	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h

Multiple application factor (MAF)	1.6		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	19	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 48: 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)	0.0151038	0.0107000	0.0092101	0.0763358	0.0866417
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0015104	0.0010700	0.0009210	0.0076336	0.0086642
% of RVNAS	0.76%	0.54%	0.46%	3.82%	4.33%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0216224	0.0138000	0.0184925	0.2544526	0.2405071
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0003604	0.0002300	0.0003082	0.0042409	0.0040085
% of RVNAS	0.18%	0.12%	0.15%	2.12%	2.00%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0151038	0.0015104
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0065864	0.0006586
Hand to mouth	0.0017190	0.0001719
Object to mouth	0.0009047	0.0000905
Entry into treated crops		
Dermal	0.0763358	0.0076336
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0216224	0.0003604
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0184925	0.0003082
Entry into treated crops (dermal)	0.2544526	0.0042409

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0083336	0.0008334
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0048222	0.0004822
Hand to mouth	0.0012585	0.0001259
Object to mouth	0.0006624	0.0000662
Entry into treated crops		
Dermal	0.0608651	0.0060865
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0102844	0.0001714
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0135391	0.0002257
Entry into treated crops (dermal)	0.2028836	0.0033814

Cucurbits**Table A 49: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Upward spraying manual-Hand held–Cucurbits		Drift reduction (DR)	0	%
Application rate (AR)	0.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	2.30%	%
Buffer strip	5	m	Drift on surface (D) - mean	1.80%	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	2.4		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	19	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.

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Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 50: 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)	0.1588738	0.0107000	0.0042745	0.0932504	0.1929579
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0158874	0.0010700	0.0004274	0.0093250	0.0192958
% of RVNAS	7.94%	0.54%	0.21%	4.66%	9.65%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.5275524	0.0138000	0.0092781	0.3108345	0.6139262
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0087925	0.0002300	0.0001546	0.0051806	0.0102321
% of RVNAS	4.40%	0.12%	0.08%	2.59%	5.12%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.1588738	0.0158874
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0033045	0.0003305
Hand to mouth	0.0006355	0.0000635
Object to mouth	0.0003345	0.0000334
Entry into treated crops		
Dermal	0.0932504	0.0093250
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.5275524	0.0087925
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0092781	0.0001546
Entry into treated crops (dermal)	0.3108345	0.0051806

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.1045611	0.0104561
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0025861	0.0002586
Hand to mouth	0.0004973	0.0000497
Object to mouth	0.0002618	0.0000262
Entry into treated crops		
Dermal	0.0743516	0.0074352
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.3450264	0.0057504
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0072611	0.0001210
Entry into treated crops (dermal)	0.2478387	0.0041306

Stone fruits**Table A 51: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted spray application outdoors to high crops (Stone Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.16	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	19	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%

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Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 52: 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)	0.0847327	0.0107000	0.0298766	0.0949392	0.1642830
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0084733	0.0010700	0.0029877	0.0094939	0.0164283
% of RVNAS	4.24%	0.54%	1.49%	4.75%	8.21%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2813613	0.0138000	0.0648495	0.3164641	0.4981523
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0046894	0.0002300	0.0010808	0.0052744	0.0083025
% of RVNAS	2.34%	0.12%	0.54%	2.64%	4.15%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0847327	0.0084733
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0230971	0.0023097
Hand to mouth	0.0044417	0.0004442
Object to mouth	0.0023378	0.0002338
Entry into treated crops		
Dermal	0.0949392	0.0094939
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2813613	0.0046894
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0648495	0.0010808
Entry into treated crops (dermal)	0.3164641	0.0052744

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0557659	0.0055766
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0170998	0.0017100
Hand to mouth	0.0032884	0.0003288
Object to mouth	0.0017307	0.0001731
Entry into treated crops		
Dermal	0.0756982	0.0075698
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1840141	0.0030669
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0480108	0.0008002
Entry into treated crops (dermal)	0.2523274	0.0042055

Intended use(s)	Hand held spray application outdoors to high crops (Stone Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.16	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	19	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor	18	%

			(CF)		
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 53: 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)	0.0847327	0.0107000	0.0298766	0.0949392	0.1642830
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0084733	0.0010700	0.0029877	0.0094939	0.0164283
% of RVNAS	4.24%	0.54%	1.49%	4.75%	8.21%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2813613	0.0138000	0.0648495	0.3164641	0.4981523
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0046894	0.0002300	0.0010808	0.0052744	0.0083025
% of RVNAS	2.34%	0.12%	0.54%	2.64%	4.15%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0847327	0.0084733
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0230971	0.0023097
Hand to mouth	0.0044417	0.0004442
Object to mouth	0.0023378	0.0002338
Entry into treated crops		
Dermal	0.0949392	0.0094939
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2813613	0.0046894
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0648495	0.0010808
Entry into treated crops (dermal)	0.3164641	0.0052744

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0557659	0.0055766
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0170998	0.0017100
Hand to mouth	0.0032884	0.0003288
Object to mouth	0.0017307	0.0001731
Entry into treated crops		
Dermal	0.0756982	0.0075698
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1840141	0.0030669
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0480108	0.0008002
Entry into treated crops (dermal)	0.2523274	0.0042055

Pome fruits**Table A 54: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted spray application outdoors to high crops (Pome Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.12	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour	0.001	mg/m ³

	10	kg/person (children)	(VC)		
Dermal absorption (DA)	19	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 55: 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)	0.0635495	0.0107000	0.0224075	0.0712044	0.1258873
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0063550	0.0010700	0.0022407	0.0071204	0.0125887
% of RVNAS	3.18%	0.54%	1.12%	3.56%	6.29%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2110210	0.0138000	0.0486372	0.2373481	0.3770642
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035170	0.0002300	0.0008106	0.0039558	0.0062844
% of RVNAS	1.76%	0.12%	0.41%	1.98%	3.14%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0635495	0.0063550
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0173228	0.0017323
Hand to mouth	0.0033313	0.0003331
Object to mouth	0.0017533	0.0001753
Entry into treated crops		
Dermal	0.0712044	0.0071204
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2110210	0.0035170
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0486372	0.0008106
Entry into treated crops (dermal)	0.2373481	0.0039558

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0418244	0.0041824
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0128248	0.0012825
Hand to mouth	0.0024663	0.0002466
Object to mouth	0.0012981	0.0001298
Entry into treated crops		
Dermal	0.0567737	0.0056774
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1380106	0.0023002
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0360081	0.0006001
Entry into treated crops (dermal)	0.1892455	0.0031541

Intended use(s)	Hand held spray application outdoors to high crops (Pome Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.12	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	19	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.2	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 56: 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)	0.0635495	0.0107000	0.0224075	0.0712044	0.1258873
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0063550	0.0010700	0.0022407	0.0071204	0.0125887
% of RVNAS	3.18%	0.54%	1.12%	3.56%	6.29%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2110210	0.0138000	0.0486372	0.2373481	0.3770642
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035170	0.0002300	0.0008106	0.0039558	0.0062844
% of RVNAS	1.76%	0.12%	0.41%	1.98%	3.14%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0635495	0.0063550
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0173228	0.0017323
Hand to mouth	0.0033313	0.0003331
Object to mouth	0.0017533	0.0001753
Entry into treated crops		
Dermal	0.0712044	0.0071204
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2110210	0.0035170
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0486372	0.0008106
Entry into treated crops (dermal)	0.2373481	0.0039558

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0418244	0.0041824
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0128248	0.0012825
Hand to mouth	0.0024663	0.0002466
Object to mouth	0.0012981	0.0001298
Entry into treated crops		
Dermal	0.0567737	0.0056774
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1380106	0.0023002
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0360081	0.0006001
Entry into treated crops (dermal)	0.1892455	0.0031541

A 3.3.1 Calculations for Prothioconazole-desthio

Cereals

Table A 57: Input parameters considered for the estimation of longer-term resident exposure

Intended use(s)	Tractor mounted boom spray application outdoors to low crops - Cereals		Drift reduction (DR)	0	%
Application rate (AR)	0.181	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.6	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.1	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h

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Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 58: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0390258	0.0107000	0.0098011	0.0842340	0.1065647
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0039026	0.0010700	0.0009801	0.0084234	0.0106565
% of RVNAS	39.03%	10.70%	9.80%	84.23%	106.56%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0558964	0.0138000	0.0204058	0.2807801	0.2791963
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0009316	0.0002300	0.0003401	0.0046797	0.0046533
% of RVNAS	9.32%	2.30%	3.40%	46.80%	46.53%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0390258	0.0039026
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0072678	0.0007268
Hand to mouth	0.0016597	0.0001660
Object to mouth	0.0008735	0.0000874
Entry into treated crops		
Dermal	0.0842340	0.0084234
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0558964	0.0009316
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0204058	0.0003401
Entry into treated crops (dermal)	0.2807801	0.0046797

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0215263	0.0021526
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0053211	0.0005321
Hand to mouth	0.0012152	0.0001215
Object to mouth	0.0006396	0.0000640
Entry into treated crops		
Dermal	0.0671626	0.0067163
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0265810	0.0004430
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0149400	0.0002490
Entry into treated crops (dermal)	0.2238753	0.0037313

Cereals 300L water min**Table A 59: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops - Cereals		Drift reduction (DR)	0	%
Application rate (AR)	0.181	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	300	L/ha	Drift on surface (D) - 75 th perc.	5.6	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.1	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.

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Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 60: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0260172	0.0107000	0.0098011	0.0842340	0.0993893
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0026017	0.0010700	0.0009801	0.0084234	0.0099389
% of RVNAS	26.02%	10.70%	9.80%	84.23%	99.39%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0372643	0.0138000	0.0204058	0.2807801	0.2703359
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0006211	0.0002300	0.0003401	0.0046797	0.0045056
% of RVNAS	6.21%	2.30%	3.40%	46.80%	45.06%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0260172	0.0026017
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0072678	0.0007268
Hand to mouth	0.0016597	0.0001660
Object to mouth	0.0008735	0.0000874
Entry into treated crops		
Dermal	0.0842340	0.0084234
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0372643	0.0006211
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0204058	0.0003401
Entry into treated crops (dermal)	0.2807801	0.0046797

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0143509	0.0014351
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0053211	0.0005321
Hand to mouth	0.0012152	0.0001215
Object to mouth	0.0006396	0.0000640
Entry into treated crops		
Dermal	0.0671626	0.0067163
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0177206	0.0002953
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0149400	0.0002490
Entry into treated crops (dermal)	0.2238753	0.0037313

Cereals + DRT**Table A 61: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops - Cereals		Drift reduction (DR)	50	%
Application rate (AR)	0.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	2.30	%
Buffer strip	2-3	m	Drift on surface (D) - mean	1.80	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.

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Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 62: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0195129	0.0107000	0.0049005	0.0842340	0.0922137
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0019513	0.0010700	0.0004901	0.0084234	0.0092214
% of RVNAS	19.51%	10.70%	4.90%	84.23%	92.21%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0279482	0.0138000	0.0102029	0.2807801	0.2584358
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0004658	0.0002300	0.0001700	0.0046797	0.0043073
% of RVNAS	4.66%	2.30%	1.70%	46.80%	43.07%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0195129	0.0019513
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0036339	0.0003634
Hand to mouth	0.0008299	0.0000830
Object to mouth	0.0004368	0.0000437
Entry into treated crops		
Dermal	0.0842340	0.0084234
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0279482	0.0004658
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0102029	0.0001700
Entry into treated crops (dermal)	0.2807801	0.0046797

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0107632	0.0010763
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0026605	0.0002661
Hand to mouth	0.0006076	0.0000608
Object to mouth	0.0003198	0.0000320
Entry into treated crops		
Dermal	0.0671626	0.0067163
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0132905	0.0002215
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0074700	0.0001245
Entry into treated crops (dermal)	0.2238753	0.0037313

Cereals + 5m buffer zone**Table A 63: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops – Oilseed rape		Drift reduction (DR)	0	%
Application rate (AR)	0.2	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	2.30	%
Buffer strip	5	m	Drift on surface (D) - mean	1.80	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.

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Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.23798	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.2175	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00009	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00017	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.12278	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.12	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00008	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00014	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 64: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0259789	0.0107000	0.0040255	0.0842340	0.0953880
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0025979	0.0010700	0.0004025	0.0084234	0.0095388
% of RVNAS	25.98%	10.70%	4.03%	84.23%	95.39%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0283382	0.0138000	0.0083810	0.2807801	0.2588851
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0004723	0.0002300	0.0001397	0.0046797	0.0043148
% of RVNAS	4.72%	2.30%	1.40%	46.80%	43.15%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0259789	0.0025979
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0029850	0.0002985
Hand to mouth	0.0006817	0.0000682
Object to mouth	0.0003588	0.0000359
Entry into treated crops		
Dermal	0.0842340	0.0084234
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0283382	0.0004723
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0083810	0.0001397
Entry into treated crops (dermal)	0.2807801	0.0046797

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0143750	0.0014375
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0023361	0.0002336
Hand to mouth	0.0005335	0.0000533
Object to mouth	0.0002808	0.0000281
Entry into treated crops		
Dermal	0.0671626	0.0067163
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0146508	0.0002442
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0065590	0.0001093
Entry into treated crops (dermal)	0.2238753	0.0037313

Oilseed rape**Table A 65: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops – Oilseed rape		Drift reduction (DR)	0	%
Application rate (AR)	0.163	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	14	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.7		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%

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Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 66: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0351448	0.0107000	0.0088264	0.0758572	0.0970312
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035145	0.0010700	0.0008826	0.0075857	0.0097031
% of RVNAS	35.14%	10.70%	8.83%	75.86%	97.03%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0503377	0.0138000	0.0183765	0.2528572	0.2528033
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0008390	0.0002300	0.0003063	0.0042143	0.0042134
% of RVNAS	8.39%	2.30%	3.06%	42.14%	42.13%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0351448	0.0035145
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0065451	0.0006545
Hand to mouth	0.0014947	0.0001495
Object to mouth	0.0007867	0.0000787
Entry into treated crops		
Dermal	0.0758572	0.0075857
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0503377	0.0008390
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0183765	0.0003063
Entry into treated crops (dermal)	0.2528572	0.0042143

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0193856	0.0019386
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0047919	0.0004792
Hand to mouth	0.0010943	0.0001094
Object to mouth	0.0005760	0.0000576
Entry into treated crops		
Dermal	0.0604834	0.0060483
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0239375	0.0003990
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0134543	0.0002242
Entry into treated crops (dermal)	0.2016115	0.0033602

Carrot**Table A 67: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted boom spray application outdoors to low crops – Carrot		Drift reduction (DR)	0	%
Application rate (AR)	0.183	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	21	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.6		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)		% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 68: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0156103	0.0107000	0.0091866	0.0789530	0.0889883
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0015610	0.0010700	0.0009187	0.0078953	0.0088988
% of RVNAS	15.61%	10.70%	9.19%	78.95%	88.99%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0223586	0.0138000	0.0191265	0.2631767	0.2482753
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0003726	0.0002300	0.0003188	0.0043863	0.0041379
% of RVNAS	3.73%	2.30%	3.19%	43.86%	41.38%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0156103	0.0015610
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0068122	0.0006812
Hand to mouth	0.0015557	0.0001556
Object to mouth	0.0008188	0.0000819
Entry into treated crops		
Dermal	0.0789530	0.0078953
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0223586	0.0003726
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0191265	0.0003188
Entry into treated crops (dermal)	0.2631767	0.0043863

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0086105	0.0008611
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0049875	0.0004987
Hand to mouth	0.0011390	0.0001139
Object to mouth	0.0005995	0.0000599
Entry into treated crops		
Dermal	0.0629519	0.0062952
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.0106324	0.0001772
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0140033	0.0002334
Entry into treated crops (dermal)	0.2098396	0.0034973

Cucurbits**Table A 69: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Upward spraying manual-Hand held–Cucurbits		Drift reduction (DR)	0	%
Application rate (AR)	0.109	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	2.30%	%
Buffer strip	5	m	Drift on surface (D) - mean	1.80%	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	2.4		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)		% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%

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AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 70: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.1216660	0.0107000	0.0034087	0.0713283	0.1503347
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0121666	0.0010700	0.0003409	0.0071328	0.0150335
% of RVNAS	121.67%	10.70%	3.41%	71.33%	150.33%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4037120	0.0138000	0.0070969	0.2377611	0.4729902
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0067285	0.0002300	0.0001183	0.0039627	0.0078832
% of RVNAS	67.29%	2.30%	1.18%	39.63%	78.83%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.1216660	0.0121666
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0025277	0.0002528
Hand to mouth	0.0005772	0.0000577
Object to mouth	0.0003038	0.0000304
Entry into treated crops		
Dermal	0.0713283	0.0071328
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.4037120	0.0067285
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0070969	0.0001183
Entry into treated crops (dermal)	0.2377611	0.0039627

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0800945	0.0080095
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0019782	0.0001978
Hand to mouth	0.0004517	0.0000452
Object to mouth	0.0002378	0.0000238
Entry into treated crops		
Dermal	0.0568725	0.0056872
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2640612	0.0044010
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0055541	0.0000926
Entry into treated crops (dermal)	0.1895749	0.0031596

Cucurbits, handheld 300L water minimum**Table A 71: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Upward spraying manual-Hand held–Cucurbits		Drift reduction (DR)	0	%
Application rate (AR)	0.109	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	300	L/ha	Drift on surface (D) - 75 th perc.	2.30%	%
Buffer strip	5	m	Drift on surface (D) - mean	1.80%	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	2.4		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)		% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor	18	%

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			(CF)		
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 72: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0811106	0.0107000	0.0034087	0.0713283	0.1236365
Total systemic exposure per kg body weight (mg/kg bw/day)	0.00811111	0.0010700	0.0003409	0.0071328	0.0123636
% of RVNAS	81.11%	10.70%	3.41%	71.33%	123.64%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2691413	0.0138000	0.0070969	0.2377611	0.3849698
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0044857	0.0002300	0.0001183	0.0039627	0.0064162
% of RVNAS	44.86%	2.30%	1.18%	39.63%	64.16%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0811106	0.0081111
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0025277	0.0002528
Hand to mouth	0.0005772	0.0000577
Object to mouth	0.0003038	0.0000304
Entry into treated crops		
Dermal	0.0713283	0.0071328
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2691413	0.0044857
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0070969	0.0001183
Entry into treated crops (dermal)	0.2377611	0.0039627

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0533964	0.0053396
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0019782	0.0001978
Hand to mouth	0.0004517	0.0000452
Object to mouth	0.0002378	0.0000238
Entry into treated crops		
Dermal	0.0568725	0.0056872
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1760408	0.0029340
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0055541	0.0000926
Entry into treated crops (dermal)	0.1895749	0.0031596

Stone fruits**Table A 73: Input parameters considered for the estimation of longer-term resident exposure**

Intended use(s)	Tractor mounted spray application outdoors to high crops (Stone Fruits,)		Drift reduction (DR)	0	%
Application rate (AR)	0.16	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	5.3	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)		% ('worst case')	Dislodgeable foliar residue (DFR)	0.5	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 74: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0714369	0.0107000	0.0198470	0.0100823	0.0804605
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0071437	0.0010700	0.0019847	0.0010082	0.0080461
% of RVNAS	71.44%	10.70%	19.85%	10.08%	80.46%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2370419	0.0138000	0.0413213	0.0336078	0.2262336
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0039507	0.0002300	0.0006887	0.0005601	0.0037706
% of RVNAS	39.51%	2.30%	6.89%	5.60%	37.71%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0714369	0.0071437
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0147172	0.0014717
Hand to mouth	0.0033609	0.0003361
Object to mouth	0.0017689	0.0001769
Entry into treated crops		
Dermal	0.0100823	0.0010082
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2370419	0.0039507
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0413213	0.0006887
Entry into treated crops (dermal)	0.0336078	0.0005601

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0470280	0.0047028
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0108957	0.0010896
Hand to mouth	0.0024882	0.0002488
Object to mouth	0.0013096	0.0001310
Entry into treated crops		
Dermal	0.0080390	0.0008039
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1550451	0.0025841
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0305919	0.0005099
Entry into treated crops (dermal)	0.0267966	0.0004466

Intended use(s)	Hand held spray application outdoors to high crops (Stone Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.145	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	5.3	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)		% ('worst case')	Dislodgeable foliar residue (DFR)	0.5	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%

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AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 75: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0714369	0.0107000	0.0198470	0.0100823	0.0804605
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0071437	0.0010700	0.0019847	0.0010082	0.0080461
% of RVNAS	71.44%	10.70%	19.85%	10.08%	80.46%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.2370419	0.0138000	0.0413213	0.0336078	0.2262336
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0039507	0.0002300	0.0006887	0.0005601	0.0037706
% of RVNAS	39.51%	2.30%	6.89%	5.60%	37.71%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0714369	0.0071437
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0147172	0.0014717
Hand to mouth	0.0033609	0.0003361
Object to mouth	0.0017689	0.0001769
Entry into treated crops		
Dermal	0.0100823	0.0010082
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.2370419	0.0039507
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0413213	0.0006887
Entry into treated crops (dermal)	0.0336078	0.0005601

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0470280	0.0047028
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0108957	0.0010896
Hand to mouth	0.0024882	0.0002488
Object to mouth	0.0013096	0.0001310
Entry into treated crops		
Dermal	0.0080390	0.0008039
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1550451	0.0025841
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0305919	0.0005099
Entry into treated crops (dermal)	0.0267966	0.0004466

Pome fruits

Table A 76: Input parameters considered for the estimation of longer-term resident exposure

Intended use(s)	Tractor mounted spray application outdoors to high crops (Pome Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.109	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	8	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16	% ('worst case')	Dislodgeable foliar residue (DFR)	1.2	µg/cm ² /kg a.s.

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Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 77: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0486664	0.0107000	0.0149201	0.0181907	0.0682879
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0048666	0.0010700	0.0014920	0.0018191	0.0068288
% of RVNAS	48.67%	10.70%	14.92%	18.19%	68.29%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1614848	0.0138000	0.0310636	0.0606358	0.1907691
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0026914	0.0002300	0.0005177	0.0010106	0.0031795
% of RVNAS	26.91%	2.30%	5.18%	10.11%	31.79%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0486664	0.0048666
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0110637	0.0011064
Hand to mouth	0.0025266	0.0002527
Object to mouth	0.0013298	0.0001330
Entry into treated crops		
Dermal	0.0181907	0.0018191
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1614848	0.0026914
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0310636	0.0005177
Entry into treated crops (dermal)	0.0606358	0.0010106

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0320378	0.0032038
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0081909	0.0008191
Hand to mouth	0.0018705	0.0001871
Object to mouth	0.0009845	0.0000984
Entry into treated crops		
Dermal	0.0145041	0.0014504
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1056245	0.0017604
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0229977	0.0003833
Entry into treated crops (dermal)	0.0483469	0.0008058

Intended use(s)	Hand held spray application outdoors to high crops (Pome Fruits)		Drift reduction (DR)	0	%
Application rate (AR)	0.109	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	500	L/ha	Drift on surface (D) - 75 th perc.	15.79%	%
Buffer strip	5	m	Drift on surface (D) - mean	11.69%	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	8	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.9		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	16%	% ('worst case')	Dislodgeable foliar residue (DFR)	1.2	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%

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AOEL	0.01	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	5.63	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	1.689	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00210	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00164	mL spray dilution (child)			
Spray drift dermal (SD) - mean	3.68	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	1.11	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00170	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00133	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 78: Estimation of longer term resident exposure towards Prothioconazole-desthio 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)	0.0486664	0.0107000	0.0149201	0.0181907	0.0682879
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0048666	0.0010700	0.0014920	0.0018191	0.0068288
% of RVNAS	48.67%	10.70%	14.92%	18.19%	68.29%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1614848	0.0138000	0.0310636	0.0606358	0.1907691
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0026914	0.0002300	0.0005177	0.0010106	0.0031795
% of RVNAS	26.91%	2.30%	5.18%	10.11%	31.79%

2. Resident exposure 75th Percentile		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0486664	0.0048666
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0110637	0.0011064
Hand to mouth	0.0025266	0.0002527
Object to mouth	0.0013298	0.0001330
Entry into treated crops		
Dermal	0.0181907	0.0018191
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1614848	0.0026914
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0310636	0.0005177
Entry into treated crops (dermal)	0.0606358	0.0010106

3. Summing of exposure pathways mean		
	Systemic exposure [mg a.s. /day]	Systemic exposure [mg a.s./kg bw/day]
1-3 year old child		
Spray drift	0.0320378	0.0032038
Vapour	0.0107000	0.0010700
Surface deposits		
Dermal	0.0081909	0.0008191
Hand to mouth	0.0018705	0.0001871
Object to mouth	0.0009845	0.0000984
Entry into treated crops		
Dermal	0.0145041	0.0014504
Hand to mouth		
Object to mouth		
Adult		
Spray drift	0.1056245	0.0017604
Vapour	0.0138000	0.0002300
Surface deposits (dermal)	0.0229977	0.0003833
Entry into treated crops (dermal)	0.0483469	0.0008058

A 3.4 Combined exposure calculations

Not relevant, the product contains only one active ingredient

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)

STONE FRUIT

Report:	KCP 7.2/01, Desiante A. (2021)
Title:	Determination of dislodgeable foliar residues of Prothioconazole and Prothioconazole-desthio in raw agricultural commodity peach following two applications of SIP41061 (Prothioconazole 400 g/l SC) (Southern Europe, 1 trial, year 2021)
Document No:	BIU-011-21, Biospheres
Guidelines:	<input type="checkbox"/> Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990. <input type="checkbox"/> Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999) <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9.

	<input type="checkbox"/> EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) <input type="checkbox"/> Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE. <input type="checkbox"/> EC guidance document 1607/VI/97 rev.2, 10/6/1999 <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
GLP	Yes

Material and Methods:***Trial location***

Trial I/PR21/PE03: Viguzzolo (AL), Italy, zip code 15058.

Test Item

SIP41061 (Prothioconazole 400 g/L SC)	
Nominal a.i. content	400 g/L
Actual a.i. content	35.2 % (w/w) 409 g/L (w/v)
Batch no.	21/0006

Test system Peach plants – Rome Star

Application

The formulated product SIP41061 was applied twice (at BBCH 83-85 and 7 Days After A1) at a rate of 400 mL prod/ha corresponding to 160 g a.i./ha of Prothioconazole.

The application water volume was selected according to Good Agricultural Practices in the respective production areas (500-1500 L/ha).

Table A 79: **Summary of actual application data**

TRIAL No.	Actual Application data					
	Date	Application	Plot	g a.i./ha	Water L/ha	% deviation from target rate
				Prothioconazole		
I/PR21/PE03	26/07/2021	A1	T	149.94	937.14	-6.28
	02/08/2021	A2	T	155.43	971.43	-2.85

Samplings

Leaf discs sampling were carried out 0 days after application 1, 0 days before application 2 and 1, 2, 3 and 7 days after application 2 (DALA).

Leaf discs were sampled by using a leaf punch sampler from the centre of the leaf. The sampling was carried out to obtain 400 cm² surface area specimens. Three replicate samples were collected from untreated plot.

At sampling S1, S3, S6 twelve replicate samples were collected from untreated plot, to have six replicate samples for field fortifications at low level (three for Prothioconazole and three for Prothioconazole-desthio) and six replicate samples for field fortifications at high level (three for Prothioconazole and three for Prothioconazole-desthio). Three replicate samples were collected from treated plot.

All leaf discs samples were used for dislodging process back at the Test Facility within 12 hours from sampling to avoid dehydration of leaf samples

Dislodging process

The leaf discs were dislodged by a 0.01% solution of dioctyl sulfosuccinate sodium salt (w/v): they were washed two times with 100 mL of washing solution each time by shaking plate.

After the washing procedure, the leaf discs were discarded, the washing solutions were frozen immediately after completion of dislodging procedure.

Field fortification

Field fortification was used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical method to analyse Prothioconazole and Prothioconazole - desthio in the field fortification samples.

Two field fortification solutions of Prothioconazole and Prothioconazole-desthio were prepared in Residue Analysis Unit laboratory of Test Facility using analytical reference item in order to obtain fortifications at the following levels:

- 0.01 µg/mL (LOQ - Limit Of Quantification) Low fortification level
- 0.05 µg/mL (5xLOQ) High fortification level

Field fortifications were carried out at sampling S1, S3, S6 in triplicate for both fortification rates.

The control leaf discs harvested for field fortification process were dislodged in the same way as all other specimens to obtain 200 mL of washing solution each. Fortification was carried out on washing solution obtained.

Analytical phase

The Analytical Phase was conducted to determine the residues of Prothioconazole and Prothioconazole-desthio in the dislodging solution, obtained by the dislodging process, on the basis of an analytical method validated in this study under GLP compliance according to SANTE/2020/12830, rev.1 (24/02/2021) guideline.

For details of the method and its validation please refer to dRR part B5 of this dossier

The results of the validation method are herewith summarized:

Table A 80: **Summary of validation data**

QUANTIFIER ION					
Matrix	Fortification Level (µg/mL)	Accuracy	Precision	Overall accuracy and precision	
		Mean Recovery (%) n=7	RSD (%) n=7	Mean Recovery (%) n=21	RSD (%) n=21
<i>Dislodging foliar</i>	Prothioconazole				
	0.01	72.95	3.62	91.46	15.86

solution	0.1	105.17	5.29		
	1.0	96.26	4.38		
	Prothioconazole-desthio				
	0.01	105.94	2.56	99.84	5.36
	0.1	94.67	1.29		
	1.0	98.91	3.37		

The samples were extracted with acetonitrile and shaken by vigorous manual stirring for few minutes. The content of a QuEChERS Extraction kit was added and then the samples were shaken and centrifuged. The samples were analyzed with a HPLC system coupled with a triple quadrupole mass analyser (LC-MS/MS). The Limit of Quantification (LOQ) was set at 0.01 mg/kg for all analytes.

The analytical method was validated in terms of Accuracy, Precision, Linearity, Selectivity, Limit of Quantification and Limit of Detection by means of recovery tests and analysis of blank samples.

Untreated samples were used for recovery tests. The target limit of quantitation (LOQ) was 0.01 mg/L for both analytes

Results:

No interferences from the matrices were observed and the analytical method worked adequately.

Procedural recoveries in the laboratory were acceptable for both Prothioconazole and Prothioconazole-desthio.

Prothioconazole was absent in the dislodging solution of its field fortification samples with no evidence either of Prothioconazole-desthio, the main degradation product. In the dislodging solution obtained from the field treated samples however, Prothioconazole was detected and the degradation of Prothioconazole to Prothioconazole-desthio was clearly observed.

The instability of Prothioconazole is therefore particularly evident at the low concentrations of the field fortification samples (1x and 5x LOQ). The results of the analysis of Prothioconazole in the dislodged samples should therefore be taken with care.

No instability was observed for Prothioconazole-desthio which recovery levels in the field fortification samples were optimal for all concentration levels. The results of the analysis of Prothioconazole-desthio in the dislodged samples are therefore adequately supported by the results from the field fortification samples analysis.

Residues of both Prothioconazole and Prothioconazole-desthio. were undetectable (less than 0.003 µg/mL corresponding to 0.0015 µg/cm²) in all untreated leaf washing specimens.

The residue values found on field specimens are reported in the following table and are expressed in µg/mL (not corrected by the mean recovery value) and µg/cm²:

Table A 81: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)**	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/PE03/01C	C	S1 0 DAA1	Dislodging solution	N.D.*	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/PE03/02C	C			N.D.			N.D.		
I/PR21/PE03/03C	C			N.D.			N.D.		
I/PR21/PE03/04C/LFP ¹	C		Dislodging solution LFP	N.D.			-		
I/PR21/PE03/05C/LFP	C			N.D.			-		
I/PR21/PE03/06C/LFP	C			N.D.			-		
I/PR21/PE03/07C/HFP ²	C		Dislodging solution - HFP	< LOQ (0.0052)	/	/	< LOQ (0.0039)	/	/
I/PR21/PE03/08C/HFP	C			< LOQ (0.0055)			< LOQ (0.0042)		
I/PR21/PE03/09C/HFP	C			< LOQ (0.0056)			< LOQ (0.0037)		
I/PR21/PE03/10C/LFD ³	C		Dislodging solution DFP	-			0.0112		
I/PR21/PE03/11C/LFD	C			-			0.0121		
I/PR21/PE03/12C/LFD	C			-			0.0124		
I/PR21/PE03/13C/HFD ⁴	C		Dislodging solution - HFD	-			0.0525		
I/PR21/PE03/14C/HFD	C			-			0.0510		
I/PR21/PE03/15C/HFD	C			-			0.0486		
I/PR21/PE03/16T	T	S2 0 DBA2	Dislodging solution	0.1330	0.0665	0.0438	0.1043	0.05215	0.0385
I/PR21/PE03/17T	T			0.0541	0.02705		0.0534	0.0267	
I/PR21/PE03/18T	T			0.0758	0.0379		0.0731	0.03655	
I/PR21/PE03/19C	C			N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/PE03/20C	C		Dislodging solution	N.D.			N.D.		
I/PR21/PE03/21C	C			N.D.			N.D.		
I/PR21/PE03/22T	T			< LOQ (0.0068)	< LOQ (0.0034)	0.0028	0.0123	0.00615	0.0049

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)*	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/PE03/23T	T			< LOQ (0.0049)	< LOQ (0.00245)		< LOQ (0.0084)	< LOQ (0.0042)	
I/PR21/PE03/24T	T			< LOQ (0.0049)	< LOQ (0.00245)		< LOQ (0.0086)	< LOQ (0.0043)	
I/PR21/PE03/25C	C	S3 0 DAA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/PE03/26C	C			N.D.			N.D.		
I/PR21/PE03/27C	C			N.D.			N.D.		
I/PR21/PE03/28C/LFP ¹	C		Dislodging solution LFP	N.D.			N.D.		
I/PR21/PE03/29C/LFP	C			N.D.			N.D.		
I/PR21/PE03/30C/LFP	C			N.D.			N.D.		
I/PR21/PE03/31C/HFP ²	C		Dislodging solution - HFP	< LOQ (0.0049)	/	/	< LOQ (0.0034)	/	/
I/PR21/PE03/32C/HFP	C			< LOQ (0.0045)			< LOQ (0.0033)		
I/PR21/PE03/33C/HFP	C			< LOQ (0.0052)			< LOQ (0.0036)		
I/PR21/PE03/34C/LFD ³	C		Dislodging solution LFD	-			< LOQ (0.0096)		
I/PR21/PE03/35C/LFD	C			-			< LOQ (0.0095)		
I/PR21/PE03/36C/LFD	C			-			< LOQ (0.0093)		
I/PR21/PE03/37C/HFD ⁴	C		Dislodging solution - HFD	-			0.0434		
I/PR21/PE03/38C/HFD	C			-			0.0435		
I/PR21/PE03/39C/HFD	C			-			0.0435		
I/PR21/PE03/40T	T	S4 1 DAA2	Dislodging solution	0.0532	0.0266	0.0265	0.0498	0.0249	0.0241
I/PR21/PE03/41T	T			0.0565	0.02825		0.0511	0.02555	
I/PR21/PE03/42T	T			0.0494	0.0247		0.0438	0.0219	
I/PR21/PE03/43C	C			N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/PE03/44C	C	S5 2 DAA2	Dislodging solution	N.D.			N.D.		
I/PR21/PE03/45C	C			N.D.			N.D.		
I/PR21/PE03/46T	T		Dislodging solution	0.0202	0.0101	0.0111	0.0590	0.0295	0.0298
I/PR21/PE03/47T	T			0.0256	0.0128		0.0679	0.03395	

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)*	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/PE03/48T	T			0.0210	0.0105		0.0519	0.02595	
I/PR21/PE03/49C	C	S6 3 DAA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/PE03/50C	C			N.D.			N.D.		
I/PR21/PE03/51C	C			N.D.			N.D.		
I/PR21/PE03/52C/LFP ¹	C		Dislodging solution LFP	N.D.	/	/	N.D.	/	/
I/PR21/PE03/53C/LFP	C			N.D.			N.D.		
I/PR21/PE03/54C/LFP	C			N.D.			N.D.		
I/PR21/PE03/55C/HFP ²	C		Dislodging solution - HFP	< LOQ (0.0052)			< LOQ (0.0045)		
I/PR21/PE03/56C/HFP	C			< LOQ (0.0053)			< LOQ (0.0047)		
I/PR21/PE03/57C/HFP	C			< LOQ (0.0048)			< LOQ (0.0045)		
I/PR21/PE03/58C/LFD ³	C		Dislodging solution LFD	-			< LOQ (0.0080)		
I/PR21/PE03/59C/LFD	C			-			< LOQ (0.0087)		
I/PR21/PE03/60C/LFD	C			-			< LOQ (0.0094)		
I/PR21/PE03/61C/HFD ⁴	C		Dislodging solution - HFD	-			0.0418		
I/PR21/PE03/62C/HFD	C			-			0.0388		
I/PR21/PE03/63C/HFD	C			-			0.0418		
I/PR21/PE03/64T	T		Dislodging solution	0.0239	0.01195	0.0109	0.0344	0.0172	0.0183
I/PR21/PE03/65T	T			0.0189	0.00945		0.0378	0.0189	
I/PR21/PE03/66T	T			0.0224	0.0112		0.0375	0.01875	
I/PR21/PE03/67C	C	S7 7 DAA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/PE03/68C	C			N.D.			N.D.		
I/PR21/PE03/69C	C			N.D.			N.D.		
I/PR21/PE03/70T	T			0.0107	0.0088	0.0044	0.0195	0.00975	0.0093
I/PR21/PE03/71T	T			< LOQ (0.0064)	< LOQ (0.0032)		0.0154	0.0077	

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)**	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/PE03/72T	T			< LOQ (0.0092)	< LOQ (0.0046)		0.0206	0.0103	

Highest value for each triplicate in **bold** for use in RA. *N.D.: Not Detectable, lower than the Limit of Detection (LOD). The LOD is 0.003 µg/mL corresponding to 0.0015 µg/cm² (calculated following the above formula).

1: Prothioconazole Low Fortification

2: Prothioconazole High Fortification

3: Prothioconazole-desthio Low Fortification

4: Prothioconazole-desthio High Fortification

** The residue expressed as µg/cm² was calculated following this formula:

$$\text{Residue as } \frac{\mu\text{g}}{\text{cm}^2} = \text{Residue as } \frac{\mu\text{g}}{\text{mL}} * 200 \text{ mL} * \frac{1}{400 \text{ cm}^2}$$

To be used in risk assessment, and to allow comparison among different trials mean and highest DFR values for each relevant triplicate were reported as µg/cm²/kg a.i./ha

Table A 82: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens normalized to kg a.i./ha

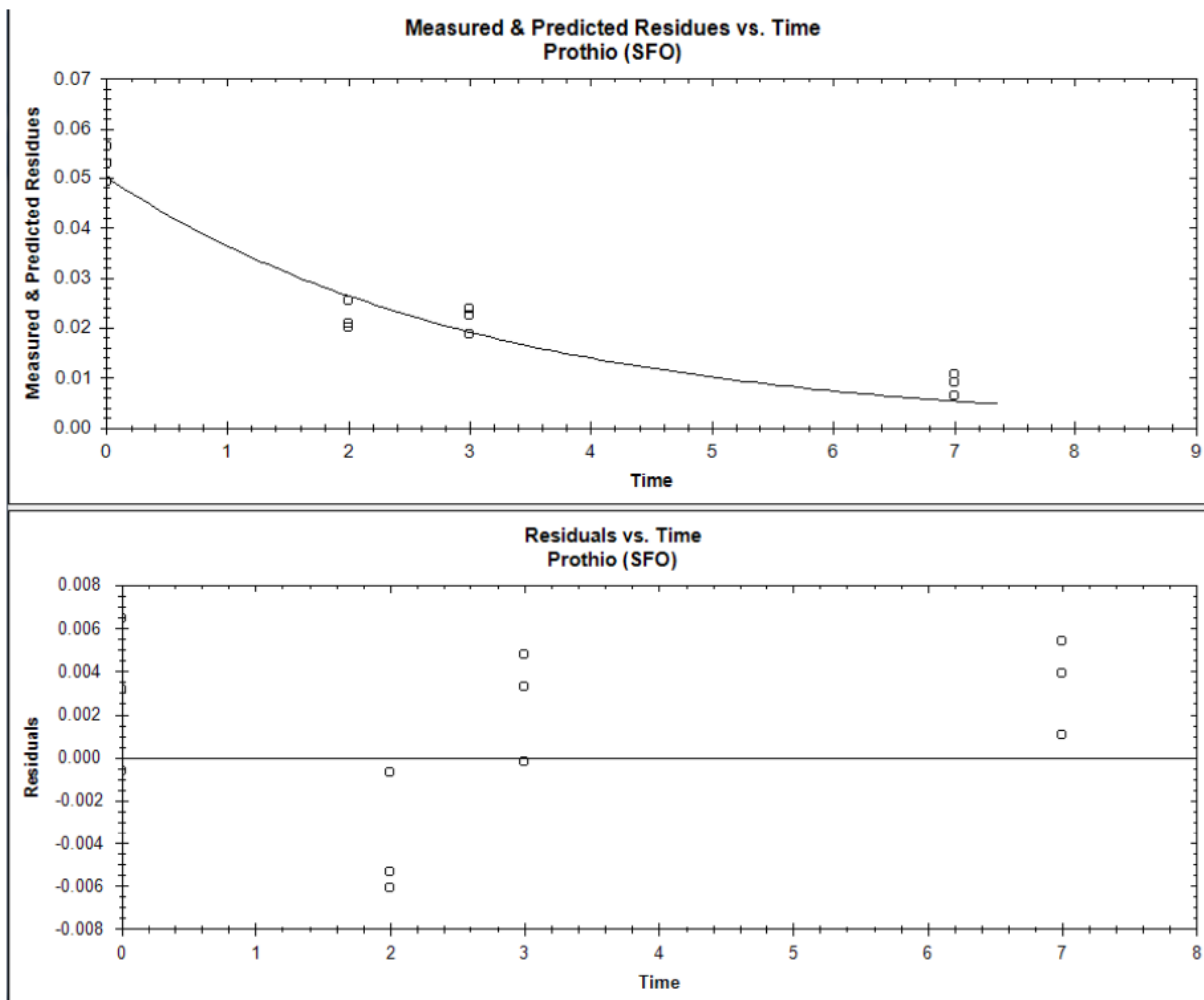
Sample	Prothioconazole		Prothioconazole - desthio	
	mean value µg/cm ² /kg a.i./ha	highest value µg/cm ² /kg a.i. /ha	mean value µg/cm ² /kg a.i./ha	highest value µg/cm ² /kg a.i. /ha
I/PR21/PE03				
S1 - 0 DAA1	0.27375	0.415625	0.240625	0.3259375
S3 - 0 DAA2	0.165625	0.1765625	0.150625	0.1596875
S5 - 2 DAA2	0.069375	0.08	0.18625	0.2121875
S6 - 3 DAA2	0.068125	0.0746875	0.114375	0.118125
S7 - 7 DAA2	0.0275	0.0334375	0.058125	0.064375

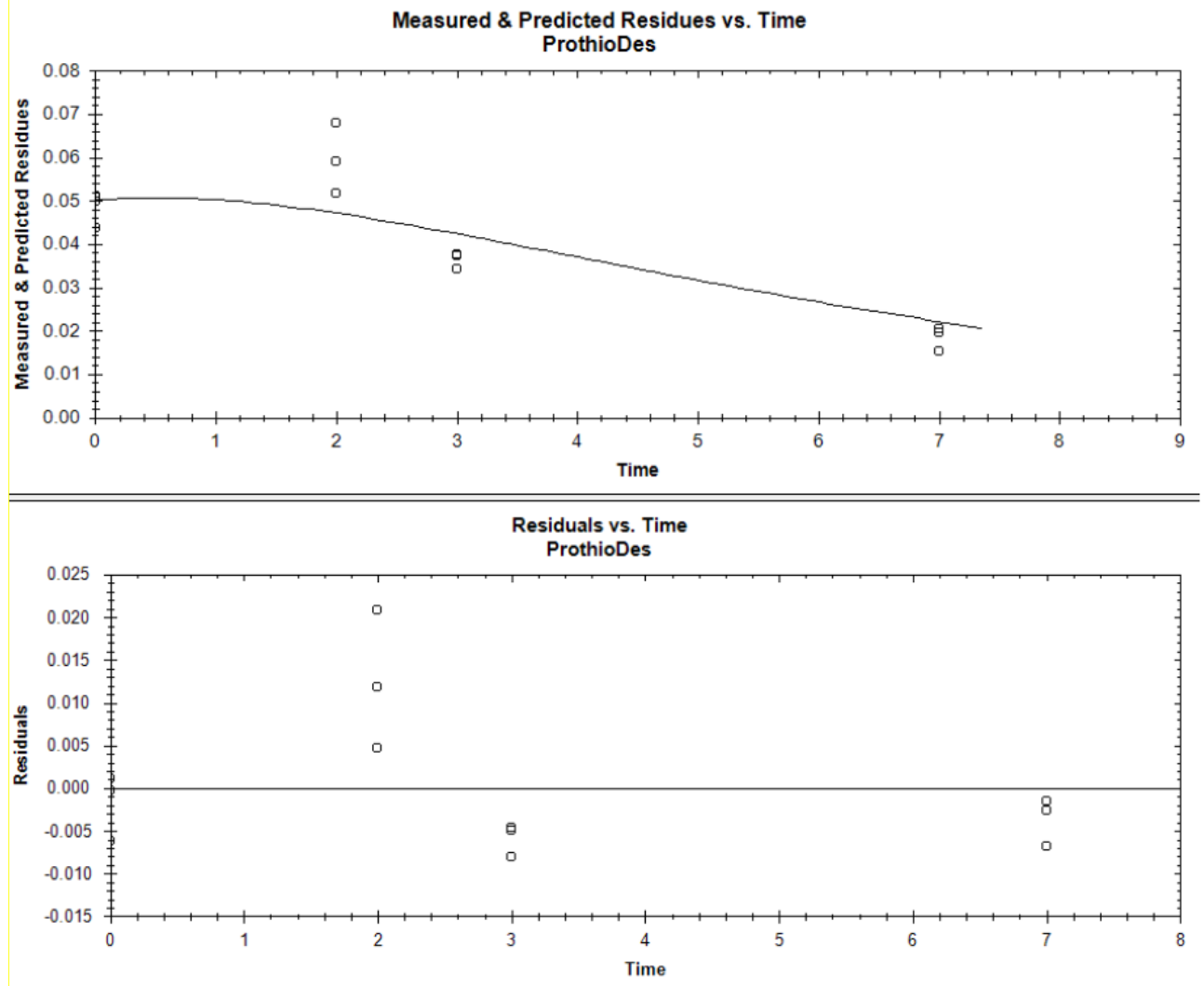
Since it is evident from the results in previous tables that the variability among the replicates of a sampling points is very low (SD generally lower than 15%, over all the trials considered) the use of the mean value it is considered suitable and sufficiently representative of the effective dislodgeable value of the considered molecules. The **worst case mean values** will be considered to select the appropriate DFR values to refine re-entry risk assessment.

The DFR residues of the field trial were used to determine DT50 value in compliance with FOCUS Kinetics 2006 guideline (SANCO/10058/2005). Both Prothioconazole and Prothioconazole-desethio degraded over time following a curve described by the Single first order kinetic model.

Curve fitting and residual plot are reported in the following tables

Prothioconazole: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



Prothioconazole -desthio: (SFO): Residues (µg/mL) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)

The calculated values are as follows:

Table A 83: **Prothioconazole and Prothioconazole - desthio in DFR samples DT₅₀ values estimation considering FOCUS kinetics guidance**

Analyte	Kinetic model	DT ₅₀ [days]	DT ₉₀ [days]	Plot visually acceptable	K1*	χ^2	r ²
Prothioconazole	SFO	2.164	7.187	Yes	0.32037	10.32	0.944
Prothioconazole-desthio	SFO	2.594	8.618	Yes	0.26717	14.39	0.7618

*K1: rate constant of decline 1/days

Conclusions

The highest dislodgeable residues from peach leaves in this study were identified just after the first application for both Prothioconazole and Prothioconazole-desthio. The partial degradation of Prothioconazole to Prothioconazole desthio appears to be immediate.

Report:	KCP 7.2/02, Desiante A. (2022)
Title:	Determination of dislodgeable foliar residues of prothioconazole and Prothioconazole-desthio in raw agricultural commodity plum following two applications of SIP41061 (prothioconazole 400 g/l SC) (Southern Europe, 1 trial, year 2021)
Document No:	RAU-022-21, Biospheres
Guidelines:	<input type="checkbox"/> Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990. <input type="checkbox"/> Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999) <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9. <input type="checkbox"/> EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) <input type="checkbox"/> Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE. <input type="checkbox"/> EC guidance document 1607/VI/97 rev.2, 10/6/1999 <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
GLP	Yes

Material and Methods:***Trial location***

- Trial S/PR21/PL01: Los Palacios y Villafranca, Spain, zip code 41720

Test Item

SIP41061 (Prothioconazole 400 g/L SC)	
Nominal a.i. content	400 g/L
Actual a.i. content	35.2 % (w/w) 409 g/L (w/v)
Batch no.	21/0006

Test system Plum plants – Showtime/Fortune/Ambra

Application

The formulated product SIP41061 was applied twice (at BBCH 81 and 7 Days After A1) at a rate of 600 mL prod/ha corresponding to 240 g a.i./ha of Prothioconazole.

The application water volume was selected according to Good Agricultural Practices in the respective production areas (500-1500 L/ha).

Table A 84: **Summary of actual application data**

TRIAL No.	Actual Application data					
	Date	Application	Plot	g a.i./ha	Water	% deviation

				Prothioconazole	L/ha	from target rate
S/PR21/PL01	06/07/2021	A1	T	236.00	984.00	-1.5
	13/07/2021	A2	T	236.00	984.00	-1.5

Samplings

Leaf discs sampling were carried out 0 days after application 1, 0 days before application 2 and 1, 2, 3, 7 days after application 2 (DALA).

Leaf discs were sampled by using a leaf punch sampler from the centre of the leaf. The sampling was carried out to obtain 400 cm² surface area specimens. Three replicate samples were collected from untreated plot.

At sampling S1, S3, S6 twelve replicate samples were collected from untreated plot, to have six replicate samples for field fortifications at low level (three for Prothioconazole and three for Prothioconazole-desthio) and six replicate samples for field fortifications at high level (three for Prothioconazole and three for Prothioconazole-desthio). Three replicate samples were collected from treated plot.

All leaf discs samples were used for dislodging process back at the Test Facility within 12 hours from sampling in order to avoid dehydration of leaf samples

Dislodging process

The leaf discs were dislodged by a 0.01% solution of dioctyl sulfosuccinate sodium salt (w/v): they were washed two times with 100 mL of washing solution each time by shaking plate.

After the washing procedure, the leaf discs were discarded, the washing solutions were frozen immediately after completion of dislodging procedure.

Field fortification

Field fortification was used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical method to analyse Prothioconazole and Prothioconazole - desthio in the field fortification samples.

Two field fortification solutions of Prothioconazole and Prothioconazole-desthio were prepared in Residue Analysis Unit laboratory of Test Facility using analytical reference item in order to obtain fortifications at the following levels:

- 0.01 µg/mL (LOQ - Limit Of Quantification) Low fortification level
- 0.05 µg/mL (5xLOQ) High fortification level

Field fortifications were carried out at sampling S1, S3, S6 in triplicate for both fortification rates.

The control leaf discs harvested for field fortification process were dislodged in the same way as all other specimens to obtain 200 mL of washing solution each. Fortification was carried out on washing solution obtained.

Analytical phase

The Analytical Phase was conducted to determine the residues of Prothioconazole and Prothioconazole-desthio in the dislodging solution, obtained by the dislodging process, on the basis of an analytical method

validated in the study BIU-011-21 above, under GLP compliance according to SANTE/2020/12830, rev.1 (24/02/2021) guideline.

For details of the method and its validation please refer to dRR part B5 of this dossier

The results of the procedural recoveries of this study are herewith summarized:

Table A 85: **Summary of procedural recoveries**

QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy	Precision	Overall accuracy and precision	
		Mean Recovery (%) n=6	RSD (%) n=6	Mean Recovery (%) n=12	RSD (%) n=12
Dislodging foliar solution	Prothioconazole				
	0.01	93.21	11.08	93.83	7.82
	0.1	94.45	3.48		
	Prothioconazole-desthio				
	0.01	97.65	2.17	93.92	5.45
	0.1	90.20	4.94		

The samples were extracted with acetonitrile and shaken by vigorous manual stirring for few minutes. The content of a QuEChERS Extraction kit was added and then the samples were shaken and centrifuged. The samples were analyzed with a HPLC system coupled with a triple quadrupole mass analyser (LC-MS/MS). The Limit of Quantification (LOQ) was set at 0.01 mg/kg for all analytes.

The analytical method was validated in terms of Accuracy, Precision, Linearity, Selectivity, Limit of Quantification and Limit of Detection by means of recovery tests and analysis of blank samples.

Untreated samples were used for recovery tests. The target limit of quantitation (LOQ) was 0.01 mg/L for both analytes

Results:

No interferences from the matrices were observed and the analytical method worked adequately.

Procedural recoveries in the laboratory were acceptable for both Prothioconazole and Prothioconazole-desthio.

Prothioconazole was absent in the dislodging solution of its field fortification samples with no evidence either of Prothioconazole-desthio, the main degradation product. In the dislodging solution obtained from the field treated samples however, Prothioconazole was detected and the degradation of Prothioconazole to Prothioconazole-desthio was clearly observed.

The instability of Prothioconazole is therefore particularly evident at the low concentrations of the field fortification samples (1x and 5x LOQ). The results of the analysis of Prothioconazole in the dislodged samples should therefore be taken with care.

No instability was observed for Prothioconazole-desthio which recovery levels in the field fortification samples were optimal for all concentration levels. The results of the analysis of Prothioconazole-desthio in the

dislodged samples are therefore adequately supported by the results from the field fortification samples analysis.

Residues of both Prothioconazole and Prothioconazole-desthio. were undetectable (less than 0.003 µg/mL corresponding to 0.0015 µg/cm²) in all untreated leaf washing specimens.

The residue values found on field specimens are reported in the following table and are expressed in µg/mL (not corrected by the mean recovery value) and µg/cm²:

Table A 86: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)**	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
S/PR21/PL01/01C	C	S1 0 DAA1	Dislodging solution	N.D. ¹	N.D.	N.D.	N.D.	N.D.	N.D.
S/PR21/PL01/02C	C			N.D			N.D		
S/PR21/PL01/03C	C			N.D			N.D		
S/PR21/PL01/04C/LFP ¹	C		Dislodging solution LFP	N.D.	/	/	N.D.	/	/
S/PR21/PL01/05C/LFP	C			N.D.			N.D		
S/PR21/PL01/06C/LFP	C			N.D.			N.D		
S/PR21/PL01/07C/HFP ²	C		Dislodging solution - HFP	N.D.			N.D		
S/PR21/PL01/08C/HFP	C			N.D.			N.D		
S/PR21/PL01/09C/HFP	C			N.D.			N.D		
S/PR21/PL01/10C/LFD ³	C		Dislodging solution DFP	/			< 0.01 (0.0091)		
S/PR21/PL01/11C/LFD	C						< 0.01 (0.0082)		
S/PR21/PL01/12C/LFD	C						< 0.01 (0.0090)		
S/PR21/PL01/13C/HFD ⁴	C		0.0426						
S/PR21/PL01/14C/HFD	C		0.0442						
S/PR21/PL01/15C/HFD	C		0.0359						
S/PR21/PL01/16T	T	S1 (0 Days After AI)	Dislodging solution	0.1832	0.0916	0.1039	0.1090	0.0545	0.0585
S/PR21/PL01/17T	T			0.2616	0.1308		0.1247	0.06235	
S/PR21/PL01/18T	T			0.1783	0.08915		0.1172	0.0586	
S/PR21/PL01/19C	C	S2 0 DBA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
S/PR21/PL01/20C	C			N.D.			N.D		
S/PR21/PL01/21C	C			N.D.			N.D		
S/PR21/PL01/22T	T			0.0370	0.0185	0.0185	0.0813	0.04065	0.0354
S/PR21/PL01/23T	T			0.0463	0.02315		0.0682	0.0341	

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio					
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)**	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)			
S/PR21/PL01/24T	T			0.0275	0.01375		0.0626	0.0313				
S/PR21/PL01/25C	C	S3 0 DAA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.			
S/PR21/PL01/26C	C			N.D.								
S/PR21/PL01/27C	C			N.D.								
S/PR21/PL01/28C/LFP ¹	C	S3 (0 Day Before A2)	Dislodging solution LFP	N.D.	/	/	N.D	/	/			
S/PR21/PL01/29C/LFP	C			N.D.			N.D					
S/PR21/PL01/30C/LFP	C			N.D.			N.D					
S/PR21/PL01/31C/HFP ²	C		Dislodging solution - HFP	N.D.			N.D					
S/PR21/PL01/32C/HFP	C			N.D.			N.D					
S/PR21/PL01/33C/HFP	C			N.D.			N.D					
S/PR21/PL01/34C/LFD ³	C		Dislodging solution LFD	/			/			< 0.01 (0.0078)	/	/
S/PR21/PL01/35C/LFD	C									< 0.01 (0.0088)		
S/PR21/PL01/36C/LFD	C									< 0.01 (0.0078)		
S/PR21/PL01/37C/HFD ⁴	C		Dislodging solution - HFD							0.0354		
S/PR21/PL01/38C/HFD	C									0.0353		
S/PR21/PL01/39C/HFD	C									0.0418		
S/PR21/PL01/40T	T	S3 (0 Day After A2)	Dislodging solution	0.2817	0.14085	0.1282	0.1651	0.08255	0.0782			
S/PR21/PL01/41T	T			0.2753	0.13765		0.1517	0.07585				
S/PR21/PL01/42T	T			0.2120	0.106		0.1526	0.0763				
S/PR21/PL01/43C	C	S4 1 DAA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.			
S/PR21/PL01/44C	C			N.D			N.D					
S/PR21/PL01/45C	C			N.D			N.D					
S/PR21/PL01/46T	T	S5 2 DAA2	Dislodging solution	0.1776	0.0888	0.0803	0.2593	0.12965	0.1155			
S/PR21/PL01/47T	T			0.1974	0.0987		0.2476	0.1238				
S/PR21/PL01/48T	T			0.1070	0.0535		0.1862	0.0931				
S/PR21/PL01/49C	C	S6	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.			

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio			
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)**	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	
S/PR21/PL01/50C	C	3 DAA2		N.D.			N.D.			
S/PR21/PL01/51C	C			N.D.			N.D.			
S/PR21/PL01/52C/LFP ¹	C		Dislodging solution LFP	N.D.	/	/	N.D	/	/	
S/PR21/PL01/53C/LFP	C			N.D.			N.D			
S/PR21/PL01/54C/LFP	C			N.D.			N.D			
S/PR21/PL01/55C/HFP ²	C		Dislodging solution - HFP	N.D.			N.D			
S/PR21/PL01/56C/HFP	C			N.D.			N.D			
S/PR21/PL01/57C/HFP	C			N.D.			N.D			
S/PR21/PL01/58C/LFD ³	C		Dislodging solution LFD				< 0.01 (0.0086)			
S/PR21/PL01/59C/LFD	C						< 0.01 (0.0086)			
S/PR21/PL01/60C/LFD	C						< 0.01 (0.0090)			
S/PR21/PL01/61C/HFD ⁴	C		Dislodging solution - HFD	/			0.0414			
S/PR21/PL01/62C/HFD	C						0.0438			
S/PR21/PL01/63C/HFD	C						0.0439			
S/PR21/PL01/64T	T		Dislodging solution	0.1241	0.06205	0.0699	0.2613	0.13065	0.1184	
S/PR21/PL01/65T	T			0.1310	0.0655		0.2081	0.10405		
S/PR21/PL01/66T	T			0.1645	0.08225		0.2408	0.1204		
S/PR21/PL01/67C	C		S7 7 DAA2	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
S/PR21/PL01/68C	C	N.D.			N.D.					
S/PR21/PL01/69C	C	N.D.			N.D.					
S/PR21/PL01/70T	T	0.1050			0.0525	0.0457	0.1521	0.07605	0.0778	
S/PR21/PL01/71T	T	0.0735			0.03675		0.1379	0.06895		
S/PR21/PL01/72T	T	0.0955			0.04775		0.1770	0.0885		

Highest value for each triplicate in **bold** for use in RA. *N.D.: Not Detectable, lower than the Limit of Detection (LOD). The LOD is 0.003 µg/mL corresponding to 0.0015 µg/cm² (calculated following the above formula).

1: Prothioconazole Low Fortification

2: Prothioconazole High Fortification

3: Prothioconazole-desthio Low Fortification

4: Prothioconazole-desthio High Fortification

** The residue expressed as µg/cm² was calculated following this formula:

$$Residue\ as\ \frac{\mu g}{cm^2} = Residue\ as\ \frac{\mu g}{mL} * 200\ mL * \frac{1}{400\ cm^2}$$

To be used in risk assessment, and to allow comparison among different trials mean and highest DFR values for each relevant triplicate were reported as $\mu g/cm^2/kg$ a.i./ha

Table A 87: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens normalized to kg a.i./ha

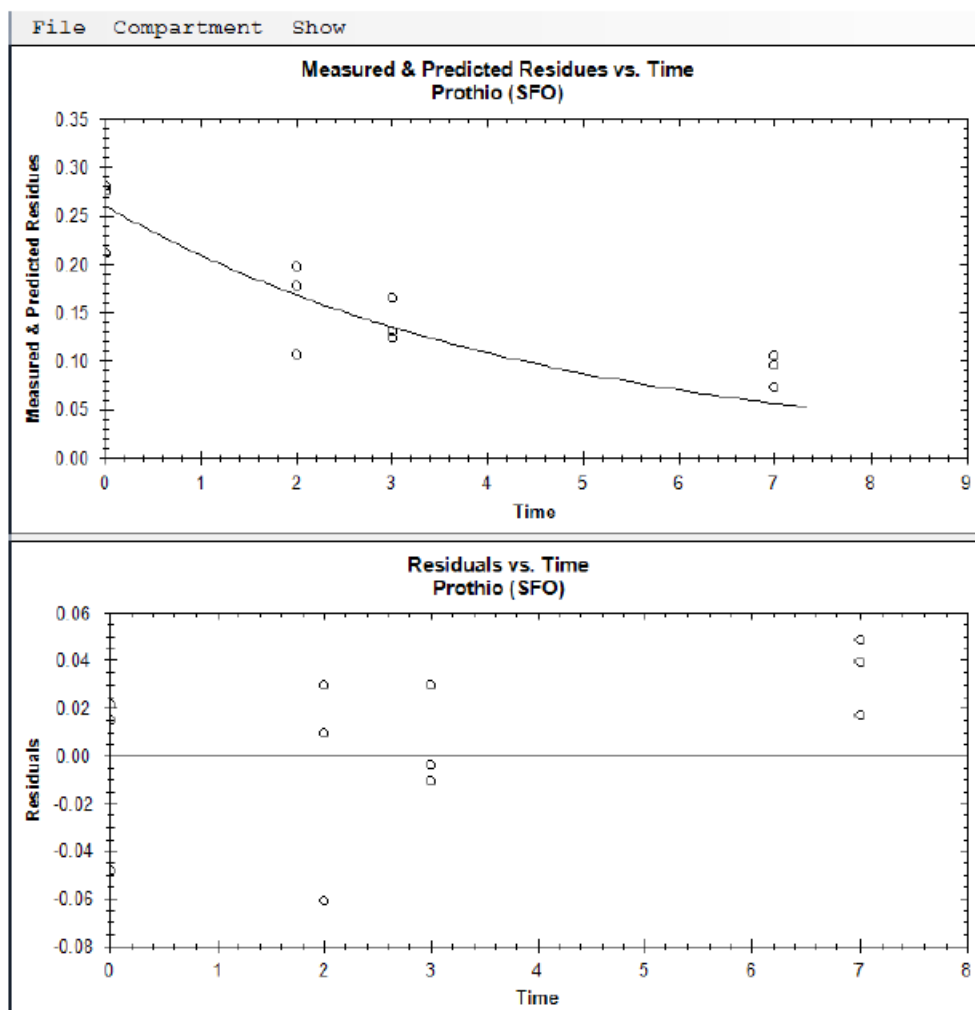
Sample	Prothioconazole		Prothioconazole - desthio	
	mean value $\mu g/cm^2/kg$ a.i./ha	highest value $\mu g/cm^2/kg$ a.i. /ha	mean value $\mu g/cm^2/kg$ a.i./ha	highest value $\mu g/cm^2/kg$ a.i. /ha
S/PR21/PL01				
S1 - 0 DAA1	0.432916667	0.545	0.24375	0.259791667
S3 - 0 DAA2	0.534166667	0.586875	0.325833333	0.343958333
S5 - 2 DAA2	0.334583333	0.41125	0.48125	0.540208333
S6 - 3 DAA2	0.29125	0.342708333	0.493333333	0.544375
S7 - 7 DAA2	0.190416667	0.21875	0.324166667	0.36875

Since it is evident from the results in previous tables that the variability among the replicates of a sampling points is very low (SD generally lower than 15%, over all the trials considered) the use of the mean value it is considered suitable and sufficiently representative of the effective dislodgeable value of the considered molecules. The **worst case mean values** will be considered to select the appropriate DFR values to refine re-entry risk assessment.

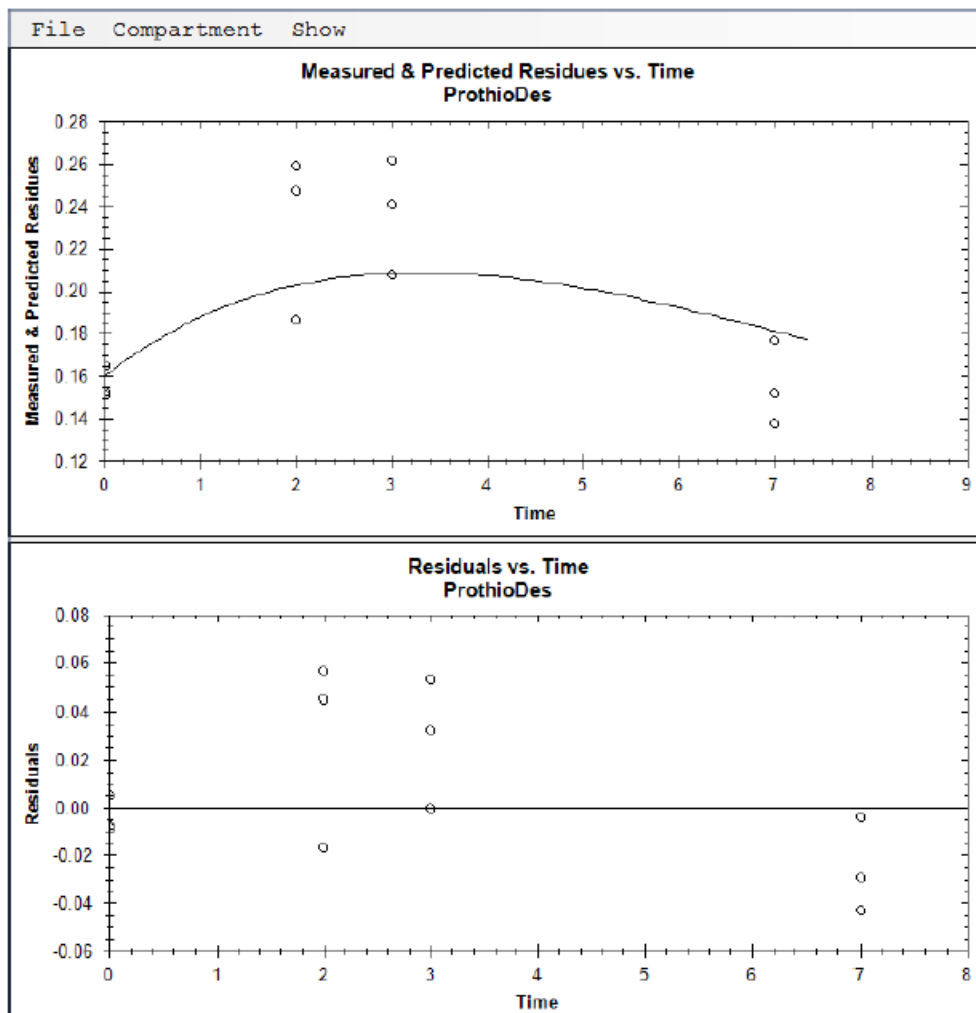
The DFR residues of the field trial were used to determine DT50 value in compliance with FOCUS Kinetics 2006 guideline (SANCO/10058/2005). Both Prothioconazole and Prothioconazole-desethio degraded over time following a curve described by the Single first order kinetic model.

Curve fitting and residual plot are reported in the following tables

Prothioconazole: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



Prothioconazole-desthio: (SFO): Residues (µg/mL) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



The calculated values are as follows:

Table A 88: **Prothioconazole and Prothioconazole - desthio in DFR samples DT₅₀ values estimation considering FOCUS kinetics guidance**

Analyte	Kinetic model	DT ₅₀ [days]	DT ₉₀ [days]	Plot visually acceptable	K1*	χ^2	r ²
Prothioconazole	SFO	3.169	10.53	Yes	0.2187	8.023	0.8085
Prothioconazole-desthio	SFO	5.218	17.33	Yes	0.13283	9.976	0.6460

Conclusions

The highest dislodgeable residues from plum leaves in this study were identified after the second application for both Prothioconazole and Prothioconazole-desmethio. The partial degradation of Prothioconazole to Prothioconazole desmethio starts immediately.

POME FRUIT

Report:	KCP 7.2/03, Casalino L. (2021)
Title:	Determination of dislodgeable foliar residues of prothioconazole and Prothioconazole-desmethio in raw agricultural commodity apple following two applications of SIP41061 (prothioconazole 400 g/l SC) (Southern Europe, 1 trial, year 2021)
Document No:	BIU-027-21, Biospheres
Guidelines:	<input type="checkbox"/> Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990. <input type="checkbox"/> Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999) <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9. <input type="checkbox"/> EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) <input type="checkbox"/> Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE. <input type="checkbox"/> EC guidance document 1607/VI/97 rev.2, 10/6/1999 <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
GLP	Yes

Material and Methods:

Trial location

- Trial I/PR21/AP05: Viguzzolo (AL), Italy, zip code 15058.

Test Item

SIP41061 (Prothioconazole 400 g/L SC)	
Nominal a.i. content	400 g/L
Actual a.i. content	35.2 % (w/w) 409 g/L (w/v)
Batch no.	21/0006

Test system Apple plants – Fuji

Application

The formulated product SIP41061 was applied twice (at BBCH 81 and 7 Days After A1) at a rate of 300 mL prod/ha corresponding to 120 g a.i./ha of Prothioconazole.

The application water volume was selected according to Good Agricultural Practices in the respective production areas (500-1500 L/ha).

Table A 89: **Summary of actual application data**

TRIAL No.	Actual Application data					
	Date	Application	Plot	g a.i./ha	Water L/ha	% deviation from target rate
				Prothioconazole		
I/PR21/AP05	07/09/2021	A1	T	120.50	1506.25	+0.42
	14/09/2021	A2	T	118.25	1478.13	-1.46

Samplings

Leaf discs sampling were carried out 0 days after application 1, 0 days before application 2 and 1, 2, 3, 7 days after application 2 (DALA).

Leaf discs were sampled by using a leaf punch sampler from the centre of the leaf. The sampling was carried out to obtain 400 cm² surface area specimens. Three replicate samples were collected from untreated plot.

At sampling S1, S3, S6 twelve replicate samples were collected from untreated plot, to have six replicate samples for field fortifications at low level (three for Prothioconazole and three for Prothioconazole-desthio) and six replicate samples for field fortifications at high level (three for Prothioconazole and three for Prothioconazole-desthio). Three replicate samples were collected from treated plot.

All leaf discs samples were used for dislodging process back at the Test Facility within 12 hours from sampling in order to avoid dehydration of leaf samples

Dislodging process

The leaf discs were dislodged by a 0.01% solution of dioctyl sulfosuccinate sodium salt (w/v): they were washed two times with 100 mL of washing solution each time by shaking plate.

After the washing procedure, the leaf discs were discarded, the washing solutions were frozen immediately after completion of dislodging procedure.

Field fortification

Field fortification was used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical method to analyse Prothioconazole and Prothioconazole - desthio in the field fortification samples.

Two field fortification solutions of Prothioconazole and Prothioconazole-desthio were prepared in Residue Analysis Unit laboratory of Test Facility using analytical reference item in order to obtain fortifications at the following levels:

- 0.01 µg/mL (LOQ - Limit Of Quantification) Low fortification level
- 0.05 µg/mL (5xLOQ) High fortification level

Field fortifications were carried out at sampling S1, S3, S6 in triplicate for both fortification rates.

The control leaf discs harvested for field fortification process were dislodged in the same way as all other specimens to obtain 200 mL of washing solution each. Fortification was carried out on washing solution obtained.

Analytical phase

The Analytical Phase was conducted to determine the residues of Prothioconazole and Prothioconazole-desthio in the dislodging solution, obtained by the dislodging process, on the basis of an analytical method validated in the study BIU-011-21 above, under GLP compliance according to SANTE/2020/12830, rev.1 (24/02/2021) guideline.

For details of the method and its validation please refer to dRR part B5 of this dossier

The results of the procedural recoveries of this study are herewith summarized:

Table A 90: **Summary of procedural recoveries**

QUANTIFIER ION					
Matrix	Fortification Level (µg/mL)	Accuracy	Precision	Overall accuracy and precision	
		Mean Recovery (%) n=6	RSD (%) n=6	Mean Recovery (%) n=12	RSD (%) n=12
Dislodging foliar solution	Prothioconazole				
	0.01	87.04	6.38	95.37	12.51
	0.1	103.70	10.37		
	Prothioconazole-desthio				
	0.01	108.15	3.17	98.57	10.48
	0.1	88.98	1.69		

The samples were extracted with acetonitrile and shaken by vigorous manual stirring for few minutes. The content of a QuEChERS Extraction kit was added and then the samples were shaken and centrifuged. The samples were analyzed with a HPLC system coupled with a triple quadrupole mass analyser (LC-MS/MS). The Limit of Quantification (LOQ) was set at 0.01 mg/kg for all analytes.

The analytical method was validated in terms of Accuracy, Precision, Linearity, Selectivity, Limit of Quantification and Limit of Detection by means of recovery tests and analysis of blank samples.

Untreated samples were used for recovery tests. The target limit of quantitation (LOQ) was 0.01 mg/L for both analytes

Results:

No interferences from the matrices were observed and the analytical method worked adequately.

Procedural recoveries in the laboratory were acceptable for both Prothioconazole and Prothioconazole-desthio.

Prothioconazole was absent in the dislodging solution of its field fortification samples with no evidence either of Prothioconazole-desthio, the main degradation product. In the dislodging solution obtained from the field treated samples however, Prothioconazole was detected and the degradation of Prothioconazole to Prothioconazole-desthio was clearly observed.

The instability of Prothioconazole is therefore particularly evident at the low concentrations of the field fortification samples (1x and 5x LOQ). The results of the analysis of Prothioconazole in the dislodged samples should therefore be taken with care.

No instability was observed for Prothioconazole–desthio which recovery levels in the field fortification samples were optimal for all concentration levels. The results of the analysis of Prothioconazole-desthio in the dislodged samples are therefore adequately supported by the results from the field fortification samples analysis.

Residues of both Prothioconazole and Prothioconazole-desthio. were undetectable (less than 0.003 µg/mL corresponding to 0.0015 µg/cm²) in all untreated leaf washing specimens.

The residue values found on field specimens are reported in the following table and are expressed in µg/mL (not corrected by the mean recovery value) and µg/cm²:

Table A 91: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/AP05/01C	C	S1 (0 Day After Application A1)	Dislodging solution	N.D. ¹	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/AP0502C	C			N.D.			N.D.		
I/PR21/AP05/03C	C			N.D.			N.D.		
I/PR21/AP05/04C/LFP ¹	C		Dislodging solution – Prothioconazole Low field fortification	N.D.	/	/	N.D.	/	/
I/PR21/AP05/05C/LFP	C			N.D.			N.D.		
I/PR21/AP05/06C/LFP	C			N.D.			N.D.		
I/PR21/AP05/07C/HFP ²	C		Dislodging solution - Prothioconazole High field fortification	N.D.			N.D.		
I/PR21/AP05/08C/HFP	C			N.D.			N.D.		
I/PR21/AP05/09C/HFP	C			N.D.			N.D.		
I/PR21/AP05/10C/LFD ³	C		Dislodging solution – Prothioconazole-desthio Low field	-			0.0104		
I/PR21/AP05/11C/LFD	C			-			0.0106		
I/PR21/AP05/12C/LFD	C			-			0.0104		
I/PR21/AP05/13C/HFD ⁴	C		Dislodging solution - Prothioconazole-desthio High field fortification	-			0.0424		
I/PR21/AP05/14C/HFD	C			-			0.0462		
I/PR21/AP05/15C/HFD	C			-			0.0446		
I/PR21/AP05/16T	T		Dislodging solution	0.0333			0.0889	0.04445	0.0433
I/PR21/AP05/17T	T			0.0331			0.0908	0.0454	
I/PR21/AP05/18T	T			0.0328			0.0798	0.0399	
I/PR21/AP05/19C	C	S2 (0 Day Before Application A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/AP05/20C	C			N.D.			N.D.		
I/PR21/AP05/21C	C			N.D.			N.D.		
I/PR21/AP05/22T	T			< 0.01 (0.0075)			0.0342	0.0171	0.0159

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/AP05/23T	T			< 0.01 (0.0062)			0.0270	0.0135	
I/PR21/AP05/24T	T			0.0119			0.0342	0.0171	
I/PR21/AP05/25C	C	S3 (0 Day After Application A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/AP05/26C	C			N.D.			N.D.		
I/PR21/AP05/27C	C			N.D.			N.D.		
I/PR21/AP05/28C/LFP ¹	C		Dislodging solution – Prothioconazole Low field fortification	N.D.	/	/	N.D.	/	/
I/PR21/AP05/29C/LFP	C			N.D.			N.D.		
I/PR21/AP05/30C/LFP	C			N.D.			N.D.		
I/PR21/AP05/31C/HFP ²	C		Dislodging solution - Prothioconazole High field fortification	N.D.			N.D.		
I/PR21/AP05/32C/HFP	C			N.D.			N.D.		
I/PR21/AP05/33C/HFP	C			N.D.			N.D.		
I/PR21/AP05/34C/LFD ³	C		Dislodging solution – Prothioconazole-desthio Low field	-			0.0101		
I/PR21/AP05/35C/LFD	C			-			0.0100		
I/PR21/AP05/36C/LFD	C			-			0.0103		
I/PR21/AP05/37C/HFD ⁴	C		Dislodging solution - Prothioconazole-desthio High field	-			0.0428		
I/PR21/AP05/38C/HFD	C			-			0.0429		
I/PR21/AP05/39C/HFD	C			-			0.0441		
I/PR21/AP05/40T	T		Dislodging solution	0.0289	0.0317	0.0158	0.1076	0.0538	0.0528
I/PR21/AP05/41T	T			0.0334			0.1245	0.06225	
I/PR21/AP05/42T	T			0.0327			0.0848	0.0424	
I/PR21/AP05/43C	C	S4 (1 Day After Application)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/AP05/44C	C			N.D.			N.D.		
I/PR21/AP05/45C	C			N.D.			N.D.		
I/PR21/AP05/46T	T	S5 (2 Days After Application)	Dislodging solution	0.0293	0.0277	0.0138	0.0933	0.04665	0.0440
I/PR21/AP05/47T	T			0.0242			0.0852	0.0426	
I/PR21/AP05/48T	T			0.0295			0.0856	0.0428	

Sample code	Plot	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
				Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
I/PR21/AP05/49C	C	S6 (3 Days After Application A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/AP05/50C	C			N.D.			N.D.		
I/PR21/AP05/51C	C			N.D.			N.D.		
I/PR21/AP05/52C/LFP ¹	C		Dislodging solution – Prothioconazole Low field fortification	N.D.	/	/	N.D.	/	/
I/PR21/AP05/53C/LFP	C			N.D.			N.D.		
I/PR21/AP05/54C/LFP/a***	C			N.D.			N.D.		
I/PR21/AP05/55C/HFP ²	C		Dislodging solution - Prothioconazole High field fortification	N.D.			N.D.		
I/PR21/AP05/56C/HFP	C			N.D.			N.D.		
I/PR21/AP05/57C/HFP	C			N.D.			N.D.		
I/PR21/AP05/58C/LFD ³	C		Dislodging solution – Prothioconazole-desthio Low field	-			0.0104		
I/PR21/AP05/59C/LFD	C			-			0.0101		
I/PR21/AP05/60C/LFD	C			-			0.0104		
I/PR21/AP05/61C/HFD ⁴	C		Dislodging solution - Prothioconazole-desthio High field	-			0.0447		
I/PR21/AP05/62C/HFD	C			-			0.0464		
I/PR21/AP05/63C/HFD	C			-			0.0441		
I/PR21/AP05/64T	T		Dislodging solution	< 0.01 (0.0058)			0.0437	0.02185	0.0210
I/PR21/AP05/65T	T			0.0104			0.0440	0.022	
I/PR21/AP05/66T	T			< 0.01 (0.0045)			0.0381	0.01905	
I/PR21/AP05/67C	C	S7 (7 Days After Application A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
I/PR21/AP05/68C	C			N.D.			N.D.		
I/PR21/AP05/69C	C			N.D.			N.D.		
I/PR21/AP05/70T	T			N.D.	0.0041	0.0021	0.0369	0.01845	0.0173
I/PR21/AP05/71T	T			< 0.01 (0.0045)			0.0328	0.0164	
I/PR21/AP05/72T	T			< 0.01 (0.0048)			0.0342	0.0171	

Highest value for each triplicate in **bold** for use in RA *N.D.: Not Detectable, lower than the Limit of Detection (LOD). The LOD is 0.003 µg/mL corresponding to 0.0015 µg/cm² (calculated following the above formula).

1: Prothioconazole Low Fortification

2: Prothioconazole High Fortification

3: Prothioconazole-desthio Low Fortification

4: Prothioconazole-desthio High Fortification

** The residue expressed as $\mu\text{g}/\text{cm}^2$ was calculated following this formula:

$$\text{Residue as } \frac{\mu\text{g}}{\text{cm}^2} = \text{Residue as } \frac{\mu\text{g}}{\text{mL}} * 200 \text{ mL} * \frac{1}{400 \text{ cm}^2}$$

To be used in risk assessment, and to allow comparison among different trials mean and highest DFR values for each relevant triplicate were reported as $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i./ha

Table A 92: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens normalized to kg a.i./ha

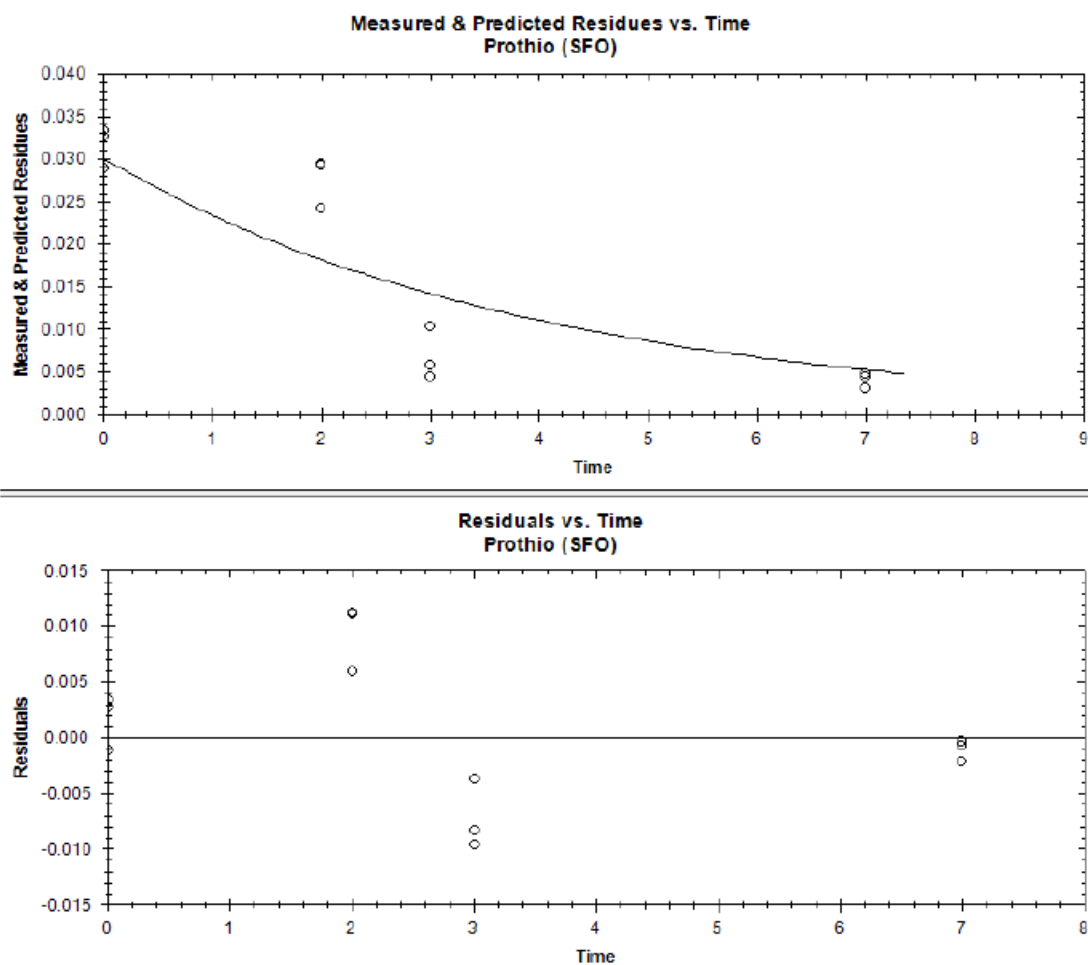
Sample	Prothioconazole		Prothioconazole - desthio	
	mean value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i./ha	highest value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i. /ha	mean value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i./ha	highest value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i. /ha
I/PR21/AP05				
S1 - 0 DAA1	0.1375	0.13875	0.360833333	0.378333333
S3 - 0 DAA2	0.131666667	0.139166667	0.44	0.51875
S5 - 2 DAA2	0.115	0.122083333	0.366666667	0.38875
S6 - 3 DAA2	0.029166667	0.043333333	0.175	0.183333333
S7 - 7 DAA2	0.0175	0.02	0.144166667	0.15375

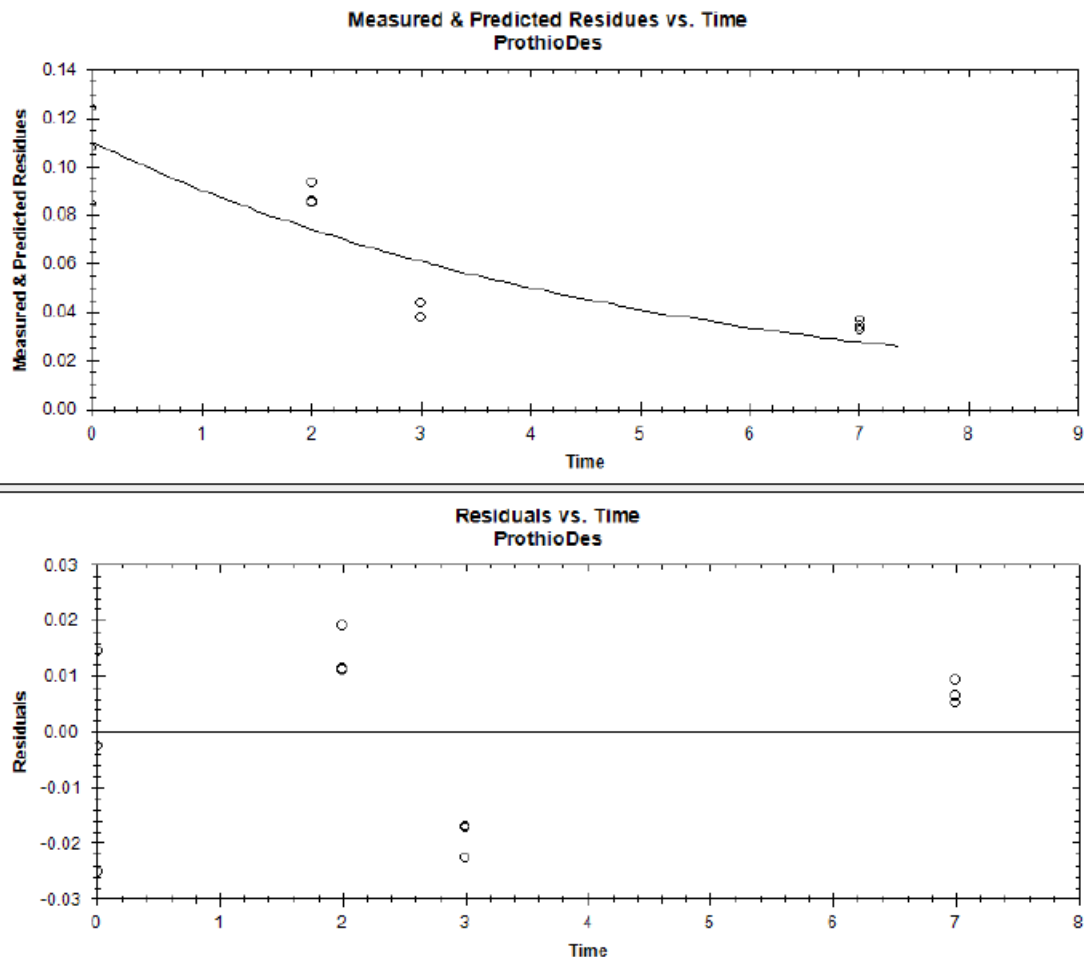
Since it is evident from the results in previous tables that the variability among the replicates of a sampling points is very low (SD generally lower than 15%, over all the trials considered) the use of the mean value it is considered suitable and sufficiently representative of the effective dislodgeable value of the considered molecules. The **worst case mean values** will be considered to select the appropriate DFR values to refine re-entry risk assessment.

The DFR residues of the field trial were used to determine DT50 value in compliance with FOCUS Kinetics 2006 guideline (SANCO/10058/2005). Both Prothioconazole and Prothioconazole-desethio degraded over time following a curve described by the Single first order kinetic model.

Curve fitting and residual plot are reported in the following figures

Prothioconazole: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



Prothioconazole -desthio: (SFO): Residues (µg/mL) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)

The calculated values are as follows:

Table A 93: **Prothioconazole and Prothioconazole - desthio in DFR samples DT₅₀ values estimation considering FOCUS kinetics guidance**

Analyte	Kinetic model	DT ₅₀ [days]	DT ₉₀ [days]	Plot visually acceptable	K1*	χ^2	r ²
Prothioconazole	SFO	2.761	9.173	Yes	0.2804	28.13	0.759
Prothioconazole-desthio	SFO	3.505	11.642	Yes	0.2672	15.05	0.7719

Conclusions

The highest dislodgeable residues from apple leaves in this study were identified immediately after the second application for both Prothioconazole and Prothioconazole-desthio. The partial degradation of Prothioconazole to Prothioconazole desthio starts immediately.

Report:	KCP 7.2/04, Casalino L. (2022)
Title:	Determination of dislodgeable foliar residues of prothioconazole and Prothioconazole-desthio in raw agricultural commodity apple following two applications of SIP41061 (prothioconazole 400 g/l SC) (Southern and Central Europe, 3 trial, year 2021)
Document No:	RAU-023-21, Biospheres
Guidelines:	<input type="checkbox"/> Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990. <input type="checkbox"/> Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999) <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9. <input type="checkbox"/> EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000) <input type="checkbox"/> Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE. <input type="checkbox"/> EC guidance document 1607/VI/97 rev.2, 10/6/1999 <input type="checkbox"/> Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
GLP	Yes

Material and Methods:

Trial location

- Trial F/PR21/AP01: Marsillargues, France, zip code 34590;
- Trial P/PR21/AP02: Bark, Poland, zip code 11-010;
- Trial P/PR21/AP03: Miastowice; Poland, zip code 89-240.

Test Item

SIP41061 (Prothioconazole 400 g/L SC)	
Nominal a.i. content	400 g/L
Actual a.i. content	35.2 % (w/w) 409 g/L (w/v)
Batch no.	21/0006

Test system Plum plants – Showtime/Fortune/Ambra

Application

According to the Study Plan the formulated product SIP41061 have been applied twice (7 Days Before A2 (BBCH >51) and 7 Days After A1 (BBCH < 85)) at a rate of 300 mL prod/ha corresponding to 120 g a.i./ha of Prothioconazole.

The application water volume, for all trials, was selected according to Good Agricultural Practices in the respective production areas (500-1500 L/ha).

Table A 94: Summary of actual application data

TRIAL No.	Actual Application data					
	Date	Application	Plot	g a.i./ha	Water L/ha	% deviation from target rate
				Prothioconazole		
F/PR21/AP01	31/08/2021	A1	T	126.00	895.00	+5.3
	07/09/2021	A2	T	114.0	807.00	-5.0
P/PR21/AP02	27/08/2021	A1	T	123.00	1027.00	+2.7
	03/09/2021	A2	T	120.00	998.00	-0.3
P/PR21/AP03	09/08/2021	A1	T	124.00	1029.00	+3.0
	16/08/2021	A2	T	125.00	1042.00	+4.3

Samplings

Leaf discs sampling were carried out 0 days after application 1, 0 days before application 2 and 1, 2, 3, 7 days after application 2 (DALA).

Leaf discs were sampled by using a leaf punch sampler from the centre of the leaf. The sampling was carried out to obtain 400 cm² surface area specimens. Three replicate samples were collected from untreated plot.

At sampling S1, S3, S6 twelve replicate samples were collected from untreated plot, to have six replicate samples for field fortifications at low level (three for Prothioconazole and three for Prothioconazole-desthio) and six replicate samples for field fortifications at high level (three for Prothioconazole and three for Prothioconazole-desthio). Three replicate samples were collected from treated plot.

All leaf discs samples were used for dislodging process back at the Test Facility within 12 hours from sampling in order to avoid dehydration of leaf samples

Dislodging process

The leaf discs were dislodged by a 0.01% solution of dioctyl sulfosuccinate sodium salt (w/v): they were washed two times with 100 mL of washing solution each time by shaking plate.

After the washing procedure, the leaf discs were discarded, the washing solutions were frozen immediately after completion of dislodging procedure.

Field fortification

Field fortification was used to demonstrate the stability of the samples during storage period of the study and the ability of the analytical method to analyse Prothioconazole and Prothioconazole - desthio in the field fortification samples.

Two field fortification solutions of Prothioconazole and Prothioconazole-desthio were prepared in Residue Analysis Unit laboratory of Test Facility using analytical reference item in order to obtain fortifications at the following levels:

- 0.01 µg/mL (LOQ - Limit Of Quantification) Low fortification level
- 0.05 µg/mL (5xLOQ) High fortification level

Field fortifications were carried out at sampling S1, S3, S6 in triplicate for both fortification rates.

The control leaf discs harvested for field fortification process were dislodged in the same way as all other specimens to obtain 200 mL of washing solution each. Fortification was carried out on washing solution obtained.

Analytical phase

The Analytical Phase was conducted to determine the residues of Prothioconazole and Prothioconazole-desthio in the dislodging solution, obtained by the dislodging process, on the basis of an analytical method validated in the study BIU-011-21 above, under GLP compliance according to SANTE/2020/12830, rev.1 (24/02/2021) guideline.

For details of the method and its validation please refer to dRR part B5 of this dossier

The results of the procedural recoveries of this study are herewith summarized:

Table A 95: Summary of procedural recoveries

QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy	Precision	Overall accuracy and precision	
		Mean Recovery (%) n=10	RSD (%) n=10	Mean Recovery (%) n=20	RSD (%) n=20
Dislodging foliar solution	Prothioconazole				
	0.01	77.05	8.25	79.42	9.39
	1.00	81.80	9.81		
	Prothioconazole-desthio				
	0.01	100.44	4.17	99.68	4.15
	1.00	98.93	4.19		

The samples were extracted with acetonitrile and shaken by vigorous manual stirring for few minutes. The content of a QuEChERS Extraction kit was added and then the samples were shaken and centrifuged. The samples were analyzed with a HPLC system coupled with a triple quadrupole mass analyser (LC-MS/MS). The Limit of Quantification (LOQ) was set at 0.01 mg/kg for all analytes.

The analytical method was validated in terms of Accuracy, Precision, Linearity, Selectivity, Limit of Quantification and Limit of Detection by means of recovery tests and analysis of blank samples.

Untreated samples were used for recovery tests. The target limit of quantitation (LOQ) was 0.01 mg/L for both analytes

Results:

No interferences from the matrices were observed and the analytical method worked adequately.

Procedural recoveries in the laboratory were acceptable for both Prothioconazole and Prothioconazole-desthio.

Prothioconazole was absent in the dislodging solution of its field fortification samples with no evidence either of Prothioconazole-desthio, the main degradation product. In the dislodging solution obtained from the field treated samples however, Prothioconazole was detected and the degradation of Prothioconazole to Prothioconazole-desthio was clearly observed.

The instability of Prothioconazole is therefore particularly evident at the low concentrations of the field fortification samples (1x and 5x LOQ). The results of the analysis of Prothioconazole in the dislodged samples should therefore be taken with care.

No instability was observed for Prothioconazole–desthio which recovery levels in the field fortification samples were optimal for all concentration levels. The results of the analysis of Prothioconazole-desthio in the dislodged samples are therefore adequately supported by the results from the field fortification samples analysis.

Residues of both Prothioconazole and Prothioconazole-desthio. were undetectable (less than 0.003 µg/mL corresponding to 0.0015 µg/cm²) in all untreated leaf washing specimens.

The residue values found on field specimens are reported in the following table and are expressed in µg/mL (not corrected by the mean recovery value) and µg/cm²:

Table A 96: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio							
			Residue (µg/mL)	Residue (µg/cm²)	Residue as mean value (µg/cm²)	Residue (µg/mL)	Residue (µg/cm²)	Residue as mean value (µg/cm²)					
F/PR21/AP01													
F/PR21/AP01/01C	S1 (0 Days Before A1)	Dislodging solution	N.D.	N.D	N.D	N.D.	N.D	N.D					
F/PR21/AP01/02C			N.D.			N.D.							
F/PR21/AP01/03C			N.D.			N.D.							
F/PR21/AP01/04C/LFP ¹		Dislodging solution – Prothioconazole_Low field fortification	< 0.01 (0.0065)	/	/	N.D.	/	/					
F/PR21/AP01/05C/LFP			< 0.01 (0.0054)			N.D.							
F/PR21/AP01/06C/LFP			< 0.01 (0.0057)			N.D.							
F/PR21/AP01/07C/HFP ²		Dislodging solution - Prothioconazole High field fortification	0.0309			N.D.							
F/PR21/AP01/08C/HFP			0.0281			< 0.01 (0.0035)							
F/PR21/AP01/09C/HFP			0.0305			N.D.							
F/PR21/AP01/10C/LFD ³		Dislodging solution – Prothioconazole-desthio Low field fortification	/			< 0.01 (0.0067)							
F/PR21/AP01/11C/LFD						< 0.01 (0.0058)							
F/PR21/AP01/12C/LFD						0.0102							
F/PR21/AP01/13C/HFD ⁴		Dislodging solution - Prothioconazole-desthio High field fortification				0.0550							
F/PR21/AP01/14C/HFD						0.0574							
F/PR21/AP01/15C/HFD						0.0428							
F/PR21/AP01/16T	S1 (0 Days After A1)	Dislodging solution				0.2331			0.2650	0.1325	0.0551	0.02755	0.0317
F/PR21/AP01/17T						0.2505					0.0669	0.03345	
F/PR21/AP01/18T						0.3115					0.0681	0.03405	
F/PR21/AP01/19C	S2 (0 Day Before A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.					
F/PR21/AP01/20C			N.D.			N.D.							
F/PR21/AP01/21C			N.D.			N.D.							
F/PR21/AP01/22T			< 0.01 (0.0055)	0.0083	0.0041	0.0350	0.0175	0.0189					
F/PR21/AP01/23T			< 0.01 (0.0068)			0.0351	0.01755						

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
F/PR21/AP01/24T			0.0125			0.0430	0.0215	
F/PR21/AP01/25C	S3 (0 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
F/PR21/AP01/26C			N.D.			N.D.		
F/PR21/AP01/27C			N.D.			N.D.		
F/PR21/AP01/28C/LFP ¹			N.D.			N.D.		
F/PR21/AP01/29C/LFP	S3 (0 Day Before A2)	Dislodging solution – Prothioconazole_Low field fortification	< 0.01 (0.0060)	/	/	N.D.	/	/
F/PR21/AP01/30C/LFP			< 0.01 (0.0053)			N.D.		
F/PR21/AP01/31C/HFP ²			< 0.01 (0.0046)			N.D.		
F/PR21/AP01/32C/HFP		Dislodging solution - Prothioconazole High field fortification	< 0.01 (0.0065)			N.D.		
F/PR21/AP01/33C/HFP			0.0129			N.D.		
F/PR21/AP01/34C/LFD ³			0.0156			N.D.		
F/PR21/AP01/35C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			< 0.01 (0.0054)		
F/PR21/AP01/36C/LFD						< 0.01 (0.0094)		
F/PR21/AP01/37C/HFD ⁴						0.0100		
F/PR21/AP01/38C/HFD						0.0553		
F/PR21/AP01/39C/HFD						0.0590		
F/PR21/AP01/40T		S3 (0 Day After A2)	Dislodging solution			0.1556		
F/PR21/AP01/41T	0.2092			0.1351	0.06755			
F/PR21/AP01/42T	0.1867			0.1205	0.06025			
F/PR21/AP01/43C	S4 (1 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
F/PR21/AP01/44C			N.D.			N.D.		
F/PR21/AP01/45C			N.D.			N.D.		
F/PR21/AP01/46T	S5 (2 Day After A2)	Dislodging solution	0.0402	0.0461	0.0231	0.1421	0.07105	0.0696
F/PR21/AP01/47T			0.0430			0.1393	0.06965	
F/PR21/AP01/48T			0.0551			0.1362	0.0681	

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
F/PR21/AP01/49C	S6 (3 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
F/PR21/AP01/50C			N.D.			N.D.		
F/PR21/AP01/51C			N.D.			N.D.		
F/PR21/AP01/52C/LFP ¹		Dislodging solution – Prothioconazole_Low field fortification	< 0.01 (0.0054)			N.D.		
F/PR21/AP01/53C/LFP			< 0.01 (0.0053)			N.D.		
F/PR21/AP01/54C/LFP			< 0.01 (0.0049)			N.D.		
F/PR21/AP01/55C/HFP ²		Dislodging solution - Prothioconazole High field fortification	0.0236	/	/	< 0.01 (0.0040)	/	/
F/PR21/AP01/56C/HFP			0.0323			< 0.01 (0.0044)		
F/PR21/AP01/57C/HFP			0.0171			< 0.01 (0.0043)		
F/PR21/AP01/58C/LFD ³		Dislodging solution – Prothioconazole-desthio Low field fortification	/			< 0.01 (0.0045)		
F/PR21/AP01/59C/LFD						< 0.01 (0.0092)		
F/PR21/AP01/60C/LFD						0.0109		
F/PR21/AP01/61C/HFD ⁴		Dislodging solution - Prothioconazole-desthio High field fortification				0.0464		
F/PR21/AP01/62C/HFD						0.0532		
F/PR21/AP01/63C/HFD						0.0536		
F/PR21/AP01/64T		Dislodging solution	0.0227	0.0323	0.0162	0.0951	0.04755	0.0520
F/PR21/AP01/65T	0.0402		0.1118			0.0559		
F/PR21/AP01/66T	0.0341		0.1050			0.0525		
F/PR21/AP01/67C	S7 (7 Day After A2)	Dislodging solution	N.D.	N.D	N.D	N.D.	N.D	N.D
F/PR21/AP01/68C			N.D.			N.D.		
F/PR21/AP01/69C			N.D.			N.D.		
F/PR21/AP01/70T			0.0158	0.0176	0.0088	0.0731	0.03655	0.0363
F/PR21/AP01/71T			0.0175			0.0720	0.036	
F/PR21/AP01/72T			0.0196			0.0728	0.0364	
P/PR21/AP02								

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
P/PR21/AP02/73C	S1 (0 Days Before A1)	Dislodging solution	N.D.	N.D	N.D	N.D.	N.D	N.D
P/PR21/AP02/74C			N.D.			N.D.		
P/PR21/AP02/75C			N.D.			N.D.		
P/PR21/AP02/76C/LFP		Dislodging solution – Prothioconazole_Low field fortification	N.D.	/	/	N.D.	/	/
P/PR21/AP02/77C/LFP			N.D.			N.D.		
P/PR21/AP02/78C/LFP			N.D.			N.D.		
P/PR21/AP02/79C/HFP		Dislodging solution - Prothioconazole High field fortification	0.0107			N.D.		
P/PR21/AP02/80C/HFP			0.0107			< 0.01 (0.0035)		
P/PR21/AP02/81C/HFP			< 0.01 (0.0071)			< 0.01 (0.0040)		
P/PR21/AP02/82C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			0.0109		
P/PR21/AP02/83C/LFD						< 0.01 (0.0078)		
P/PR21/AP02/84C/LFD						< 0.01 (0.0082)		
P/PR21/AP02/85C/HFD		0.0376						
P/PR21/AP02/86C/HFD		0.0568						
P/PR21/AP02/87C/HFD		0.0590						
P/PR21/AP02/88T	S1 (0 Days After A1)	Dislodging solution	0.1200	0.1004	0.0502	0.1077	0.05385	0.0494
P/PR21/AP02/89T			0.0742			0.0901	0.04505	
P/PR21/AP02/90T			0.1071			0.0983	0.04915	
P/PR21/AP02/91C	S2 (0 Day Before A2)	Dislodging solution	N.D.	N.D	N.D	N.D.	N.D	N.D
P/PR21/AP02/92C			N.D.			N.D.		
P/PR21/AP02/93C			N.D.			N.D.		
P/PR21/AP02/94T			< 0.01 (0.0037)	0.0048	0.0024	0.0469	0.02345	0.0215
P/PR21/AP02/95T			< 0.01 (0.0056)			0.0284	0.0142	
P/PR21/AP02/96T			< 0.01 (0.0051)			0.0534	0.0267	
P/PR21/AP02/97C	S3 (0 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP02/98C			N.D.			N.D.		

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
P/PR21/AP02/99C			N.D.			N.D.		
P/PR21/AP02/100C/LFP	S3 (0 Day Before A2)	Dislodging solution – Prothioconazole_Low field fortification	N.D.	/	/	N.D.	/	/
P/PR21/AP02/101C/LFP			N.D.			N.D.		
P/PR21/AP02/102C/LFP			N.D.			N.D.		
P/PR21/AP02/103C/HFP			N.D.			N.D.		
P/PR21/AP02/104C/HFP		Dislodging solution - Prothioconazole High field fortification	< 0.01 (0.0070)			< 0.01 (0.0032)		
P/PR21/AP02/105C/HFP			0.0138			< 0.01 (0.0036)		
P/PR21/AP02/106C/LFD			0.0184			< 0.01 (0.0033)		
P/PR21/AP02/107C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			< 0.01 (0.0076)		
P/PR21/AP02/108C/LFD						0.0103		
P/PR21/AP02/109C/HFD		< 0.01 (0.0059)						
P/PR21/AP02/110C/HFD		0.0577						
P/PR21/AP02/111C/HFD		0.0441						
P/PR21/AP02/112T		0.0568						
P/PR21/AP02/113T	S3 (0 Day After A2)	Dislodging solution	0.0936	0.1105	0.0553	0.1112	0.0556	0.0637
P/PR21/AP02/114T			0.1119			0.1453	0.07265	
P/PR21/AP02/115C			0.1261			0.1254	0.0627	
P/PR21/AP02/116C	S4 (1 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP02/117C			N.D.			N.D.		
P/PR21/AP02/118T			N.D.			N.D.		
P/PR21/AP02/119T	S5 (2 Day After A2)	Dislodging solution	0.0644	0.0644	0.0322	0.1336	0.0668	0.0689
P/PR21/AP02/120T			0.0750			0.1559	0.07795	
P/PR21/AP02/121C			0.0537			0.1239	0.06195	
P/PR21/AP02/122C	S6 (3 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP02/123C			N.D.			N.D.		
P/PR21/AP02/123C			N.D.			N.D.		

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio							
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)					
P/PR21/AP02/124C/LFP		Dislodging solution – Prothioconazole Low field fortification	N.D.	/	/	N.D.	/	/					
P/PR21/AP02/125C/LFP			N.D.			N.D.							
P/PR21/AP02/126C/LFP			N.D.			N.D.							
P/PR21/AP02/127C/HFP		Dislodging solution - Prothioconazole High field fortification	0.0223			< 0.01 (0.0036)							
P/PR21/AP02/128C/HFP			N.D.			N.D.							
P/PR21/AP02/129C/HFP			N.D.			N.D.							
P/PR21/AP02/130C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			0.0108							
P/PR21/AP02/131C/LFD						< 0.01 (0.0086)							
P/PR21/AP02/132C/LFD						< 0.01 (0.0089)							
P/PR21/AP02/133C/HFD		Dislodging solution - Prothioconazole-desthio High field fortification				0.0505							
P/PR21/AP02/134C/HFD						0.0577							
P/PR21/AP02/135C/HFD						0.0445							
P/PR21/AP02/136T		Dislodging solution	0.0352			0.0351	0.0175	0.1219	0.06095	0.0557			
P/PR21/AP02/137T			0.0302					0.0937	0.04685				
P/PR21/AP02/138T			0.0398					0.1185	0.05925				
P/PR21/AP02/139C	S7 (7 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.					
P/PR21/AP02/140C			N.D.			N.D.							
P/PR21/AP02/141C			N.D.			N.D.							
P/PR21/AP02/142T			0.0152	0.0125	0.0062	0.0798	0.0399	0.0356					
P/PR21/AP02/143T			< 0.01 (0.0095)			0.0517	0.02585						
P/PR21/AP02/144T			0.0127			0.0818	0.0409						
P/PR21/AP03													
P/PR21/AP03/145C	S1 (0 Days Before A1)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.					
P/PR21/AP03/146C			N.D.			N.D.							
P/PR21/AP03/147C			N.D.			N.D.							

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
P/PR21/AP03/148C/LFP		Dislodging solution – Prothioconazole_Low field fortification	< 0.01 (0.0064)	/	/	N.D.	/	/
P/PR21/AP03/149C/LFP			< 0.01 (0.0077)			N.D.		
P/PR21/AP03/150C/LFP			< 0.01 (0.0079)			N.D.		
P/PR21/AP03/151C/HFP		Dislodging solution - Prothioconazole High field fortification	0.0408			< 0.01 (0.0073)		
P/PR21/AP03/152C/HFP			0.0452			< 0.01 (0.0049)		
P/PR21/AP03/153C/HFP			0.0379			< 0.01 (0.0063)		
P/PR21/AP03/154C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			0.0120		
P/PR21/AP03/155C/LFD						0.0117		
P/PR21/AP03/156C/LFD						0.0110		
P/PR21/AP03/157C/HFD						0.0594		
P/PR21/AP03/158C/HFD						0.0594		
P/PR21/AP03/159C/HFD		field fortification	0.0593					
P/PR21/AP03/160T		S1 (0 Days After A1)	Dislodging solution			0.1460		
P/PR21/AP03/161T	0.2380			0.1850	0.0925			
P/PR21/AP03/162T	0.2106			0.0907	0.04535			
P/PR21/AP03/163C	S2 (0 Day Before A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP03/164C			N.D.			N.D.		
P/PR21/AP03/165C			N.D.			N.D.		
P/PR21/AP03/166T			0.0349	0.0460	0.0230	0.0948	0.0474	0.0594
P/PR21/AP03/167T			0.0454			0.1060	0.053	
P/PR21/AP03/168T			0.0578			0.1556	0.0778	
P/PR21/AP03/169C	S3 (0 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP03/170C			N.D.			N.D.		
P/PR21/AP03/171C			N.D.			N.D.		
P/PR21/AP03/172C/LFP	S3 (0 Day Before A2)	Dislodging solution – Prothioconazole_Low field fortification	< 0.01 (0.0069)	/	/	N.D.	/	/
P/PR21/AP03/173C/LFP			< 0.01 (0.0077)			N.D.		

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)	Residue (µg/mL)	Residue (µg/cm ²)	Residue as mean value (µg/cm ²)
P/PR21/AP03/174C/LFP	A2)	tion	< 0.01 (0.0075)			N.D.		
P/PR21/AP03/175C/HFP		Dislodging solution - Prothioconazole High field fortification	0.0328			N.D.		
P/PR21/AP03/176C/HFP			0.0443			< 0.01 (0.0034)		
P/PR21/AP03/177C/HFP			0.0402			< 0.01 (0.0037)		
P/PR21/AP03/178C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			0.0108		
P/PR21/AP03/179C/LFD						< 0.01 (0.0087)		
P/PR21/AP03/180C/LFD						< 0.01 (0.0077)		
P/PR21/AP03/181C/HFD		0.0444						
P/PR21/AP03/182C/HFD		0.0516						
P/PR21/AP03/183C/HFD		0.0342						
P/PR21/AP03/184T	S3 (0 Day After A2)	Dislodging solution	0.3177	0.3043	0.1521	0.3111	0.15555	0.1404
P/PR21/AP03/185T			0.2847			0.2331	0.11655	
P/PR21/AP03/186T			0.3104			0.2984	0.1492	
P/PR21/AP03/187C	S4 (1 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP03/188C			N.D.			N.D.		
P/PR21/AP03/189C			N.D.			N.D.		
P/PR21/AP03/190T	S5 (2 Day After A2)	Dislodging solution	0.0988	0.0887	0.0444	0.1878	0.0939	0.0824
P/PR21/AP03/191T			0.0710			0.1358	0.0679	
P/PR21/AP03/192T			0.0964			0.1710	0.0855	
P/PR21/AP03/193C	S6 (3 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP03/194C			N.D.			N.D.		
P/PR21/AP03/195C			N.D.			N.D.		
P/PR21/AP03/196C/LFP		Dislodging solution – Prothioconazole_Low field fortification	< 0.01 (0.0059)	/	/	N.D.	/	/
P/PR21/AP03/197C/LFP			< 0.01 (0.0057)			N.D.		
P/PR21/AP03/198C/LFP			< 0.01 (0.0060)			N.D.		
P/PR21/AP03/199C/HFP		Dislodging solution - Prothio-	0.0430			< 0.01 (0.0058)		

Sample code	Sampling	Sample material	Prothioconazole			Prothioconazole - desthio		
			Residue (µg/mL)	Residue (µg/cm²)	Residue as mean value (µg/cm²)	Residue (µg/mL)	Residue (µg/cm²)	Residue as mean value (µg/cm²)
P/PR21/AP03/200C/HFP		conazole High field fortification	0.0356			< 0.01 (0.0056)		
P/PR21/AP03/201C/HFP			0.0324			< 0.01 (0.0068)		
P/PR21/AP03/202C/LFD		Dislodging solution – Prothioconazole-desthio Low field fortification	/			< 0.01 (0.0086)		
P/PR21/AP03/203C/LFD						0.0113		
P/PR21/AP03/204C/LFD						0.0109		
P/PR21/AP03/205C/HFD	S6 (3 Day After A2)	Dislodging solution - Prothioconazole-desthio High field fortification	/	/	/	0.0580	/	/
P/PR21/AP03/206C/HFD						0.0577		
P/PR21/AP03/207C/HFD						0.0584		
P/PR21/AP03/208T		Dislodging solution	0.0504	0.0578	0.0289	0.1549	0.07745	0.0918
P/PR21/AP03/209T			0.0556			0.1919	0.09595	
P/PR21/AP03/210T			0.0674			0.2037	0.10185	
P/PR21/AP03/211C	S7 (7 Day After A2)	Dislodging solution	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.
P/PR21/AP03/212C			N.D.			N.D.		
P/PR21/AP03/213C			N.D.			N.D.		
P/PR21/AP03/214T			0.0327	0.0348	0.0174	0.2226	0.1113	0.1018
P/PR21/AP03/215T			0.0435			0.2347	0.11735	
P/PR21/AP03/216T			0.0281			0.1534	0.0767	

Highest value for each triplicate in **bold** for use in RA *N.D.: Not Detectable, lower than the Limit of Detection (LOD). The LOD is 0.003 µg/mL corresponding to 0.0015 µg/cm² (calculated following the above formula).

1: Prothioconazole Low Fortification

2: Prothioconazole High Fortification

3: Prothioconazole-desthio Low Fortification

4: Prothioconazole-desthio High Fortification

** The residue expressed as µg/cm² was calculated following this formula:

$$\text{Residue as } \frac{\mu\text{g}}{\text{cm}^2} = \text{Residue as } \frac{\mu\text{g}}{\text{mL}} * 200 \text{ mL} * \frac{1}{400 \text{ cm}^2}$$

To be used in risk assessment, and to allow comparison among different trials mean and highest DFR values for each relevant triplicate were reported as $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i./ha.

Table A 97: Summary of Prothioconazole and Prothioconazole-desthio residues in Leaf Washing Specimens normalized to kg a.i./ha

Sample	Prothioconazole		Prothioconazole - desthio	
	mean value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i./ha	highest value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i. /ha	mean value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i./ha	highest value $\mu\text{g}/\text{cm}^2/\text{kg}$ a.i. /ha
CHR-21-51470 FR01				
S1 - 0 DAA1	1.104166667	1.297916667	0.264166667	0.28375
S3 - 0 DAA2	0.765833333	0.871666667	0.515833333	0.562916667
S5 - 2 DAA2	0.1925	0.229583333	0.58	0.592083333
S6 - 3 DAA2	0.135	0.1675	0.433333333	0.465833333
S7 - 7 DAA2	0.073333333	0.081666667	0.3025	0.303333333
CHR-21-51470 PL02				
S1 - 0 DAA1	0.418333333	0.5	0.411666667	0.44875
S3 - 0 DAA2	0.460833333	0.525416667	0.530833333	0.605416667
S5 - 2 DAA2	0.268333333	0.3125	0.574166667	0.649583333
S6 - 3 DAA2	0.145833333	0.165833333	0.464166667	0.507916667
S7 - 7 DAA2	0.051666667	0.063333333	0.296666667	0.340833333
CHR-21-51470 PL03				
S1 - 0 DAA1	0.825833333	0.991666667	0.5325	0.770833333
S3 - 0 DAA2	1.2675	1.32375	1.17	1.29625
S5 - 2 DAA2	0.37	0.411666667	0.686666667	0.7825
S6 - 3 DAA2	0.240833333	0.280833333	0.765	0.84875
S7 - 7 DAA2	0.145	0.18125	0.848333333	0.977916667

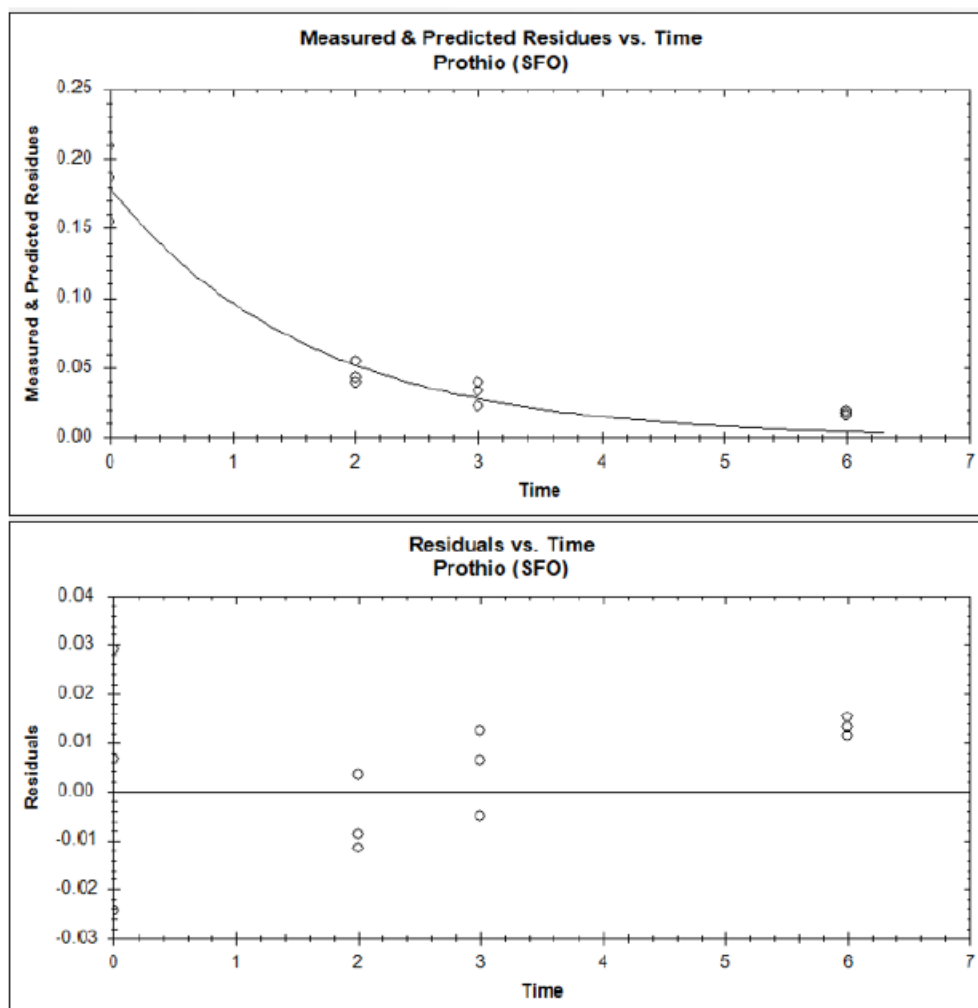
Since it is evident from the results in previous tables that the variability among the replicates of a sampling points is very low (SD generally lower than 15%, over all the trials considered) the use of the mean value it is considered suitable and sufficiently representative of the effective dislodgeable value of the considered molecules. The **worst case mean values** will be considered to select the appropriate DFR values to refine re-entry risk assessment.

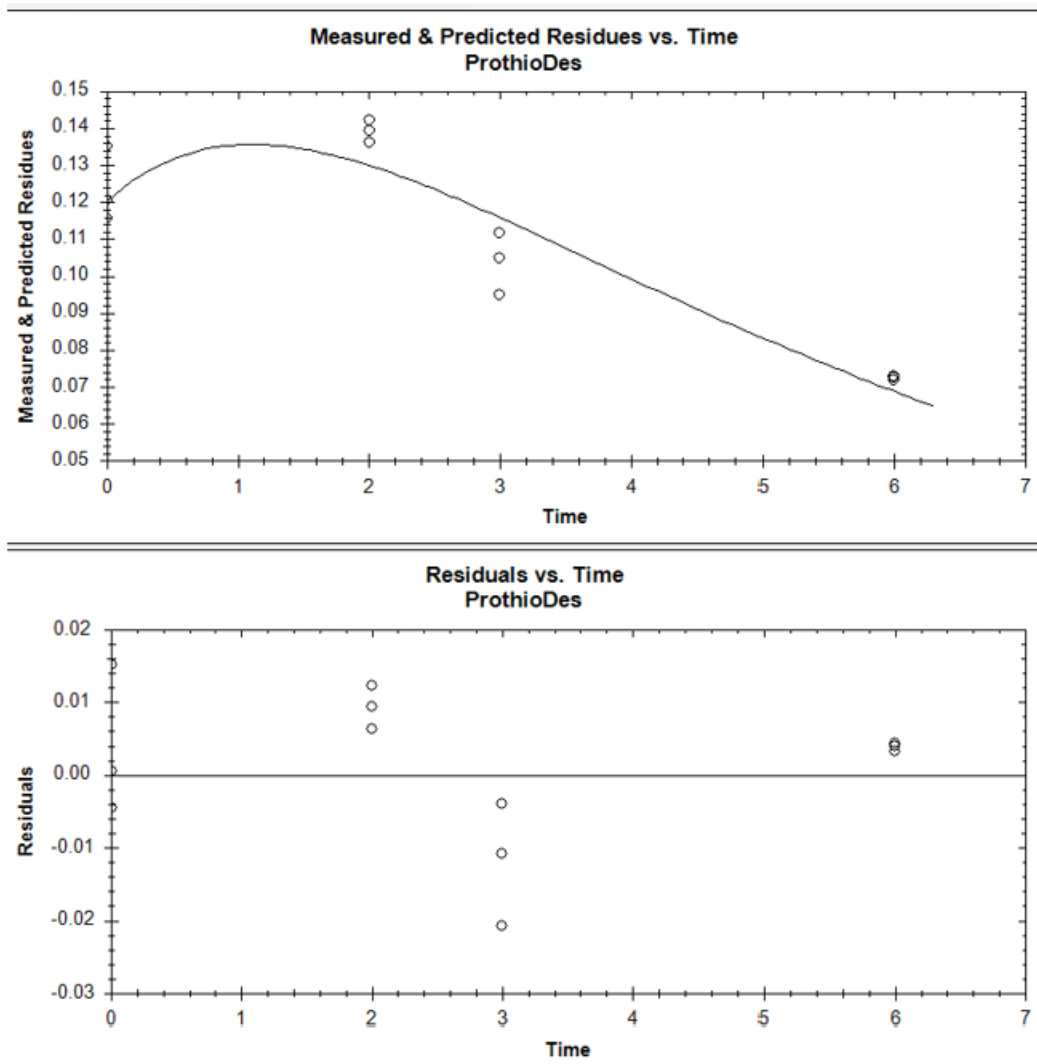
The DFR residues of the field trial were used to determine DT50 value in compliance with FOCUS Kinetics 2006 guideline (SANCO/10058/2005). Both Prothioconazole and Prothioconazole-desestio degraded over time following a curve described by the Single first order kinetic model.

Curve fitting and residual plot for each trial are reported in the following figures

TRIAL F/PR21/AP01

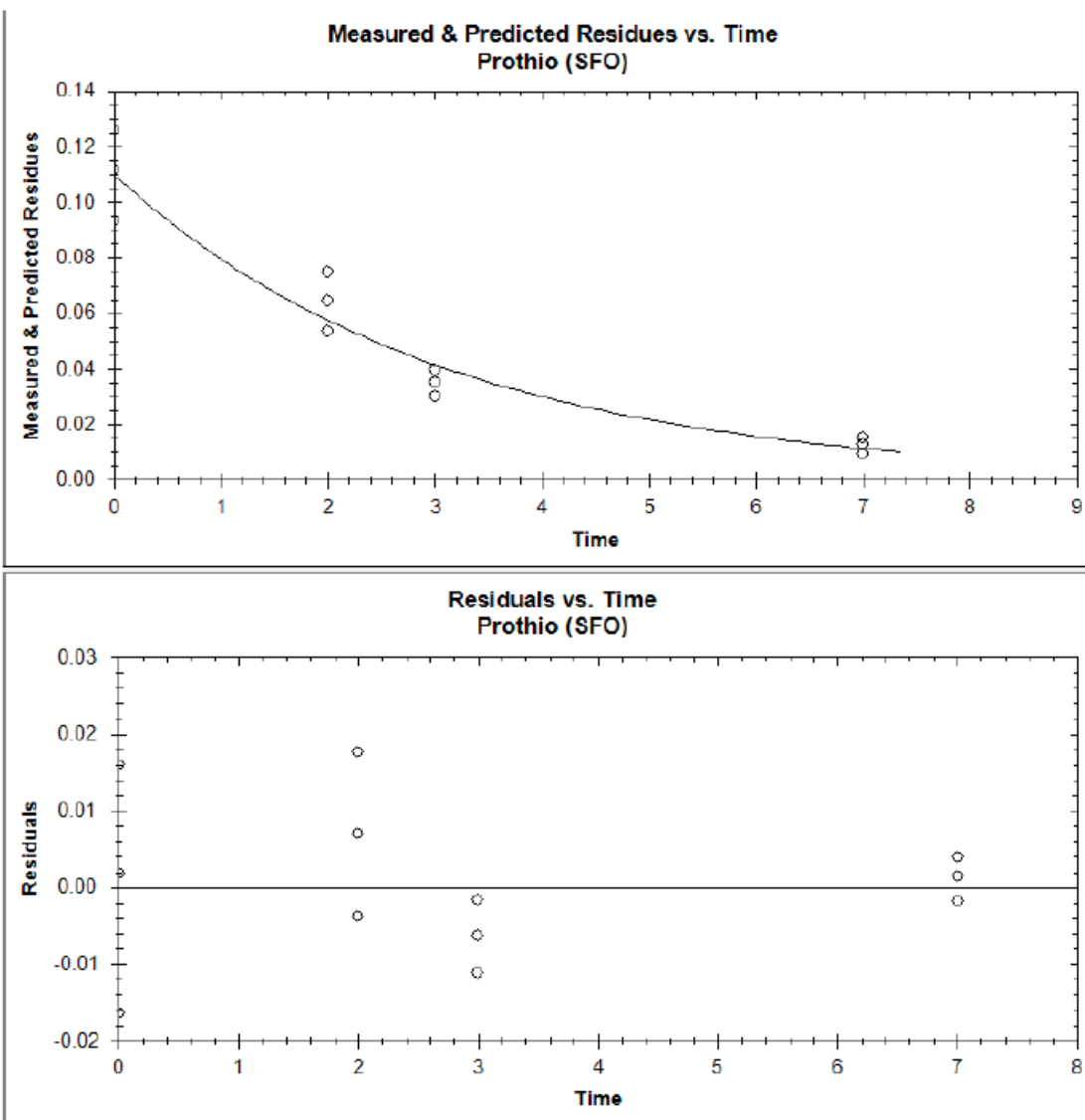
Prothioconazole: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



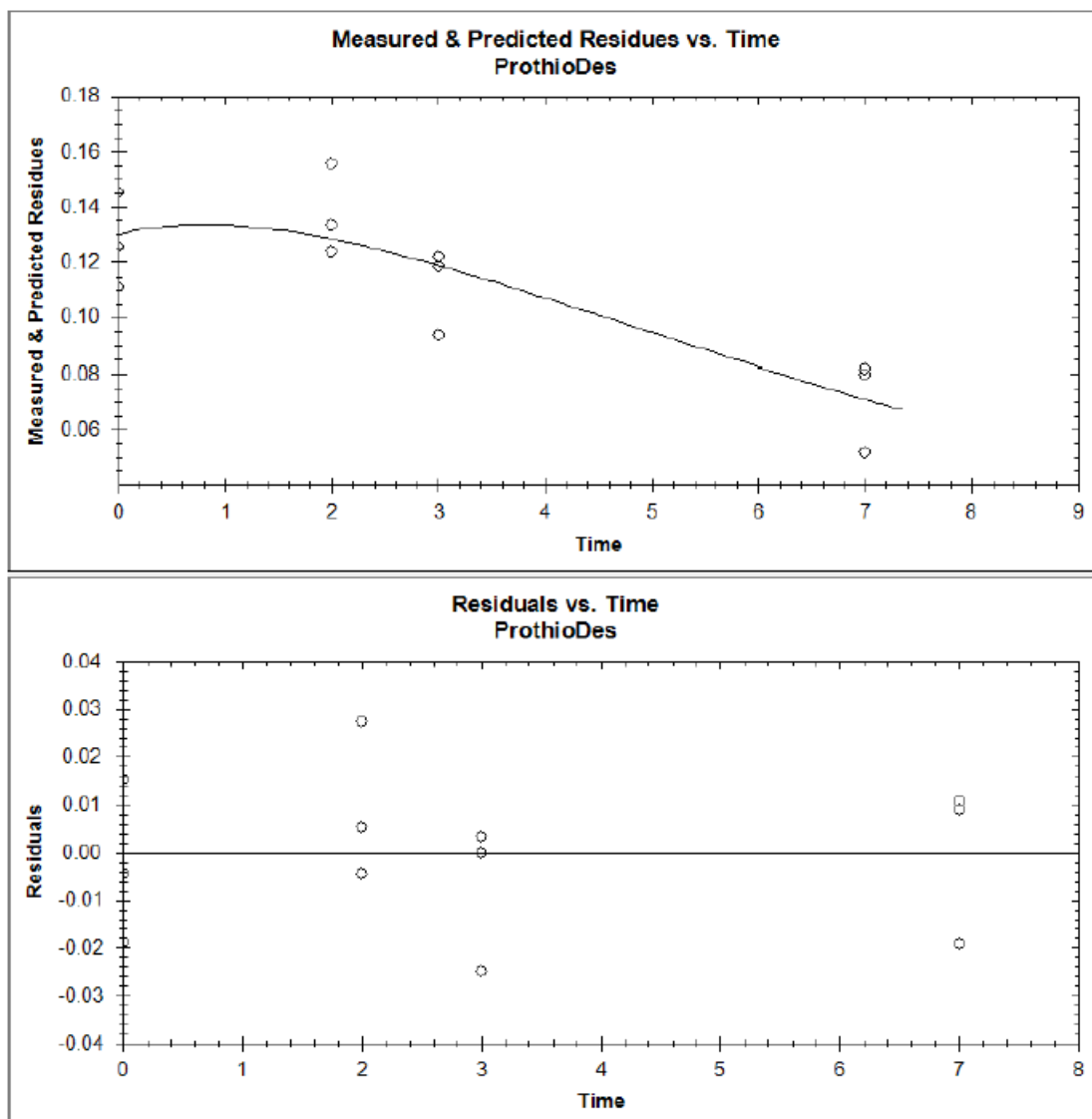
Prothioconazole -desthio: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)

TRIAL P/PR21/AP02

Prothioconazole: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)

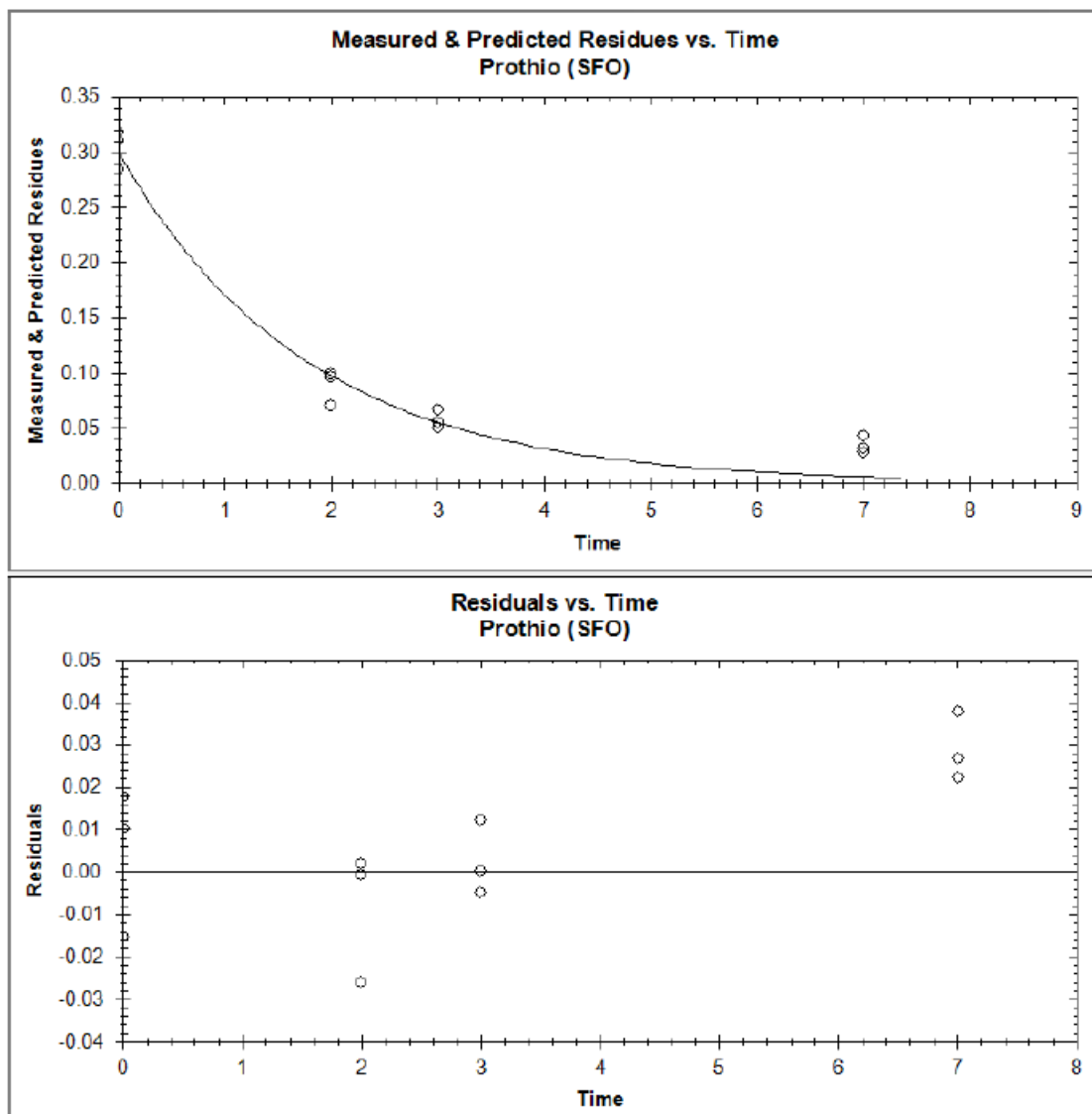


Prothioconazole -desthio: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)

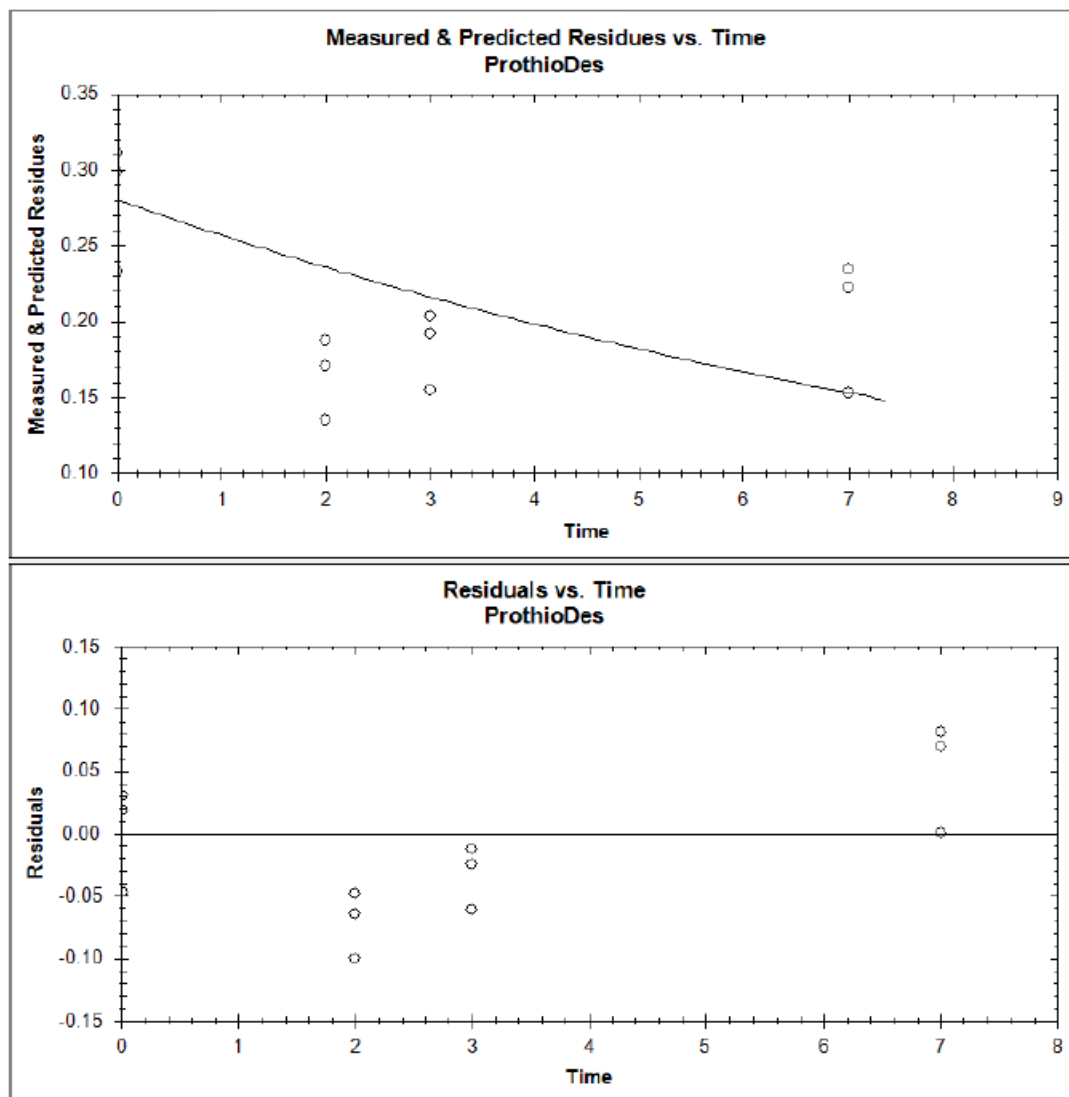


TRIAL P/PR21/AP03

Prothioconazole: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



Prothioconazole -desthio: (SFO): Residues ($\mu\text{g/mL}$) versus time plot (above) and residuals (differences between calculated and measured concentrations) versus time plot (below)



The calculated values are as follows:

Table A 98: **Prothioconazole and Prothioconazole - desthio in DFR samples DT_{50} values estimation considering FOCUS kinetics guidance**

Trial	Analyte	Kinetic model	DT₅₀ [days]	DT₉₀ [days]	Plot visually acceptable	K1*	χ^2	r²
F/PR21/AP01	Prothioconazole	SFO	1.112	3.212	Yes	0.6233 5	9.158	0.9591
	Prothioconazole - -desthio	SFO	3.694	10.671	Yes	0.2157 7	5.944	0.8572
P/PR21/AP02	Prothioconazole	SFO	2.130	7.076	Yes	0.32543	7.015	0.9359
	Prothioconazole- desthio	SFO	3.366	11.181	Yes	0.20593	4.502	0.7351
P/PR21/AP03	Prothioconazole	SFO	1.228	4.079	Yes	0.5645	10.29	0.9767
	Prothioconazole- desthio	SFO	8.010	26.608	Yes	0.8654	18.22	0.1802

Conclusions

The highest dislodgeable residues from apple leaves in this study were mostly identified immediately after the second application for both Prothioconazole and Prothioconazole-desthio. The partial degradation of Prothioconazole to Prothioconazole-desthio starts immediately.

Appendix 5 Additional exposure assessment after commenting phase

Based on comments from cMS Germany during the commenting phase, an additional exposure assessment is presented, based on a different ratio (50%/50%) between Prothioconazole and Prothioconazole-desthio. Detailed calculations are available upon request.

As in this case both ingredients are expected to coexist, also a combined RA is provided.

6.6.6.1 Estimation of operator exposure**Table 6.6-10: Exposure models for intended uses**

Critical use(s)	Wheat, Barley (field crops, max. 0.5 L product/ha) Stone fruits (orchard, max 0.4 L product/ha) Cucurbits (fruiting vegetables, greenhouse, max 0.2 L product/ha)
Model(s)	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

Table 6.6-11: Estimated operator exposure (acute exposure)

Not required, see above

Table 6.6-12: Estimated operator exposure (longer term exposure)

		Prothioconazole		Prothioconazole-desthio	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (wheat, barley)					
50% Application rate		0.05 kg a.s./ha		0.905 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0033	1.63	0.0020	19.98
	Work wear (arms, body and legs covered) M/L and A + type of PPE/RPE				
Tractor mounted spray application outdoors to high crops (stone fruits)					
Application rate		0.08 kg a.s./ha		0.0725 kg a.s./ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0108	5.42	0.0085	84.63
	Work wear (arms, body and legs covered) M/L and				

	A + type of PPE/RPE				
Manual, hand-held sprayer, upwards spraying outdoors to high crops (stone fruits)					
Application rate		0.08 kg a.s./ha		0.0725 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.0075	3.76	0.0061	61.28
	Work wear (arms, body and legs covered) M/L and A + type of PPE/RPE				
Manual, hand-held sprayer, upwards spraying (cucurbits) greenhouse (ECPA/CropLife model)					
Application rate		0.06 kg a.s./ha		0.0545 kg a.s./ha	
Spray application (ECPA/CropLife; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.07091	35.5	0.05493	549.3
	Work wear (arms, body and legs covered) M/L and A + gloves, impervious coverall A	0.010208	5.1	0.008573	85.7
Manual, hand-held sprayer, upwards spraying (cucurbits) greenhouse (Dutch model)					
Application rate		0.06 kg a.s./ha		0.0545 kg a.s./ha	
Spray application Dutch Model Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	2.34	17	1.7985	257
	Work wear (arms, body and legs covered) M/L and A + gloves, impervious coverall, mask	0.2580	2	0.2017	29

6.6.6.2 Estimation of worker exposure**Table 6.6-13: Exposure models for intended uses**

Critical use(s)	Cereals (max. 2 x 0.5 L product/ha, interval 14 days) Cucurbits indoor and outdoor (max 3 x 0.3 L product/ha, interval 10 days) Sugar beet (bolting only, max 2 x 0.4 product/ha, interval 14 days) Stone trees (max 2 x 0.4 L product/ha, interval 7 days) Apple trees (max 2 x 0.3 L product/ha, interval 7 days)
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

Table 6.6-14: Estimated worker exposure (acute exposure)

Not required, see above

Table 6.6-15: Estimated worker exposure (longer term exposure)

		Prothioconazole		Prothioconazole-desmethio	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, Inspection Outdoor Body weight: 60 kg Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.1 kg a.s./ha		2 x 0.0905 kg a.s./ha	
EFSA model	Potential TC: 12500 cm ² /person/h	0.0302	15.08	0.0312	311.98
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0034	1.69	0.0035	34.94
	Work wear (arms, body and legs covered) and gloves TC: n.a. cm ² /person/h				
Cucurbits, Reaching, picking Indoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 x 0.06 kg a.s./ha		3 x 0.0545 kg a.s./ha	
EFSA model	Potential TC: 5800 cm ² /person/h	0.0641	32.05	0.0646	646.25
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0276	13.81	0.0279	278.56
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0064	3.21	0.0065	64.62
Sugar beet, bolting Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.08 kg a.s./ha		2 x 0.0725 kg a.s./ha	
EFSA model TC values	Potential TC: 18600 cm ² /person/h	0.16415	82.07	0.14888	1488.8

Baumann J., 2019 ²	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.03971	19.86	0.03602	360.19
	Work wear (arms, body and legs covered) and gloves TC: 430 cm ² /person/h	0.00379	1.9	0.00344	34.42
Stone fruits, Reaching, picking Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days Prothioconazole DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.65 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.08 kg a.s./ha		2 x 0.0725 kg a.s./ha	
EFSA model	Potential TC: 22500 cm ² /person/h	0.2532	126.59	0.0419	418.62
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0506	25.32	0.0084	83.72
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0253	12.66	0.0042	41.86
Pome fruits, Reaching, picking Outdoor Body weight: 60 kg Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.65 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.06 kg a.s./ha		2 x 0.0545 kg a.s./ha	
EFSA model	Potential TC: 22500 cm ² /person/h	0.1899	94.94	0.0315	314.69
	Work wear (arms, body and legs covered) TC: 4500 cm ² /person/h	0.0380	18.99	0.0063	62.94
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm ² /person/h	0.0190	9.49	0.0031	31.47

6.6.6.3 Refinement of generic DFR value (KCP 7.2)

² Baumann J, Anft T, Doughty KJ and Kuster CJ, 2019. Exposure to pesticide residues during manual removal of bolting sugar beets: determination of transfer coefficients for worker risk assessment. Journal of Consumer Protection and Food Safety 2019; 14, 283-286).

Upon suggestion from Germany cMS during the commenting phase, considering that obtained DFR-values for all experiments (except trial PL 03) are comparable, data from all sites may be used in a combined analysis to derive a common DFR-value for all pome and stone fruits. In the table below a mean is calculated from the worst-case sample of each trial or, alternatively, averaging the mean of the worst case triplicates. The two resulting values are very similar, demonstrating that in the case of these data, the analysis of three samples for each experimental point is sufficiently representative. However, the worst-case value of DFR = **0.65 µg/cm²/kg a.i./ha** has been used for calculations

	DFR	Worst case Highest value µg/cm ² /kg a.i./ha	Worst case Mean value µg/cm ² /kg a.i./ha
SEU	I/PR21/PE03	0.325938	0.240625
SEU	S/PR21/PL01	0.544375	0.493333
SEU	I/PR21/AP05	0.51875	0.44
SEU	CHR-21-51470 FR01	0.592083	0.58
CEU	CHR-21-51470 PL02	0.649583	0.574167
CEU	CHR-21-51470 PL03	1.29625	1.17
	overall mean µg/cm ² /kg a.i./ha	0.654497	0.583021

6.6.6.4 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 and re-entry intervals, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.7 Resident and bystander exposure (KCP 7.2.2)

6.6.7.1 Estimation of resident and bystander exposure

Table 6.6-16: Exposure models for intended uses

Critical use(s)	Cereals (max. 2 x 0.5 L product/ha, interval 14 days) Oilseed rape (max. 2 x 0.45 L product/ha, interval 14 days) Carrot (max. 2 x 0.5 L product/ha, interval 21 days) Cucurbits indoor (max 3 x 0.3 L product/ha, interval 10 days) Stone trees (max 2 x 0.4 L product/ha, interval 7 days) Apple trees (max 2 x 0.3 L product/ha, interval 7 days)
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

Table 6.6-17: Estimated resident exposure (longer term exposure)

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops - Cereals Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.1 kg a.s./ha 200L		2 x 0.0905 kg a.s./ha 200L	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0019	0.94	0.0020	19.5
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0005	0.25	0.0005	4.90
	Re-entry (75 th perc.)	0.0041	2.04	0.0042	42.12
	Sum (mean)	0.0057	2.86	0.0059	58.63
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0005	0.23	0.0005	4.66
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0002	0.08	0.0002	1.70
	Re-entry (75 th perc.)	0.0023	1.13	0.0023	23.40
	Sum (mean)	0.0024	1.18	0.0024	24.42

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops – Oilseed rape (covers also sugar beet) Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 x 0.09 kg a.s./ha, 200 L water		2 x 0.0815 kg a.s./ha, 200 L water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0034	0.0017	0.0018	17.57
	Vapour (75 th perc.)	0.0011	0.0011	0.0011	10.70
	Deposits (75 th perc.)	0.0009	0.0004	0.0004	4.41
	Re-entry (75 th perc.)	0.0073	0.0037	0.0038	37.93
	Sum (mean)	0.0094	0.0053	0.0054	53.87
Resident adult	Drift (75 th perc.)	0.0008	0.0004	0.0004	4.19

Body weight: 60 kg	Vapour (75 th perc.)	0.0002	0.0002	0.0002	2.30
	Deposits (75 th perc.)	0.0003	0.0001	0.0002	1.53
	Re-entry (75 th perc.)	0.0041	0.0020	0.0021	21.07
	Sum (mean)	0.0041	0.0022	0.0022	22.22

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops - carrot Buffer zone: 2-3 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 21 days					
Number of applications and application rate		2 x 0.1 kg a.s./ha, 500 l water		2 x 0.0905 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0010	0.51	0.0008	7.81
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0006	0.29	0.0005	4.59
	Re-entry (75 th perc.)	0.0052	2.59	0.0039	39.48
	Sum (mean)	0.0062	3.09	0.0050	49.84
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0002	0.12	0.0002	1.86
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0002	0.10	0.0002	1.59
	Re-entry (75 th perc.)	0.0029	1.44	0.0022	21.93
	Sum (mean)	0.0028	1.40	0.0022	21.84

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held application, indoor - cucurbits Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 days					
Number of applications and application rate		3 x 0.06 kg a.s./ha, 200 l water		3 x 0.0545 kg a.s./ha, 200 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0079	3.97	0.0061	60.83
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70

	Deposits (75 th perc.)	0.0002	0.11	0.0002	1.70
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)	0.00965	4.825	0.00468	46.75
	Drift (75 th perc.)	0.0044	2.20	0.0034	33.64
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
Resident adult Body weight: 60 kg	Deposits (75 th perc.)	0.0001	0.04	0.0001	0.59
	Re-entry (75 th perc.)*				
	Sum (mean) no re-entry (indoor)	0.0051	2.56	0.0024	23.5

*re-entry not relevant for indoor application

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole 5.3 days Prothioconazole-desthio DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.5 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.08 kg a.s./ha, 500 l water		2 x 0.0725 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0042	2.12	0.0032	32.37
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0015	0.75	0.0012	11.89
	Re-entry (75 th perc.)	0.0047	2.37	0.0008	7.85
	Sum (mean)	0.0087	4.37	0.0052	52.08
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0023	1.17	0.0018	17.90
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0005	0.27	0.0004	4.12
	Re-entry (75 th perc.)	0.0026	1.32	0.0004	4.36
	Sum (mean)	0.0043	2.13	0.0021	20.54

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted spray application outdoors to high crops (Pome Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days Prothioconazole DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.65 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.06 kg a.s./ha, 500 l water		2 x 0.0545 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0032	1.59	0.0024	24.33
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0011	0.56	0.0009	8.93
	Re-entry (75 th perc.)	0.0036	1.78	0.0006	5.90
	Sum (mean)	0.0068	3.41	0.0038	38.04
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0018	0.88	0.0013	13.46
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0004	0.20	0.0003	3.10
	Re-entry (75 th perc.)	0.0020	0.99	0.0003	3.28
	Sum (mean)	0.0033	1.63	0.0016	16.01

		Prothioconazole		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Hand held spray application outdoors to high crops (Stone Fruits) Buffer zone: 5 (m) Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Prothioconazole 0.65 µg/cm²/kg a.s./ha Prothioconazole-desthio Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.08 kg a.s./ha, 500 l water		2 x 0.0725 kg a.s./ha, 500 l water	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0042	2.12	0.0032	32.37
	Vapour (75 th perc.)	0.0011	0.54	0.0011	10.70
	Deposits (75 th perc.)	0.0015	0.75	0.0012	11.89
	Re-entry (75 th perc.)	0.0047	2.37	0.0008	7.85
	Sum (mean)	0.0087	4.37	0.0047	47.07
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0023	1.17	0.0018	17.90
	Vapour (75 th perc.)	0.0002	0.12	0.0002	2.30
	Deposits (75 th perc.)	0.0005	0.27	0.0004	4.12

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	Re-entry (75 th perc.)	0.0026	1.32	0.0004	4.36
	Sum (mean)	0.0043	2.13	0.0021	20.54

6.6.8 Combined exposure

The combined effect of Prothioconazole and its metabolite is calculated herewith. For residents, only the worst case scenario (cereals) has been included

Table 6.6-18: Risk assessment from combined exposure (long term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – tractor mounted application low crops (Cereals)	Prothioconazole	0.02
	Prothioconazole-desthio	0.2
	Cumulative risk operators (HI)	0.22
Operators – tractor mounted application high crops (Stone fruit)	Prothioconazole	0.05
	Prothioconazole-desthio	0.85
	Cumulative risk operators (HI)	0.9
Operators – manual hand-held application indoor ECPA/CropLife model Work wear (arms, body and legs covered) M/L and A + gloves, impervious coverall A	Prothioconazole	0.05
	Prothioconazole-desthio	0.86
	Cumulative risk operators (HI)	0.91
Operators – manual handheld application Work wear (arms, body and legs covered) M/L and A + gloves, impervious coverall, mask	Prothioconazole	0.02
	Prothioconazole-desthio	0.29
	Cumulative risk operators (HI)	0.31
Workers – crop inspection of cereals	Prothioconazole	0.02
	Prothioconazole-desthio	0.35
	Cumulative risk workers (HI)	0.37
Workers – reaching, picking cucurbits Work wear (arms, body and legs covered) and gloves	Prothioconazole	0.03
	Prothioconazole-desthio	0.65
	Cumulative risk workers (HI)	0.68
Workers – beet bolting Work wear (arms, body and legs covered) and gloves	Prothioconazole	0.02
	Prothioconazole-desthio	0.34
	Cumulative risk workers (HI)	0.36
Workers – Reaching, picking orchards (Stone Fruits) Work wear (arms, body and legs covered) and gloves	Prothioconazole	0.13
	Prothioconazole-desthio	0.42
	Cumulative risk workers (HI)	0.55
Workers – Reaching, picking orchards (Pome Fruits) Work wear (arms, body and legs covered)	Prothioconazole	0.19
	Prothioconazole-desthio	0.63
	Cumulative risk workers (HI)	0.82
Resident – child Tractor mounted boom spray application outdoors to low crops Cereals	Prothioconazole	
	Drift	0.009
	Vapour	0.005

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Deposits	0.0025
	Re-entry	0.002
	Sum of all pathways	0.03
	Prothioconazole-desthio	
	Drift	0.2
	Vapour	0.11
	Deposits	0.05
	Re-entry	0.42
	Sum of all pathways	0.59
	Cumulative risk resident – child (HI)	
	Drift	0.21
	Vapour	0.12
	Deposits	0.05
	Re-entry	0.42
	Sum of all pathways	0.62
Resident – adult	Prothioconazole	
	Drift	0.002
	Vapour	0.001
	Deposits	0.001
	Re-entry	0.011
	Sum of all pathways	0.012
	Prothioconazole-desthio	
	Drift	0.047
	Vapour	0.023
	Deposits	0.017
	Re-entry	0.23
	Sum of all pathways	0.24
	Cumulative risk resident – adult (HI)	
	Drift	0.049
	Vapour	0.024
	Deposits	0.018
	Re-entry	0.24
	Sum of all pathways	0.125

The Hazard Index is < 1 either at Tier I or Tier II approaches for all uses. Thus, combined exposure to both active substances in SIP 31743 is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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