

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: CHR/F/PROTAZO 375 SC

Product name(s): CLARO 375 SC, KAJMAN 375 SC

Chemical active substance(s):

Prothioconazole, 175 g/L

Azoxystrobin, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: May 2020

MS Finalisation date: 28/04/2022

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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Version history

When	What
May 2021	Dossier sent for evaluation
December 2021	Applicant updated dRR on the zRMS request
January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on CHR/F/PROTAZO *

Product name and code	CHR/F/PROTAZO
Formulation type	SC
Active substance(s) (incl. content)	Prothioconazole; 175 g/L Azoxystrobin 200 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 CHR/F/PROTAZO 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 CHR/F/PROTAZO 375 SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Eye Irrit. 2, H319 Acute Tox. 4, H332.
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS07
Signal word	Warning
Hazard statement(s)	H319 – Causes serious eye damage irritation H332 - Harmful if inhaled
Precautionary statement(s)	<p>P280 – Wear protective gloves/protective clothing/eye protection/face protection P 305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 – Immediately call a Poison center/doctor/...</p> <p>Other section of the label: P201: Obtain special instructions before use. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P362+364: Take off contaminated clothing and wash before reuse. P405: Store locked up. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P501: Dispose of contents/container to... P330 – Rinse mouth.</p> <p>And P280 as follows:</p> <p>WORKER: “Stosować rękawice ochronne oraz odzież ochronną” “Wear protective gloves and protective clothing”</p> <p>Section “First Aid” P301+P310, P331, P330 P332 + P313 P304+P340 P301 + P312 P308 + P313</p> <p>For polish version: see the label</p> <p>See commentary in gray table</p>
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-Benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May produce an allergic reaction. [EUH208]

Comments of zRMS:	Justified proposals for classification and labelling for CHR/F/PROTAZO 375 SC according to Regulation (EC) No 1272/2008 Hazard class(es), categories: Acute Tox. 4, Eye Irrit. 2
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	Hazard pictograms or Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H332, H319 Precautionary statement(s): P261, P280, P304 + P340, P305 + P351 + P338 Additional labelling phrases: EUH 401 – To avoid risks to human health and the environment, comply with the instructions for use. EUH208 – Contains 1,2-benzisothiazolinone. May produce an allergic reaction.
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Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for CHR/F/PROTAZO

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves and work wear at mixing and loading + gloves and work wear at application
Workers	Acceptable	Work with PPE only for cereals and oilseeds rape The forestry tree, ornamental and tobacco pose unacceptable risk for worker. Work wear and gloves during inspection
Residents	Acceptable	- install warning signs informing about recent use of PPP next to the treated area and to inform effectively the residents about the scheduled spraying action. - use 5 meters buffer zone - use vehicle mounted drift reduction
Bystanders		

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

Comments of zRMS:	Justified proposals for classification and labelling for CHR/F/PROTAZO 375 SC according to Regulation (EC) No 1272/2008 Hazard class(es), categories: Acute Tox. 4, Eye Irrit. 2 Hazard pictograms or Code(s) for hazard pictogram(s): GHS07 Signal word: Warning Hazard statement(s): H332, H319 Precautionary statement(s): P261, P280, P304 + P340, P305 + P351 + P338 Additional labelling phrases: EUH 401 – To avoid risks to human health and the environment, comply with the instructions for use. EUH208 – Contains 1,2-benzisothiazolinone. May produce an allergic reaction.
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Table 6.1-3 are applied.

It is noted that an unacceptable risk has been identified for workers and residents/bystander regarding tobacco, coniferous/ deciduous forest nurseries, ornamental shrubs, *Salix viminalis*, wicker, ornamental as indicated in Table 6.1-4 below.

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

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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, F _{pn} , G, G _n , G _{pn} or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***)	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
	Winter oil seed rape (BBCH 59-69)	F	Spraying, LCTM	1 ; 1	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	56		R	A ****	R ****	R ****
	Spring/Winter cereals (BBCH 25-69)	F	Spraying, LCTM	2/14	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	35		R	N ****	N ****	N ****
									R	**** cMS level	R **** cMS level	R **** cMS level
	Spring rye [BBCH 25-69]	F	Spraying	2/14	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	35		R	N ****	N ****	N ****
									R	**** cMS level	R **** cMS level	R **** cMS level
	Spring oil seed rape (BBCH 59-69)	F	Spraying	1:1	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	56		R	A ****	R ****	R ****
	Sunflower (BBCH 18-69)	F	Spraying	1:1	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	56		R	A ****	R ****	R ****
	Soya (BBCH 12-69)	F	Spraying	1:1	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	56		R	A ****	R ****	R ****
	Breadseed poppy (BBCH 59-69)	F	Spraying	1:1	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	56		R	A ****	R ****	R ****
	Mustard (BBCH 59-69)	F	Spraying	1:1	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400	56		R	A ****	R ****	R ****
	Tobacco (BBCH 10-89)	F	Spraying	2/14	a) 0.175 g prothioconazole/ha b) 0.200 g	200 - 400			R	N ****	N ****	N ****

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1	2	3	4	5	6	7	8	9	10			
					azoxystrobin/ha							
	Coniferous/ deciduous forest nurseries, Ornamental shrubs (BBCH 10-89)	F	Spraying	2/14	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400			R	N ****	N ****	N ****
	<i>Salix viminalis</i> , Wicker (BBCH 10-89)	F	Spraying	2/14	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400			R	N ****	N ****	N ****
	Ornamental (BBCH 10-89)	F	Spraying	2/14	a) 0.175 g prothioconazole/ha b) 0.200 g azoxystrobin/ha	200 - 400			R	N ****	N ****	N ****

* 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

**** exposure assessment assuming 50% conversion of prothioconazole to its metabolite

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

None

6.2 Toxicological Information on Active Substance(s)

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

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

	Prothioconazole	Azoxystrobin
Common Name	Prothioconazole	Azoxystrobin
CAS-No.	178928-70-6	131860-33-8
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: NA Code(s) for hazard pictogram(s): NA Signal word: NA Hazard statement(s): NA Precautionary statement(s): NA	Hazard classes, categories: Acute Tox. 3 Code(s) for hazard pictogram(s): GHS06 Signal word: Danger Hazard statement(s): H331 Toxic if inhaled inhalation: ATE = 0.7 mg/L (dusts/mists)
Additional C&L	Please insert proposal for additional C&L if no	Please insert proposal for additional C&L if no

	Prothioconazole	Azoxystrobin
proposal	(sufficient) harmonised classification is available Not applicable	(sufficient) harmonised classification is available Not applicable
Agreed EU endpoints		
AOEL systemic	0.2 mg/kg bw/d (for active substance) 0.01 mg/kg bw/d (for Prothioconazole-desthio)	0.2 mg/kg bw/d
Reference	EFSA Scientific Report (2007) 106, 1-98,	EFSA Journal 2010; 8(4):1542
Conditions to take into account/critical areas of concern with regard to toxicology		
According to EFSA Scientific Report (2007) 106, 1-98 for prothioconazole EFSA Journal 2010; 8(4):1542	The metabolite prothioconazole-desthio is more toxic than Prothioconazole in the rat and rabbit developmental studies (the classification Repro cat 2, R61 is proposed)	<p>Operator: Exposure estimates predict that the proposed uses of „Amistar“ (application rate of 0.250 kg azoxystrobin/ha) will result in levels of systemic exposure to azoxystrobin equivalent to: Tractor mounted or trailed field crop sprayers Without PPE: 0.7 % of the AOEL (German model) Without PPE: 7 % of the AOEL (UK POEM)</p> <p>Workers Estimates using the EUROPOEM re-entry exposure model predict that levels of systemic exposure to azoxystrobin for unprotected workers will be equivalent to 0.63 % of the AOEL when inspecting treated crops, and 1.25 % of the AOEL during hand-harvesting activities</p> <p>Bystanders Using published surrogate data, bystander exposure to azoxystrobin vapour is estimated to be equivalent to 0.3 % of the AOEL. Based on a simulated exposure study, bystander exposure to spray drift containing azoxystrobin is estimated to be equivalent to 0.14 % of the AOEL. Using published drift data and US EPA exposure data, children's exposure to spray drift fallout is estimated to be equivalent to 0.05 % of the AOEL.</p>

6.3 Toxicological Evaluation of Plant Protection Product

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

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for CHR/F/PROTAZO

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (calculation method)	> 2000 mg/kg bw	Yes, see Part C for details	None	M. Kolodziej, 2020
LD ₅₀ dermal, rat (calculation method)	> 2000 mg/kg bw	Yes, see Part C for details	None	M. Kolodziej, 2020
LC ₅₀ inhalation, rat (calculation method)	16.3 3.81 mg/L air	Yes, see Part C for details	Acute Tox. 4, H332.	M. Kolodziej, 2020
Skin irritation, (calculation method)	No Irritant	Yes, see Part C for details	None	M. Kolodziej, 2020
Eye irritation, (calculation method)	Irritant	Yes, see Part C for details	Eye Irrit. 2, H319	M. Kolodziej, 2020
Skin sensitisation, (calculation method)	Non Sensitising	Yes, see Part C for details	None	M. Kolodziej, 2020
Supplementary studies for combinations of plant protection products	No data – not required	-	None	

Table 6.3-2: Additional toxicological information relevant for classification/labelling of CHR/F/PROTAZO

	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)	Azoxystrobin 97.8% (18.38 %)	Acute Tox. 3, H331	Reg. 1272/2008	Acute Tox. 4, H332.
Toxicological properties of non-active substance(s) (relevant for classification of product)	Detailed information provided in Part C			
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

The following data on metabolites with the potential to reach the groundwater in concentrations above

0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarised in this document.

6.4.1 R234886

An overview of the results of the accepted toxicological studies for groundwater metabolite R234886 is given in the following table.

Table 6.4-1: Summary of the results of toxicity studies for R234886

Type of test, species (Guideline)	Result	Acceptability	Reference*
Bacterial mutagenicity	Non mutagenicity	Accepted at EU level, not assessed as part of this evaluation	Callander, R., 2005
Acute oral toxicity	LD50 > 5000 mg/kg	Accepted at EU level, not assessed as part of this evaluation	xxxxxxxxxxxxxxxx

* indicates that a study was reviewed at EU level

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in CHR/F/PROTAZO are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in CHR/F/PROTAZO

	CHR/F/PROTAZO	
	Value	Reference
Concentrate	10%	EFSA Journal 2017;15(6):4873
Dilution (dilution factor)	50%	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Prothioconazole

No data on dermal absorption for Prothioconazole in CHR/F/PROTAZO is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Prothioconazole

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

6.5.2 Justification for proposed values – Prothioconazole-desthio

No data on dermal absorption for Prothioconazole-desthio in CHR/F/PROTAZO is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

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

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

6.5.3 Justification for proposed values - Azoxystrobin

No data on dermal absorption for Azoxystrobin in CHR/F/PROTAZO is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-4: Default dermal absorption rates for Azoxystrobin

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

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	CHR/F/PROTAZO
Formulation type	SC
Category	fungicide
Active substance(s) (incl. content)	Prothioconazole 175 g/L Azoxystrobin 200 g/L
AOEL systemic	Prothioconazole, Azoxystrobin: 0.2 mg/kg bw/d Prothioconazole-desthio: 0.01 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 10% Dilution: 50% (Default)

6.6.1 Selection of critical use(s) and justification

The critical GAP(s) 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 central is given in Part B, Section 0.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of CHR/F/PROTAZO according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (acute exposure) and **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Cereals, Ornamentals, Tobacco, Forestry tree, Salix (max. 2 x 1 L product/ha) Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard (1 x 1 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 long term)

Prothioconazole			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 2x 0.175 kg a.s./ha (winter cereals, spring cereals, ornamental and forestry tree), 1x 0.175 kg a.s./ha (winter oilseed rape, spring oilseed rape, breadseed poppy, sunflower, soya, mustard)			
EFSA Model (Cereals)	no PPE	0.0883778	44.19%
	+PPE (gloves during M/L) + potential exposure M/L i A	0.0456206	22.81
EFSA Model (Oilseed rape, Soya, Sunflower, Breadseed poppy, Mustard covered by crop type: oilseeds)	no PPE	0.0883778	44.19%
	+PPE (gloves during M/L) + potential exposure M/L i A	0.0456206	22.81
EFSA Model (Ornamental)	no PPE potential exposure	0.0778509	38.93
EFSA Model (Forestry tree, Salix covered by crop type: pome fruit)	no PPE potential exposure	0.0778509	38.93
EFSA Model (Tobacco covered by crop type leaf vegetables and fresh herbs)	no PPE potential exposure	0.0883778	44.19

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Prothioconazole-desthio			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
EFSA Model (Cereals)	no PPE (potential exposure)	0.0817732	817.73
	+PPE (gloves at mixing and loading and application) +potential exposure during mixing, loading and application	0.0333982	333.98
	+ PPE (gloves and work wear at mixing and loading + gloves application) +potential exposure during application	0.0081491	81.49
EFSA Model (Oilseed rape, Soya, Sunflower, Breadseed poppy, Mustard covered by crop type: oilseeds)	no PPE (potential exposure)	0.0817732	817.73
	+PPE (gloves at mixing and loading and application) +potential exposure during mixing, loading and application	0.0333982	333.98
	+ PPE (gloves and work wear at mixing and loading + gloves application) + potential exposure during application	0.0081491	81.49
EFSA Model (Ornamental)	no PPE (potential exposure)	0.0711022	711.02
	+PPE (gloves at mixing and loading and application) + potential exposure during M/L i A	0.0384328	384.33
	+ PPE (gloves and work wear at mixing and loading + gloves and work wear at application)	0.0012334	12.33
EFSA Model (Forestry tree, Salix covered by crop type: pome fruit)	no PPE (potential exposure)	0.0711022	711.02
	+PPE (gloves at mixing and loading and application) + potential exposure during M/L i A	0.0384328	384.33

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	+ PPE (gloves and work wear at mixing and loading + gloves and work wear at application)	0.0012334	12.33
EFSA Model (Tobacco covered by crop type leaf vegetables and fresh herbs)	no PPE (potential exposure)	0.0817732	817.73
	+PPE (gloves at mixing and loading and application) + potential exposure during M/L i A	0.0333982	333.98
	+ PPE (gloves and work wear at mixing and loading + gloves application) + potential exposure during application	0.0081491	81.49
Azoxystrobin			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops Application rate: 2x 0.2 kg a.s./ha (winter cereals, spring cereals, ornamental and forestry tree), 1x 0.2 kg a.s./ha (winter oilseed rape, spring oilseed rape, breadseed poppy, sunflower, soya, mustard)			
EFSA Model (Cereals)	no PPE potential exposure	0.0982863	49.14
	+PPE (gloves) M/L i A potential exposure	0.0508958	19.88
	+ PPE (gloves and work wear at mixing and loading + gloves application) + potential exposure during application	0.0100744	5.04
EFSA Model (Oilseed rape, Soya, Sunflower, Breadseed poppy, Mustard covered by crop type: oilseeds)	no PPE	0.0982863	49.14
	+PPE (gloves) +potential exposure M/L i A	0.0508958	25.45
	+ PPE (gloves and work wear at mixing and loading + gloves application) potential exposure during application	0.0212016	10.60
EFSA Model (Ornamental)	no PPE (Potential exposure)	0.0881340	44.07
EFSA Model (Forestry tree, Salix covered by crop type: pome fruit)	no PPE	0.0881340	44.07
EFSA Model (Tobacco covered by crop type: tobacco)	no PPE	0.0982863	49.14
	+PPE (gloves during M/L)	0.0508958	25.45

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type leaf vegetables and fresh herbs)	+ PPE (gloves and work wear at mixing and loading + gloves application and potential exposure)	0.0212016	10.60
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6.6.2.2 Measurement of operator exposure

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

Comments of zRMS:	zRMS does not agree with the operator systemic exposure calculations for the active substances as they presented in the Appendix 3 and Table 6.6-4. Applicant approach of choosing PPE and other risk mitigating measures in the EFSA calculator is not appropriate. It is difficult to have a clear view of the appropriate personal protective equipment (PPE). Initially, the assessment shall be made with the assumption that the operator is not using any PPE. However, regular workwear is assumed.							
	Critical GAPS for operator exposure:							
			Azoxystrobin		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	Total absorbed dose (mg/kg/day)	% of systemic AOEL
	Tractor mounted downward spray application outdoors to low crops 2 x cereals							
	Application rate		2 x 0.2 kg as/ha		2 x 0.175 kg as/ha		2 x 0.158 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	0,0618	30,94	0,05545	27,73	0,051	510,06
		Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0,00335	1,68	0,00303	1,52	0,0028	28,6
	* A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied							
	Combined exposure							
Application scenario		Active ingredient			Estimated exposure / AOEL (HQ)			
Operators – work wear and gloves during M/L		Azoxystrobin			0.0168			
		Prothioconazole-desthio			0.286			

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and A		Cumulative risk operators (HI)		0.303			
		Azoxystrobin		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	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted downward spray application outdoors to high crops Ornamentals 2x							
Application rate		2 x 0.2 kg as/ha		2 x 0.175 kg as/ha		2 x 0.158 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	0,0757	37,90	0,0673	33,65	0,0614	614,64
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A	0,023	11,89	0,0209	10,45	0,0189	189,45
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L and A + hood and visor during application /closed cab	0,0187/0,0262	9,37/1,31	0,00486/0,0023	2,43/1,16	0,00446/0,0021	44,61/21,1
* A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied							
Application scenario		Active ingredient		Estimated exposure / AOEL (HQ)			
Operators – Work wear M/L and A + gloves during M/L and A + hood and visor during application /closed cab		Azoxystrobin		0.093/0.013			
		Prothioconazole-desthio		0.446/0.21			
		Cumulative risk operators (HI)		0.539/0.223			

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	<p>According to the model calculation, it can be concluded that the risk for the operator using CHR/F/PROTAZO 375 SC is acceptable with the use of gloves at mixing/loading/application and hood and visor during application or closed cab. In the light of the risk assessment and the product classification with respect to human health, the final operator protection phrases should be:</p> <ul style="list-style-type: none"> - Operators must wear suitable gloves, face/eyes protection and workwear when handling the concentrate or handling contaminated surfaces. - Operators must wear standard workwear, gloves and additionally hood and visor or closed vehicle cab when applying
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6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with CHR/F/PROTAZO according to the critical use(s). Outcome of the estimation is presented in Table 6.6-8 (acute exposure) and **Błąd! Nie można odnaleźć źródła odwołania.** (longer term exposure). Detailed calculations are in Appendix 3.

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Table 6.6-5: Exposure models for intended uses

Critical use(s)	Cereals, Ornamentals, Tobacco, Forestry tree, Salix (max. 2 x 1 L product/ha) Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard (1 x 1 L product/ha)
Model	EFSA MODEL

Table 6.6-6: Estimated worker exposure

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Prothioconazole			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Cereals 8 hours/day ⁽¹⁾ , 2 h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.188525	94.26
	with PPE ⁽⁴⁾ -work wear	0.0211145	10.56
Number of applications and application rate:		1 x 0.175 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽¹⁾ , 2 h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure	0.1093750	54.69
	With PPE ⁽⁴⁾ work wear	0.0122500	6.13
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Ornamentals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure TC=14000 cm ² /hr	0.8445810	422.29
	With PPE ⁽⁴⁾ (working wear and gloves) TC=1400 cm ² /hr	0.0844581	42.23
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure TC=22500 cm ² /hr	1.3573623	678.68
	with PPE ⁽⁴⁾ (working wear and gloves) TC=2250 cm ² /hr	0.1357362	67.87
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure TC=5800 cm ² /hr	0.3498978	174.95
	with PPE ⁽⁴⁾ (working wear and gloves) TC=580 cm ² /hr	0.0349898	17.49
Prothioconazole-desthio			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	

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Cereals 8 hours/day ⁽⁴⁾ ; TC: 2500 cm ² /person/h ⁽²⁾ 2 h Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.1709630	1709.63
	with PPE ⁽⁴⁾ work wear (TC= 1400 cm ² /hr)	0.0191479	191.48
Number of applications and application rate:		1 x 0.1587 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽⁴⁾ ; 2 h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.0991875	991.88%
	with PPE ⁽⁴⁾ work wear (TC= 1400 cm ² /hr)	0.0111090	111.09%
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Ornamentals 8 hours/day ⁽¹⁾ ; TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ (TC= 14000 cm ² /hr)	0.7659143	7659.14
	with PPE ⁽⁴⁾ – working wear and gloves (TC= 1400 cm ² /hr)	0.0765914	765.91
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ ; TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	1.2309337	12309.34
	with PPE ⁽⁴⁾ – working wear	0.1230934	1230.93
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ ; TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ (TC= 5800 cm ² /hr)	0.3173073	3173.07
	with PPE ⁽⁴⁾ – working wear and gloves (TC= 580 cm ² /hr)	0.0317307	317.31
Prothioconazole-desthio - when 100% conversion of the parent into the metabolite			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Cereals 8 hours/day ⁽⁴⁾ ; 2 h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.1709630	1709.63
	with PPE ⁽⁴⁾ work wear (TC= 1400 cm ² /hr)	0.0191479	191.48
Number of applications and application rate:		1 x 0.1587 kg a.s./ha	

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Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.0991875	991.88%
	with PPE ⁽⁴⁾ work wear (TC= 1400 cm ² /hr)	0.0111090	111.09%
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Ornametnals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 14000 cm ² /hr)	0.7659143	7659.14
	with PPE ⁽⁴⁾ – workin wear and gloves (TC= 14000 cm ² /hr)	0.0765914	765.91
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ (TC= 14000 cm ² /hr)	1.2309337	12309.34
	with PPE ⁽⁴⁾ – working wear +gloves (TC= 2250 cm ² /hr)	0.1230934	1230.93
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 5800 cm ² /hr)	0.3173073	3173.07
	with PPE ⁽⁴⁾ – working wear and gloves (TC= 580 cm ² /hr)	0.0317307	317.31
Prothioconazole-desthio - when 50% conversion of the parent into the metabolite			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Cereals 8 hours/day ⁽¹⁾ , 2 h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.0854707	854.71
	with PPE ⁽⁴⁾ work wear (TC= 1400 cm ² /hr)	0.0095727	95.73
Number of applications and application rate:		1 x 0.07934 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽¹⁾ , 2h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.0495875	495.88
	with PPE ⁽⁴⁾ work wear (TC= 1400 cm ² /hr)	0.0055538	55.45
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	

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Ornamentals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 14000 cm ² /hr)	0.3829089	3829.09
	with PPE ⁽⁴⁾ – working wear and gloves (TC= 1400 cm ² /hr)	0.0382909	382.91
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 22500 cm ² /hr)	0.6153893	6153.89
	with PPE ⁽⁴⁾ – working wear +gloves (TC= 2250 cm ² /hr)	0.0615389	615.39
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 5800 cm ² /hr)	0.1586337	1586.34
	with PPE ⁽⁴⁾ – working wear and gloves (TC= 580 cm ² /hr)	0.0158634	158.63
		Azoxystrobin	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Cereals 8 hours/day ⁽¹⁾ , 2h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.2154543	107.73
	with PPE ⁽⁴⁾ (TC= 1400 cm ² /hr)	0.0241309	12.07
Number of applications and application rate:		1 x 0.2 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽¹⁾ , 2 h TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 12500 cm ² /hr)	0.1250	62.50
	with PPE ⁽⁴⁾ (TC= 1400 cm ² /hr)	0.0140	7.00
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Ornamentals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 14000 cm ² /hr)	0.9652354	482.62
	with PPE ⁽⁴⁾ (working wear and gloves) (TC= 1400 cm ² /hr)	0.0965235	48.26

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Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 22500 cm ² /hr)	1.5512712	775.64
	with PPE ⁽⁴⁾ working wear and gloves (TC= 2250 cm ² /hr)	0.1551271	77.56
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾ potential exposure (TC= 5800 cm ² /hr)	0.3998832	199.94
	with PPE ⁽⁴⁾ working wear and gloves (TC=580 cm ² /hr)	0.0399883	19.99

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Table 6.6-7: Exposure models for intended uses

Critical use(s)	Cereals, Ornamentals, Tobacco, Forestry tree, Salix (max. 2 x 1 L product/ha) Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard (1 x 1 L product/ha)
Model	EUROPOEM II MODEL

Table 6.6-8: Estimated worker exposure

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Prothioconazole			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Cereals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.14	70
	with PPE ⁽⁴⁾	0.028	14
Number of applications and application rate:		1 x 0.175 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.0875	44
	with PPE ⁽⁴⁾	0.0175	9
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Ornamentals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ TC: 5000 cm ² /person/h Body weight: 60 kg	no PPE ⁽³⁾	0.280	140
	with PPE ⁽⁴⁾	0.056	28
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ TC: 3000 cm ² /person/h Body weight: 60 kg	no PPE ⁽³⁾	0.14	70 84
	with PPE ⁽⁴⁾	0.028	14 17
Number of applications and application rate:		2 x 0.175 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.168	84 70
	with PPE ⁽⁴⁾	0.0336	17 14
Prothioconazole-desthio – when 100% conversion of the parent into the metabolite			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Cereals 2 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.03173	317
	with PPE ⁽⁴⁾ (gloves)	0.00635	63
Number of applications and application rate:		1 x 0.1587 kg a.s./ha	
Oilseed rape, Soya, Sunflower,	no PPE ⁽³⁾	0.01983	198

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Breadseeds poppy, Mustard covered by crop type: oilseed 2 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	with PPE ⁽⁴⁾ (gloves)	0.003967	40
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Ornamentals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ TC: 5000 cm ² /person/h Body weight: 60 kg	no PPE ⁽³⁾	0.2539	2539
	with PPE ⁽⁴⁾ (gloves)	0.05078	508
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 253000 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.1523	1523
	with PPE ⁽⁴⁾ (gloves)	0.0305	305
Number of applications and application rate:		2 x 0.1587 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 253000 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.1523	1523
	with PPE ⁽⁴⁾ (gloves)	0.0305	305
Prothioconazole-dethio - 50% conversion of the parent into prothioconazole-dethio			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Cereals 2 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.0159	159
	with PPE ⁽⁴⁾ (gloves)	0.0032	32
Number of applications and application rate:		1 x 0.07934 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 2 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.0099	99
	with PPE ⁽⁴⁾ (gloves)	0.0020	20
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Ornamentals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ TC: 5000 cm ² /person/h Body weight: 60 kg	no PPE ⁽³⁾	0.1270	1270
	with PPE ⁽⁴⁾ (gloves)	0.0254	254
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Forestry tree, Salix covered by crop	no PPE ⁽³⁾	0.0762	762

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type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ TC: 3000 cm ² /person/h Body weight: 60 kg	with PPE ⁽⁴⁾ (gloves)	0.0152	152
Number of applications and application rate:		2 x 0.07934 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ TC: 3000 cm ² /person/h Body weight: 60 kg	no PPE ⁽³⁾	0.0752	752-762
	with PPE ⁽⁴⁾ (gloves)	0.0152	152
Azoxystrobin			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Cereals 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.160	80
	with PPE ⁽⁴⁾ (gloves)	0.032	16
Number of applications and application rate:		1 x 0.2 kg a.s./ha	
Oilseed rape, Soya, Sunflower, Breadseeds poppy, Mustard covered by crop type: oilseed 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.1	50
	with PPE ⁽⁴⁾ (gloves)	0.02	10
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Ornamentals 7 hours/day ⁽¹⁾ , 8 h TC: 2500 cm ² /person/h ⁽²⁾ TC: 5000 cm ² /person/h Body weight: 60 kg	no PPE ⁽³⁾	0.32	160
	with PPE ⁽⁴⁾ (gloves)	0.064	32
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Forestry tree, Salix covered by crop type: pome fruit 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.16	80-84
	with PPE ⁽⁴⁾ (gloves)	0.032	16-17
Number of applications and application rate:		2 x 0.2 kg a.s./ha	
Tobacco covered by crop type: leafy vegetables and fresh herbs 8 hours/day ⁽¹⁾ , TC: 2500 cm ² /person/h ⁽²⁾ Body weight: 60 kg	no PPE ⁽³⁾	0.192	96-80
	with PPE ⁽⁴⁾ (gloves)	0.0384	19-16

(1) 8 h/day hours for harvesting and maintenance type activities and 2h/day for crop inspection and irrigation-type activities

(2) 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) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable"), covered body, but no gloves

(4) with PPE: type of PPE / see 'Instructions for use'

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.3.3 Measurement of worker exposure

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

Comments of zRMS:	AOEM model results are incorrectly described (working time, TC value, PPE) in Table 6.6 5. EFSA model is agreed exposure model to estimate the exposure of workers and therefore zRMS includes exposure calculation for the sake of clarity. zRMS agrees that for some crops the risk for workers is unacceptable even if 50 % conversion from prothioconazole to prothioconazole-desthio is considered.							
	Critical GAPS for worker exposure							
			Azoxystrobin		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	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 1 application at 1.0 L product/ha Cereals							
	Number of applications and application rate		1 × 0.2 kg a.s./ha		1 × 0.175 kg a.s./ha		1 × 0.158* kg a.s./ha	
	Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0,125	62,5	0,1093	54,69	0,0987	987,50
		Work wear (arms, body and legs covered) TC: 1400	0,014	7,00	0,01225	6,13	0,01106	110,60

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		cm ² /person/h						
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 2 applications at 1.0 L product/ha Interval between treatments: 14 days Cereals								
Number of applications and application rate			2 × 0.2 kg a.s./ha		2 × 0.175 kg a.s./ha		2 × 0.158* kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0,215	107,73	0,1885	94,26	0,1702	1702,09	
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0,024	12,07	0,0211	10,56	0,019	190,63	
		Azoxystrobin		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	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
Cutting, sorting, bundling, carrying Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 2 application at 1.0 L product/ha Interval between treatments: 14 days Ornamentals								
Number of applications and application rate			2 × 0.2 kg a.s./ha		2 × 0.175 kg a.s./ha		2 × 0.158* kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm ² /person/h	0,965	482,62	0,8445	422,29	0,7625	7625,36	
	Work wear (arms, body and legs covered) TC: 5000cm ² /person/h	0,3447	172,36	0,301	150,82	0,272	2723,34	
	Work wear	0,0965	48,26	0,0844	42,23	0,07625	762,54	

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	(arms, body and legs covered) and gloves						
Reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 2 application at 1.0 L product/ha Interval between treatments: 14 days Leaf vegetables and fresh herbs Tobacco							
Number of applications and application rate		2 × 0.2 kg a.s./ha		2 × 0.175 kg a.s./ha		2 × 0.158* kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.3998	199.94	0349	174.95	0.3159	3159.08
	Work wear TC: 2500cm ² /person/h	0.172	86.18	0.15	75.41	0.136	1361.67
	Work wear and gloves TC: 580cm ² /person/h	0.0399	19.99	0.0349	17.49	0.0316	316
* A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied Refinement – 50 % conversion from prothioconazole to prothioconazole-desthio							
		Azoxystrobin		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	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 1 application at 1.0 L product/ha Cereals							
Number of applications and application rate		1 × 0.2 kg a.s./ha		1 × 0.0875 kg a.s./ha		1 × 0.079* kg a.s./ha	

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	Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0,125	62,5	0.0546	27.34	0.0493	493.75
		Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0,014	7,00	0.00612	3.06	0.00553	55.3
	Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 2 applications at 1.0 L product/ha Interval between treatments: 14 days Cereals							
	Number of applications and application rate		2 × 0.2 kg a.s./ha		2 × 0.0875 kg a.s./ha		2 × 0.079* kg a.s./ha	
	Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0,215	107,73	0.094	47.13	0.085	851
		Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0,024	12,07	0.01	5.28	0.0095	95.32
			Azoxystrobin		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	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Cutting, sorting, bundling, carrying Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha 2 application at 1.0 L product/ha Interval between treatments: 14 days Ornamentals							
	Number of applications and application rate		2 × 0.2 kg a.s./ha		2 × 0.0875 kg a.s./ha		2 × 0.079* kg a.s./ha	
	Body weight: 60 kg	Potential TC: 14000 cm ² /person/h	0,965	482,62	0.4222	211.15	0.3812	3812.68

	Work wear (arms, body and legs covered) TC: 5000cm ² /person/h	0,3447	172,36	0.15	75.41	0.136	1361.67
	Work wear (arms, body and legs covered) and gloves	0,0965	48,26	0.04222	21.11	0.038	381.27
<p>Reaching, picking Outdoor Work rate: 8 hours/day, DT₅₀: 30 days DFR: 3 µg/cm²/kg a.s./ha 2 application at 1.0 L product/ha Interval between treatments: 14 days Leaf vegetables and fresh herbs Tobacco</p>							
Number of applications and application rate		2 × 0.2 kg a.s./ha		2 × 0.0875 kg a.s./ha		2 × 0.079* kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.3998	199.94	0.174	87.47	0.1579	1579.5
	Work wear TC: 2500cm ² /person/h	0.172	86.18	0.0754	37.7	0.068	680.84
	Work wear and gloves TC: 580cm ² /person/h	0.0399	19.99	0.017	8.75	0.0157	157.95
*A conversion of 50% is assumed							
<p><u>Cereals 1x application (covered sunflower, soya, breadseed poppy, mustard)</u> The risk for workers when re-entering crops treated with CHR/F/PROTAZO 375 SC, is acceptable with the use of workwear.</p>							
<p><u>Cereals 2x applications</u> The exposure to two applications of azoxystrobin, prothioconazole and prothioconazole-desthio of the worker with work wear (arms, body and legs covered, no gloves) was estimated as 12,07 % of the AOEL for azoxystrobin, 5,28 % of the AOEL for prothioconazole and 95,3 % of the AOEL for prothioconazole-desthio. Combined exposure > 1 (1.12). Workers should wear impermeable gloves and work wear at work. The use of gloves by workers performing crop inspection activities should be considered at the</p>							

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	MS level. Other crops (tobacco, coniferous/ deciduous forest nurseries, ornamental shrubs, <i>Salix viminalis</i> , wicker; ornamental) The risk for workers is not acceptable.
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6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-9 shows the exposure model(s) used for estimation of resident and bystander exposure to prothioconazole. The outcome of the estimation is presented in below. Detailed calculations are in Appendix 3.

Table 6.6-9: Exposure models for intended uses

Critical use(s)	Winter wheat (max. 2 x 1 L product/ha) Winter oilseed rape (max. 1 x 1 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-10: Estimated bystander and resident exposure

	Prothioconazole	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops		
Application rate:	2 x 0.175 kg a.s./ha (cereals)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0135917	6.80
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0296220	14.81
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0135917	6.80

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Residents (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0296220	14.81
Application rate:	1 x 0.175 kg a.s./ha (oilseed rape, soya, sunflower, breadseeds poppy, mustard covered by crop type: oilseeds)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0085428	4.27
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0203523	10.18
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0085428	4.27
Residents (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0203523	10.18
Application rate:	2 x 0.175 kg a.s./ha (ornamentals)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0135917	6.80
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0296220	14.81
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0135917	6.80
Residents (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0296220	14.81
Application rate:	2 x 0.175 kg a.s./ha (forestry tree, salix covered by crop type: pome fruit)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0163185	8.16
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0360989	18.05
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0163185	8.16
Residents (children) Drift rate: 2.77 % (1 m) Body weight:10 kg	0.0360989	18.05
Application rate:	2 x 0.175 kg a.s./ha (Tobacco covered by crop type: leafy vegetables and fresh herbs)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0135917	6.80

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Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0296220	14.81
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0135917	6.80
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0296220	14.81

Table 6.6-11: Estimated bystander and resident exposure for prothioconazole-destho for winter cereals with 5 metres buffer strip and vehicle-mounted drift reduction

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)	0.0354476	0.0107000	0.0045456	0.2308001	0.2178576
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035448	0.0010700	0.0004546	0.0230800	0.0217858
% of RVNAS	35.45%	10.70%	4.55%	230.80%	217.86%
Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0114819	0.7693335	0.6562051
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0006458	0.0002300	0.0001914	0.0128222	0.0109368

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% of RVNAS	6.46%	2.30%	1.91%	128.22%	109.37%
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Table 6.6-12: Estimated bystander and resident exposure for prothioconazole-destho for winter oilseed rape with 5 metres buffer strip and vehicle-mounted drift reduction

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)	0.0354476	0.0107000	0.0026372	0.1339031	0.1391050
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035448	0.0010700	0.0002637	0.0133903	0.0139105
% of RVNAS	35.45%	10.70%	2.64%	133.90%	139.10%
Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0066614	0.4463438	0.3949021
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0006458	0.0002300	0.0001110	0.0074391	0.0065817
% of RVNAS	6.46%	2.30%	1.11%	74.39%	65.82%

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Table 6.6-13: Estimated bystander and resident exposure for prothioconazole-desthio for ornamentals with 5 meters buffer strip and vehicle-mounted drift reduction

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)	0.0354476	0.0107000	0.0045456	0.2308001	0.2178576
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035448	0.0010700	0.0004546	0.0230800	0.0217858
% of RVNAS	35.45%	10.70%	4.55%	230.80%	217.86%
Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0114819	0.7693335	0.6562051
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0006458	0.0002300	0.0001914	0.0128222	0.0109368
% of RVNAS	6.46%	2.30%	1.91%	128.22%	109.37%

Table 6.6-14: Estimated bystander and resident exposure for prothioconazole-desthio for forestry tree, Salix, Wicker with 5 meters buffer strip and vehicle-mounted drift reduction

1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops	All pathways (mean)

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				(75th percentile)	
Total systemic exposure (mg a.s./day)	0.0354476	0.0107000	0.0312063	0.2308001	0.2374036
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0035448	0.0010700	0.0031206	0.0230800	0.0237404
% of RVNAS	35.45%	10.70%	31.21%	230.80%	237.40%
Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0788256	0.7693335	0.7055772
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0006458	0.0002300	0.0013138	0.0128222	0.0117596
% of RVNAS	6.46%	2.30%	13.14%	128.22%	117.60%

Table 6.6-15: Estimated bystander and resident exposure for prothioconazole-desthio for tobacco with 5 meters buffer strip and vehicle-mounted drift reduction

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)	0.0354476	0.0107000	0.0045456	0.2308001	0.2178576
Total systemic	0.0035448	0.0010700	0.0004546	0.0230800	0.0217858

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exposure per kg body weight (mg/kg bw/day)					
% of RVNAS	35.45%	10.70%	4.55%	230.80%	217.86%
Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total sys- temic expo- sure (mg a.s./day)	0.0387473	0.0138000	0.0114819	0.7693335	0.6562051
Total sys- temic expo- sure per kg body weight (mg/kg bw/day)	0.0006458	0.0002300	0.0001914	0.0128222	0.0109368
% of RVNAS	6.46%	2.30%	1.91%	128.22%	109.37%

Table 6.6-16: Estimated bystander and resident exposure

	Azoxystrobin	
Model data	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops		
Application rate:	2 x 0.2 kg a.s./ha (cereals)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0155005	7.75
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0337008	16.85
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0155005	7.75
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0337008	16.85

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Application rate:	1 x 0.2 kg a.s./ha (oilseed rape, soya, sunflower, breadseeds poppy, mustard covered by crop type: oilseeds)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0097304	4.87
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0231069	11.55
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0097304	4.87
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0231069	11.55
Application rate:	2 x 0.2 kg a.s./ha (ornamentals)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0155005	7.75
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0337008	16.85
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0155005	7.75
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0337008	16.85
Application rate:	2 x 0.2 kg a.s./ha (forestry tree, salix covered by crop type: pome fruit)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0186168	9.31
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0411031	20.55
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0186168	9.31
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0411031	20.55
Application rate:	2 x 0.2 kg a.s./ha (Tobacco covered by crop type: leafy vegetables and fresh herbs)	
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0155005	7.75
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0337008	16.85

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Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0155005	7.75
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 10 kg	0.0337008	16.85

6.6.4.2 Measurement of resident and/or bystander exposure

The estimations performed according to AOEM, indicate that the systemic exposure to cyprodinil contained in the formulation CHR/F/PROTAZO exceeds the value of AOEL for prothioconazole.

Therefore, additional counter-measures must be introduced to reduce resident exposure to cyprodinil contained in the formulation CHR/F/PROTAZO 250 EC.

Based on the estimation according to AOEM, it can be concluded that the majority of resident exposure results from the entry to the treated area. Thus, it is crucial to minimize the incidence of resident (and bystander) entry into the treated area. It is proposed to:

- install warning signs informing about recent use of PPP next to the treated area and to inform effectively the residents about the scheduled spraying action.
- use 5meters buffer zone for forestry tree, Salix , Wicker for other crop for GAP table

Comments of zRMS:	The text in the point 6.6.4.2 is not understandable. The information below is provided for the clarity of the assessment.							
	Critical use(s)		Cereals (max. 2 × 1.0L product/ha) Ornamentals (max. 2 x 1.0 L product/ha)					
	Model		Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015					
			Azoxystrobin		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	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 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 × 0.200 kg a.s./ha		2 × 0.175 kg a.s./ha		2 × 0.158* kg a.s./ha	

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	Resident child Body weight: 10 kg	Drift (75 th perc.)	0.00446	2.23	0.0039	1.95	0,00352	35,29
		Vapour (75 th perc.)	0.00107	0.54	0.00107	0.54	0,00107	10,70
		Deposits (75 th perc.)	0.000572	0.29	0.000501	0.25	0,0004526	4,53
		Re-entry (75 th perc.)	0.029	14.54	0.02545	12.73	0,0229	229,78
		All pathways (mean)	0.0271	13.59	0.0239	11.96	0,0216	216,94
	Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.000813	0.41	0.000712	0.36	0,0006429	6,43
		Vapour (75 th perc.)	0.00023	0.12	0.00023	0.12	0,00023	2,3
		Deposits (75 th perc.)	0.00024	0.12	0.000211	0.11	0,0001905	1,91
		Re-entry (75 th perc.)	0.0161	8.08	0.0141	7.07	0,0127	127,66
		All pathways (mean)	0.0137	6.86	0.012	6.02	0,0108	108,9
	Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: na							
	Number of applications and application rate		1 × 0.200 kg a.s./ha		1 × 0.175 kg a.s./ha		1 × 0.158* kg a.s./ha	
	Resident child Body weight: 10 kg	Drift (75 th perc.)	0.00446	2.23	0.0039	1.95	0,0035	35,29
		Vapour (75 th perc.)	0.00107	0.54	0.000107	0.54	0,00107	10,70
		Deposits (75 th perc.)	0.000332	0.17	0.00029	0.15	0,00026	2,63
		Re-entry	0.0168	8.44	0.0147	7.38	0,01333	133,31

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		(75 th perc.)						
		All pathways (mean)	0.0172	8.63	0.0152	7.61	0,0138	138,54
	Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.000813	0.41	0.000712	0.36	0,0006429	6,43
		Vapour (75 th perc.)	0.00023	0.12	0.00023	0.12	0,00023	2,3
		Deposits (75 th perc.)	0.000139	0.07	0.000122	0.06	0,0001105	1,11
		Re-entry (75 th perc.)	0.00937	4.69	0.0082	4.1	0,0074	74,06
		All pathways (mean)	0.0082	4.12	0.0072	3.62	0,00655	65,54
	Ornamentals, Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14							
	Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0347	17.35	0.0303	15.18	0,0274	274,18
		Vapour (75 th perc.)	0.00107	0.54	0.00107	0.54	0,00107	10,70
		Deposits (75 th perc.)	0.000572	0.29	0.000501	0.25	0,0004526	4,53
		Re-entry (75 th perc.)	0.029	14.54	0.0254	12.73	0,0229	229,78
		All pathways (mean)	0.0475	23.77	0.0417	20.86	0,03777	377,74
	Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.01925	9.63	0.0168	8.42	0,0152	152,1
		Vapour (75 th perc.)	0.00023	0.12	0.00023	0.12	0,00023	2,3
		Deposits (75 th perc.)	0.000241	0.12	0.000211	0.11	0,0001905	1,91
		Re-entry	0.0161	8.08	0.0141	7.07	0,01276	127,66

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		(75 th perc.)						
	All pathways (mean)	0.0258	12.95	0.0226	11.34	0,0205	205	
	50 % converse							
			Azoxystrobin		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	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
	Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 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: 2							
	Resident child Body weight: 10 kg	Drift (75 th perc.)	0.00446	2.23	0.0019	0.98	0,00176	17,65
		Vapour (75 th perc.)	0.00107	0.54	0.00107	0.54	0,00107	10,7
		Deposits (75 th perc.)	0.000572	0.29	0.00025	0.13	0,0002263	2,26
		Re-entry (75 th perc.)	0.029	14.54	0.0127	6.36	0,01148	114,89
		All pathways (mean)	0.0271	13.59	0.0124	6.25	0,01138	113,82
	Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.00081	0.41	0.000356	0.18	0,00032	3,21
		Vapour (75 th perc.)	0.00023	0.12	0.00023	0.12	0,00023	2,3
		Deposits (75 th perc.)	0.00024	0.12	0.00010	0.05	0,0000953	0,95
		Re-entry (75 th perc.)	0.0161	8.08	0.007	3.53	0,00638	63,83
		All pathways	0.0137	6.86	0.0061	3.07	0,00555	55,60

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	(mean)						
Tractor mounted boom spray application outdoors to low crops Buffer zone: 5 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: NA Number of applications: 1							
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.00446	2.23	0.0019	0.98	0,00176	17,65
	Vapour (75 th perc.)	0.001	0.54	0.00107	0.54	0,00107	10,7
	Deposits (75 th perc.)	0.000332	0.17	0.000145	0.07	0,0001313	1,31
	Re-entry (75 th perc.)	0.0168	8.44	0.00738	3.69	0,00666	66,66
	All pathways (mean)	0.0172	8.63	0.0081	4.07	0,00746	74,62
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.00081	0.41	0.000356	0.18	0,0003215	3,21
	Vapour (75 th perc.)	0.00023	0.12	0.00023	0.12	0,00023	2,3
	Deposits (75 th perc.)	0.00013	0.07	0.00006	0.03	0,0000553	0,55
	Re-entry (75 th perc.)	0.0093	4.69	0.0041	2.05	0,0037	37,03
	All pathways (mean)	0.0082	4.12	0.0037	1.87	0,00339	33,92
Tractor mounted boom spray application outdoors to high crops Buffer zone: 5 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 Number of applications: 2							
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0347	17.35	0.015	7.59	0,0137	137,09
	Vapour (75 th perc.)	0.001	0.54	0.00107	0.54	0,0010	10,70

		Deposits (75 th perc.)	0.00057	0.29	0.00025	0.13	0,0002263	2,26
		Re-entry (75 th perc.)	0.029	14.54	0.0127	6.36	0,01148	114,89
		All pathways (mean)	0.047	23.77	0.0213	10.70	0,0194	194,22
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.019	9.63	0.0084	4.21	0,0076	76,05	
	Vapour (75 th perc.)	0.00023	0.12	0.00023	0.12	0,00023	2,3	
	Deposits (75 th perc.)	0.00024	0.12	0.000105	0.05	0,0000953	0,95	
	Re-entry (75 th perc.)	0.0161	8.08	0.00706	3.53	0,00638	63,83	
	All pathways (mean)	0.0258	12.95	0.0114	5.73	0,0103	103,66	
<u>Cereals 1x application (covered sunflower, soya, breadseed poppy, mustard)</u> The estimations performed according to AOEM model indicate that the systemic exposure to prothioconazole-desthio (100% conversion) exceed the value of AOEL (resident child) for this substance. <u>Cereals 2 x application</u> The estimations performed according to AOEM model indicate that the systemic exposure to prothioconazole-desthio exceed the value of AOEL. <u>Ornamentals 2 x application</u> The estimations performed according to AOEM model indicate that the systemic exposure to prothioconazole-desthio exceed the value of AOEL. The 50 % conversion of prothioconazole to prothioconazole desthio <u>Cereals 1x application (covered sunflower, soya, breadseed poppy, mustard)</u> For residents, the exposure estimates to one application of azoxystrobin (adults 4.12% AOEL, children 8.63% AOEL), prothioconazole (adults 1.87% AOEL, children 4.07% AOEL) and to prothioconazole-desthio (adults 33.92% AOEL, children 74.62% AOEL) result in values that are lower than the respective AOEL values. It is concluded that there is no undue risk to residents by application of CHR/F/PROTAZO 375 SC, considering only one application, with a buffer zone of 5 m and drift reduction equipment. Combined exposure								

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Application scenario	Active ingredient	Estimated exposure/AOEL (HQ)
Resident – child; one application (Buffer zone 5 m, drift reduction equipment)	Azoxystrobin	
	drift	0.0223
	Vapour	0.0054
	Deposits	0.0017
	Re-entry	0.044
	Sum of all pathways	0.0863
	Prothioconazole	
	drift	0.0098
	Vapour	0.0054
	Deposits	0.0007
	Re-entry	0.0369
	Sum of all pathways	0.0407
	Prothioconazole-desthio	
	drift	0.1765
	Vapour	0.107
	Deposits	0.0131
	Re-entry	0.666
	Sum of all pathways	0.746
	Cumulative risk resident – child (HI)	
	drift	0.21
	Vapour	0.118
	Deposits	0.016
	Re-entry	0.75
	Sum of all pathways	0.87
Resident – adult; one application (Buffer zone 5 m, drift reduction equipment)	Azoxystrobin	
	drift	0.0041
	Vapour	0.0012
	Deposits	0.0007
	Re-entry	0.0469
	Sum of all pathways	0.0412
	Prothioconazole	
	drift	0.0018
	Vapour	0.0012
	Deposits	0.0003
	Re-entry	0.0205
	Sum of all pathways	0.0187
	Prothioconazole-desthio	
	drift	0.0321
	Vapour	0.023
	Deposits	0.0055
	Re-entry	0.370
	Sum of all pathways	0.339
	Cumulative risk resident – adult (HI)	
	drift	0.038
	Vapour	0.025
	Deposits	0.0065
	Re-entry	0.437
	Sum of all pathways	0.399

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<p>The Hazard Index is < 1. Thus, combined exposure to all active substances in CHR/F/PROTAZO 375 SC is not expected to present a risk for residents and bystanders. No further refinement of the assessment is required</p> <p><u>Cereals 2 x application</u></p> <p>The estimations performed according to AOEM indicate that the systemic exposure to prothioconazole-desthio exceed the value of AOEL for this substance.</p> <p>Combined exposure</p>		
Application scenario	Active ingredient	Estimated exposure/AOEL (HQ)
Resident – child; two applications (Buffer zone 5 m, drift reduction equipment)	Azoxystrobin	
	drift	0.0223
	Vapour	0.0054
	Deposits	0.0029
	Re-entry	0.145
	Sum of all pathways	0.136
	Prothioconazole	
	drift	0.0098
	Vapour	0.0054
	Deposits	0.0013
	Re-entry	0.064
	Sum of all pathways	0.0625
	Prothioconazole-desthio	
	drift	0.177
	Vapour	0.107
	Deposits	0.0226
	Re-entry	1.15
	Sum of all pathways	1.14
Resident – adult; two applications (Buffer zone 5 m, drift reduction equipment)	Cumulative risk resident – child (HI)	
	drift	0.21
	Vapour	0.118
	Deposits	0.027
	Re-entry	1.36
	Sum of all pathways	1.34
	Azoxystrobin	
	drift	0.0041
	Vapour	0.0012
	Deposits	0.0012
	Re-entry	0.008
	Sum of all pathways	0.0686
	Prothioconazole	
	drift	0.0036
	Vapour	0.0012
	Deposits	0.0011
	Re-entry	0.0707
	Sum of all pathways	0.0602
	Prothioconazole-desthio	
	drift	0.0321
	Vapour	0.023
	Deposits	0.0095

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		Re-entry	0.64
		Sum of all pathways	0.56
		Cumulative risk resident – adult (HI)	
		drift	0.04
		Vapour	0.025
		Deposits	0.012
		Re-entry	0.72
		Sum of all pathways	0.69
	<p>The Hazard Index is > 1 (child).</p> <p>Based on the exposure data, the following risk mitigation techniques are recommended:</p> <ol style="list-style-type: none"> 1. drift reduction equipment (vehicle-mounted) 2. buffer strip: 5 m 3. spraying only during stable (windless) weather <p>In addition, warning boards prohibiting the entrance to the treated area must be installed because the majority of the unacceptable exposure results from the entry to the treated area. The boards can be removed after the harvest of the crop. The following sentence is recommended to be placed on the warning board:</p> <p><i>Zakaz wejścia na teren poddany zabiegowi do czasu zakończenia uprawy.</i></p> <p><i>No entry to treated area till harvesting.</i></p> <p>Ornamentals – 2x application, high crop (covered Coniferous/ deciduous forest nurseries, Ornamental shrubs, <i>Salix viminalis</i>, Wicker)</p>		
	Application scenario	Active ingredient	Estimated exposure/AOEL (HQ)
	Resident – child; two applications (Buffer zone 5 m, drift reduction equipment)	Azoxystrobin	
		drift	0.174
		Vapour	0.0054
		Deposits	0.0029
		Re-entry	0.145
		Sum of all pathways	0.238
		Prothioconazole	
		drift	0.076
		Vapour	0.0054
		Deposits	0.0013
		Re-entry	0.064
		Sum of all pathways	0.107
		Prothioconazole-desthio	
		drift	1.371
		Vapour	0.107
		Deposits	0.023
		Re-entry	1.15
		Sum of all pathways	1.94
		Cumulative risk resident – child (HI)	
		drift	1.62
		Vapour	0.118
		Deposits	0.027
		Re-entry	1.36
		Sum of all pathways	2.3

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Resident – adult; two applications (Buffer zone 5 m, drift reduction equipment)	Azoxystrobin	
	drift	0.096
	Vapour	0.0012
	Deposits	0.0012
	Re-entry	0.0808
	Sum of all pathways	0.13
	Prothioconazole	
	drift	0.0421
	Vapour	0.0012
	Deposits	0.0005
	Re-entry	0.0353
	Sum of all pathways	0.0573
	Prothioconazole-desthio	
	drift	0.7605
	Vapour	0.023
	Deposits	0.0095
	Re-entry	0.64
	Sum of all pathways	1.04
	Cumulative risk resident – adult (HI)	
	drift	0.899
	Vapour	0.0254
	Deposits	0.0112
	Re-entry	0.76
	Sum of all pathways	1.23
The Hazard Index is > 1. Refinement of the assessment is not presented. An unacceptable risk has been identified. According to the AOEM model calculations, it can be concluded that the risk for the resident/bystander is not acceptable.		

6.6.5 Combined exposure

The product is a mixture of two active substances.

6.6.5.1 Exposure Assessment of prothioconazole and azoxystrobin in CHR/F/PROTAZO

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-17: Acute risk assessment from combined exposure in winter cereals

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole	0.4419
	Azoxystrobin	0.4914
	Cumulative risk Operators (HI)	0.9333

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Workers – EFSA Model	Prothioconazole	0.1056
	Azoxystrobin	0.1207
	Cumulative risk Workers (HI)	0.2263
Worker - EUROPOEM	Prothioconazole	0.14
	Azoxystrobin	0.16
	Cumulative risk Workers (HI)	0.30
Resident - Adult	Prothioconazole	0.068
	Azoxystrobin	0.0775
	Cumulative risk Resident – Adult (HI)	0.1455
Resident - Child	Prothioconazole	0.1481
	Azoxystrobin	0.1685
	Cumulative risk Resident – Child (HI)	0.3166

Table 6.6-18: Acute risk assessment from combined exposure in winter oilseed rape

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole	0.4419
	Azoxystrobin	0.2545
	Cumulative risk Operators (HI)	0.6964
Workers – EFSA Model	Prothioconazole	0.0613
	Azoxystrobin	0.07
	Cumulative risk Workers (HI)	0.1313
Worker - EUROPOEM	Prothioconazole	0.09
	Azoxystrobin	0.10
	Cumulative risk Workers (HI)	0.19
Resident - Adult	Prothioconazole	0.0427
	Azoxystrobin	0.0487
	Cumulative risk Resident – Adult (HI)	0.0914
Resident - Child	Prothioconazole	0.1018
	Azoxystrobin	0.1155
	Cumulative risk Resident – Child (HI)	0.2173

Table 6.6-19: Acute risk assessment from combined exposure in ornamentals

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole	0.3893

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	Azoxystrobin	0.4407
	Cumulative risk Operators (HI)	0.83
Workers – EFSA Model	Prothioconazole	0.4223
	Azoxystrobin	0.4826
	Cumulative risk Workers (HI)	0.9049
Worker - EUROPOEM	Prothioconazole	0.25
	Azoxystrobin	0.32
	Cumulative risk Workers (HI)	0.57
Resident - Adult	Prothioconazole	0.068
	Azoxystrobin	0.0775
	Cumulative risk Resident – Adult (HI)	0.1455
Resident - Child	Prothioconazole	0.1481
	Azoxystrobin	0.1685
	Cumulative risk Resident – Child (HI)	0.3166

Table 6.6-20: Acute risk assessment from combined exposure in forestry tree, Salix, Wicker

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole	0.3893
	Azoxystrobin	0.4407
	Cumulative risk Operators (HI)	0.83
Workers – EFSA Model	Prothioconazole	0.6787
	Azoxystrobin	0.7756
	Cumulative risk Workers (HI)	1.4543
Worker - EUROPOEM	Prothioconazole	0.17
	Azoxystrobin	0.19
	Cumulative risk Workers (HI)	0.36
Resident - Adult	Prothioconazole	0.0816
	Azoxystrobin	0.0931
	Cumulative risk Resident – Adult (HI)	0.1747
Resident - Child	Prothioconazole	0.1805
	Azoxystrobin	0.2055
	Cumulative risk Resident – Child (HI)	0.386

Table 6.6-21: Acute risk assessment from combined exposure in tobacco

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole	0.4419
	Azoxystrobin	0.4914
	Cumulative risk Operators (HI)	0.9333
Workers – EFSA Model	Prothioconazole	0.1749
	Azoxystrobin	0.1999
	Cumulative risk Workers (HI)	0.3748
Worker - EUROPOEM	Prothioconazole	0.14
	Azoxystrobin	0.16
	Cumulative risk Workers (HI)	0.30
Resident - Adult	Prothioconazole	0.068
	Azoxystrobin	0.0775
	Cumulative risk Resident – Adult (HI)	0.1455
Resident - Child	Prothioconazole	0.1481
	Azoxystrobin	0.1685
	Cumulative risk Resident – Child (HI)	0.3166

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

6.6.5.2 Exposure Assessment of prothioconazole-desthio and azoxystrobin in CHR/F/PROTAZO

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Results for workers are provided for 50% conversion form parent.

Table 6.6-22: Acute risk assessment from combined exposure in winter cereals

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole-desthio	0.8145
	Azoxystrobin	0.0504
	Cumulative risk Operators (HI)	0.8649

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Workers – EFSA Model	Prothioconazole-desthio	0.9573
	Azoxystrobin	0.1207
	Cumulative risk Workers (HI)	1.078
Worker - EUROPOEM	Prothioconazole-desthio	0.32
	Azoxystrobin	0.16
	Cumulative risk Workers (HI)	0.48
Resident - Adult	Prothioconazole-desthio	1.0937
	Azoxystrobin	0.0775
	Cumulative risk Resident – Adult (HI)	1.1712
Resident - Child	Prothioconazole-desthio	2.1786
	Azoxystrobin	0.1685
	Cumulative risk Resident – Child (HI)	2.3471

Table 6.6-23: Acute risk assessment from combined exposure in winter oilseed rape

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole-desthio	0.8149
	Azoxystrobin	0.1060
	Cumulative risk Operators (HI)	0.9209
Workers – EFSA Model	Prothioconazole-desthio	0.5545
	Azoxystrobin	0.0700
	Cumulative risk Workers (HI)	0.6245
Worker - EUROPOEM	Prothioconazole-desthio	0.2000
	Azoxystrobin	0.1000
	Cumulative risk Workers (HI)	0.3000
Resident - Adult	Prothioconazole-desthio	0.6582
	Azoxystrobin	0.0487
	Cumulative risk Resident – Adult (HI)	0.7069
Resident - Child	Prothioconazole-desthio	1.3910
	Azoxystrobin	0.1155
	Cumulative risk Resident – Child (HI)	1.5065

Table 6.6-24: Acute risk assessment from combined exposure in ornamentals

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole-desthio	0.1233

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Workers – EFSA Model	Azoxystrobin	0.4407
	Cumulative risk Operators (HI)	0.5640
	Prothioconazole-desthio	3.8291
Worker - EUROPOEM	Azoxystrobin	0.4826
	Cumulative risk Workers (HI)	4.3117
	Prothioconazole-desthio	2.54
Resident - Adult	Azoxystrobin	0.32
	Cumulative risk Workers (HI)	2.86
	Prothioconazole-desthio	1.0937
Resident - Child	Azoxystrobin	0.0775
	Cumulative risk Resident – Adult (HI)	1.1712
	Prothioconazole-desthio	2.1786
Resident - Adult	Azoxystrobin	0.1685
	Cumulative risk Resident – Child (HI)	2.3471
	Prothioconazole-desthio	2.1786

Table 6.6-25: Acute risk assessment from combined exposure in forestry tree, Salix, Wicker

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole-desthio	0.1233
	Azoxystrobin	0.5640
	Cumulative risk Operators (HI)	0.5633
Workers – EFSA Model	Prothioconazole-desthio	6.1539
	Azoxystrobin	0.7756
	Cumulative risk Workers (HI)	6.9295
Worker - EUROPOEM	Prothioconazole-desthio	1.52
	Azoxystrobin	0.19
	Cumulative risk Workers (HI)	1.71
Resident - Adult	Prothioconazole-desthio	1.1760
	Azoxystrobin	0.0931
	Cumulative risk Resident – Adult (HI)	1.2691
Resident - Child	Prothioconazole-desthio	2.3740
	Azoxystrobin	0.2055
	Cumulative risk Resident – Child (HI)	2.5795

Table 6.6-26: Acute risk assessment from combined exposure in tobacco

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators	Prothioconazole-desthio	0.8149
	Azoxystrobin	0.1060
	Cumulative risk Operators (HI)	0.9209
Workers – EFSA Model	Prothioconazole-desthio	1.5863
	Azoxystrobin	0.1999
	Cumulative risk Workers (HI)	1.7862
Worker - EUROPOEM	Prothioconazole-desthio	1.52
	Azoxystrobin	0.16
	Cumulative risk Workers (HI)	1.68
Resident - Adult	Prothioconazole-desthio	1.0937
	Azoxystrobin	0.0775
	Cumulative risk Resident – Adult (HI)	1.1712
Resident - Child	Prothioconazole-desthio	2.1786
	Azoxystrobin	0.1685
	Cumulative risk Resident – Child (HI)	2.3471

The Hazard Index is > 1 for resident/bystander for all of crops so for risk refinement used:

- install warning signs informing about recent use of PPP next to the treated area and to inform effectively the residents about the scheduled spraying action.

- use 5meters buffer zone for forestry tree, Salix , Wicker for other crop for GAP table

The Hazard Index is > 1 for ornamental, tobacco and forestry tree so those crop pose unacceptable risk for operator, worker and resident/bystander.

Comments of zRMS:	No description of application scenario. For the sake of clarity, zRMS has included combined exposure calculations in the gray tables at points for operator, worker, and resident exposure, respectively.
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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 7.1.1 KCP 7.1.2 KCP 7.1.4 KCP 7.1.5 KCP 7.1.6	-	2020	Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; Chemirof Sp. z o.o. Non GLP Unpublished	N	Chemirof Sp. z o.o.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1	xxxxxxxxxxxxx	2005	Azoxystrobin metabolite R234886: Acute Oral Toxicity Study in The Rat (Up and Down Procedure) A12284, Syngenta File No R234886/0004 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	Y	Syngenta
KCP 7.1	Callander, R.	2005	Azoxystrobin Metabolite R234886: Bacterial Mutation Assay In S. Typhimurium And E.Coli Syngenta File No R234886/0005 Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CRL), Cheshire, United Kingdom, YV7083-REG GLP Unpublished	N	Syngenta

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Not applicable
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The plant protection product CHR/F/PROTAZO 375 SC was classified by calculation method as described in Regulation (EC) No 1272/2008. According to Regulation (EC) No 1272/2008, no classification for acute oral toxicity is required. For details, please refer to Part C.
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Reference: 7.1.1

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” A test for acute oral toxicity shall be carried out, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute oral toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

Each type of hazard is considered separately, taking into account the sum of the components posing a hazard. We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

Table 3.1.2

Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500

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Dermal (mg/kg bodyweight)	$0 < \text{Category 1} \leq 50$ $50 < \text{Category 2} \leq 200$ $200 < \text{Category 3} \leq 1\,000$ $1\,000 < \text{Category 4} \leq 2\,000$	5 50 300 1 100
Gases (ppmV)	$0 < \text{Category 1} \leq 100$ $100 < \text{Category 2} \leq 500$ $500 < \text{Category 3} \leq 2\,500$ $2\,500 < \text{Category 4} \leq 20\,000$	10 100 700 4 500
Vapours (mg/l)	$0 < \text{Category 1} \leq 0,5$ $0,5 < \text{Category 2} \leq 2,0$ $2,0 < \text{Category 3} \leq 10,0$ $10,0 < \text{Category 4} \leq 20,0$	0,05 0,5 3 11
Dust/mist (mg/l)	$0 < \text{Category 1} \leq 0,05$ $0,05 < \text{Category 2} \leq 0,5$ $0,5 < \text{Category 3} \leq 1,0$ $1,0 < \text{Category 4} \leq 5,0$	0,005 0,05 0,5 1,5

Note 1

These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Ingredients E₁, F and I₁ are classified in this class of hazard.

- E₁ – 0.80% (Acute Tox. 4, H302)
- F – 0.54% (Acute Tox. 4, H302)
- I₁ – 0.018% (Acute Tox. 4, H302; LD₅₀ = 1020 mg/kg)

LD₅₀ for the ingredient I₁ is 1020 mg/kg (according to MSDS). For the rest of components the estimated values from the table 3.1.2 were used.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{0.80}{500} + \frac{0.54}{500} + \frac{0.018}{1020}} = 37069$$

Conclusion

According to the table 3.1.2, a result (37069 mg/kg bw > 2 000 mg/kg bw) is significantly higher from the ATE_{mix} triggering classification. Therefore the formulation is not classified as Acute Tox. 4, H302.

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

Comments of zRMS:	The plant protection product CHR/F/PROTAZO 375 SC was classified by calculation method. According to Regulation (EC) No 1272/2008, no classification for acute dermal toxicity is required. For details, please refer to Part C.
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A 2.3.1 Study 1

Reference: 7.1.2

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” A test for dermal toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

Conclusion

The active substance and the other co-formulants are not classified as acute dermal toxicity, it can be assumed that entire formulation is not classified in this class. According to point 7.1.1 of PART A of Annex Regulation no 284/2013, it is possible to waive from acute dermal toxicity test..

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	The plant protection product CHR/F/PROTAZO 375 SC was classified by calculation method. According to Regulation (EC) No 1272/2008, CHR/F/PROTAZO 375 SC should be classified as Acute Tox. 4, H332.
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A 2.4.1 Study 1

Reference: 7.1.3

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 7.1.1 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” A test for inhalation toxicity shall be carried out on a case by case basis, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, acute dermal toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.”

Each type of hazard is considered separately, taking into account the sum of the components posing a hazard. We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

Table 3.1.2

Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	0 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100

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	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	1,5

Note 1

These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

Only an ingredient A is classified in this hazard class.

- A – 18.38 % (Acute Tox. 3, H331, ATE=0.7mg/L)

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{18.38}{0.7}} = 3.81$$

According to the table 3.1.2, the result (1.0 mg/L < 3.81 mg/L ≤ 5.0 mg/L) is lower than ATE_{mix} for dust/mist triggering classification. Therefore the formulation is classified as **Acute Tox. 4, H332**

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	The plant protection product CHR/F/PROTAZO 375 SC was classified by calculation method. According to Regulation (EC) No 1272/2008, no classification for skin irritation is required. For details, please refer to Part C.
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A 2.5.1 Study 1

Reference: 7.1.4

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

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According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

For consideration of corrosive and irritant properties the following table applies:

Table 3.2.3

Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	$\geq 5 \%$	$\geq 1 \%$ but $< 5 \%$
Skin irritant Category 2		$\geq 10 \%$
$10 \times$ Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		$\geq 10 \%$

Note

The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be $\geq 5 \%$ respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is $< 5 \%$ but the sum of Category 1A+1B ingredients is $\geq 5 \%$, the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is $< 5 \%$ but the sum of Category 1A+1B+1C ingredients is $\geq 5 \%$ the mixture shall be classified as Skin Corrosive Category 1C.

Only an ingredient C_1 is classified in this hazard class at the concentration of 58.9%.

An ingredient I_1 is classified in this hazard class. Components classified in higher class of the same hazard are also considered.

- I_1 – 0.018% (Skin Irrit. 2, H315)
- F – 0.54% (Skin Corr. 1, H314)
- I_2 – 0.0054% (Skin Corr. 1, H314)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class and taking into account ingredients classified in higher class (according to the table 3.2.3).

$$10 \times \sum C_{SkinCorr} + \sum C_{SkinIrrit} = 5.454\% + 0.018\% = 5.472\%$$

Conclusion

According to the table 3.2.3, the sum of components classified as irritant and corrosive to skin (5.5%) is lower than generic concentration level (10%). Therefore the formulation is not classified in this class of hazard.

A 2.5.2 Study 2

Reference: 7.1.4

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 7.1.4 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” The skin irritancy of the plant protection product shall be reported based on the tiered approach, unless the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

The complete composition of the formulation with the classification of individual ingredients is available in part C.

For consideration of corrosive and irritant properties the following table applies:

Table 3.2.3

Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin.

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	$\geq 5 \%$	$\geq 1 \%$ but $< 5 \%$
Skin irritant Category 2		$\geq 10 \%$
$10 \times$ Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		$\geq 10 \%$

Note

The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be $\geq 5 \%$ respectively in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C. If the sum of the Skin Corrosive Category 1A ingredients is $< 5 \%$ but the sum of Category 1A+1B ingredients is $\geq 5 \%$, the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is $< 5 \%$ but the sum of Category 1A+1B+1C ingredients is $\geq 5 \%$ the mixture shall be classified as Skin Corrosive Category 1C.

Ingredients F and I2 are relevant.

F – 0.54% (Skin Corr. 1, H314)

I2 – 0.0054% (Skin Corr. 1, H314)

We use the summation method, consisting in adding up the percentages of all ingredients classified in the each class (according to the table 3.2.3).

$$\sum C_{\text{SkinCorr}} = 0.54\% + 0.0054\% = 0.5454\%$$

Conclusion

According to the table 3.2.3, the sum of components classified as corrosive to skin (0.55%) is lower than concentration triggering classification (1%). Therefore the formulation is not classified in this class of hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	In accordance with the provisions of the Regulation EC 1272/2008, the formulation
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	requires classification in respect to eye irritation/corrosion as Eye Irrit. 2, H319. For details please see part C of dRR.
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A 2.6.1 Study 1

Reference: 7.1.5

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 7.1.5 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” Eye irritation tests shall be provided, unless it is likely that severe effects on the eyes may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, eye irritation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

Due to the fact, that all components of the formulation CHR/F/PROTAZO are known, eye corrosion test is not necessary.

Ingredients E₁, I₁ and I₂ are classified in this hazard class. An ingredient classified as Skin Corr. 1, H314 (F) is also take into account.

- E₁ – 0.80% (Eye Dam. 1, H318)
- F – 0.54% (Skin Corr. 1, H314)
- I₁ – 0.018% (Eye Dam. 1, H318)
- I₂ – 0.0054% (Eye Dam. 1, H318)

We use the summation method, consisting in adding up the percentages of all ingredients classified in this class of hazard.

$$\sum C_{EyeDam.} + C_{SkinCorr} = 0.80\% + 0.54\% + 0.018\% + 0.0054\% = 1.36\%$$

The sum of concentration (1.36%) is higher than a concentration triggering the classification in second class (1%). Therefore the formulation is classified as **Eye Irrit. 2, H319**.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	The classification of CHR/F/PROTIO 375 SC is based on the analysis of components present in the formulation. In accordance with the provisions of the Regulation EC 1272/2008, the formulation is not classified in this class of hazard.
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A 2.7.1 Study 1

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Reference: 7.1.6

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According to point 7.1.6 of Part A of Annex to the Commission Regulation (EU) No 284/2013 as regards the data requirements for plant protection products:

” Skin sensitisation tests shall be provided, unless it is likely that severe effects on the skin may be produced or the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. In the latter case, skin sensitisation properties of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the irritant potential of the total mixture.”

Due to the fact, that all components of the formulation CHR/F/PROTAZO are known, eye corrosion test is not necessary.

We use the table:

Table 3.4.5

Generic concentration limits of ingredients of a mixture classified as either skin sensitisers or respiratory sensitisers that trigger classification of the mixture

Ingredient classified as:	Concentration triggering classification of a mixture as:		
	Skin Sensitiser	Respiratory Sensitiser	
	All physical states	Solid/Liquid	Gas
Skin Sensitiser Category 1	$\geq 1,0 \%$	-	-
Skin Sensitiser Category 1A	$\geq 0,1 \%$	-	-
Skin Sensitiser Category 1B	$\geq 1,0 \%$		
Respiratory Sensitiser Category 1	-	$\geq 1,0 \%$	$\geq 0,2 \%$
Respiratory Sensitiser Category 1A	-	$\geq 0,1 \%$	$\geq 0,1 \%$
Respiratory Sensitiser Category 1B		$\geq 1,0 \%$	$\geq 0,2 \%$

Only ingredient I₁ is classified as sensitizer at the concentration of 0.018%. The content of component I₁ is significantly lower than concentration triggering classification (1%). Therefore the formulation is not classified as Skin Sens. 1, H317.

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

Not required

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

For the dermal absorption of the active substance the Applicant refers to Guidance on Dermal Absorption¹ EFSA, EFSA Journal 2017;15(6):4873.

Based on an evaluation of agreed dermal absorption values for a range of concentrated pesticide formulations and their dilutions, the following default values are recommended (see opinion section 4.1.1.for details):

	Azoxystrobin, Prothioconazole, Prothioconazole-desthio	
	Value	Reference
Concentrate	10%	EFSA Journal 2017;15(6):4873
Dilution (dilution factor)	50%	EFSA Journal 2017;15(6):4873

~~A default dermal absorption value of 25% may be applied for concentrated products that are organic solvent formulated or in other types of formulations.~~

~~A default dermal absorption value of 70% may be applied for (in-use) dilutions of organic solvent formulated or in other types of formulation.~~

A 2.11 Other/Special Studies

A 2.11.1 Specific target organ toxicity

Reference: 7.1.1

Report Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 3.8.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:

” Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following single exposure. Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively”

~~Due to the fact, that all components of the formulation CHR/F/PROTAZO are known, eye corrosion test is not necessary.~~

Materials and methods

For consideration of specific target organ properties the following table applies:

Table 3.8.3

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2.

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration $\geq 10\%$	$1,0\% \leq \text{concentration} < 10\%$
Category 2 Specific Target Organ Toxicant		Concentration $\geq 10\%$ [(Note 1)]

Note 1

If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration $\geq 1,0\%$ a SDS shall be available for the mixture upon request.

We also took into account the point 3.8.3.4.5.: “Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20 % value. Expert judgement shall be exercised.”

Results and discussions

We consider the ingredient I₁ at the concentration of 0.018 %. According to point 3.8.3.4.5. CLP Regulation, the content of the ingredient classified in this hazard class is below triggering value (1%), therefore the formulation is not classified as STOT RE 1, H372.

A 2.11.2 Carcinogenicity

Reference: 7.1.1

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Toxicological classification of product CHR/F/PROTAZO based on calculation method taking into consideration health hazards of constituent substances; 2019; according to Part C, appendix 2

According to point 3.8.3 of Regulation (EC) No 1272/2008 as regards the data requirements for plant protection products:

” Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures shall be classified for specific target organ toxicity following single exposure. Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate generic concentration limit as mentioned in Table 3.8.3 for Category 1 and 2 respectively”

Due to the fact, that all components of the formulation CHR/F/PROTAZO are known, eye corrosion test is not necessary.

Materials and methods

For consideration of carcinogenicity the following table applies:

Table 3.6.2

Generic concentration limits of ingredients of a mixture classified as carcinogen that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	$\geq 0,1 \%$	-	-
Category 1B carcinogen	-	$\geq 0,1 \%$	
Category 2 carcinogen	-	-	$\geq 1,0 \%$ [Note 1]

Note

The concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).

Note 1

If a Category 2 carcinogen is present in the mixture as an ingredient at a concentration $\geq 0,1 \%$ a SDS shall be available for the mixture upon request.

We consider the ingredient I₁ at the concentration of 0.018 %. According to the table 3.6.2 CLP Regulation, the content of the ingredient classified in this hazard class is below triggering value (0.1%), therefore the formulation is not classified as Carc. 1, H350.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Prothiconazole

a) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.175 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	8.75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	25796	96345	AOEM	
	Body	16387	135256	AOEM	
	Head	454	2490	AOEM	
	Protected hands (gloves)	141	1733	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	163	1280	AOEM	
	Protected head (hood and face shield)	7	141	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1298	11223	AOEM	
	Body	726	3741	AOEM	
	Head	34	103	AOEM	
	Protected hands (gloves)	138	4292	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	49	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.3026694	2.7372346	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0883778	0.0456206	
% of RVNAS	44.19%	22.81%	

b) Oilssedrape, mustard, soya, sunflower, breadseed poppy

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.175 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	8.75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	25796	96345	AOEM	
	Body	16387	135256	AOEM	
	Head	454	2490	AOEM	
	Protected hands (gloves)	141	1733	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	163	1280	AOEM	
	Protected head (hood and face shield)	7	141	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1298	11223	AOEM	
	Body	726	3741	AOEM	
	Head	34	103	AOEM	
	Protected hands (gloves)	138	4292	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	49	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.3026694	2.7372346	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0883778	0.0456206	
% of RVNAS	44.19%	22.81%	

c) Ornamentals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.175 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	1.75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Hands	7472	27515	AOEM		
Body	5287	84740	AOEM		
Head	91	498	AOEM		
Protected hands (gloves)	50	347	AOEM		
Protected body (workwear or protective garment and sturdy footwear)	39	256	AOEM		
Protected head (hood and face shield)	1	28	AOEM		
Inhalation	4	29	AOEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves	Yes		Incl. in AOEM model		
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Hands	2836	5647	AOEM	This scenario assumes that small area equipment is used	
Body	3890	4930	AOEM		
Head	23	273	AOEM		
Protected hands (gloves)	29	23	AOEM		
Protected body (workwear or protective garment and sturdy footwear)	49	57	AOEM		
Inhalation	7	56	AOEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves	No				
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.6710546	3.9287743	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0778509	0.0654796	
% of RVNAS	38.93%	32.74%	

d) Tobacco

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.175 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	8.75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	25796	96345	AOEM	
	Body	16387	135256	AOEM	
	Head	454	2490	AOEM	
	Protected hands (gloves)	141	1733	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	163	1280	AOEM	
	Protected head (hood and face shield)	7	141	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1298	11223	AOEM	
	Body	726	3741	AOEM	
	Head	34	103	AOEM	
	Protected hands (gloves)	138	4292	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	20	49	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.3026694	2.7372346	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0883778	0.0456206	
% of RVNAS	44.19%	22.81%	

e) Forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.175 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	1.75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	7472	27515	AOEM	
	Body	5287	84740	AOEM	
	Head	91	498	AOEM	
	Protected hands (gloves)	50	347	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	39	256	AOEM	
	Protected head (hood and face shield)	1	28	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	2836	5647	AOEM	This scenario assumes that small area equipment is used
	Body	3890	4930	AOEM	
	Head	23	273	AOEM	
	Protected hands (gloves)	29	23	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	49	57	AOEM	
	Inhalation	7	56	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.6710546	3.9287743	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0778509	0.0654796	
% of RVNAS	38.93%	32.74%	

A 3.1.2**Calculations for Prothioconazole-desthio**

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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Applicant version

a) Cereals

Operator exposure for outdoor spray applications

Operator exposure for outdoor spray applications					
Application rate of active substance		0.1587 kg a.s./ha		i_AppRate	
Assumed area treated		50 ha/day		d_AreaTreated	
Amount of active substance applied		7.935 kg a.s./day		i_AmountAS	
Dermal absorption of the product		10.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		50.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	23925	89283	AOEM	
	Body	15298	131468	AOEM	
	Head	412	2258	AOEM	
	Protected hands (gloves)	133	1572	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	149	1161	AOEM	
	Protected head (hood and face shield)	7	128	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1177	10447	AOEM	
	Body	658	3392	AOEM	
	Head	31	94	AOEM	
	Protected hands (gloves)	131	4244	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	18	44	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.9063925	0.4889487	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0817732	0.0081491	
% of RVNAS	817.73%	81.49%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	29.3071628	4.4036068	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4884527	0.0733934	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

b) Oilseedrape, mustard, soya, sunflower, breadseed poppy

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Operator exposure for outdoor spray applications

Application rate of active substance	0.1587 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	7.935 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Mixing and loading	Hands	23925	89283	AOEM	
	Body	15298	131468	AOEM	
	Head	412	2258	AOEM	
	Protected hands (gloves)	133	1572	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	149	1161	AOEM	
	Protected head (hood and face shield)	7	128	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Application	Hands	1177	10447	AOEM	
	Body	658	3392	AOEM	
	Head	31	94	AOEM	
	Protected hands (gloves)	131	4244	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	18	44	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.9063925	0.4889487	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0817732	0.0081491	
% of RVNAS	817.73%	81.49%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	29.3071628	4.4036068	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4884527	0.0733934	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

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c) Ornaments

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Operator exposure for outdoor spray applications

Operator exposure for outdoor spray applications		0.1587 kg a.s./ha	i_AppRate		
Application rate of active substance		10 ha/day	d_AreaTreated		
Assumed area treated		1.587 kg a.s./day	i_AmountAS		
Amount of active substance applied		10.00%	i_AbsorpProduct		
Dermal absorption of the product		50.00%	i_AbsorInuse		
Dermal absorption of in-use dilution		Soluble concentrates, emulsifiable concentrate, etc.			
Formulation type		Outdoor			
Indoor or Outdoor application		Downward spraying			
Application method		Vehicle-mounted			
Application equipment		not relevant			
Season		OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingVehicle-mounted			
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	6931	25498	AOEM	
	Body	4935	82367	AOEM	
	Head	82	452	AOEM	
	Protected hands (gloves)	47	314	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	36	232	AOEM	
	Protected head (hood and face shield)	1	26	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	2571	5257	AOEM	This scenario assumes that small area equipment is used
	Body	3528	4471	AOEM	
	Head	21	248	AOEM	
	Protected hands (gloves)	28	23	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	52	AOEM	
	Inhalation	7	53	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.2661309	0.0740059	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0711022	0.0012334	
% of RVNAS	711.02%	12.33%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	15.9010761	0.3429014	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2650179	0.0057150	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

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d) Tobacco

Operator exposure for outdoor spray applications

Operator exposure for outdoor spray applications	Application rate of active substance		0.1587 kg a.s./ha	<i>i_AppRate</i>	
	Assumed area treated		50 ha/day	<i>d_AreaTreated</i>	
	Amount of active substance applied		7.935 kg a.s./day	<i>i_AmountAS</i>	
	Dermal absorption of the product		10.00%	<i>i_AbsorpProduct</i>	
	Dermal absorption of in-use dilution		50.00%	<i>i_AbsorInuse</i>	
	Formulation type		Soluble concentrates, emulsifiable concentrate, etc.		
	Indoor or Outdoor application		Outdoor		
	Application method		Downward spraying		
	Application equipment		Vehicle-mounted		
	Season		not relevant		
Outdoor Soluble concentrates, emulsifiable concentrate, etc. Downward spraying Vehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	23925	89283	AOEM	
	Body	15298	131468	AOEM	
	Head	412	2258	AOEM	
	Protected hands (gloves)	133	1572	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	149	1161	AOEM	
	Protected head (hood and face shield)	7	128	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
Water soluble bag	No		1		
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1177	10447	AOEM	
	Body	658	3392	AOEM	
	Head	31	94	AOEM	
	Protected hands (gloves)	131	4244	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	18	44	AOEM	
	Inhalation	3	10	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.9063925	0.4889487	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0817732	0.0081491	
% of RVNAS	817.73%	81.49%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	29.3071628	4.4036068	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.4884527	0.0733934	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

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e) Forestry tree, Salix, Wicker

Operator exposure for outdoor spray applications

Operator exposure for outdoor spray applications					
Application rate of active substance		0.1587 kg a.s./ha		i_AppRate	
Assumed area treated		10 ha/day		d_AreaTreated	
Amount of active substance applied		1.587 kg a.s./day		i_AmountAS	
Dermal absorption of the product		10.00%		i_AbsorpProduct	
Dermal absorption of in-use dilution		50.00%		i_AbsorInuse	
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.			
Indoor or Outdoor application		Outdoor			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			
Season		not relevant			
OutdoorSoluble concentrates, emulsifiable concentrate, etc Downward sprayingVehicle-mounted					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	6931	25498	AOEM	
	Body	4935	82367	AOEM	
	Head	82	452	AOEM	
	Protected hands (gloves)	47	314	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	36	232	AOEM	
	Protected head (hood and face shield)	1	26	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	2571	5257	AOEM	This scenario assumes that small area equipment is used
	Body	3528	4471	AOEM	
	Head	21	248	AOEM	
	Protected hands (gloves)	28	23	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	52	AOEM	
	Inhalation	7	53	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4.2661309	0.0740059	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0711022	0.0012334	
% of RVNAS	711.02%	12.33%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	15.9010761	0.3429014	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2650179	0.0057150	
% of RVAAS	#DZIEL/0!	#DZIEL/0!	

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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A 3.1.3 Calculations for Azoxystrobin

a) Cereals

Operator exposure for outdoor spray applications

Operator exposure data - outdoor spray applications					
Application rate of active substance	0.2 kg a.s./ha	i_AppRate			
Assumed area treated	50 ha/day	d_AreaTreated			
Amount of active substance applied	10 kg a.s./day	i_AmountAS			
Dermal absorption of the product	10.00%	i_AbsorpProduct			
Dermal absorption of in-use dilution	50.00%	i_AbsorInuse			
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Do not change any of the values in this table, as they are determined by the product label					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28588	106902	AOEM	
	Body	17999	140606	AOEM	
	Head	519	2846	AOEM	
	Protected hands (gloves)	154	1981	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	183	1463	AOEM	
	Protected head (hood and face shield)	8	161	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1483	12376	AOEM	
	Body	829	4275	AOEM	
	Head	39	118	AOEM	
	Protected hands (gloves)	148	4360	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	23	56	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8971790	2.3861157	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0982863	0.0397686	
% of RVNAS	49.14%	19.88%	

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Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	10 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28588	106902	AOEM	
	Body	17999	140606	AOEM	
	Head	519	2846	AOEM	
	Protected hands (gloves)	154	1981	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	183	1463	AOEM	
	Protected head (hood and face shield)	8	161	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1483	12376	AOEM	
	Body	829	4275	AOEM	
	Head	39	118	AOEM	
	Protected hands (gloves)	148	4360	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	23	56	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8971790	0.6044637	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0982863	0.0100744	
% of RVNAS	49.14%	5.04%	

b) Oilseedrape, mustard, soya, sunflower, breadseed poppy

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Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	10 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28588	106902	AOEM	
	Body	17999	140606	AOEM	
	Head	519	2846	AOEM	
	Protected hands (gloves)	154	1981	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	183	1463	AOEM	
	Protected head (hood and face shield)	8	161	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1483	12376	AOEM	
	Body	829	4275	AOEM	
	Head	39	118	AOEM	
	Protected hands (gloves)	148	4360	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	23	56	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8971790	3.0537486	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0982863	0.0508958	
% of RVNAS	49.14%	25.45%	

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Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	10 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28588	106902	AOEM	
	Body	17999	140606	AOEM	
	Head	519	2846	AOEM	
	Protected hands (gloves)	154	1981	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	183	1463	AOEM	
	Protected head (hood and face shield)	8	161	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1483	12376	AOEM	
	Body	829	4275	AOEM	
	Head	39	118	AOEM	
	Protected hands (gloves)	148	4360	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	23	56	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8971790	1.2720966	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0982863	0.0212016	
% of RVNAS	49.14%	10.60%	

c) Ornamentals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	2 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	8281	30530	AOEM	
	Body	5807	88092	AOEM	
	Head	104	569	AOEM	
	Protected hands (gloves)	54	396	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
	Protected head (hood and face shield)	2	32	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	3241	6227	AOEM	This scenario assumes that small area equipment is used
	Body	4446	5634	AOEM	
	Head	27	312	AOEM	
	Protected hands (gloves)	32	23	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	66	AOEM	
	Inhalation	8	60	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.2880372	4.4653067	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0881340	0.0744218	
% of RVNAS	44.07%	37.21%	

d) Tobacco

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Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	10 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28588	106902	AOEM	
	Body	17999	140606	AOEM	
	Head	519	2846	AOEM	
	Protected hands (gloves)	154	1981	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	183	1463	AOEM	
	Protected head (hood and face shield)	8	161	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1483	12376	AOEM	
	Body	829	4275	AOEM	
	Head	39	118	AOEM	
	Protected hands (gloves)	148	4360	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	23	56	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8971790	3.0537486	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0982863	0.0508958	
% of RVNAS	49.14%	25.45%	

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Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	10 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

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

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	28588	106902	AOEM	
	Body	17999	140606	AOEM	
	Head	519	2846	AOEM	
	Protected hands (gloves)	154	1981	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	183	1463	AOEM	
	Protected head (hood and face shield)	8	161	AOEM	
	Inhalation	7	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Incl. in AOEM model		
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1483	12376	AOEM	
	Body	829	4275	AOEM	
	Head	39	118	AOEM	
	Protected hands (gloves)	148	4360	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	23	56	AOEM	
	Inhalation	3	11	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
Clothing	Potential exposure		Incl. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.8971790	1.2720966	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0982863	0.0212016	
% of RVNAS	49.14%	10.60%	

e) Forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

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Applicant version

Operator exposure for outdoor spray applications

Application rate of active substance	0.2 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	10 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	2 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%	<i>i_AbsorInuse</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	8281	30530	AOEM	
	Body	5807	88092	AOEM	
	Head	104	569	AOEM	
	Protected hands (gloves)	54	396	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
	Protected head (hood and face shield)	2	32	AOEM	
	Inhalation	5	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	3241	6227	AOEM	This scenario assumes that small area equipment is used
	Body	4446	5634	AOEM	
	Head	27	312	AOEM	
	Protected hands (gloves)	32	23	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	56	66	AOEM	
	Inhalation	8	60	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Potential exposure		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	5.2880372	4.4653067	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0881340	0.0744218	
% of RVNAS	44.07%	37.21%	

A 3.2**Worker exposure calculations (KCP 7.2.3.1)**

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

A 3.2.1 Calculations for Prothioconazole**a) Cereals**

Worker exposure from residues on foliage for				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.175	kg a.s./ha		<i>i_AppRate</i>
Number of applications	2			<i>i_AppNo</i>
Interval between multiple applications	14	days		<i>i_AppInt</i>
Half-life of active substance	30	days		<i>d_HalfLifeAS</i>
Multiple application factor	1.7			<i>d_MAF</i>
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.525	µg a.s./cm ²		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	11.3113522	1.2668714	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1885225	0.0211145		
% of RVNAS	94.26%	10.56%		

b) Oilseed rape, mustard, sunflower, soya, breadseed poppy

Worker exposure from residues on foliage for				
Crop type	oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.175	kg a.s./ha		<i>i_AppRate</i>
Number of applications	1			<i>i_AppNo</i>
Interval between multiple applications	365	days		<i>i_AppInt</i>
Half-life of active substance	30	days		<i>d_HalfLifeAS</i>
Multiple application factor	1.0			<i>d_MAF</i>
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.525	µg a.s./cm ²		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	6.5625000	0.7350000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1093750	0.0122500		
% of RVNAS	54.69%	6.13%		

c) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Ornamentals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Cutting, sorting, bundling, carrying			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.175	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.525	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	14000	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	5000	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	50.6748578	18.0981635	5.0674858	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.8445810	0.3016361	0.0844581	
% of RVNAS	422.29%	150.82%	42.23%	

d) Tobacco

Worker exposure from residues on foliage for				
Crop type	Leaf vegetables and fresh herbs			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.175	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.525	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	5800	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	2500	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	20.9938697	9.0490817	2.0993870	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.3498978	0.1508180	0.0349898	
% of RVNAS	174.95%	75.41%	17.49%	

e) Forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.175	kg a.s./ha		<i>i_AppRate</i>
Number of applications	2			<i>i_AppNo</i>
Interval between multiple applications	14	days		<i>i_AppInt</i>
Half-life of active substance	30	days		<i>d_HalfLifeAS</i>
Multiple application factor	1.7			<i>d_MAF</i>
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.525	µg a.s./cm ²		<i>d_DFR</i>
Working hours	8	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	81.4417357	16.2883471	8.1441736	
Total systemic exposure per kg body weight (mg/kg bw/day)	1.3573623	0.2714725	0.1357362	
% of RVNAS	678.68%	135.74%	67.87%	

f) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.28	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.25	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	16.8	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	8.400	1.680	DE(int) = DE x (DA/100)
Total	8.400	1.680	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	70	14	%AOEL = 100 x DE(int) / AOEL
Total	70	14	sum

g) Oilseed rape, mustard, breadseed poppy, soya, sunflower

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.175	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	10.5	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	5.250	1.050	DE(int) = DE x (DA/100)
Total	5.250	1.050	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	44	9	%AOEL = 100 x DE(int) / AOEL
Total	44	9	sum

f) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.28	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.5	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	33.6	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	16.800	3.360	DE(int) = DE x (DA/100)
Total	16.800	3.360	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	140	28	%AOEL = 100 x DE(int) / AOEL
Total	140	28	sum

g) Tobacco

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.28	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.25	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	16.8	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	8.400	1.680	DE(int) = DE x (DA/100)
Total	8.400	1.680	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	70	14	%AOEL = 100 x DE(int) / AOEL
Total	70	14	sum

h) Forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.28	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.3	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	20.16	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	10.080	2.016	DE(int) = DE x (DA/100)
Total	10.080	2.016	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	84	17	%AOEL = 100 x DE(int) / AOEL
Total	84	17	sum

A 3.2.2 Calculations for Prothioconazole-desthio

- a) Cereals:
100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.1587	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	10.2577805	1.1488714	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1709630	0.0191479		
% of RVNAS	1709.63%	191.48%		

50% conversion:

Worker exposure from residues on foliage for				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.07934	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.23802	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	5.1282439	0.5743633	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0854707	0.0095727		
% of RVNAS	854.71%	95.73%		

b) Oilseed rape, mustard, sunflower, soya, breadseed poppy

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.1587	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	5.9512500	0.6665400	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0991875	0.0111090		
% of RVNAS	991.88%	111.09%		

50% conversion:

Worker exposure from residues on foliage for				
Crop type	Oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.07934	kg a.s./ha		i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.23802	µg a.s./cm ²		d_DFR
Working hours	2	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	2.9752500	0.3332280	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0495875	0.0055538		
% of RVNAS	495.88%	55.54%		

c) Ornamental

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Ornamentals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Cutting, sorting, bundling, carrying			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.1587	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	14000	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	5000	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	45.9548568	16.4124488	4.5954857	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.7659143	0.2735408	0.0765914	
% of RVNAS	7659.14%	2735.41%	765.91%	

50% conversion:

Worker exposure from residues on foliage for				
Crop type	Ornamentals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Cutting, sorting, bundling, carrying			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.07934	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.23802	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	14000	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	5000	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	22.9745327	8.2051902	2.2974533	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.3829089	0.1367532	0.0382909	
% of RVNAS	3829.09%	1367.53%	382.91%	

d) Tobacco

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Leaf vegetables and fresh herbs			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.1587	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	5800	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	2500	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	19.0384407	8.2062244	1.9038441	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.3173073	0.1367704	0.0317307	
% of RVNAS	3173.07%	1367.70%	317.31%	

50% conversion:

Worker exposure from residues on foliage for				
Crop type	Leaf vegetables and fresh herbs			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.07934	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.23802	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	5800	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	2500	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	9.5180207	4.1025951	0.9518021	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1586337	0.0683766	0.0158634	
% of RVNAS	1586.34%	683.77%	158.63%	

e) Forestry tree, Salix, Wicker

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.1587	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	73.8560198	14.7712040	7.3856020	
Total systemic exposure per kg body weight (mg/kg bw/day)	1.2309337	0.2461867	0.1230934	
% of RVNAS	12309.34%	2461.87%	1230.93%	

50% conversion:

Worker exposure from residues on foliage for				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted-Drift Reduction			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.07934	kg a.s./ha		i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14	days		i_AppInt
Half-life of active substance	30	days		d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.23802	µg a.s./cm ²		d_DFR
Working hours	8	hr		d_WorkHr
Dermal transfer coefficient - Total potential exposure	22500	cm ² /hr		d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	4500	cm ² /hr		d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	2250	cm ² /hr		d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ^{^(-3)}		d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ^{^(-3)}		d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	36.9233561	7.3846712	3.6923356	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.6153893	0.1230779	0.0615389	
% of RVNAS	6153.89%	1230.78%	615.39%	

f) Cereals

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	prothioconazole-desthio			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.2539	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				
	no model available	-		w ithout PPE
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		3.8085	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1.904	0.381	DE(int) = DE x (DA/100)
	Total	1.904	0.381	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	317	63	%AOEL = 100 x DE(int) / AOEL
	Total	317	63	sum

50% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	prothioconazole-desthio			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.127	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				w ithout PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		1.905	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
Internal exposure		[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0.953	0.191	DE(int) = DE x (DA/100)
	Total	0.953	0.191	sum
% AOEL				
	Inhalation	-	-	no model available
	Dermal	159	32	%AOEL = 100 x DE(int) / AOEL
	Total	159	32	sum

g) Oilseed rape, mustard, breadseed poppy, soya, sunflower

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	prothioconazole-desthio			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.1587	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				
	no model available	-		w ithout PPE
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		2.3805	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
Internal exposure		[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1.190	0.238	DE(int) = DE x (DA/100)
	Total	1.190	0.238	sum
% AOEL				
	Inhalation	-	-	no model available
	Dermal	198	40	%AOEL = 100 x DE(int) / AOEL
	Total	198	40	sum

50% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole-desthio		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.07934	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.25	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	1.1901	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	0.6	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	0.595	0.119	DE(int) = DE x (DA/100)
Total	0.595	0.119	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	99	20	%AOEL = 100 x DE(int) / AOEL
Total	99	20	sum

f) Ornamental

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole-desthio		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.252	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available		-	w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.5	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	7.56	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE
Internal exposure		[mg a.s./ day]	[mg a.s./ day]
Inhalation	-	-	no model available
Dermal	3.780	0.756	DE(int) = DE x (DA/100)
Total	3.780	0.756	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	630	126	%AOEL = 100 x DE(int) / AOEL
Total	630	126	sum

50% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole-desthio		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.127	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.5	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	15.24	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	0.6	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	7.620	1.524	DE(int) = DE x (DA/100)
Total	7.620	1.524	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	1270	254	%AOEL = 100 x DE(int) / AOEL
Total	1270	254	sum

g) Tobacco

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	prothioconazole-desthio			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.252	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				w ithout PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.3	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		4.536	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	2.268	0.454	DE(int) = DE x (DA/100)
	Total	2.268	0.454	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	378	76	%AOEL = 100 x DE(int) / AOEL
	Total	378	76	sum

50% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	prothioconazole-desthio			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.127	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				
	no model available	-		w ithout PPE
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.3	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		9.144	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
Internal exposure		[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	4.572	0.914	DE(int) = DE x (DA/100)
	Total	4.572	0.914	sum
% AOEL				
	Inhalation	-	-	no model available
	Dermal	762	152	%AOEL = 100 x DE(int) / AOEL
	Total	762	152	sum

h) Forestry tree, Salix, Wicker

100% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	prothioconazole-desthio			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.2539	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				w ithout PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.3	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		18.2808	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	0.6	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	9.140	1.828	DE(int) = DE x (DA/100)
	Total	9.140	1.828	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	1523	305	%AOEL = 100 x DE(int) / AOEL
	Total	1523	305	sum

50% conversion:

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	prothioconazole-desthio		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.127	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.3	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	9.144	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	0.6	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	4.572	0.914	DE(int) = DE x (DA/100)
Total	4.572	0.914	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	762	152	%AOEL = 100 x DE(int) / AOEL
Total	762	152	sum

A 3.2.3 Calculations for Azoxystrobin

a) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Cereals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.2 kg a.s./ha			i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14 days			i_AppInt
Half-life of active substance	30 days			d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm ²			d_DFR
Working hours	2 hr			d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr			d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr			d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 [^] (-3)			d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 [^] (-3)			d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 [^] (-3)			d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	12.9272596	1.4478531	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.2154543	0.0241309		
% of RVNAS	107.73%	12.07%		

b) Oilseed rape, mustard, sunflower, soya, breadseed poppy

Worker exposure from residues on foliage for				
Crop type	oilseeds			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Inspection, irrigation			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.2 kg a.s./ha			i_AppRate
Number of applications	1			i_AppNo
Interval between multiple applications	365 days			i_AppInt
Half-life of active substance	30 days			d_HalfLifeAS
Multiple application factor	1.0			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm ²			d_DFR
Working hours	2 hr			d_WorkHr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr			d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr			d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 [^] (-3)			d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 [^] (-3)			d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 [^] (-3)			d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	7.5000000	0.8400000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.1250000	0.0140000		
% of RVNAS	62.50%	7.00%		

c) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Ornamentals			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Cutting, sorting, bundling, carrying			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.2 kg a.s./ha			i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14 days			i_AppInt
Half-life of active substance	30 days			d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm ²			d_DFR
Working hours	8 hr			d_WorkHr
Dermal transfer coefficient - Total potential exposure	14000 cm ² /hr			d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	5000 cm ² /hr			d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	1400 cm ² /hr			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}			d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}			d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}			d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	57.9141232	20.6836154	5.7914123	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.9652354	0.3447269	0.0965235	
% of RVNAS	482.62%	172.36%	48.26%	

d) Tobacco

Worker exposure from residues on foliage for				
Crop type	Leaf vegetables and fresh herbs			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.2 kg a.s./ha			i_AppRate
Number of applications	2			i_AppNo
Interval between multiple applications	14 days			i_AppInt
Half-life of active substance	30 days			d_HalfLifeAS
Multiple application factor	1.7			d_MAF
Dermal absorption of the product	10.00%			i_AbsorpProduct
Dermal absorption of the in-use dilution	50.00%			i_Absorplnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm ²			d_DFR
Working hours	8 hr			d_WorkHr
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr			d_DermTcUCV
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr			d_DermTcCV1
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr			d_DermTcCV2
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^(-3)}			d_InhalTcAut
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^(-3)}			d_InhalTcCut
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^(-3)}			d_InhalTcSort
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	23.9929939	10.3418077	2.3992994	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.3998832	0.1723635	0.0399883	
% of RVNAS	199.94%	86.18%	19.99%	

e) Forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Worker exposure from residues on foliage for				
Crop type	Pome fruit			
Indoor or outdoor	Outdoor			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			
Worker's task	Searching, reaching, picking			
Main body parts in contact with foliage	Hand and body			
Application rate of active substance	0.2 kg a.s./ha			<i>i_AppRate</i>
Number of applications	2			<i>i_AppNo</i>
Interval between multiple applications	14 days			<i>i_AppInt</i>
Half-life of active substance	30 days			<i>d_HalfLifeAS</i>
Multiple application factor	1.7			<i>d_MAF</i>
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.6 µg a.s./cm ²			<i>d_DFR</i>
Working hours	8 hr			<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	22500 cm ² /hr			<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	4500 cm ² /hr			<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm ² /hr			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³			<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³			<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³			<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	93.0762694	18.6152539	9.3076269	
Total systemic exposure per kg body weight (mg/kg bw/day)	1.5512712	0.3102542	0.1551271	
% of RVNAS	775.64%	155.13%	77.56%	

f) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE			EUROPOEM II MODEL	
form			Re-entry in the field	
a.s.	azoxystrobin			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.32	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				w ithout PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		19.2	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	50	%	
	PPE-factor dermal	5		gloves*
	AOEL	12	mg a.s./ day	based on 70 kg bw
		Without PPE	With PPE	
Internal exposure		[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	9.600	1.920	DE(int) = DE x (DA/100)
	Total	9.600	1.920	sum
% AOEL				
	Inhalation	-	-	no model available
	Dermal	80	16	%AOEL = 100 x DE(int) / AOEL
	Total	80	16	sum

g) Oilseed rape, mustard, breadseed poppy, soya, sunflower

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	azoxystrobin		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.2	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.25	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	12	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	6.000	1.200	DE(int) = DE x (DA/100)
Total	6.000	1.200	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	50	10	%AOEL = 100 x DE(int) / AOEL
Total	50	10	sum

f) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	azoxystrobin		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.32	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.5	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	38.4	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	19.200	3.840	DE(int) = DE x (DA/100)
Total	19.200	3.840	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	160	32	%AOEL = 100 x DE(int) / AOEL
Total	160	32	sum

g) Tobacco

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	azoxystrobin		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.32	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.25	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	19.2	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	9.600	1.920	DE(int) = DE x (DA/100)
Total	9.600	1.920	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	80	16	%AOEL = 100 x DE(int) / AOEL
Total	80	16	sum

h) Forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

WORKER EXPOSURE		EUROPOEM II MODEL	
form		Re-entry in the field	
a.s.	azoxystrobin		
Parameter	Value	Unit	References, comments
Re-entry activities in the field			
AR Application rate	0.32	kg a.s./ha	summary of intended uses
Worker			
Duration			
T	8	hours / day	default: 6 h (Europoem II)
Inhalation Exposure			
no model available	-		w ithout PPE
Dermal Exposure			
DFR Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC Transfer coefficient	0.3	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure	23.04	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure			
DA Dermal Absorption	50	%	
PPE-factor dermal	5		gloves*
AOEL	12	mg a.s./ day	based on 70 kg bw
	Without PPE	With PPE	
Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
Inhalation	-	-	no model available
Dermal	11.520	2.304	DE(int) = DE x (DA/100)
Total	11.520	2.304	sum
% AOEL			
Inhalation	-	-	no model available
Dermal	96	19	%AOEL = 100 x DE(int) / AOEL
Total	96	19	sum

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Prothioconazole

a) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype		Cereals			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			<i>I_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>I_FormVal</i>
Buffer strip		2-3 m			<i>i_Buffer</i>
Application rate of the product		0.175 kg a.s./ha			<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)		0.875 g a.s./l			<i>d_ConcAS</i>
Dermal absorption of product		10.00%			<i>I_AbsorpProduct</i>
Dermal absorption of in-use dilution		50.00%			<i>I_Absorplnuse</i>
Oral absorption		100.00%			<i>I_AbsorpOrallnuse</i>
Dislodgeable foliar residue (i_AppRate*i_DFR)		0.525 µg a.s./cm²			<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa			<i>I_Volat</i>
Concentration in air		0.001 mg/m³			<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult		0.47 ml spray dilution/person			
Resident dermal spray drift exposure 75th percentile - child		0.327 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - adult		0.00010 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - child		0.00022 ml spray dilution/person			
Resident dermal spray drift exposure mean - adult		0.22318 ml spray dilution/person			
Resident dermal spray drift exposure mean - child		0.18 ml spray dilution/person			
Resident inhal. spray drift exposure mean - adult		0.00009 ml spray dilution/person			
Resident inhal. spray drift exposure mean - child		0.00017 ml spray dilution/person			
Exposure duration dermal		2 hours			<i>d_ReExpDur</i>
Exposure duration inhalation		24 hours			<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops		0.25 hours			<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor		18.0%			<i>d_ClothAF</i>
Breathing rate adult		0.23 m³/day/kg			<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)		1.07 m³/day/kg			<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)		5.60%			
Drift percentage on surface (mean)		4.10%			
Turf transferable residues percentage		5.00%			<i>d_Turf</i>
Transfer coeff. of surface deposits-adult		7300 cm²/hour			<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)		2600 cm²/hour			<i>d_ReTCCh</i>
Saliva extraction percentage		50.00%			<i>d_SolExt</i>
Surface area of hands mouthed		20 cm²			<i>d_AreaHM</i>
Frequency of hand to mouth activity		9.5 events/hour			<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day		25 cm²			<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth		20.00%			<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad		7500 cm²/h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi		2250 cm²/h			<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult		5980 cm²/h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child		1794 cm²/h			<i>d_TcEntryCh</i>
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)	0.1175038	0.0107000	0.0244084	0.2545054	0.2962198
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0117504	0.0010700	0.0024408	0.0254505	0.0296220
% of RVNAS	5.88%	0.54%	1.22%	12.73%	14.81%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1687000	0.0138000	0.0616544	0.8483514	0.8155033
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0028117	0.0002300	0.0010276	0.0141392	0.0135917
% of RVNAS	1.41%	0.12%	0.51%	7.07%	6.80%

b) Oilseed rape, mustard, soya, sunflower, breadseed poppy

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	oilseeds				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				<i>I_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>I_FormVal</i>
Buffer strip	2-3 m				<i>I_Buffer</i>
Application rate of the product	0.175 kg a.s./ha				<i>I_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.875 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	10.00%				<i>I_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%				<i>I_Absorplnuse</i>
Oral absorption	100.00%				<i>I_AbsorpOrallnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.525 µg a.s./cm²				<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa		Pa		<i>I_Volat</i>
Concentration in air	0.001 mg/m³				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m³/day/kg				<i>d_BreathRAD</i>
Breathing rate child (1-3 year old)	1.07 m³/day/kg				<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm²/hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%				<i>d_SolExt</i>
Surface area of hands mouthed	20 cm²				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm²				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				<i>d_TcEntryCh</i>
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)	0.1175038	0.0107000	0.0141610	0.1476563	0.2035229
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0117504	0.0010700	0.0014161	0.0147656	0.0203523
% of RVNAS	5.88%	0.54%	0.71%	7.38%	10.18%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1687000	0.0138000	0.0357700	0.4921875	0.5125708
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0028117	0.0002300	0.0005962	0.0082031	0.0085428
% of RVNAS	1.41%	0.12%	0.30%	4.10%	4.27%

c) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Ornamentals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.175 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.875 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.525 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.1175038	0.0107000	0.0244084	0.2545054	0.2962198
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0117504	0.0010700	0.0024408	0.0254505	0.0296220
% of RVNAS	5.88%	0.54%	1.22%	12.73%	14.81%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1687000	0.0138000	0.0616544	0.8483514	0.8155033
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0028117	0.0002300	0.0010276	0.0141392	0.0135917
% of RVNAS	1.41%	0.12%	0.51%	7.07%	6.80%

d) Tobacco

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Leaf vegetables and fresh herbs				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.175 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.875 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.525 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.1175038	0.0107000	0.0244084	0.2545054	0.2962198
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0117504	0.0010700	0.0024408	0.0254505	0.0296220
% of RVNAS	5.88%	0.54%	1.22%	12.73%	14.81%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1687000	0.0138000	0.0616544	0.8483514	0.8155033
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0028117	0.0002300	0.0010276	0.0141392	0.0135917
% of RVNAS	1.41%	0.12%	0.51%	7.07%	6.80%

e) forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Pome fruit				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				<i>I_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>I_FormVal</i>
Buffer strip	2-3 m				<i>I_Buffer</i>
Application rate of the product	0.175 kg a.s./ha				<i>I_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)	0.875 g a.s./l				<i>d_ConcAS</i>
Dermal absorption of product	10.00%				<i>I_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%				<i>I_Absorpinuse</i>
Oral absorption	100.00%				<i>I_AbsorpOrallnuse</i>
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.525 µg a.s./cm²				<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa			Pa	<i>I_Volat</i>
Concentration in air	0.001 mg/m³				<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				<i>d_ReExpDur</i>
Exposure duration inhalation	24 hours				<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops	0.25 hours				<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%				<i>d_ClothAF</i>
Breathing rate adult	0.23 m³/day/kg				<i>d_BreathRAd</i>
Breathing rate child (1-3 year old)	1.07 m³/day/kg				<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)	23.96%				
Drift percentage on surface (mean)	18.96%				
Turf transferable residues percentage	5.00%				<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	7300 cm²/hour				<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				<i>d_ReTCCh</i>
Saliva extraction percentage	50.00%				<i>d_SolExt</i>
Surface area of hands mouthed	20 cm²				<i>d_AreaHM</i>
Frequency of hand to mouth activity	9.5 events/hour				<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm²				<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%				<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				<i>d_TcEntryCh</i>
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)	0.1175038	0.0107000	0.1044330	0.2545054	0.3609892
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0117504	0.0010700	0.0104433	0.0254505	0.0360989
% of RVNAS	5.88%	0.54%	5.22%	12.73%	18.05%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1687000	0.0138000	0.2637928	0.8483514	0.9791077
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0028117	0.0002300	0.0043965	0.0141392	0.0163185
% of RVNAS	1.41%	0.12%	2.20%	7.07%	8.16%

A 3.3.2 Calculations for Prothioconazole-desthio

a) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Cereals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.1587 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.7935 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)
Total systemic exposure (mg a.s./day)			0.0354476	0.0107000	0.0045456
Total systemic exposure per kg body weight (mg a.s./day/kg)			0.0035448	0.0010700	0.0004546
% of RVNAS			35.45%	10.70%	4.55%
1.2 Adult					
Spray drift			Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)			0.0387473	0.0138000	0.0114819
Total systemic exposure per kg body weight (mg a.s./day/kg)			0.0006458	0.0002300	0.0001914
% of RVNAS			6.46%	2.30%	1.91%

b) Oilseed rape, mustard, soya, sunflower, breadseed poppy

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Oilseeds				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.1587 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.7935 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.0354476	0.0107000	0.0026372	0.1339031	0.1391050
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0035448	0.0010700	0.0002637	0.0133903	0.0139105
% of RVNAS	35.45%	10.70%	2.64%	133.90%	139.10%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0066614	0.4463438	0.3949021
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0006458	0.0002300	0.0001110	0.0074391	0.0065817
% of RVNAS	6.46%	2.30%	1.11%	74.39%	65.82%

c) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Ornamentals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.1587 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.7935 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.0354476	0.0107000	0.0045456	0.2308001	0.2178576
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0035448	0.0010700	0.0004546	0.0230800	0.0217858
% of RVNAS	35.45%	10.70%	4.55%	230.80%	217.86%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0114819	0.7693335	0.6562051
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0006458	0.0002300	0.0001914	0.0128222	0.0109368
% of RVNAS	6.46%	2.30%	1.91%	128.22%	109.37%

d) Tobacco

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Leaf vegetables and fresh herbs				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.1587 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.7935 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	2.30%				
Drift percentage on surface (mean)	1.80%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.0354476	0.0107000	0.0045456	0.2308001	0.2178576
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0035448	0.0010700	0.0004546	0.0230800	0.0217858
% of RVNAS	35.45%	10.70%	4.55%	230.80%	217.86%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0114819	0.7693335	0.6562051
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0006458	0.0002300	0.0001914	0.0128222	0.0109368
% of RVNAS	6.46%	2.30%	1.91%	128.22%	109.37%

e) forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Pome fruit				
Application method	Downward spraying				
Application equipment	Vehicle-mounted-Drift Reduction				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	5 m				
Application rate of the product	0.1587 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.7935 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.4761 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.23798 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.2175 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00017 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.12278 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.12 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00008 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00014 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	15.79%				
Drift percentage on surface (mean)	11.69%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.0354476	0.0107000	0.0312063	0.2308001	0.2374036
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0035448	0.0010700	0.0031206	0.0230800	0.0237404
% of RVNAS	35.45%	10.70%	31.21%	230.80%	237.40%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0387473	0.0138000	0.0788256	0.7693335	0.7055772
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0006458	0.0002300	0.0013138	0.0128222	0.0117596
% of RVNAS	6.46%	2.30%	13.14%	128.22%	117.60%

A 3.3.3 Calculations for Azoxystrobin

a) Cereals

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype		Cereals			
Application method		Downward spraying			
Application equipment		Vehicle-mounted			<i>I_AppEquip</i>
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				<i>I_FormVal</i>
Buffer strip		2-3 m			<i>i_Buffer</i>
Application rate of the product		0.2 kg a.s./ha			<i>i_AppRate</i>
Concentration of active substance (in-use dilution for liquid applications)		1 g a.s./l			<i>d_ConcAS</i>
Dermal absorption of product		10.00%			<i>I_AbsorpProduct</i>
Dermal absorption of in-use dilution		50.00%			<i>I_Absorplnuse</i>
Oral absorption		100.00%			<i>I_AbsorpOrallnuse</i>
Dislodgeable foliar residue (i_AppRate*i_DFR)		0.6 µg a.s./cm²			<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa			<i>I_Volat</i>
Concentration in air		0.001 mg/m³			<i>d_AirCon</i>
Resident dermal spray drift exposure 75th percentile - adult		0.47 ml spray dilution/person			
Resident dermal spray drift exposure 75th percentile - child		0.327 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - adult		0.00010 ml spray dilution/person			
Resident inhal. spray drift exposure 75th percentile - child		0.00022 ml spray dilution/person			
Resident dermal spray drift exposure mean - adult		0.22318 ml spray dilution/person			
Resident dermal spray drift exposure mean - child		0.18 ml spray dilution/person			
Resident inhal. spray drift exposure mean - adult		0.00009 ml spray dilution/person			
Resident inhal. spray drift exposure mean - child		0.00017 ml spray dilution/person			
Exposure duration dermal		2 hours			<i>d_ReExpDur</i>
Exposure duration inhalation		24 hours			<i>d_ReExpDurInhal</i>
Exposure duration entry into treated crops		0.25 hours			<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor		18.0%			<i>d_ClothAF</i>
Breathing rate adult		0.23 m³/day/kg			<i>d_BreathRAD</i>
Breathing rate child (1-3 year old)		1.07 m³/day/kg			<i>d_BreathRCh</i>
Drift percentage on surface (75th percentile)		5.60%			
Drift percentage on surface (mean)		4.10%			
Turf transferable residues percentage		5.00%			<i>d_Turf</i>
Transfer coeff. of surface deposits-adult		7300 cm²/hour			<i>d_ReTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)		2600 cm²/hour			<i>d_ReTCCh</i>
Saliva extraction percentage		50.00%			<i>d_SolExt</i>
Surface area of hands mouthed		20 cm²			<i>d_AreaHM</i>
Frequency of hand to mouth activity		9.5 events/hour			<i>d_ReFreqHM</i>
Ingestion rate for mouthing of grass per day		25 cm²			<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth		20.00%			<i>d_DRP</i>
Transfer coefficient for entry into treated crops (75th percentile) - ad		7500 cm²/h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (75th percentile) - chi		2250 cm²/h			<i>d_TcEntryCh</i>
Transfer coefficient for entry into treated crops (mean) - adult		5980 cm²/h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops (mean) - child		1794 cm²/h			<i>d_TcEntryCh</i>
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)	0.1342900	0.0107000	0.0278953	0.2908633	0.3370084
Total systemic exposure per kg body weight	0.0134290	0.0010700	0.0027895	0.0290863	0.0337008
% of RVNAS	6.71%	0.54%	1.39%	14.54%	16.85%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1928000	0.0138000	0.0704622	0.9695445	0.9300323
Total systemic exposure per kg body weight	0.0032133	0.0002300	0.0011744	0.0161591	0.0155005
% of RVNAS	1.61%	0.12%	0.59%	8.08%	7.75%

b) Oilseed rape, mustard, soya, sunflower, breadseed poppy

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	oilseeds				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	2-3 m				i_Buffer
Application rate of the product	0.2 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	1 g a.s./l				d_ConcAS
Dermal absorption of product	10.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%				i_AbsorpInuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa		Pa		i_Volat
Concentration in air	0.001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRAd
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SolExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
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)	0.1342900	0.0107000	0.0161840	0.1687500	0.2310690
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0134290	0.0010700	0.0016184	0.0168750	0.0231069
% of RVNAS	6.71%	0.54%	0.81%	8.44%	11.55%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1928000	0.0138000	0.0408800	0.5625000	0.5838238
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0032133	0.0002300	0.0006813	0.0093750	0.0097304
% of RVNAS	1.61%	0.12%	0.34%	4.69%	4.87%

c) Ornamental

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Ornamentals				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				i_FormVal
Buffer strip	2-3 m				i_Buffer
Application rate of the product	0.2 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	1 g a.s./l				d_ConcAS
Dermal absorption of product	10.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%				i_AbsorpInuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa		Pa		i_Volat
Concentration in air	0.001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRAd
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCh
Saliva extraction percentage	50.00%				d_SolExt
Surface area of hands mouthed	20 cm²				d_AreaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
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)	0.1342900	0.0107000	0.0278953	0.2908633	0.3370084
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0134290	0.0010700	0.0027895	0.0290863	0.0337008
% of RVNAS	6.71%	0.54%	1.39%	14.54%	16.85%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1928000	0.0138000	0.0704622	0.9695445	0.9300323
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0032133	0.0002300	0.0011744	0.0161591	0.0155005
% of RVNAS	1.61%	0.12%	0.59%	8.08%	7.75%

d) Tobacco

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Leaf vegetables and fresh herbs				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.2 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	1 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)
Total systemic exposure (mg a.s./day)			0.0107000	0.0278953	0.2908633
Total systemic exposure per kg body weight (mg a.s./day/kg)			0.0010700	0.0027895	0.0290863
% of RVNAS			0.54%	1.39%	14.54%
1.2 Adult					
Spray drift			Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)			0.0138000	0.0704622	0.9695445
Total systemic exposure per kg body weight (mg a.s./day/kg)			0.0002300	0.0011744	0.0161591
% of RVNAS			0.12%	0.59%	8.08%

e) forestry tree, Salix, Wicker

CHR/F/PROTAZO 375 SC / CLARO 375 SC, KAJMAN 375 SC

Part B – Section 6 - Core Assessment

Applicant version

Resident exposure for					
Croptype	Pome fruit				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.				
Buffer strip	2-3 m				
Application rate of the product	0.2 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	1 g a.s./l				
Dermal absorption of product	10.00%				
Dermal absorption of in-use dilution	50.00%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.6 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				
Exposure duration inhalation	24 hours				
Exposure duration entry into treated crops	0.25 hours				
Light clothing adjustment factor	18.0%				
Breathing rate adult	0.23 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/day/kg				
Drift percentage on surface (75th percentile)	23.96%				
Drift percentage on surface (mean)	18.96%				
Turf transferable residues percentage	5.00%				
Transfer coeff. of surface deposits-adult	7300 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
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)	0.1342900	0.0107000	0.1193520	0.2908633	0.4110306
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0134290	0.0010700	0.0119352	0.0290863	0.0411031
% of RVNAS	6.71%	0.54%	5.97%	14.54%	20.55%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.1928000	0.0138000	0.3014775	0.9695445	1.1170087
Total systemic exposure per kg body weight (mg a.s./day/kg)	0.0032133	0.0002300	0.0050246	0.0161591	0.0186168
% of RVNAS	1.61%	0.12%	2.51%	8.08%	9.31%

A 3.4 Combined exposure calculations

Please refer to the point 6.6.5.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)