

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: FGF11

Product name(s): Telaron Alpha / Patton Alpha
Azoxystrobin 160 + Prothioconazole g/L 200 SC

Chemical active substance(s):

Azoxystrobin, 160 g/L
Prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, updated March 2025

MS Finalisation date: March 2025 (initial Core Assessment)

August 2025, update February 2026 (final Core Assessment)

Version history

When	What
November, 2024	dRR Part B – Section 6, version 1 submitted by the applicant
March, 2025	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.
March, 2025	Applicant update - In Vitro Dermal Absorption studies.
March, 2025	Updated initial assessment by the zRMS reflecting additional data regarding dermal absorption provided by the notifier The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.
August, 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.
February, 2026	Final report (update Core Assessment) Updated information/assessments included by the zRMS in the report in response to comments received by e-mail from the Polish Authority (Ministry of Agriculture Agriculture and Rural Development) are highlighted in green . Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.

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Reviewer general comment:

This part of dossier (B6) summarizes data related to the toxicological profile and NDE assessment for the plant protection product Patton Alpha (product code FGF11) containing the active substances 160 g/L a.s. azoxystrobin + 200 g/l a.s. prothiconazole, for use as a fungicide intended for the control of foliar pathogens on cereals with a maximum application rate of 1L/ha.

All information has been submitted to support registration according art. 33 of 1107/2009 for the first authorization of the product FGF11 in Poland also for zonal registration for which PL was designated zRMS. The zRMS's reviewed all of the elements that are crucial for risk assessment and decision-making. Regarding evaluation of the toxicity profile of the product FGF11, in the absence of experimentally derived acute toxicity data for registered product the Additivity Formula 3.1.3.6.1 has been used to classify a mixture based on acute toxicity estimates (ATE) or converted ATE (cATE) for each ingredient.

Discussion regarding conversion factor PTZ to PTZ-desthio: Some experimental data implies that a conversion rate of 50% is closer to reality (observed conversion rates in exposure studies were between 1 and 70%; 50% conversion was the 90th percentile from the whole dataset). During PPRM TC 22 (EFSA, 2020) it was agreed by the majority of experts to use the reduced conversion factor PTZ to PTZ-desthio in case further refinement when is needed. Therefore, zRMS decided to provide recalculation of NDE taking into account conversion factor of 50% PTZ to PTZ-desthio. However, Reviewer is aware that some experts from cMS may prefer a conversion factor of 100% for this reason updated DABs used for NDE calculation also 100% conversion PTZ to PTZ-desthio has been left in the report but not considered by the zRMS for current registration.

NDE assessment for operator, workers and B&R has been calculated using the EFSA calculator, on-line version 1.1.1 (2025) considering the worst-case exposure scenario to cover all the intended uses (highest application rate per application as well as the highest application rate per year with the shorter interval between each application). All NDE calculations provided for operator, workers and B&R resulting from use of PPP, considering all tasks according to the critical use(s), identify safe use of the product FGF11.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on FGF11*

Product name and code	Azoxystrobin 160 + Prothioconazole g/L 200 SC /FGF11
Formulation type	SC
Active substance(s) (incl. content)	Azoxystrobin, 160 g/L (technical: 165.8 g/L) Prothioconazole, 200 g/L (technical: 206.2 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 FGF11 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 FGF11 according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Acute Toxicity (inhalation:dust, mist) Category 4 ~~Skin sensitisation, Category 1~~ Skin sensitisation, Category 1
Hazard pictograms or Code(s) for hazard pictogram(s)	 GHS07
Signal word	Warning
Hazard statement(s)	~~H317~~ H317 - May cause an allergic skin reaction H332 - Harmful if inhaled
Precautionary statement(s)	~~P261, P271, P272, P280, P302+P352, P304 + P340, P312, P333+P313, P362+P364~~ P261, P271, P280, P302 + P352, P304+P340, P312, P333 + P313, P362+P364,
Additional labelling phrases	~~To avoid risks to man and the environment, comply with the instructions for use.~~ To avoid risks to human health and the environment, comply with the instructions for use [EUH401] ~~Contains (1,2-benzisothiazolin-3-one). May produce an allergic reaction [EUH208]~~

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for FGF11 (conversion factor PTZ to PTZ-desthio 50%)

	Result	PPE / Risk mitigation measures
Operators	Acceptable	~~Gloves during application~~ MLA: Workwear * Taking into account the CLP classification of the plant protection product, it is recommended that operators use PPE (protective gloves).
Workers	Acceptable	~~Gloves during inspection and irrigation after a re-entry period of 9 days~~ Workwear; Inspection, irrigation
Residents/Bystanders	Acceptable	~~Drift reduction measures and buffer zone of 10 m~~ None

zRMS Reviewer comment: in the table 6.1-3 (see below) updated by the applicant, there is summary of proposed RMM considering newly provided DAb*in vitro* studies and 100% conversion factor PTZ to PTZ-desthio. Proposed RMM scientifically is valid but not considered by the zRMS for the current registration.

Updated by the Applicant

Table 6.1-4: Summary of risk assessment for operators, workers, residents and bystanders for FGF11 (In vitro dermal absorption study; conversion factor PTZ to PTZ-desthio 100%)

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) M/L and A *Taking into account the CLP classification of the plant protection product, it is recommended that operators use PPE (protective gloves).
Workers	Acceptable	Work wear (arms, body and legs covered) M/L and A
Residents/Bystander	Acceptable	None

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

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

Table 6.1-5 Critical uses and overall conclusion of exposure assessment (conversion factor PTZ to PTZ-desthio 50%)

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha a) a.s. azoxystrobin b) a.s. prothioconazole	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Cereals (BBCH 30 – 69, 61-73)	F	Spraying, LCTM	a) 1 b) 1	a) 0.16 b) 0.2	100-400	35	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				*

* 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: field crops, HC: high crop, TM: tractor-mounted, HH: hand-held

exposure for bystander is covered by the resident data

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

Noticed data gaps are: none.

zRMS assessment:

Table 6.1-6a Critical uses and overall conclusion of exposure assessment (conversion factor PTZ to PTZ-desthio 50%) OPEX version: 1.1.1 (for details of assessment refer point 6.6.2 and Appendix 3 and 3a)

Field crops (Outdoor) Short term exposure (operator)

Mixing/loading	Application	azoxystrobin (% AOEL)	prothioconazole (% AOEL)	prothioconazole desthio (% AOEL)	Combined (hazard index)
		48.1	34.9	0.2	0.831
		31.4	23.1	0.1	0.547

There are no AAOEL values had been allocated for all active substances contained in the product, therefore no NDE calculation for *Acute exposure*

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha a) a.s. azoxystrobin b) a.s. prothioconazole	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Cereals (BBCH 30 – 69, 61-73)	F	Spraying, LCTM	a) 1 b) 1	a) 0.16 b) 0.2	100-400	35	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				#

* 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: field crops, HC: high crop, TM: tractor-mounted, HH: hand-held

exposure for bystander is covered by the resident data

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

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)

Information on active substance(s)			
	Azoxystrobin	Prothioconazole	Prothioconazole-desthio
Common Name	Azoxystrobin	Prothioconazole	Prothioconazole-desthio
CAS-No.	131860-33-8	178928-70-6	120983-64-4
Classification and proposed labelling			
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: Acute Tox. 3 (inhalation: ATE = 0.7 mg/L (dusts or mists)) Code(s) for hazard pictogram(s): GHS06, Signal word: Danger, Hazard statement(s): H331 Toxic if inhaled, Precautionary statement(s): P261; P271, P304 + P340, P311; P403+P233, P405, P501	Hazard classes, categories: NA Code(s) for hazard pictogram(s): NA Signal word: NA Hazard statement(s): NA Precautionary statement(s): NA. Regarding ATP Inserted / Updated: ATP17 only for Aquatic Hazard Class and Category have been allocated	~~Hazard classes, categories: Repr. 1B~~ ~~Code(s) for hazard pictogram(s): GHS08~~ ~~Signal word: Warning~~ ~~Hazard statement(s): H360D~~ ~~Precautionary statement(s): P201, P280, P308+P313, P405, P501~~ There is no harmonised CLP classification for this substance. According to the classification provided by companies to ECHA in CLP notifications this substance is very toxic to aquatic life with long lasting effects, is harmful if swallowed, causes serious eye irritation, causes skin irritation and may cause respiratory irritation. <u>There is only one proposal H361d</u> (EChA webside acces 12/03/2025 https://echa.europa.eu/substance-information/-/substanceinfo/100.219.133)
Additional C&L proposal	Not applicable		
Agreed EU endpoints			
AOEL systemic	0.2 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
AAOEL systemic	Not relevant	Not relevant	Not relevant
Reference	EFSA Conclusion (EFSA Journal 2010; 8(4):1542) RAC Opinion CLH-O-0000001412-86-206/F adopted 8 June 2018 and RR SANCO/11027/2011 Rev 3, 20 March 2015	EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of Prothioconazole RAC Opinion CLH-O-0000001412-86-269/F – Adopted 15 March 2019	EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Conditions to take into account/critical areas of concern with regard to toxicology			
According to Review Report/EFSA Conclusion for active substance	The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.	Member States must pay particular attention to the operator safety in spray applications. Conditions of use shall include adequate protective measures. Risk mitigation measures such as buffer zones shall be applied, where appropriate.	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for FGF11 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 FGF11

End-points <i>Type of test, species, model system</i> <i>(Guideline)</i>	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral toxicity (calculation)	> 2000 mg/kg bw	Yes	None	Calculation method (dRR part C)
LD ₅₀ dermal toxicity (calculation)	> 2000 mg/kg bw	Yes	None	Calculation method (dRR part C)
LC ₅₀ inhalation toxicity (calculation)	4.00 mg/L air	Yes	Acute Tox. 4, H332	Calculation method (dRR part C)
Skin irritation (calculation)	Non-irritant	Yes	None	Calculation method (dRR part C)
Eye irritation (calculation)	Non-irritant	Yes	None	Calculation method (dRR part C)
Skin sensitisation (calculation)	~~Non-Sensitising*~~ Sensitising**	Yes	~~None*~~ H317**	Calculation method (dRR part C)
Supplementary studies for combinations of plant protection products	No data – not required			

* **zRMS comment:** Neither the active substance azoxystrobin nor the active substance prothioconazole are classified for skin sensitization. However, one co-formulant is classified as skin sensitizer. According to the CLP Regulation (Table 3.4.5), as the content of the classified co-formulant is below the generic concentration limit of 1.0%, the mixture does not need to be classified as skin sensitizer.

**The changes made by zRMS PL in the updated RR reflect the comments provided by cMS during the commenting phase. Corresponding amendments have been implemented in the revised Registration Report, taking into account the updated regulation — Commission Delegated Regulation (EU) 2024/197 of 19 October 2023 amending Regulation (EC) No 1272/2008 concerning the harmonised classification and labelling of certain substances — for the purpose of verifying the proposed CLP/GHS classification of the product under evaluation

Table 6.3-2: Additional toxicological information relevant for classification/labelling of FGF11

	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 (16% (w/w))	Acute Tox. 3; H331	Reg (EC) No. 1272/2008	Yes, H332
	Prothioconazole (20% (w/w))	Not classified for toxicological properties	Reg (EC) No. 1272/2008 Regulation (EU) No. 2021/849	None
Toxicological properties of non-active substance(s) (relevant for classification of product)	Detailed information provided in Part C ~~One co-formulant is classified as skin sensitizer. According to the CLP Regulation (Table 3.4.5), as the content of the classified co-formulant is below the generic concentration limit of 1.0%, the mixture does not need to be classified as skin sensitizer but required Additional labelling phrases ***~~		~~Reg (EC) No. 1272/2008~~ Commission Delegated Regulation (EU) 2024/197 of 19 October 2023	~~EUH208~~ H317
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

*** Refer zRMS comment below the table 6.3-1

6.4 Toxicological Evaluation of Groundwater Metabolites

The metabolite R234886 of azoxystrobin is predicted to occur in groundwater at concentrations above 0.1 µg/L when the product is applied to alkaline soils (see dRR Part B, Section 8.8.2).

An overview of the results of the accepted toxicological studies for Azoxystrobin groundwater metabolite R234886 is given in the following table. Full summaries of the EU peer reviewed studies on the metabolite are not described in this document but short summaries are provided in Appendix 2 (A 2.11.1 Other/Special Studies).

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

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral test Azoxystrobin metabolite R234886: Acute Oral Toxicity Study in The Rat (Up and Down procedure)	The acute oral LD ₅₀ of azoxystrobin metabolite R234886 to female rats is greater than 5000 mg/kg bodyweight.	Yes	Straube E., 2005* Azoxystrobin DAR, May 2009. Vol3_B6 KIIA 5.8/01
Ames test Azoxystrobin metabolite R234886: Bacterial Mutation Assay In <i>S. Typhimurium</i> and <i>E. Coli</i>	Non-genotoxic	Yes	Callander R., 2005* Azoxystrobin DAR, May 2009. Vol3_B6 KIIA 5.8/02

* Indicates that a study was reviewed at EU level

The metabolite R234886 (M02) was shown to have an acute oral LD₅₀ of > 5000 mg/kg bw in rats and to be negative in an Ames test. It was assessed according to the groundwater metabolites guidance document and found to be a non-relevant metabolite.

The groundwater metabolite R234886 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.11. Details are given in Part B, Section 10 chapter 10.2.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in FGF11 are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in FGF11

	Azoxystrobin		Prothioconazole		Prothioconazole-desthio	
	Value	Reference	Value	Reference	Value	Reference
Concentrate	10%	Default value according to the EFSA Guidance on dermal absorption, EFSA Journal 2017;15(6):487	10%	Default value according to the EFSA Guidance on dermal absorption, EFSA Journal 2017;15(6):487	Not relevant for Prothioconazole-desthio*	
Dilution	50%		50%		50%	Default value according to the EFSA Guidance on dermal absorption, EFSA Journal 2017;15(6):487

* Prothioconazole-desthio exposure only relevant for in-use dilution during application.

zRMS Reviewer comment: in the **table 6.5-1 (see below)** updated by the applicant, there is summary of newly provided DAbs *in vitro* studies reflecting absorption of active substances in FGF11. Provided data are valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Updated by the applicant

Table 6.5-2: Dermal absorption rates for active substances in FGF11

	Azoxystrobin		Prothioconazole		Prothioconazole-desthio	
	Value	Reference	Value	Reference	Value	Reference
Concentrate	0.48 %	KCP 7.3 -01	10%	Default value according to the EFSA Guidance on dermal absorption, EFSA Journal 2017;15(6):487	Not applicable*	
Dilution (1:100)	1.9 %		50%		4.2%	KCP 7.3 -02
Dilution (1:400)	3.5 %				10%	

* Prothioconazole-desthio is a product of degradation and is not present in the concentrate.

6.5.1 Justification for proposed values - Azoxystrobin

No data on dermal absorption for Azoxystrobin in FGF11 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 Azoxystrobin

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	Default value for soluble concentrate (SC) formulations	Justification accepted. Endpoint can be used for current product
Dilution	50 %		Justification accepted. Endpoint can be used for current product

zRMS Reviewer comment: in the **table 6.5-2 (see below)** updated by the applicant, there is summary of newly provided DAbs *in vitro* studies reflecting azoxystrobin absorption. Outcome of the study is scientifically valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Proposed dermal absorption rates for azoxystrobin are based on dermal absorption studies on a formulation identical to FGF11. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of FGF11 that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table updated by the applicant

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

Test	Concentrate	Spray dilution (1:100)	Spray dilution (1:400)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference
In vitro (human)	0.48%	1.9%	3.5%	FGF11	Supplementary	Not required	Justification accepted. However	Desai, 2024

						endpoint has not been used for current registration	
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6.5.2 Justification for proposed values – Prothioconazole

No data on dermal absorption for prothioconazole in FGF11 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):487) are presented in the following table.

Table 6.5-3: Default dermal absorption rates for Prothioconazole

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	Default value for soluble concentrate (SC) formulations	Justification accepted. Endpoint can be used for current product
Dilution	50 %		Justification accepted. Endpoint can be used for current product

6.5.3 Justification for proposed values – Prothioconazole-desthio

No data on dermal absorption for prothioconazole-desthio in FGF11 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):487) are presented in the following table.

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

	Value	Justification for value	Acceptability of justification
Concentrate	Not relevant	Default value for soluble concentrate (SC) formulations	Justification accepted. Endpoint can be used for current product
Dilution	50 %		Justification accepted. Endpoint can be used for current product

zRMS Reviewer comment: in the table (see below) updated by the applicant, there is summary of newly provided DABs *in vitro* studies reflecting prothioconazole-desthio absorption. Outcome of the study is scientifically valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Proposed dermal absorption rates for azoxystrobin are based on dermal absorption studies on a formulation identical to FGF11. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of FGF11 that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Updated by the applicant

Summary of the results of submitted dermal absorption studies for prothioconazole-desthio

Test	Concentrate	Spray dilution (1:100)	Spray dilution (1:400)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference
In vitro (human)	Not applicable	4.2%	10%	FGF11	Supplementary	Not required	Justification accepted. However end-point has not	Desai, 2024b

							been used for current registration	
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6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

zRMS Reviewer discussion regarding conversion factor PTZ to PTZ-desthio: Some experimental data implies that a conversion rate of 50% is closer to reality (observed conversion rates in exposure studies were between 1 and 70%; 50% conversion was the 90th percentile from the whole dataset). During PPRM TC 22 2020 it was agreed by the majority of experts to use the reduced conversion factor PTZ to PTZ-desthio in case further refinement when is needed. Therefore, zRMS decided to provide recalculation of NDE taking into account conversion factor of 50% PTZ to PTZ-desthio.

However, Reviewer is aware that some experts from cMS may prefer a conversion factor of 100% for this reason updated DABs used for NDE calculation (100% conversion) has been left in the report but not considered by the zRMS for current registration.

According to the DAR (2005)¹, diluted prothioconazole can degrade to the metabolite prothioconazole-desthio:

"It has been found that JAU 6476-desthio (SXX 0665) may be formed in diluted prothioconazole formulations. This may happen on clothing, skin or certain plant surfaces during the drying process. The degradation product, JAU 6476-desthio, is known to have an embryotoxic potential in experimental animals."

According to the EFSA conclusion of prothioconazole², the degradation product prothioconazole-desthio is more toxic than the parent compound and is therefore considered in the risk assessments of all relevant population groups. The content of prothioconazole-desthio in the concentrate is however assumed to be very low. This assumption is based on the Commission Implementing Regulation (EU) No 540/2011 (amending Regulation (EU) No 1107/2009), in which it is declared that the amount of prothioconazole-desthio may not exceed 0.5 g/kg, i.e. 0.05 % (w/w) in the technical material³. To reflect this non-availability of prothioconazole-desthio when handling the concentrate, i.e. during mixing and loading, the value for the dermal absorption of prothioconazole-desthio in the concentrate was set to 0 %.

This assessment reflects exposure to 50% prothioconazole and 50% prothioconazole-desthio when handling the concentrate, the dilution or the dried formulation. For the estimation of the amount of prothioconazole-desthio that may be formed when handling the product, a conversion factor is calculated based of the molecular weights of prothioconazole-desthio and prothioconazole:

$$\frac{MW_{\text{prothioconazole-desthio}}}{MW_{\text{prothioconazole}}} = \frac{312.2 \text{ g/mol}}{344.26 \text{ g/mol}} = 0.907$$

Taking the above calculated conversion factor of 0.907 into account and a 50% conversion factor of prothioconazole to prothioconazole-desthio, 0.103/ha prothioconazole and ~~0.0934 kg~~ **93.4 g/L** prothioconazole-desthio/ha is to be considered for an application rate of 1.0 L prod./ha, containing 0.206 kg prothioconazole/ha. (*)

Product name and code	Azoxystrobin 160 + Prothioconazole g/L 200 SC / FGF11		
Formulation type	Soluble concentrate [SC]		
Category	Fungicide		
Active substance(s) (incl. content)	Azoxystrobin 160 g/L	Prothioconazole 103 g/L(*)	Prothioconazole-desthio 93.4 ~~0.0934~~ g/L(*)
AOEL systemic	0.2 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
AAOEL systemic	Not relevant	Not relevant	Not relevant
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	100%
Dermal absorption (update)	Concentrate: 10% Dilution: 50%	Concentrate: 10% Dilution: 50%	Concentrate: 0% Not relevant Dilution: 50%

¹ DAR (2005). B.6.15.1 Operator exposure (III 7.2.1), p. 327.

² EFSA (2007). Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Journal 2007; 5(8): RN-106, 1-98. doi:10.2903/j.efsa.2007.106r.

³ dRR Part B Section 1: Identity, Section 2: Physical and chemical properties, Section 4: Further information, 2021

	(Default)	(Default)	(Default)
6.6.2 OPERATOR			
6.6.2/01 azoxystrobin			
Application method	PPE/RPE*	%AOEL	%AAOEL
Patton Alpha Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha, 100-400 L water/ha Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	31.4	na
*PPE/RPE: personal protective equipment/respiratory protective equipment			
6.6.2/02 prothioconazole			
Application method	PPE/RPE*	%AOEL	%AAOEL
Patton Alpha Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha, 100-400 L water/ha Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	23.1	na
*PPE/RPE: personal protective equipment/respiratory protective equipment			
6.6.2/03 prothioconazole desthio			
Application method	PPE/RPE*	%AOEL	%AAOEL
Patton Alpha Use 1: Field crops, Outdoor, 1 x 9.34e-05kg a.s./ha, 100-400 L water/ha Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	0.1	na
*PPE/RPE: personal protective equipment/respiratory protective equipment			
6.6.2/04 Combined Exposure (Hazard Indexes, HI)			
Application method	PPE/RPE*	HI (short term)	HI (acute)
Patton Alpha Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha, 100-400 L water/ha Model: EFSA Opex (v1.1.1) results expressed as HI (sum of hazard quotients) for short term or acute exposure			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	0.5	na
	MLA: None	0.8	na
*PPE/RPE: personal protective equipment/respiratory protective equipment			
Measurement of operator exposure (RMM)			
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.			
6.6.3 WORKER			
6.6.3/01 azoxystrobin			
Re-entry task	PPE	%AOEL	
Patton Alpha Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha, 100-400 L water/ha Model: EFSA Opex (v1.1.1) exposure estimates as % of AOEL (short term exposure)			
Inspection, irrigation (refined DT50: 30, refined DFR: 3)	Workwear	5.6	

6.6.3/02 prothioconazole

Re-entry task	PPE	%AOEL
<i>Patton Alpha</i> <i>Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha, 100-400 L water/ha</i> <i>Model: EFSA Opex (v1.1.1) exposure estimates as % of AOEL (short term exposure)</i>		
Inspection, irrigation (refined DT50: 30, refined DFR: 3)	Workwear	3.6

6.6.3/03 prothioconazole desthio

Re-entry task	PPE	%AOEL
<i>Patton Alpha</i> <i>Use 1: Field crops, Outdoor, 1 x 9.34e-05kg a.s./ha, 100-400 L water/ha</i> <i>Model: EFSA Opex (v1.1.1) exposure estimates as % of AOEL (short term exposure)</i>		
Inspection, irrigation (refined DT50: 30, refined DFR: 3)	Workwear	0.07

6.6.3/04 Combined Exposure (Hazard Indexes, HI)

Re-entry task	PPE	HI (short term)
<i>Patton Alpha</i> <i>Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha, 100-400 L water/ha</i> <i>Model: EFSA Opex (v1.1.1) exposure estimates as HI (sum of hazard quotients) for short term exposure</i>		
Inspection, irrigation (refined DT50: 30, refined DFR: 3)	Workwear	0.09
	Potential	0.8

Measurement of worker exposure (RMM)

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.

6.6.4 RESIDENT and BYSTANDER

6.6.4/01 azoxystrobin

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
<i>Patton Alpha</i> <i>Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha</i> <i>Season: Not relevant, Buffer 2-3 m, Drift reduction 0 %</i> <i>Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)</i>					
Resident child	10.8	0.4	0.6	6.8	12.2
Resident adult	2.6	0.1	0.3	3.8	4.5
Bystander child	na	na	na	na	na
Bystander adult	na	na	na	na	na
<i>Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha</i> <i>Season: Not relevant, Buffer 5 m, Drift reduction 0 %</i> <i>Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)</i>					
Resident child	7.2	0.4	0.3	6.8	9.9
Resident adult	1.3	0.1	0.1	3.8	3.9
Bystander child	na	na	na	na	na
Bystander adult	na	na	na	na	na

6.6.4/02 prothioconazole

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
<i>Patton Alpha</i> Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	7	0.4	0.4	4.3	8
Resident adult	1.7	0.1	0.2	2.4	3
Bystander child	na	na	na	na	na
Bystander adult	na	na	na	na	na
Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha Season: Not relevant, Buffer 5 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	4.7	0.4	0.2	4.3	6.5
Resident adult	0.8	0.1	0.07	2.4	2.5
Bystander child	na	na	na	na	na
Bystander adult	na	na	na	na	na

6.6.4/04 prothioconazole desthio

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
<i>Patton Alpha</i> Use 1: Field crops, Outdoor, 1 x 9.34e-05kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	0.1	8	0.008	0.08	8.1
Resident adult	0.03	2.7	0.003	0.04	2.8
Bystander child	na	na	na	na	na
Bystander adult	na	na	na	na	na
Use 1: Field crops, Outdoor, 1 x 9.34e-05kg a.s./ha Season: Not relevant, Buffer 5 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	0.08	8	0.003	0.08	8.1
Resident adult	0.02	2.7	0.001	0.04	2.7
Bystander child	na	na	na	na	na
Bystander adult	na	na	na	na	na

6.6.4/05 Combined Exposure (Hazard Indexes, HI)

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
<i>Patton Alpha</i> Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as HI (sum of hazard quotients) for short term (residents) or acute (bystanders) exposure					
Resident child	0.2	0.09	0.01	0.1	0.3
Resident adult	0.04	0.03	0.005	0.06	0.1
Bystander child	0	0	0	0	

Bystander adult	0	0	0	0	
<i>Use 1: Field crops, Outdoor, 1 x 0.16kg a.s./ha</i> <i>Season: Not relevant, Buffer 5 m, Drift reduction 0 %</i> <i>Model: EFSA Opex (v1.1.1) results expressed as HI (sum of hazard quotients) for short term (residents) or acute (bystanders) exposure</i>					
Resident child	0.1	0.09	0.004	0.1	0.2
Resident adult	0.02	0.03	0.002	0.06	0.09
Bystander child	0	0	0	0	
Bystander adult	0	0	0	0	

Measurement of resident and/or bystander exposure (RMM)

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary

Final conclusion:

NDE assessment for operator, workers and B&R has been calculated using the EFSA calculator, on-line version 1.1.1 (2025) considering the worst-case exposure scenario to cover all the intended uses (highest application rate per application as well as the highest application rate per year with the shorter interval between each application). All NDE calculations provided for operator, workers and B&R resulting from use of PPP, considering all tasks according to the critical use(s), identify safe use of the product FGF1.

Updated by the Applicant

Taking the approach presented by zRMS in table above it is acknowledged that risk assessments have been presented with EFSA default values which is very conservative approach. In addition, as it is presented here below and accepted with zRMS, applicant has presented own dermal absorption studies which could lead to more realistic approach and therefore here applicant has presented table with input data and risk assessments results by taking into consideration zRMS approach of 50% conversion prothioconazole into prothioconazole-desthio and new dermal absorption studies which are in detailed presented in point 6.5.3 and Appendix 2 of this dossier.

The exposure to Prothioconazole-desthio was estimated assuming as proposed by zRMS that there is 50% conversion from the parent Prothioconazole to the metabolite prothioconazole-desthio during mixing with water. Dermal absorption of prothioconazole-desthio during mixing and loading was assumed to be 10% as a worst case scenario and during application 10%.

Product name and code	Azoxystrobin 160 + Prothioconazole g/L 200 SC / FGF11		
Formulation type	Soluble concentrate [SC]		
Category	Fungicide		
Active substance(s) (incl. content)	Azoxystrobin 160 g/L	Prothioconazole 103 g/L(*)	Prothioconazole-desthio 93.4 g/L(*)
AOEL systemic	0.2 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
AAOEL systemic	Not relevant	Not relevant	Not relevant
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	100%
Dermal absorption (update)	Concentrate: 0.48 Dilution (1.6): 1.9% Dilution (0.4): 3.5%	Concentrate: 10% Dilution: 50% (Default)	Concentrate: 10% Dilution (0.5 g/L): 10%

6.6.2 Operator

6.6.2/01 azoxystrobin

Application method	PPE/RPE*	%AOEL	%AAOEL
patton alpha			
Use 1: Field crops, Outdoor, 1 x 0.1658kg a.s./ha, 100-400 L water/ha			
Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	1.7	

6.6.2/02 prothioconazole

Application method	PPE/RPE*	%AOEL	%AAOEL
patton alpha			
Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha, 100-400 L water/ha			
Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	23.1	

6.6.2/03 prothioconazole-desthio

Application method	PPE/RPE*	%AOEL	%AAOEL
patton alpha			
Use 1: Field crops, Outdoor, 1 x 0.0934kg a.s./ha, 100-400 L water/ha			
Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	397	
	ML: Workwear + Gloves; AP: Workwear	36.1	

6.6.2/04 Combined exposure (Hazard Indexes, HI)

Application method	PPE/RPE*	HI (short term)	HI (acute)
patton alpha			
Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha, 100-400 L water/ha			
Model: EFSA Opex (v1.1.1) results expressed as HI (sum of hazard quotients) for short term or acute exposure			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	4.2	
	ML: Workwear + Gloves	0.4	
	AP: Workwear		

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.

6.6.3 Worker

6.6.3/01 azoxystrobin

Re-entry task	PPE	%AOEL
patton alpha		
Use 1: Field crops, Outdoor, 1 x 0.1658kg a.s./ha, 100-400 L water/ha		
Model: EFSA Opex (v1.1.1) exposure estimates as % of AOEL (short term exposure)		
Inspection, irrigation	Workwear	0.4

6.6.3/02 prothioconazole

Re-entry task	PPE	%AOEL
patton alpha		
Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha, 100-400 L water/ha		
Model: EFSA Opex (v1.1.1) exposure estimates as % of AOEL (short term exposure)		
Inspection, irrigation	Workwear	3.6

6.6.3/03 prothioconazole-desthio

Re-entry task	PPE	%AOEL
patton alpha		
Use 1: Field crops, Outdoor, 1 x 0.0934kg a.s./ha, 100-400 L water/ha		
Model: EFSA Opex (v1.1.1) exposure estimates as % of AOEL (short term exposure)		
Inspection, irrigation	Workwear	28

6.6.3/04 Combined Exposure (Hazard Indexes, HI)

Re-entry task	PPE	HI (short term)
patton alpha Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha, 100-400 L water/ha Model: EFSA Opex (v1.1.1) exposure estimates as HI (sum of hazard quotients) for short term exposure		
Inspection, irrigation	Workwear	0.3

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.

6.6.4 Resident and Bystander

6.6.4/01 azoxystrobin

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
patton alpha Use 1: Field crops, Outdoor, 1 x 0.1658kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	0.8	7e-06	0.1	0.5	0.9
Resident adult	0.2	2e-06	0.02	0.3	0.3
Bystander child					
Bystander adult					

6.6.4/02 prothioconazole

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
patton alpha Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	7	0.02	0.4	4.3	7.6
Resident adult	1.7	0.008	0.2	2.4	2.8
Bystander child					
Bystander adult					

6.6.4/03 prothioconazole-desthio

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
patton alpha Use 1: Field crops, Outdoor, 1 x 0.0934kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)					
Resident child	54.3	0.4	3.7	33.8	59.6
Resident adult	12.9	0.1	1.4	18.8	22.1
Bystander child					
Bystander adult					

6.4.4/04 Combined Exposure (Hazard Indexes, HI)

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
patton alpha Use 1: Field crops, Outdoor, 1 x 0.103kg a.s./ha Season: Not relevant, Buffer 2-3 m, Drift reduction 0 % Model: EFSA Opex (v1.1.1) results expressed as HI (sum of hazard quotients) for short term (residents) or acute (bystanders) exposure					
Resident child	0.6	0.004	0.04	0.4	0.7
Resident adult	0.1	0.001	0.02	0.2	0.3
Bystander child	0	0	0	0	
Bystander adult	0	0	0	0	

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

Product name and code	Azoxystrobin 160 + Prothioconazole g/L 200 SC / FGF11		
Formulation type	Soluble concentrate [SC]		
Category	Fungicide		
Active substance(s) (incl. content)	Azoxystrobin 160 g/L (technical: 165.8 g/L)	Prothioconazole 200 g/L (technical: 206.2 g/L)	Prothioconazole-desthio Spray dilution 1.87 – 0.47 g/L (assuming a 1:1 conversion rate from prothioconazole)
AOEL systemic	0.2 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
AAOEL systemic	Not relevant	Not relevant	Not relevant
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	100%
Dermal absorption (update)	Concentrate: 10% Dilution: 50% (Default)	Concentrate: 10% Dilution: 50% (Default)	Concentrate: 0% Not relevant Dilution: 50% (Default)

zRMS Reviewer comment: in the **table 6.6-1 (see below)** updated by the applicant, there is summary of newly provided DABs *in vitro* studies reflecting absorption of active substances in FGF11. Provided data are valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Updated by the applicant, new data has been bolded by the zRMS

Table 6.6-2: Product information and toxicological reference values used for exposure assessment

Product name and code	Azoxystrobin 160 + Prothioconazole g/L 200 SC / FGF11		
Formulation type	Soluble concentrate [SC]		
Category	Fungicide		
Active substance(s) (incl. content)	Azoxystrobin 160 g/L (technical: 165.8 g/L)	Prothioconazole 200 g/L (technical: 206.2 g/L)	Prothioconazole-desthio Spray dilution 1.87 - 0.47 g/L (assuming a 1:1 conversion rate from prothioconazole)
AOEL systemic	0.2 mg/kg bw/d	0.2 mg/kg bw/d	0.01 mg/kg bw/d
AAOEL systemic	Not relevant	Not relevant	Not relevant
Inhalation absorption	100%	100%	100%
Oral absorption	100%	100%	100%
Dermal absorption (update)	Concentrate: 0.48 % Dilution 1: 1.6 g/L (1:100): 1.9% Dilution 2: 0.4 g/L (1:400): 3.5%	Concentrate: 10% Dilution: 50% (Default)	Concentrate: not applicable Dilution 1: 2.0 g/L (1:100): 4.2% Dilution 2: 0.5 g/L (1:400): 10%

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-5. A list of all intended uses within the southern zone is given in Part B, Section 0.

Justification

The use in cereals is therefore the critical use selected for the exposure assessment.

- Cereals (field crops) 1 application x 1 L product/ha in 100-400 L water/ha

The highest application rate of FGF11 applies leads to a higher exposure for operators, workers and residents.

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 FGF11 according to the critical use(s) is presented in Table 6.6-3. The outcome of the estimation is presented in

Table 6.6-4 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-3: Exposure models for intended uses

Critical use(s)	Cereals: max 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 2022;20(1):7032 calculator version: 1.0.2

Table 6.6-4: Estimated operator exposure (longer term 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-field-crops							
Application rate		0.1658 kg as/ha		0.2062 kg as/ha		0.187 kg a.s./ha**	
Body weight: 60 kg	Work-wear (arms, body and legs covered) M/L and A	0.06	32.2	0.08	37.6	0.01	122
	Work-wear (arms, body and legs covered) M/L and A + gloves during M/L	0.003	1.6	0.003	1.8	0.002	18.5 [#]

* Exposure only relevant for in-use dilution during application

** 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.

[#] Wearing gloves at M&L is not relevant for prothioconazole-desthio, as only formed after M&L, during spray application.

The potential total systemic exposure of the operator, wearing workwear covering the body, arms and legs and gloves, at mixing and loading and during application, corresponds to 1.6% of the AOEL for azoxystrobin, 1.8% of the AOEL for prothioconazole and 18.5% of the AOEL for prothioconazole-desthio, regarding the critical use in cereals during tractor mounted application. Since prothioconazole-desthio is formed only after mixing and loading, gloves should be worn only during the application phase.

zRMS Reviewer comment regarding point 6.6.2 updated by the applicant (for details see Appendix 5 to this dRR). There is summary of newly provided NDE assessment which took into account new DABs *in vitro* studies reflecting absorption of active substances in FGF11 also conversion factor PTZ to PTZ-desthio 100%. zRMS is in the position that for refinement as second step we consider agreed by the PPR meeting TC 22 (2020 EFSA) reduced conversion factor PTZ to PTZ-desthio. Therefore, provided NDE assessment for operator is valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Updated by the applicant

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Cereals: max 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 2022;20(1):7032 calculator version: 1.1.1

Table 6.6-6: Estimated operator exposure (longer term 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 field crops							
Application rate		0.1658 kg as/ha		0.2062 kg as/ha		0.187 kg a.s./ha**	
Body weight: 60 kg	Potential exposure	0.005	2.6	0.1	58	0.004	41
	Work wear (arms, body and legs covered) M/L and A	0.003	1.7	0.08	37.6	0.003	27.5

* Exposure only relevant for in-use dilution during application

** 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.

The potential total systemic exposure of the operator, wearing workwear covering the body, arms and legs, at mixing and loading and during application, corresponds to 1.7% of the AOEL for azoxystrobin, 37.6% of the AOEL for prothioconazole and 27.5% of the AOEL for prothioconazole-desthio, regarding the critical use in cereals during tractor mounted application.

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6 44 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with FGF11 according to the critical use(s). Outcome of the estimation is presented in Table 6.6 5 (acute exposure) and Table 6.6 6 (longer term exposure). Detailed

calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Cereals: max. 1 appl. 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 2022;20(1):7032 calculator version: 1.0.2

Table 6.6-5: Estimated worker exposure (acute exposure)

According to the EFSA exposure guidance (EFSA Journal 2022;20(1):7032, 7 pp.,) for PPPs that are acutely toxic an acute worker exposure assessment is in principle needed, but in the current guidance insufficient data are available to perform it.

Table 6.6-6: Estimated worker exposure (longer term 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 L product/ha Interval between treatments: NA							
Number of applications and application rate		1 × 0.1658 kg a.s./ha		1 × 0.2062 kg a.s./ha		1 × 0.187* kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.1	51.8	0.1	64.4	0.1	1169
	No PPE: Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.01	5.8	0.01	7.2	0.01	131
	PPE: Work wear (arms, body and legs covered) + gloves TC: 1250 cm ² /person/h	0.01	5.2	0.01	6.4	0.01	117 (7) [#]

*: 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

TC: Transfer coefficient

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

PPE: type of PPE / see 'Instructions for use'

[#]: re-entry period (days)

The potential total systemic exposure of the operator, wearing workwear covering the body, arms and legs and gloves, during irrigation and inspection, corresponds to 5.2% of the AOEL for azoxystrobin, 6.4% of the AOEL for prothioconazole and 117% of the AOEL for prothioconazole-desthio, regarding the critical use in cereals during tractor mounted application.

Therefore, it is concluded that there is an acceptable risk for workers, when re-entering into the crops after 7 days using workwear and gloves.

zRMS Reviewer comment regarding point 6.6.3 updated by the applicant (for details see Appendix 5 to this dRR). There is summary of newly provided NDE assessment which took into account new DABs *in vitro* studies reflecting absorption of active substances in FGF11 also conversion factor PTZ to PTZ-desthio 100%. zRMS is in the position that for refinement as second step we consider agreed by the PPR meeting TC 22 (2020 EFSA) reduced conversion factor PTZ to PTZ-desthio. Therefore, provided NDE assessment for worker is valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Updated by the applicant

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Cereals: max. 1 appl. 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 2022;20(1):7032 calculator version: 1.1.1

Table 6.6-6: Estimated worker exposure (longer term 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 L product/ha Interval between treatments: NA							
Number of applications and application rate		1 × 0.1658 kg a.s./ha		1 × 0.2062 kg a.s./ha		1 × 0.187* kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.007	3.7	0.1	64.6	0.03	250
	No PPE: Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0008	0.4	0.01	7.2	0.003	28
	PPE: Work wear (arms, body and legs covered) + gloves TC: 1250 cm ² /person/h	0.0007	0.4	0.01	6.5	0.003	25

* 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

TC: Transfer coefficient

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

PPE: type of PPE / see 'Instructions for use'

re-entry period (days)

The potential total systemic exposure of the operator, wearing workwear covering the body, arms and legs, during irrigation and inspection, corresponds to 0.4% of the AOEL for azoxystrobin, 7.2% of the AOEL for prothioconazole and 28% of the AOEL for prothioconazole-desthio.

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.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6.7 shows the exposure model(s) used for estimation of bystander and resident exposure azoxystrobin, prothioconazole and prothioconazole desethio. Outcome of the estimation is presented in Table 6.6.8. Detailed calculations are in Appendix 3.

Table 6.6.7: Exposure models for intended uses

Critical use(s)	Cereals: max. 1 appl. 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 2022;20(1):7032 calculator version: 1.0.2

Table 6.6.8: Estimated resident exposure (longer term exposure)

		Azoxystrobin		Prothioconazole		Prothioconazole desethio	
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 field crops Buffer zone: 2-3 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: NA							
Number of applications and application rate		1 × 0.1658 kg a.s./ha		1 × 0.2062 kg a.s./ha		1 × 0.187* kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.02	11.2	0.03	14	0.03	253
	Vapour (75 th perc.)	1e-08	7e-06	5e-05	0.02	5e-05	0.5
	Deposits (75 th perc.)	0.001	0.7	0.002	0.8	0.002	15.1
	Re-entry (75 th perc.)	0.01	7	0.02	8.7	0.02	158
	All pathways	0.02	12.2	0.03	15.2	0.03	276

		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
	(mean)						
Resident adult Body weight: 60 kg	Drift (75 th -perc.)	0.005	2.7	0.007	3.3	0.006	60.1
	Vapour (75 th -perc.)	5e-09	2e-06	2e-05	0.008	2e-05	0.2
	Deposits (75 th -perc.)	0.0006	0.3	0.0007	0.4	0.0006	6.4
	Re-entry (75 th -perc.)	0.008	3.9	0.01	4.8	0.009	87.7
	All pathways (mean)	0.009	4.6	0.01	5.7	0.01	103
Tractor mounted boom spray application outdoors to field crops Buffer zone: 10 m Drift reduction technology: 50% DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: NA							
Number of applications and application rate		1 × 0.1658 kg a.s./ha		1 × 0.2062 kg a.s./ha		1 × 0.187* kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th -perc.)	0.006	3.1	0.008	3.8	0.007	69.1
	Vapour (75 th -perc.)	1e-08	7e-06	5e-05	0.02	5e-05	0.5
	Deposits (75 th -perc.)	0.0002	0.08	0.0002	0.1	0.0002	1.8
	Re-entry (75 th -perc.)	0.01	7	0.02	8.7	0.02	158
	All pathways (mean)	0.01	7.3	0.02	9.2	0.02	166
Resident adult Body weight: 60 kg	Drift (75 th -perc.)	0.001	0.6	0.001	0.7	0.001	12.8
	Vapour (75 th -perc.)	5e-09	2e-06	2e-05	0.008	2e-05	0.2
	Deposits (75 th -perc.)	7e-05	0.03	8e-05	0.04	7e-05	0.7
	Re-entry (75 th -perc.)	0.008	3.9	0.01	4.8	0.009	87.7
	All pathways (mean)	0.007	3.4	0.009	4.3	0.008	77.7

* 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

For residents, the exposure estimates to one application of azoxystrobin (adults 4.6% AOEL, children 12.2% AOEL), prothioconazole (adults 5.7% AOEL, children 15.2% AOEL) result in values that are lower than the respective AOEL values. However, exposure to prothioconazole-desthio results in values that are higher than the respective AOEL value for children (276% AOEL) and adult (103% AOEL) and a higher value for children only (166% AOEL) when RMM are applied (i.e., 10 m buffer zone and spray drift), while a lower value is estimated for adults (77.7% AOEL).

In order to prepare refinement, applicant would like to inform that dermal absorption study on FGF11 formulation is currently ongoing and will be delivered upon completion.

zRMS Reviewer comment regarding point 6.6.4 updated by the applicant (for details see Appendix 5 to this dRR). There is summary of newly provided NDE assessment which took into account new DABs *in vitro* studies reflecting absorption of active substances in FGF11 also conversion factor PTZ to PTZ-desthio 100%. zRMS is in the position that for refinement as second step we consider agreed by the PPR meeting TC 22 (2020 EFSA) reduced conversion factor PTZ to PTZ-desthio. Therefore, provided NDE assessment for resident and bystander exposure is valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.

Updated by the applicant

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

		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 field crops Buffer zone: 2-3 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: NA							
Number of applications and application rate		1 × 0.1658 kg a.s./ha		1 × 0.2062 kg a.s./ha		1 × 0.187* kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.002	0.8	0.03	14	0.005	54.4
	Vapour (75 th perc.)	1e-08	7e-06	5e-05	0.02	4e-05	0.4
	Deposits (75 th perc.)	0.0002	0.1	0.002	0.8	0.0004	4.4
	Re-entry (75 th perc.)	0.001	0.5	0.02	8.7	0.003	33.8
	All pathways (mean)	0.002	0.9	0.03	15.2	0.006	60.3
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0004	0.2	0.007	3.3	0.001	12.9
	Vapour (75 th perc.)	5e-09	2e-06	2e-05	0.008	1e-05	0.1
	Deposits (75 th perc.)	4e-05	0.02	0.0007	0.4	0.0001	.14
	Re-entry (75 th perc.)	0.0006	0.3	0.01	4.8	0.002	18.8
	All pathways (mean)	0.0007	0.3	0.01	5.7	0.002	22.1

* 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

For residents, the exposure estimates to one application of azoxystrobin (adults 0.3% AOEL, children 0.9% AOEL), prothioconazole (adults 5.7% AOEL, children 15.2% AOEL) and prothioconazole-desthio (adults 22.1% AOEL, children 60.3% AOEL).

6.6.4.2 Measurement of resident and/or bystander exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for prothioconazole-desthio will be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a refinement is considered necessary.

6.6.5 Combined exposure

The product is a mixture of two active substances azoxystrobin and prothioconazole. However, the prothioconazole metabolite, prothioconazole-desthio, was identified to be relevant for the human health risk assessment of FGF11. Since a conversion rate of 100% from prothioconazole to prothioconazole-desthio is considered in the risk assessment, exposure can only occur towards either the active substance or the metabolite. Thus, two separate combined exposure assessment have been performed, one combined exposure assessment for azoxystrobin and prothioconazole and one assessment for azoxystrobin and prothioconazole-desthio.

Additionally, no combined acute exposure assessment for operators or bystander is required as no AAOELs have been set.

6.6.5.1 Exposure assessment of Azoxystrobin and Prothioconazole or Azoxystrobin and Prothioconazole-desthio in FGF11

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

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 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-9: Risk assessment from combined exposure (long term exposure) of azoxystrobin and prothioconazole

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – Tractor-mounted boom spray application outdoors to field crops. Work wear (arms, body and legs covered) M/L and A	Azoxystrobin	0.32
	Prothioconazole	0.38
	Cumulative risk operators (HI)	0.7
Workers – Inspection, irrigation. Work wear – arms body and legs covered	Azoxystrobin	0.06
	Prothioconazole	0.07
	Cumulative risk workers (HI)	0.13
Resident – child – Buffer zone 2-3 m)	Azoxystrobin	
	Drift	0.1
	Vapour	7e-06
	Deposits	0.007
	Re-entry	0.07
	Sum of all pathways	0.12
	Prothioconazole	
	Drift	0.14
	Vapour	0.0002
	Deposits	0.008
	Re-entry	0.09
	Sum of all pathways	0.15
	Cumulative risk resident – child (HI)	
	Drift	0.3

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.0002
	Deposits	0.02
	Re-entry	0.2
	Sum of all pathways	0.3
Resident—adult—Buffer zone 2-3 m)	Azoxystrobin	
	Drift	0.03
	Vapour	2e-08
	Deposits	0.003
	Re-entry	0.039
	Sum of all pathways	0.05
	Prothioconazole	
	Drift	0.03
	Vapour	0.00008
	Deposits	0.004
	Re-entry	0.05
	Sum of all pathways	0.06
	Cumulative risk resident—adult (HI)	
	Drift	0.06
	Vapour	8e-05
	Deposits	0.006
	Re-entry	0.09
	Sum of all pathways	0.1
Resident—child—Buffer zone 10 m and drift reduction)	Azoxystrobin	
	Drift	2.7
	Vapour	7e-06
	Deposits	0.07
	Re-entry	6.1
	Sum of all pathways	6.4
	Prothioconazole	
	Drift	0.5
	Vapour	2e-06
	Deposits	0.03
	Re-entry	3.4
	Sum of all pathways	3
	Cumulative risk resident—child (HI)	
	Drift	0.07
	Vapour	0.0002
	Deposits	0.002
	Re-entry	0.2
	Sum of all pathways	0.2

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Resident—adult—Buffer zone 10 m and drift reduction)	Azoxystrobin	
	Drift	0.006
	Vapour	2e-08
	Deposits	0.0003
	Re-entry	0.04
	Sum of all pathways	0.034
	Prothioconazole	
	Drift	0.007
	Vapour	0.00008
	Deposits	0.0004
	Re-entry	0.05
	Sum of all pathways	0.05
	Cumulative risk resident—adult (HI)	
	Drift	0.01
	Vapour	8e-05
	Deposits	0.0007
	Re-entry	0.09
	Sum of all pathways	0.08

The Hazard Index of azoxystrobin and prothioconazole is < 1. Thus, combined exposure to azoxystrobin and prothioconazole in FGF11 is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

Table 6.6 7: Risk assessment from combined exposure (longer term exposure) of azoxystrobin and prothioconazole-desthio

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators—Tractor-mounted boom spray application outdoors to field crops. Work wear (arms, body and legs covered) M/L and A	Azoxystrobin	0.32
	Prothioconazole-desthio	1.22
	Cumulative risk operators (HI)	1.5
Operators—Tractor-mounted boom spray application outdoors to field crops. Work wear (arms, body and legs covered) M/L and A and gloves during A	Azoxystrobin	0.02
	Prothioconazole-desthio	0.19
	Cumulative risk operators (HI)	0.21
Workers—Inspection, irrigation. Work wear—arms body and legs covered	Azoxystrobin	0.072
	Prothioconazole-desthio	1.31
	Cumulative risk workers (HI)	1.4 (14)[#]
Workers—Inspection, irrigation. Work wear—arms body and legs covered and gloves	Azoxystrobin	0.06
	Prothioconazole-desthio	1.17
	Cumulative risk workers (HI)	1.2 (9)[#]
Resident—child—Buffer zone 2-3)	Azoxystrobin	
	Drift	0.11
	Vapour	7e-08

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Deposits	0.007
	Re-entry	0.07
	Sum of all pathways	0.12
	Prothioconazole-desthio	
	Drift	2.53
	Vapour	0.005
	Deposits	0.15
	Re-entry	1.58
	Sum of all pathways	2.76
	Cumulative risk resident – child (HI)	
	Drift	2.6
	Vapour	0.005
	Deposits	0.2
	Re-entry	1.6
	Sum of all pathways	2.9
Resident – adult – Buffer zone 2-3)	Azoxystrobin	
	Drift	0.027
	Vapour	2e-08
	Deposits	0.003
	Re-entry	0.04
	Sum of all pathways	0.05
	Prothioconazole-desthio	
	Drift	0.60
	Vapour	0.002
	Deposits	0.064
	Re-entry	0.88
	Sum of all pathways	1.03
	Cumulative risk resident – adult (HI)	
	Drift	0.6
	Vapour	0.002
	Deposits	0.07
	Re-entry	0.9
	Sum of all pathways	1.1
Resident – child – Buffer zone 10 m and drift reduction)	Azoxystrobin	
	Drift	0.03
	Vapour	7e-08
	Deposits	0.0008
	Re-entry	0.07
	Sum of all pathways	0.073
	Prothioconazole-desthio	
	Drift	0.69

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.005
	Deposits	0.01
	Re-entry	1.58
	Sum of all pathways	1.66
	Cumulative risk resident—child (HI)	
	Drift	0.7
	Vapour	0.005
	Deposits	0.02
	Re-entry	1.6
	Sum of all pathways	1.7
Resident—adult—Buffer zone 10 and drift reduction)	Azoxystrobin	
	Drift	0.006
	Vapour	2e-08
	Deposits	0.0003
	Re-entry	0.04
	Sum of all pathways	0.034
	Prothioconazole-desthio	
	Drift	0.13
	Vapour	0.002
	Deposits	0.007
	Re-entry	0.88
	Sum of all pathways	0.78
	Cumulative risk resident—adult (HI)	
	Drift	0.1
	Vapour	0.002
	Deposits	0.008
	Re-entry	0.9
	Sum of all pathways	0.8

The Hazard Index for azoxystrobin and prothioconazole-desthio is > 1 for resident exposure. In order to prepare refinement, applicant would like to inform that dermal absorption study on FGF11 formulation is currently ongoing and will be delivered upon completion.

zRMS Reviewer comment regarding point 6.6.5 (combined exposure) updated by the applicant (for details see Appendix 5 to this dRR). There is summary of newly provided combined exposure assessment which took into account new DABs *in vitro* studies reflecting absorption of active substances in FGF11, conversion factor PTZ to PTZ-desthio 100% and also relevant PPE/RMM. zRMS is in the position that for refinement as second step we consider agreed by the PPR meeting TC 22 (2020 EFSA) reduced conversion factor PTZ to PTZ-desthio. Therefore, provided assessment for combined exposure is valid but not considered by the zRMS for the current risk assessment (combined exposure). Default values according to the EFSA Guidance on dermal absorption has been also maintained by the zRMS for this registration.

Updated by the applicant

Table 6.6-9: Risk assessment from combined exposure (long term exposure) of azoxystrobin and prothioconazole

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – Tractor mounted boom spray application outdoors to field crops. Work wear (arms, body and legs covered) M/L and A	Azoxystrobin	0.02
	Prothioconazole	0.38
	Cumulative risk operators (HI)	0.4
Workers – Inspection, irrigation. Work wear – arms body and legs covered	Azoxystrobin	0.004
	Prothioconazole	0.07
	Cumulative risk workers (HI)	0.08
Resident – child – Buffer zone 2-3 m)	Azoxystrobin	
	Drift	0.08
	Vapour	8e-06
	Deposits	0.01
	Re-entry	0.05
	Sum of all pathways	0.09
	Prothioconazole	
	Drift	0.14
	Vapour	0.0002
	Deposits	0.008
	Re-entry	0.09
	Sum of all pathways	0.15
	Cumulative risk resident – child (HI)	
	Drift	0.1
	Vapour	0.0002
	Deposits	0.009
	Re-entry	0.09
	Sum of all pathways	0.2
Resident – adult – Buffer zone 2-3 m)	Azoxystrobin	
	Drift	0.02
	Vapour	3e-06
	Deposits	0.002
	Re-entry	0.03
	Sum of all pathways	0.03
	Prothioconazole	
	Drift	0.03
	Vapour	0.00008
	Deposits	0.004
	Re-entry	0.05
	Sum of all pathways	0.06
	Cumulative risk resident – adult (HI)	
	Drift	0.04
	Vapour	8e-05

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Deposits	0.004
	Re-entry	0.05
	Sum of all pathways	0.06

The Hazard Index of azoxystrobin and prothioconazole is < 1. Thus, combined exposure to azoxystrobin and prothioconazole in FGF11 is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

Table 6.6-8: Risk assessment from combined exposure (longer term exposure) of azoxystrobin and prothioconazole-desthio

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – Tractor mounted boom spray application outdoors to field crops. Work wear (arms, body and legs covered) M/L and A	Azoxystrobin	0.02
	Prothioconazole-desthio	0.28
	Cumulative risk operators (HI)	0.3
Workers – Inspection, irrigation. Work wear – arms body and legs covered	Azoxystrobin	0.004
	Prothioconazole-desthio	0.28
	Cumulative risk workers (HI)	0.3
Resident – child – Buffer zone 2-3)	Azoxystrobin	
	Drift	0.08
	Vapour	8e-06
	Deposits	0.01
	Re-entry	0.05
	Sum of all pathways	0.09
	Prothioconazole-desthio	
	Drift	0.544
	Vapour	0.004
	Deposits	0.044
	Re-entry	0.338
	Sum of all pathways	0.603
	Cumulative risk resident – child (HI)	
	Drift	0.6
	Vapour	0.004
	Deposits	0.05
	Re-entry	0.3
	Sum of all pathways	0.6
Resident – adult – Buffer zone 2-3)	Azoxystrobin	
	Drift	0.02
	Vapour	3e-06
	Deposits	0.002
	Re-entry	0.03
	Sum of all pathways	0.03
	Prothioconazole-desthio	

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Drift	0.129
	Vapour	0.001
	Deposits	0.014
	Re-entry	0.188
	Sum of all pathways	0.221
	Cumulative risk resident – adult (HI)	
	Drift	0.1
	Vapour	0.001
	Deposits	0.01
	Re-entry	0.2
	Sum of all pathways	0.2

The Hazard Index of azoxystrobin and prothioconazole-desthio is < 1. Thus, combined exposure to azoxystrobin and prothioconazole-desthio in FGF11 is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on (zRMS: updated data provided by the applicant has been bolded)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2/01a KCP 7.2/01b	EFSA OPEX	2024	Exposure assessment for operator, worker, resident and bystander: product FGF11 (azoxystrobin and prothioconazole) EFSA Online OPEX calculator v.1.0.2 non GLP Unpublished	N	UPL
KCP 7.2/02a KCP 7.2/02b	EFSA OPEX	2024	Exposure assessment for operator, worker, resident and bystander: product FGF11 (azoxystrobin and prothioconazole-desthio) EFSA Online OPEX calculator v.1.0.2 non GLP Unpublished	N	UPL
KCP 7.2/01a KCP 7.2/01b	EFSA OPEX	2024	Exposure assessment for operator, worker, resident and bystander: product FGF11 (azoxystrobin and prothioconazole-desthio) EFSA Online OPEX calculator v.1.1.1 non GLP; Unpublished	N	UPL
KCP 7.2/02a KCP 7.2/02b	EFSA OPEX	2024	Exposure assessment for operator, worker, resident and bystander: product FGF11 (azoxystrobin and prothioconazole) EFSA Online OPEX calculator v.1.1.1 non GLP; Unpublished	N	UPL
KCP 7.3 -01	Desai, K.R.	2024a	Azoxystrobin 160 G/L + Prothioconazole 200 G/L Sc: In Vitro Dermal Absorption Of Azoxystrobin Using Human Split-thickness Skin In A Flow Through Diffusion System Company Report UPL/2024/1335 JAI RESEARCH FOUNDATION GLP; Unpublished	N	UPL
KCP 7.3 -02	Desai, K.R.	2024b	Azoxystrobin 160 g/L+ Prothioconazole 200 g/L SC: In Vitro Dermal Absorption of Prothioconazole-desthio Using Human Split-Thickness Skin In A Flow Through Diffusion System Company Report UPL/2024/1442 JAI RESEARCH FOUNDATION GLP; Unpublished	N	UPL

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
-	-	-	-	-	-

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Bridging is not applicable. Hazard classification via the application of bridging principles is not possible since data on a similar mixture are not available.
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No bridging performed. The classification of FGF11 has been determined by calculation. The assessment of all acute toxicological properties of FGF11 are derived from the classification of the active substances and co-formulants. For confidentiality reasons, the detailed calculations and information on co-formulants have been included in Part C of the dRR.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Hazard assessment and proposed classification of the product based on content of ingredients of the mixture has been accepted (for details see Part C).
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In the absence of experimentally derived acute oral toxicity data for FGF11 the Additivity Formula outlined in the CLP Regulation (EC) No 1272/2008 (point 3.1.3.6.1) may be used to classify a mixture based on acute toxicity estimates (ATE) or converted ATE (cATE) for each ingredient.

Methods

According to CLP Regulation (point 3.1.3.3.c), if the converted acute toxicity point estimates for all relevant ingredients of a mixture are within the same category, then the mixture should be classified in that category.

Results and discussions

Neither azoxystrobin nor prothioconazole nor relevant co-formulants are classified for acute oral toxicity, FGF11 does not meet the criteria to be classified for acute oral toxicity according to Regulation (EC) No 1272/2008.

Conclusion

The oral LD₅₀ of FGF11 is estimated to be higher than 2000 mg/kg bw. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

Comments of zRMS:	Hazard assessment and proposed classification of the product based on content of ingredients of the mixture has been accepted (for details see Part C).
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In the absence of experimentally derived acute dermal toxicity data for FGF11 the Additivity Formula outlined in the CLP Regulation (EC) No 1272/2008 (point 3.1.3.6.1) may be used to classify a mixture based on acute toxicity estimates (ATE) or converted ATE (cATE) for each ingredient.

Methods

According to CLP regulation point 3.1.3.3:

If the converted acute toxicity point estimates for all components of a mixture are within the same category, then the mixture should be classified in that category.

Results and discussions

Neither the active substance azoxystrobin nor the active substance Prothioconazole nor relevant co-formulants are classified for acute dermal toxicity. FGF11 does not meet the criteria to be classified for acute dermal toxicity according to Regulation (EC) No 1272/2008.

Conclusion

The dermal LD₅₀ of FGF11 is estimated to be higher than 2000 mg/kg bw. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Hazard assessment and proposed classification of the product based on content of ingredients of the mixture has been accepted (for details see Part C).
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In the absence of experimentally derived acute inhalation toxicity data for FGF11, the Additivity Formula outlined in the CLP Regulation (EC) No 1272/2008 (point 3.1.3.6.1) may be used to classify a mixture based on acute toxicity estimates (ATE) or converted ATE (cATE) for each ingredient.

Methods

According to CLP regulation point 3.1.3.6.1:

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Inhalation Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

Where:

C_i= concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n= the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i.

Results and discussions

The active substance azoxystrobin is classified for acute inhalation toxicity Category 3; H331 Toxic if inhaled. Additionally, one co-formulant is classified for acute inhalation toxicity.

Therefore, the ATE_{mix} of FGF11 is calculated using the following formula:

$$\frac{100}{ATE_{mix}} = \frac{C_{Azoxystrobin}}{ATE_{Azoxystrobin}} (=) ATE_{mix} = 4.00 \text{ mg/L}$$

Where:

C_{Azoxystrobin} = 14.55%,

ATE_{Azoxystrobin} = 0.7 mg/L is used for the calculation according to EFSA conclusion⁴ and RAC opinion⁵

⁴ Peer Review of the pesticide risk assessment of the active substance Azoxystrobin, EFSA Journal 2010; 8(4):1542

⁵ Committee for Risk Assessment RAC Opinion proposing harmonized classification and labelling at EU level of Azoxystrobin CLH-O-0000001412-86-206/F adopted in 2018

Conclusion

The inhalation LC₅₀ of FGF11 is calculated as 4.00 mg/L air. Thus, classification as Acute Inhalation Toxicity cat. 4 (H332) is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Hazard assessment and proposed classification of the product based on content of ingredients of the mixture has been accepted (for details see Part C).
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In the absence of experimentally derived skin irritation/corrosion data for FGF11, the Additivity Formula outlined in the CLP Regulation (EC) No 1272/2008 (point 3.4.3.2) may be used to classify a mixture based on the data available for each ingredient.

Materials and methods

A mixture shall be classified for skin corrosion when the sum of the ingredient that has been classified for skin corrosion is at or above the appropriate generic or specific concentration limit as shown in Table 3.2.3 where the additivity approach applies, or in Table 3.2.4 when the additivity approach does not apply.

Results and discussions

Neither the active substance azoxystrobin nor the active substance prothioconazole are classified for skin irritation/corrosion. However, one co-formulant is classified as skin corrosive. According to the CLP Regulation (Table 3.2.3), as the content of the classified co-formulants is below the generic concentration limit of 1%, the mixture does not need to be classified as skin irritant.

Conclusion

Based on the criteria for mixture of the CLP Regulation, FGF11 is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Hazard assessment and proposed classification of the product based on content of ingredients of the mixture has been accepted (for details see Part C).
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In the absence of experimentally derived eye irritation/corrosion data for FGF11, the Additivity Formula outlined in the CLP Regulation (EC) No 1272/2008 (point 3.3.3) may be used to classify a mixture based on the data available for each ingredient.

Materials and methods

A mixture shall be classified for eye corrosion or eye irritation when the sum of the ingredient that has been classified for skin corrosion and eye corrosion/irritation is at or above the appropriate generic or specific concentration limit as shown in Table 3.3.3 where the additivity approach applies, or in Table 3.3.4 when the additivity approach does not apply.

Results and discussions

Neither the active substance azoxystrobin nor the active substance prothioconazole are classified for eye irritation/corrosion. However, one relevant co-formulant is classified as eye irritant. According to the CLP

Regulation (Table 3.3.3), as the content of the classified co-formulants is below the generic concentration limit of 10%, the mixture does not need to be classified as eye irritant.

Conclusion

Based on the criteria for mixture of the CLP Regulation, FGF11 is not an eye irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Hazard assessment and proposed classification of the product based on content of ingredients of the mixture has been accepted (for details see Part C). The updated regulation, „COMMISSION DELEGATED REGULATION (EU) 2024/197 of 19 October 2023 amending Regulation (EC) No 1272/2008 concerning the harmonised classification and labelling of certain substances”, has been taken into account for the purpose of verifying the proposed CLP/GHS classification of the product under evaluation
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In the absence of experimentally derived skin sensitization data for FGF11, the Additivity Formula outlined in the CLP Regulation (EC) No 1272/2008 (point 3.4.3.2) may be used to classify a mixture based on the data available for each ingredient.

Materials and methods

As no specific concentration limits applied, the generic concentration limits of components of a mixture classified as either respiratory sensitizers or skin sensitizers that trigger classification of the mixture, were used to determine the classification of the mixture.

Results and discussions

Neither the active substance azoxystrobin nor the active substance prothioconazole are classified for skin sensitization. However, one co-formulant is classified as skin sensitizer.

~~According to the CLP Regulation (Table 3.4.5), as the content of the classified co-formulant is below the generic concentration limit of 1.0%, the mixture does not need to be classified as skin sensitizer.~~

According to the CLP Regulation (Table 3.4.5), as the content of the classified co-formulant is above the specific concentration limit the mixture needs to be classified as skin sensitizer.

Conclusion

~~Based on the criteria for mixture of the CLP Regulation, FGF11 is not a skin sensitiser. Thus, no classification is required according to Regulation (EC) No. 1272/2008.~~

Based on the criteria for mixture of the CLP Regulation, FGF11 meets the criteria to be classified as Skin Sens. 1 (H317) according to Regulation (EC) No. 1272/2008.

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

Not relevant.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

~~No study performed.~~

Comments of zRMS:	Study has been performed according to OECD 428 and is considered acceptable. Provided data are scientifically valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration.
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Reference	KCP 7.3-01
Report	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC: In Vitro Dermal Absorption of Azoxystrobin using Human Split-Thickness Skin in a Flow through Diffusion System, Karishma R. Desai , 2024, year, report No 617-1-06-37463)
Guideline(s)	Yes (OECD 428)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	NR

Materials and methods

Test material	Name (Lot/Batch No.)	[C14-phenyl] Azoxystrobin
	Test preparation	Radioformulation
	Specific activity	30 mCi/mmol (1110 MBq/mmol), 74.37 μ Ci/mg
	Radiochemical purity	100%
Product	Name (Lot/Batch No.)	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC (ARD/AP/360/SC/36)
	Company code	FGF11/GPF 1021
	Concentration a.s.	Azoxystrobin: $14.45 \pm 0.014\%$ w/w or 162.20 ± 0.48 g/L
	Formulation type	SC
Blank product	Name (Lot/Batch No.)	Semi-Blank (without Azoxystrobin) (ARD/AP/360/SC/SMBLK/WOA/02)
	Concentration a.s.	Azoxystrobin: 0.0 g/kg w/w and Prothioconazole: 22.21 % w/w

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.6 ml/h
	Exposed skin area	0.64 cm ²
	Cover	open
Membrane	Skin type	dermatomed
	Skin thickness range	200-400 μ m
	Skin donors age	39 to 50
	Skin donors sex	m+f

	Location	Abdomen
	Source	ex vivo
	Integrity test	Yes - tritiated water ($\approx 0.1 \mu\text{Ci/skin membrane}$)
Receptor	Receptor medium	Dulbecco's phosphate
	Solubility in receptor medium	y
Sample Time	Exposure time	8 h $\pm$ 10 minutes
	Observation time	24 h $\pm$ 10 minutes
Sampling	Sample intervals	0 h (before exposure), 0-1 h, 1-2 h, 2-4 h, 4-6 h, 6-8 h, 8-10 h, 10-12 h, 12-14 h, 14-16 h, 16-18 h, 18-20 h, 20-22 h, and 22-24 h
Washing		post exposure & post observation
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks: NA		

Tested doses	Concentrate	Spray dilution 1	Spray dilution 2
Target concentration [mg/ml]	160	1.6	0.40
Area dose [$\mu\text{g}/\text{cm}^2$]	1600	16	4.0
Specific activity [kBq/ml]	5.8	4.4	1.1
No. of donors	4	4	4
No of cells used/valid cells*	8/8	8/8	8/8

* Justification for excluded cells, if applicable

Results and discussions

Table A 11: In-vitro dermal penetration of azoxystrobin formulated as FGF11 through human skin - Recovery data

Dose group		High dose		Mid dose		Low dose	
		(Formulation concentrate)		(Spray dilution 1:100)		(Spray dilution 1:400)	
Target concentration	[mg/mL]	160		1.6		0.40	
Target dose	[$\mu\text{g}/\text{cm}^2$]	1600		16		4.0	
Mean actual applied dose	[$\mu\text{g}/\text{cm}^2$]	1620		15.4		3.78	
		Recovery [%]		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.	Mean	S.D.
Dislodgeable dose							
e.g. Skin washing after 8 h		98.5	1.79	96.1	1.51	95.1	2.44
e.g. Skin washing after 24 h		1.49	1.10	1.01	0.477	1.82	2.24
Donor chamber wash		0.0876	0.103	0.141	0.0786	0.242	0.193
Dose associated to skin							
Tape strips: 1 st sample, strips 1 + 2		0.0499	0.0321	0.247	0.0492	0.435	0.203
Tape strips: 2 nd sample; strips 3 - n		0.134	0.0444	0.354	0.0555	0.616	0.136
Skin preparation		0.184	0.0760	0.602	0.0901	1.05	0.316
Absorbed dose							

Receptor fluid	0.193	0.0438	1.27	0.345	2.40	0.153
Receptor chamber wash	0.00929	0.00184	0.0277	0.0135	0.0762	0.0450
Total recovery¹						
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at t _{0.5}]	No (63.28%)		Yes (79.69%)		No (73.75%)	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	0.395	0.0987	NA	NA	3.34	0.231
If yes: Absorption estimates = absorbed dose + skin preparation	NA	NA	1.63	0.355	NA	NA
Absorption estimate normalised ³	NA		NA		NA	
Relevant absorption estimate ⁴	0.477		1.928		3.534	
Absorption estimates used for risk assessment⁵	0.48 %		1.9 %		3.5 %	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.21) Finally, the skin preparation is also considered potentially absorbable.

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

⁴ In accordance with the EFSA Guidance on Dermal Absorption, one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was $\geq 25\%$ of the mean value. To address variability between replicates/animals, dermal absorption should be calculated as follows (Mean value + ks; k=0.84)

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

N/A: not applicable

Remarks

N/A

Conclusion/endpoint:

The dermal penetration of azoxystrobin formulated as FGF11 through human dermatomed skin was determined in vitro. The amount of applied dose penetrating within 24 hours was determined to be 0.477 (mean $\pm$ standard deviation*k), 1.928 and 3.534 for the formulation concentrate, the 1:100 spray dilution and the 1:400 spray dilution, respectively. The dermal penetration estimates to be used for risk assessment were set at 0.48%, 1.9% and 3.5% for the formulation concentrate, the 1:100 spray dilution and the 1:400 spray dilution, based on the EFSA Journal 2017;15(6):4873 criteria.

A 2.10.1 Study 2 – Prothioconazole-desthio in FGF11

Comments of zRMS:	Study has been performed according to OECD 428 and is considered acceptable. Provided data are scientifically valid but not considered by the zRMS for the current risk assessment (NDE calculation). Default values for risk assessment according to the EFSA Guidance on dermal absorption (2017) has been maintained by the zRMS for this registration
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Reference	KCP 7.3-02
Report	Azoxystrobin 160 g/l + prothioconazole 200 g/l sc: in vitro dermal absorption of prothioconazole-desthio using human split-thickness skin in a flow through diffusion system, Desai, Karishma R., 2024, report No 617-1-06-37465
Guideline(s)	Yes (OECD 428)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	NR

Materials and methods

Test material	Name (Lot/Batch No.)	[C14-triazole] Prothioconazole-desthio (23BLY066-Desthio)
	Test preparation	radioformulation
	Specific activity	35 mCi/mmol (1295 MBq/mmol), 112.11 µCi/mg
	Radiochemical purity	>98%
Product	Name (Lot/Batch No.)	Azoxystrobin 160 g/L + Prothioconazole 200 g/L SC (ARD/AP/360/SC/36)
	Company code	FGF11/GPF 1021
	Concentration a.s.	Azoxystrobin: 14.45 g/L ± 0.04% w/w or 162.20 ± 0.48 g/L; Prothioconazole: 17.86 ± 0.06% w/w or 200.54 ± 0.65 g/L
	Formulation type	SC
Blank product	Name (Lot/Batch No.)	Semi-blank (without Prothioconazole) (ARD/AP/360/SC/SMBLK/WOP/01)
	Concentration a.s.	Azoxystrobin: 18.27 % w/w Prothioconazole: 0.0 % w/w

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.6 ml/h
	Exposed skin area	0.64 cm²
	Cover	open
Membrane	Skin type	dermatomed
	Skin thickness range	200-400 µm
	Skin donors age	39 to 50

	Skin donors sex	f
	Location	Abdomen
	Source	ex vivo
	Integrity test	Yes - tritiated water ($\approx 0.1 \mu\text{Ci/skin membrane}$)
Receptor	Receptor medium	Dulbecco's phosphate
	Solubility in receptor medium	y
Sample Time	Exposure time	8 h $\pm$ 10 minutes
	Observation time	24 h $\pm$ 10 minutes
Sampling	Sample intervals	0 h (before exposure), 0-1 h, 1-2 h, 2-4 h, 4-6 h, 6-8 h, 8-10 h, 10-12 h, 12-14 h, 14-16 h, 16-18 h, 18-20 h, 20-22 h, and 22-24 h
Washing		post exposure & post observation
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks: NA		

Tested doses	Spray dilution 1	Spray dilution 2
Target concentration [mg/ml]	2.0 g/L	0.50 g/L
Area dose [$\mu\text{g}/\text{cm}^2$]	20 $\mu\text{g}/\text{cm}^2$	5.0 $\mu\text{g}/\text{cm}^2$
Specific activity [kBq/ml]		
No. of donors	4	4
No of cells used/valid cells*	8/8	8/8

* Justification for excluded cells, if applicable

Results and discussions

Table A 11: In-vitro dermal penetration of prothioconazole-desthio formulated as FGF11 through human skin – Recovery data

Dose group		Mid dose		Low dose	
		(Spray dilution 1:100)		(Spray dilution 1:400)	
Target concentration	[mg/mL]	2.0		0.5	
Target dose	[$\mu\text{g}/\text{cm}^2$]	20		5.0	
Mean actual applied dose	[$\mu\text{g}/\text{cm}^2$]	20		5.0	
		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.
Dislodgeable dose					
e.g. Skin washing after 8 h		95.0	1.99	88.8	3.54
e.g. Skin washing after 24 h		0.507	0.245	1.43	0.313
Donor chamber wash		0.0271	0.0153	0.0918	0.0325
Dose associated to skin					
Tape strips: 1 st sample, strips 1 + 2		0.0191	0.00812	0.112	0.0786
Tape strips: 2 nd sample; strips 3 - n		0.0655	0.0185	0.245	0.0885
Skin preparation		0.0846	0.0238	0.357	0.164

Absorbed dose				
Receptor fluid	3.09	0.845	7.66	2.04
Receptor chamber wash	95.6	1.76	90.4	3.25
Total recovery¹	0.0846	0.0238	0.357	0.164
Absorption essentially complete at end of study (>75% absorption within half the study duration) [%Absorption at t _{0.5}]	Yes [84.61%]		Yes [81.06%]	
If no: Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²	N/A	N/A	N/A	N/A
If yes: Absorption estimates = absorbed dose + skin preparation	3.40	0.933	8.58	2.10
Absorption estimate normalised ³	N/A		N/A	
Relevant absorption estimate ⁴	4.183		10.34	
confAbsorption estimates used for risk assessment⁵	4.2		10	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.21) Finally, the skin preparation is also considered potentially absorbable.

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

⁴ In accordance with the EFSA Guidance on Dermal Absorption, one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was $\geq 25\%$ of the mean value. To address variability between replicates/animals, dermal absorption should be calculated as follows (Mean value + ks; k=0.84)

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

N/A: not applicable

Remarks

N/A

Conclusion/endpoint:

The dermal penetration of prothioconazole-desthio formulated as product FGF11 through human dermated skin was determined in vitro. The amount of applied dose penetrating within 24 hours was determined to be 4.183 (mean $\pm$ standard deviation*k) and 10.34 for the 1:100 spray dilution and the 1:400 spray dilution, respectively. The dermal penetration estimates to be used for risk assessment were set at 4.2% and 10% for the 1:100 spray dilution and the 1:400 spray dilution based on the EFSA guidance criteria.

A 2.11 Other/Special Studies

A 2.11.1 Study 1

Comments of zRMS:	Study has been already evaluated at EU peer review and accepted, therefore no zRMS further assessment.
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Reference	KIIA 5.8/01 (Reference number as allocated in DAR Azoxystrobin, May 2009)
Report	Azoxystrobin metabolite R234886: Acute oral toxicity study in the rat (Up and Down Procedure), XXXXXXXX, 2005, Report No.: A12284

No detailed evaluation required, since the study was already evaluated and accepted at EU peer review; see DAR Azoxystrobin May 2009 – Volume 3, B.6, B.6.8.1.2.

Conclusion

Under the experimental conditions, the oral LD50 of R234886 is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.11.2 Study 2

Comments of zRMS:	Study has been already evaluated at EU peer review and accepted, therefore no zRMS further assessment.
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Reference	KIIA 5.8/02 (Reference number as allocated in DAR Azoxystrobin, May 2009)
Report	Azoxystrobin Metabolite R234886: Bacterial Mutation Assay In <i>S.Typhi-murium</i> and <i>E.coli</i> , Callander, R, 2005, Report No.: CTL/YV7083

No detailed evaluation required, since the study was already evaluated and accepted at EU peer review; see DAR Azoxystrobin May 2009 – Volume 3, B.6, B.6.8.1.2.

Conclusion

Under the experimental conditions, the response is negative, i.e. non-mutagenic, in the presence and absence of metabolic activation.

~~Appendix 3 – Exposure calculations~~

~~A 3.1 – Combined Operator, worker, bystander and resident exposure calculations for azoxystrobin and prothioconazole (KCP 7.2.1)~~

~~For details calculations see KCP 7.2/01~~

~~A 3.2 – Combined Operator, worker, bystander and resident exposure calculations for azoxystrobin and prothioconazole desthio (KCP 7.2.2)~~

~~For details calculations see KCP 7.2/02~~

~~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)~~

~~Not relevant.~~

Appendix 3 Exposure calculations

Exposure assessment for operator, worker, resident and bystander

Product: Patton Alpha

OPEX version: 1.1.1

12 March 2025

- Information on product and active substance(s)

Product name	Patton Alpha
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	azoxystrobin
Concentration of active substance in product [g a.s./l or kg]	160
AOEL [mg/kg bw per day]	0.2
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10
Dermal absorption [%] (dilution) NA [g a.s./l or kg]	50
Name of active substance	prothioconazole
Concentration of active substance in product [g a.s./l or kg]	103
AOEL [mg/kg bw per day]	0.2
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	10
Dermal absorption [%] (dilution) NA [g a.s./l or kg]	50
Name of active substance	prothioconazole desthio
Concentration of active substance in product [g a.s./l or kg]	0.0934
AOEL [mg/kg bw per day]	0.01
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	0
Dermal absorption [%] (dilution) NA [g a.s./l or kg]	50

• **Assessed uses**

Use	Crops	Max. application rate of the product [l or kg/ha]	Unit	Max. no. of applications	Interval between multiple applications [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/outdoor	Application method	Type of cultivation	Application technique	Buffer strip [m]	Drift reduction [%]
Use 1	Field crops	1	l/ha	1	NA	100	400	Outdoor	Downward spraying	normal	Vehicle-mounted	2-3	0
Use 1	Field crops	1	l/ha	1	NA	100	400	Outdoor	Downward spraying	normal	Vehicle-mounted	5	0

- **Operator**
- **Use 1 : Field crops (Outdoor)**

Short term exposure

		azoxystrobin (% AOEL) Normal & vehicle-mounted	prothioconazole (% AOEL)	prothioconazole desthio (% AOEL)	Combined (hazard index)
Mixing/loading	Application				
		48.1	34.9	0.2	0.831
		31.4	23.1	0.1	0.547

Acute exposure

		azoxystrobin (% AOEL) Normal & vehicle-mounted	prothioconazole (% AOEL)	prothioconazole desthio (% AOEL)	Combined (hazard index)
Mixing/loading	Application				
					
					

• **Scenario 1 : Normal, downward spraying, vehicle-mounted**

• **Summary data - Short term exposure**

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0% Crop density: Normal			
azoxystrobin	Application rate: 1 x 0.16 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.06	31.4
	M/L: Potential exposure App: Potential exposure	0.1	48.1
prothioconazole	Application rate: 1 x 0.103 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	0.05	23.1
	M/L: Potential exposure App: Potential exposure	0.07	34.9
prothioconazole desthio	Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear	1e-05	0.1
	M/L: Potential exposure App: Potential exposure	2e-05	0.2
Combined exposure			Hazard index
MLA: Workwear			0.5
MLA: None			0.8

• Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0% Crop density: Normal			
azoxystrobin	Application rate: 1 x 0.16 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear		No results!
	M/L: NA + NA + NA App: NA + NA + NA		No results!
prothioconazole	Application rate: 1 x 0.103 kg a.s./ha Dermal absorption (concentrate): 10 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear		No results!
	M/L: NA + NA + NA App: NA + NA + NA		No results!
prothioconazole desthio	Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption (concentrate): 0 % Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear App: Workwear		No results!
	M/L: NA + NA + NA App: NA + NA + NA		No results!
Combined exposure			Hazard index
MLA: Workwear			
MLA: NA			

- **Worker**

- **Use 1 : Field crops (Outdoor)**

- **Scenario 1 : Inspection, irrigation**

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation; Outdoor Work rate: 2 hours/day ; Interval: NA ; Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h			
azoxystrobin Application rate: 1 x 0.16 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Potential	0.1	50	0
Workwear	0.01	5.6	0
Workwear and gloves	0.01	5	0
prothioconazole Application rate: 1 x 0.103 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Potential	0.06	32.2	0
Workwear	0.007	3.6	0
Workwear and gloves	0.006	3.2	0
prothioconazole desthio Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50 Foliar: 30 days DT50 Air: 30 days DT50 Soil: 30 days			
Potential	6e-05	0.6	0
Workwear	7e-06	0.07	0
Workwear and gloves	6e-06	0.06	0
Combined		Hazard index	
Potential		0.8	0
Workwear		0.09	0
Workwear and gloves		0.08	0
Hands covered, no workwear			0

- Resident

- Use 1 : Field crops (Outdoor)

- Scenario 1 : Season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 100 l			
azoxystrobin		Application rate: 1 x 0.16 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.02	10.8
	Vapour (75th perc.)	0.0008	0.4
	Deposits (75th perc.)	0.001	0.6
	Re-entry (75th perc.)	0.01	6.8
	Sum (mean)	0.02	12.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.005	2.6
	Vapour (75th perc.)	0.0003	0.1
	Deposits (75th perc.)	0.0005	0.3
	Re-entry (75th perc.)	0.008	3.8
	Sum (mean)	0.009	4.5
prothioconazole		Application rate: 1 x 0.103 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.01	7
	Vapour (75th perc.)	0.0008	0.4
	Deposits (75th perc.)	0.0008	0.4
	Re-entry (75th perc.)	0.009	4.3
	Sum (mean)	0.02	8
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.003	1.7
	Vapour (75th perc.)	0.0003	0.1
	Deposits (75th perc.)	0.0004	0.2
	Re-entry (75th perc.)	0.005	2.4
	Sum (mean)	0.006	3
prothioconazole desthio		Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	1e-05	0.1
	Vapour (75th perc.)	0.0008	8
	Deposits (75th perc.)	8e-07	0.008
	Re-entry (75th perc.)	8e-06	0.08
	Sum (mean)	0.0008	8.1
Resident adult Body weight: 60 kg	Drift (75th perc.)	3e-06	0.03
	Vapour (75th perc.)	0.0003	2.7
	Deposits (75th perc.)	3e-07	0.003
	Re-entry (75th perc.)	4e-06	0.04

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
	Sum (mean)	0.0003	2.8
Combined exposure			Hazard index
	Drift (75th perc.)		0.2
	Vapour (75th perc.)		0.09
Resident child Body weight: 10 kg	Deposits (75th perc.)		0.01
	Re-entry (75th perc.)		0.1
	Sum (mean)		0.3
	Drift (75th perc.)		0.04
	Vapour (75th perc.)		0.03
Resident adult Body weight: 60 kg	Deposits (75th perc.)		0.005
	Re-entry (75th perc.)		0.06
	Sum (mean)		0.1

• **Scenario 2 : Season not relevant, drift reduction 0 [%] buffer strip 5 [m]**

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:5m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 100 l			
azoxystrobin		Application rate: 1 x 0.16 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
	Drift (75th perc.)	0.01	7.2
	Vapour (75th perc.)	0.0008	0.4
Resident child Body weight: 10 kg	Deposits (75th perc.)	0.0005	0.3
	Re-entry (75th perc.)	0.01	6.8
	Sum (mean)	0.02	9.9
	Drift (75th perc.)	0.003	1.3
	Vapour (75th perc.)	0.0003	0.1
Resident adult Body weight: 60 kg	Deposits (75th perc.)	0.0002	0.1
	Re-entry (75th perc.)	0.008	3.8
	Sum (mean)	0.008	3.9
prothioconazole		Application rate: 1 x 0.103 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
	Drift (75th perc.)	0.009	4.7
	Vapour (75th perc.)	0.0008	0.4
Resident child Body weight: 10 kg	Deposits (75th perc.)	0.0003	0.2
	Re-entry (75th perc.)	0.009	4.3
	Sum (mean)	0.01	6.5
	Drift (75th perc.)	0.002	0.8
	Vapour (75th perc.)	0.0003	0.1
Resident adult Body weight: 60 kg	Deposits (75th perc.)	0.0001	0.07
	Re-entry (75th perc.)	0.005	2.4
	Sum (mean)	0.005	2.5

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
prothioconazole desthio		Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	8e-06	0.08
	Vapour (75th perc.)	0.0008	8
	Deposits (75th perc.)	3e-07	0.003
	Re-entry (75th perc.)	8e-06	0.08
	Sum (mean)	0.0008	8.1
Resident adult Body weight: 60 kg	Drift (75th perc.)	2e-06	0.02
	Vapour (75th perc.)	0.0003	2.7
	Deposits (75th perc.)	1e-07	0.001
	Re-entry (75th perc.)	4e-06	0.04
	Sum (mean)	0.0003	2.7
Combined exposure			Hazard index
Resident child Body weight: 10 kg	Drift (75th perc.)		0.1
	Vapour (75th perc.)		0.09
	Deposits (75th perc.)		0.004
	Re-entry (75th perc.)		0.1
	Sum (mean)		0.2
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.02
	Vapour (75th perc.)		0.03
	Deposits (75th perc.)		0.002
	Re-entry (75th perc.)		0.06
	Sum (mean)		0.09

- Bystander**

- Use 1 : Field crops (Outdoor)**

- Scenario 1 : Outdoor, season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]**

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 100 l			
azoxystrobin		Application rate: 1 x 0.16 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.05	NA
	Vapour (95th perc.)	0.0008	NA
	Deposits (95th perc.)	0.004	NA
	Re-entry (95th perc.)	0.01	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.01	NA
	Vapour (95th perc.)	0.0003	NA
	Deposits (95th perc.)	0.002	NA
	Re-entry (95th perc.)	0.008	NA
prothioconazole		Application rate: 1 x 0.103 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.03	NA
	Vapour (95th perc.)	0.0008	NA
	Deposits (95th perc.)	0.002	NA
	Re-entry (95th perc.)	0.009	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.009	NA
	Vapour (95th perc.)	0.0003	NA
	Deposits (95th perc.)	0.001	NA
	Re-entry (95th perc.)	0.005	NA
prothioconazole desthio		Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	3e-05	NA
	Vapour (95th perc.)	0.0008	NA
	Deposits (95th perc.)	2e-06	NA
	Re-entry (95th perc.)	8e-06	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	8e-06	NA
	Vapour (95th perc.)	0.0003	NA
	Deposits (95th perc.)	1e-06	NA
	Re-entry (95th perc.)	4e-06	NA
Combined exposure			Hazard index
Bystander child Body weight: 10 kg	Drift (95th perc.)		0
	Vapour (95th perc.)		0
	Deposits (95th perc.)		0
	Re-entry (95th perc.)		0

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
	Drift (95th perc.)		0
Bystander adult	Vapour (95th perc.)		0
Body weight: 60 kg	Deposits (95th perc.)		0
	Re-entry (95th perc.)		0
Scenario 2 : Outdoor, season not relevant, drift reduction 0 [%] buffer strip 5 [m]			
Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:5m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 100 l			
azoxystrobin		Application rate: 1 x 0.16 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
	Drift (95th perc.)	0.03	NA
Bystander child	Vapour (95th perc.)	0.0008	NA
Body weight: 10 kg	Deposits (95th perc.)	0.002	NA
	Re-entry (95th perc.)	0.01	NA
	Drift (95th perc.)	0.006	NA
Bystander adult	Vapour (95th perc.)	0.0003	NA
Body weight: 60 kg	Deposits (95th perc.)	0.0007	NA
	Re-entry (95th perc.)	0.008	NA
prothioconazole		Application rate: 1 x 0.103 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
	Drift (95th perc.)	0.02	NA
Bystander child	Vapour (95th perc.)	0.0008	NA
Body weight: 10 kg	Deposits (95th perc.)	0.001	NA
	Re-entry (95th perc.)	0.009	NA
	Drift (95th perc.)	0.004	NA
Bystander adult	Vapour (95th perc.)	0.0003	NA
Body weight: 60 kg	Deposits (95th perc.)	0.0004	NA
	Re-entry (95th perc.)	0.005	NA
prothioconazole desthio		Application rate: 1 x 9.34e-05 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
	Drift (95th perc.)	2e-05	NA
Bystander child	Vapour (95th perc.)	0.0008	NA
Body weight: 10 kg	Deposits (95th perc.)	9e-07	NA
	Re-entry (95th perc.)	8e-06	NA
	Drift (95th perc.)	4e-06	NA
Bystander adult	Vapour (95th perc.)	0.0003	NA
Body weight: 60 kg	Deposits (95th perc.)	4e-07	NA
	Re-entry (95th perc.)	4e-06	NA
Combined exposure			Hazard index

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Bystander child Body weight: 10 kg	Drift (95th perc.)		0
	Vapour (95th perc.)		0
	Deposits (95th perc.)		0
	Re-entry (95th perc.)		0
Bystander adult Body weight: 60 kg	Drift (95th perc.)		0
	Vapour (95th perc.)		0
	Deposits (95th perc.)		0
	Re-entry (95th perc.)		0

• Appendix 3a Input Data

• Operator

• Use 1 : Field crops (Outdoor)

• Scenario 1 : Normal, downward spraying, vehicle-mounted, drift reduction 0 %

Azoxystrobin , Input Data

Formulation type	Soluble concentrates, emulsi- fiable concentrate, etc.	Name of active substance	azoxystrobin
Concentration of active substance in product [g a.s./l or kg]	160	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (di- lution)	50	Indoor/ outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw per day]	0.2		
AAOEL [mg/kg bw]			

Azoxystrobin , Per body part - Short term exposure

Activity	Systemic exposure per body part	With work- wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	51.3	51.3
	Body protection	Workwear	None
	Body exposure	0.3	28.2
	Head protection	None	None
	Head exposure	0.8	0.8
	Inhalation protection	None	None
	Inhalation exposure	0.1	0.1
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	9.9	9.9
	Body protection	Workwear	None
	Body exposure	0.1	5.5

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
	Head protection	None	None
	Head exposure	0.3	0.3
	Inhalation protection	None	None
	Inhalation exposure	0.05	0.05
Total	Total systemic exposure [mg/kg bw per day]	0.06	0.1
	% of AOEL	31.4	48.1

Prothioconazole , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	prothioconazole
Concentration of active substance in product [g a.s./l or kg]	103	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/ outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw per day]	0.2		
AAOEL [mg/kg bw]			

Prothioconazole , Per body part - Short term exposure

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	38.7	38.7
	Body protection	Workwear	None
	Body exposure	0.2	20.4
	Head protection	None	None
	Head exposure	0.5	0.5
	Inhalation protection	None	None
	Inhalation exposure	0.1	0.1
Application (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	6.3	6.3
	Body protection	Workwear	None
	Body exposure	0.1	3.6
	Head protection	None	None
	Head exposure	0.2	0.2
	Inhalation protection	None	None
	Inhalation exposure	0.04	0.04
Total	Total systemic exposure [mg/kg bw per day]	0.05	0.07
	% of AOEL	23.1	34.9

Prothioconazole desthio , Input Data

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	Name of active substance	prothioconazole desthio
Concentration of active substance in product [g a.s./l or kg]	0.0934	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	Indoor/ outdoor	Outdoor
Oral absorption [%]	100	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw per day]	0.01		
AAOEL [mg/kg bw]			

Prothioconazole desthio , Per body part - Short term exposure

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	Hand protection	None	None
	Hands exposure	0	0
	Body protection	Workwear	None
	Body exposure	0	0
	Head protection	None	None
	Head exposure	0	0
	Inhalation protection	None	None

Activity	Systemic exposure per body part	With work-wear	With workwear + PPE/RPE
Application (µg/kg bw per day)	Inhalation exposure	0.007	0.007
	Hand protection	None	None
	Hands exposure	0.006	0.006
	Body protection	Workwear	None
	Body exposure	9e-05	0.003
	Head protection	None	None
	Head exposure	0.0002	0.0002
	Inhalation protection	None	None
	Inhalation exposure	0.001	0.001
Total	Total systemic exposure [mg/kg bw per day]	1e-05	2e-05
	% of AOEL	0.1	0.2

• **Worker**

• **: Field crops (Outdoor)**

• **Scenario 1 : Inspection, irrigation, na**

Azoxystrobin , Input data

Indoor/ outdoor	Outdoor	AOEL [mg/kg bw per day]	0.2
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs cov- ered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no work- wear [cm²/h]	
Max. application rate of the product [l or kg/ha]	1	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	azoxystrobin		
Dermal absorption [%] (di- lution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Azoxystrobin , Exposure per body part

Exposure route	Description	Potential	Work- wear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	6	0.7	0.6	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	6	0.7	0.6	NA
Total	Total systemic exposure [mg/kg bw per day]	0.1	0.01	0.01	NA
	% of AOEL	50	5.6	5	NA

Prothioconazole , Input data

Indoor/ outdoor	Outdoor	AOEL [mg/kg bw per day]	0.2
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs cov- ered [cm²/h]	1400

Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	1	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	prothioconazole		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

Prothioconazole , Exposure per body part

Exposure route	Description	Potential	Workwear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	3.9	0.4	0.4	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	3.9	0.4	0.4	NA
Total	Total systemic exposure [mg/kg bw per day]	0.06	0.007	0.006	NA
	% of AOEL	32.2	3.6	3.2	NA

Prothioconazole desthio , Input data

Indoor/ outdoor	Outdoor	AOEL [mg/kg bw per day]	0.01
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	1	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	prothioconazole desthio		

Dermal absorption [%] (dilution)	50
Inhalation absorption [%]	100
Time [hours per day]	2

Prothioconazole desthio , Exposure per body part

Exposure route	Description	Potential	Work-wear	Workwear and gloves	Gloves
Dermal	Systemic dermal exposure [mg a.s. per day]	0.004	0.0004	0.0004	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	0.004	0.0004	0.0004	NA
Total	Total systemic exposure [mg/kg bw per day]	6e-05	7e-06	6e-06	NA
	% of AOEL	0.6	0.07	0.06	NA

Appendix 5 Exposure calculations (zRMS comment: updated by the applicant)

A 5.1 Combined Operator, worker, bystander and resident exposure calculations for azoxystrobin and prothioconazole-desthio (KCP 7.2.1)

INFORMATION ON Azoxystrobin 160+Prothioconazole 200 SC

Product information and toxicological reference values used for exposure assessment

Product name and code	Azoxystrobin 160+Prothioconazole 200 SC	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc. (please specify formulation type)	
Category	Other	
Active substance(s) (incl. content)	Azoxystrobin 165.8 g/L or g/kg	Prothio-destio 187 g/L or g/kg
AOEL systemic	0.2 mg/kg bw per day	0.01 mg/kg bw per day
AAOEL systemic	No AAOEL set	No AAOEL set
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 0.48% Dilution: 3.6% (0.4 g/L)	Concentrate: 0% Dilution: 10% (0.5 g/L)

OPERATOR

Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 1 x 0.1658kg a.s./ha, 100-400 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.1

Estimated operator exposure (acute exposure)

Estimated operator exposure (short term exposure)

WORKER

Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 1 x 0.1658kg a.s./ha, 100-400 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.1

Estimated worker exposure (short term exposure)

Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry re- striction [days]	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry re- striction [days]
Inspection, irrigation; Outdoor ; Work rate: 2 hours/day ; Interval: NA							
Azoxystrobin				Prothio-destio			

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
		Application rate: 1 x 0.1658 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			Application rate: 1 x 0.187 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
	Potential TC: 12500 cm²/h/person	0.007	3.7	0	0.03	250	40
	Workwear TC: 1400 cm²/h/person	0.0008	0.4	0	0.003	28	0
	Workwear and gloves TC: 1250 cm²/h/person	0.0007	0.4	0	0.003	25	0

RESIDENT and BYSTANDER

Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 1 x 0.1658kg a.s./ha, 100-400 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.1

Estimated resident exposure (short term exposure)

Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA					
		Azoxystrobin		Prothio-destio	
		Application rate: 1 x 0.1658 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		Application rate: 1 x 0.187 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.002	0.8	0.005	54.4
	Vapour (75th perc.)	1e-08	7e-06	4e-05	0.4
	Deposits (75th perc.)	0.0002	0.1	0.0004	4.4
	Re-entry (75th perc.)	0.001	0.5	0.003	33.8
	Sum (mean)	0.002	0.9	0.006	60.3
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0004	0.2	0.001	12.9
	Vapour (75th perc.)	5e-09	2e-06	1e-05	0.1
	Deposits (75th perc.)	4e-05	0.02	0.0001	1.4
	Re-entry (75th perc.)	0.0006	0.3	0.002	18.8
	Sum (mean)	0.0007	0.3	0.002	22.1

Estimated bystander exposure (acute exposure)

Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of sys- temic AOEL	Total absorbed dose [mg/kg bw per day]	% of sys- temic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA					
		Azoxystrobin		Prothio-destio	
		Application rate: 1 x 0.1658 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		Application rate: 1 x 0.187 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.004	NA	0.01	NA
	Vapour (95th perc.)	1e-08	NA	4e-05	NA
	Deposits (95th perc.)	0.0006	NA	0.001	NA
	Re-entry (95th perc.)	0.001	NA	0.003	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.001	NA	0.003	NA
	Vapour (95th perc.)	5e-09	NA	1e-05	NA
	Deposits (95th perc.)	0.0001	NA	0.0004	NA
	Re-entry (95th perc.)	0.0006	NA	0.002	NA

COMBINED EXPOSURE

Acute exposure

Use 1: Field crops

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Bystander - child Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Prothio-destio	
	Cumulative risk Bystander - child (HI)	
	Spray drift	0
	Vapour	0
	Surface deposits	0
	Entry into treated crops	0
Bystander - adult Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Prothio-destio	
	Cumulative risk Bystander - adult (HI)	
	Spray drift	0
	Vapour	0
	Surface deposits	0
	Entry into treated crops	0

Short term exposure

Use 1: Field crops

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Azoxystrobin	0.4

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Workers Inspection, irrigation / Outdoor	Prothio-destio	28
Workwear	Cumulative risk workers (HI)	0.3
Resident - child Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Spray drift	0.8
	Vapour	7e-06
	Surface deposits	0.1
	Entry into treated crops	0.5
	All pathways (mean)	0.9
	Prothio-destio	
	Spray drift	54.4
	Vapour	0.4
	Surface deposits	4.4
	Entry into treated crops	33.8
	All pathways (mean)	60.3
	Cumulative risk Resident - child (HI)	
	Spray drift	0.6
	Vapour	0.004
	Surface deposits	0.05
	Entry into treated crops	0.3
	All pathways (mean)	0.6
Resident - adult Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Spray drift	0.2
	Vapour	2e-06
	Surface deposits	0.02
	Entry into treated crops	0.3
	All pathways (mean)	0.3
	Prothio-destio	
	Spray drift	12.9
	Vapour	0.1
	Surface deposits	1.4
	Entry into treated crops	18.8
	All pathways (mean)	22.1
	Cumulative risk Resident - adult (HI)	
	Spray drift	0.1
	Vapour	0.001
	Surface deposits	0.01
	Entry into treated crops	0.2
	All pathways (mean)	0.2

No AAOEL set
No AAOEL set

A 5.2

Combined Operator, worker, bystander and resident exposure calculations for azoxystrobin and prothioconazole (KCP 7.2.2)

INFORMATION ON Azoxystrobin 160+Prothioconazole 200 SC

Product information and toxicological reference values used for exposure assessment

Product name and code	Azoxystrobin 160+Prothioconazole 200 SC	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc. (please specify formulation type)	
Category	Other	
Active substance(s) (incl. content)	Azoxystrobin 165.8 g/L or g/kg	Prothioconazole 206.6 g/L or g/kg
AOEL systemic	0.2 mg/kg bw per day	0.2 mg/kg bw per day
AAOEL systemic	No AAOEL set	No AAOEL set
Inhalation absorption	100%	100%
Oral absorption	100%	100%
Dermal absorption	Concentrate: 0.48% Dilution: 3.5% (0.4 g/L)	Concentrate: 10% Dilution: 50% (NA g/L)

OPERATOR

Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 1 x 0.1658kg a.s./ha, 100-400 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and by-standers in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.1

Estimated operator exposure (acute exposure)

Estimated operator exposure (short term exposure)

WORKER

Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 1 x 0.1658kg a.s./ha, 100-400 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and by-standers in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.1

Estimated worker exposure (short term exposure)

Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation; Outdoor ; Work rate: 2 hours/day ; Interval: NA							
		Azoxystrobin		Prothioconazole			
		Application rate: 1 x 0.1658 kg a.s./ha DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days		Application rate: 1 x 0.2066 kg a.s./ha DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
	Potential TC: 12500 cm ² /h/person	0.007	3.6	0	0.1	64.6	0

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
	Workwear TC: 1400 cm ² /h/person	0.0008	0.4	0	0.01	7.2	0
	Workwear and gloves TC: 1250 cm ² /h/person	0.0007	0.4	0	0.01	6.5	0

RESIDENT and BYSTANDER

Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 1 x 0.1658kg a.s./ha, 100-400 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.1

Estimated resident exposure (short term exposure)

Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA					
		Azoxystrobin		Prothioconazole	
		Application rate: 1 x 0.1658 kg a.s./ha DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days		Application rate: 1 x 0.2066 kg a.s./ha DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.002	0.8	0.03	14
	Vapour (75th perc.)	1e-08	7e-06	5e-05	0.02
	Deposits (75th perc.)	0.0002	0.1	0.002	0.8
	Re-entry (75th perc.)	0.001	0.5	0.02	8.7
	Sum (mean)	0.002	0.9	0.03	15.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0004	0.2	0.007	3.3
	Vapour (75th perc.)	5e-09	2e-06	2e-05	0.008
	Deposits (75th perc.)	4e-05	0.02	0.0007	0.4
	Re-entry (75th perc.)	0.0005	0.3	0.01	4.8
	Sum (mean)	0.0006	0.3	0.01	5.7

Estimated bystander exposure (acute exposure)

Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA					
		Azoxystrobin		Prothioconazole	

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of sys- temic AOEL	Total absorbed dose [mg/kg bw per day]	% of sys- temic AOEL
		Application rate: 1 x 0.1658 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		Application rate: 1 x 0.2066 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.004	NA	0.06	NA
	Vapour (95th perc.)	1e-08	NA	5e-05	NA
	Deposits (95th perc.)	0.0006	NA	0.005	NA
	Re-entry (95th perc.)	0.001	NA	0.02	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.001	NA	0.02	NA
	Vapour (95th perc.)	5e-09	NA	2e-05	NA
	Deposits (95th perc.)	0.0001	NA	0.002	NA
	Re-entry (95th perc.)	0.0005	NA	0.01	NA

COMBINED EXPOSURE

Acute exposure

Use 1: Field crops

Application scenario	Active ingredient	Estimated exposure / AAOEL (HQ)
Bystander - child Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Prothioconazole	
	Cumulative risk Bystander - child (HI)	
	Spray drift	0
	Vapour	0
	Surface deposits	0
	Entry into treated crops	0
Bystander - adult Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Prothioconazole	
	Cumulative risk Bystander - adult (HI)	
	Spray drift	0
	Vapour	0
	Surface deposits	0
	Entry into treated crops	0

Short term exposure

Use 1: Field crops

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Workers Inspection, irrigation / Outdoor	Azoxystrobin	3.6
	Prothioconazole	64.6
<i>Potential</i>	Cumulative risk workers (HI)	0.7
	Azoxystrobin	

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Resident - child Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Spray drift	0.8
	Vapour	7e-06
	Surface deposits	0.1
	Entry into treated crops	0.5
	All pathways (mean)	0.9
	Prothioconazole	
	Spray drift	14
	Vapour	0.02
	Surface deposits	0.8
	Entry into treated crops	8.7
	All pathways (mean)	15.2
	Cumulative risk Resident - child (HI)	
	Spray drift	0.1
	Vapour	0.0002
	Surface deposits	0.009
	Entry into treated crops	0.09
	All pathways (mean)	0.2
Resident - adult Outdoor Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 %	Azoxystrobin	
	Spray drift	0.2
	Vapour	2e-06
	Surface deposits	0.02
	Entry into treated crops	0.3
	All pathways (mean)	0.3
	Prothioconazole	
	Spray drift	3.3
	Vapour	0.008
	Surface deposits	0.4
	Entry into treated crops	4.8
	All pathways (mean)	5.7
	Cumulative risk Resident - adult (HI)	
	Spray drift	0.04
	Vapour	8e-05
	Surface deposits	0.004
	Entry into treated crops	0.05
	All pathways (mean)	0.06

No AAOEL set

No AAOEL set