REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: BAS 736 00 F

Product name(s): **Miralon**

Chemical active substance(s):

Fluxapyroxad, 50 g/L
Azoxystrobin, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: 12/2021

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When	What
12/2021	Initial dRR - BASF DocID 2020/2101122
09/2022	Version evaluated by zRMS PL
01/2023	Version revised to take into account comments of cMSs and the applicant

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on BAS 736 00 F*

Product name and code	BAS 736 00 F
Formulation type	EC
Active substance(s) (incl. content)	Fluxapyroxad, 50 g/L Azoxystrobin, 75 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 BAS 736 00 F 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 BAS 736 00 F according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Acute Tox.4 (oral) Acute Tox 4 (inhalation) Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Lact.
Hazard pictograms or Code(s) for hazard pictogram(s):	 GHS05, GHS07
Signal word:	Warning
Hazard statement(s):	H302: Harmful if swallowed H332: Harmful if inhaled H315: Causes skin irritation H317: May cause an allergic skin reaction H318: Causes serious eye damage H362: May cause harm to breast-fed children
Precautionary statement(s): - General: - Prevention: - Response: - Storage - Disposal	 P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P201: Obtain special instructions before use ~~P202:. Do not handle until all safety precautions have been read and understood~~ P260: Do not breathe mist/vapours/spray. P263: Avoid contact during pregnancy while nursing. P264: Wash contaminated body parts thoroughly after handling. P270: Do not eat, drink or smoke when using this product P271: Use only outdoors or in a well-ventilated area P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves and eye or face protection. P305 + P351 + P338, P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor P301 + P312, P330: IF SWALLOWED: Call a POISON CENTRE/doctor/ if you feel unwell. Rinse mouth P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing P308 + P313: IF exposed or concerned: Get medical advice/attention. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container to hazardous or special waste collection point.

Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains *Octabenzone and 2-Propenoic acid, 2-methyl-, polymer with tert-Bu acrylate, Me meth-acrylate, polyethylene glycol meth-acrylate C16-18-alkyl ethers and vinyl-pyrrolidone, tert-Bu 2-ethyl-hexane-peroxoate – initiated, compds. with 2-amino-2-methyl-1-propanol*

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for BAS 736 00 F

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Protective clothes, protective gloves and face/eye protection when handling, mixing and loading ~~Gloves during mixing/loading~~
Workers	Acceptable	Workwear wen inspecting treated crops
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents 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 bystanders/residents is presented in the following table.

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

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Application**		**Application rate**		**PHI (d)**	**Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, bystander or resident 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) fluxapyroxad b) azoxystrobin**	**Water L/ha min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1-15, 21-25	Cereals (BBCH 30-69)	F	Spraying, LCTM	a) 2 (21 days) b) 2 (21 days)	a) 0.10 b) 0.15	100 - 300	35	Critical gap for operator, worker, bystander or resident exposure based on EFSA AOEM	R	R	A	A
16-20	Cereals (BBCH 30-69)	F	Spraying, LCTM	a) 1 b) 1	a) 0.10 b) 0.15	100 - 300	35					

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

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

Data gaps

Noticed data gaps are:

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)

	BAS 700 F	**BAS 9164 F**
Common Name	Fluxapyroxad	Azoxystrobin
CAS-No.	~~907204-31-03~~ 907204-31-3	131860-33-8
Classification and proposed labelling With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)		
Hazard classes (s), categories:	Lact.	Acute Tox. 3
Code(s) for hazard pictogram(s):	 GHS09	 GHS06
Signal word:	Warning	Danger
Hazard statement(s):	H362: May cause harm to breast-fed children.	H331: Toxic if inhaled [ATE = 0.7 mg/L (dusts or mists)]
Precautionary statement(s):	P201: Obtain special instructions before use P260: Do not breathe dust or mist. P263: Avoid contact during pregnancy and while nursing. P308 + P313: IF exposed or concerned: Get medical advice/attention.	P261: Avoid breathing dust or mist. P304 + P340: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. P311: Call a POISON CENTER or doctor/physician. P403 + P233: Store in a well-ventilated place. Keep container tightly closed P501: Dispose of contents/container to hazardous or special waste collection point.
Reference:	Com. Del. Reg.(EU) 2020/1182	Com. Del. Reg.(EU) 2020/1182
Additional C&L proposal	None.	None.
Agreed EU endpoints		
AOEL systemic	0.04 mg/kg bw/d (corrected for 68% oral absorption)	0.2 mg/kg bw/d (no correction for oral absorption required)
AAOEL	Not allocated	Not allocated
Reference	EFSA Conclusion (EFSA Journal 2012;10(1):2522) Review Report Fluxapyroxad, SANCO/10692/2012 Rev 1, 1 June 2012	EFSA Conclusion (EFSA Journal 2010;8(4):1542) Review Report Azoxystrobin, SANCO/11027/2011 Rev.3, 20 Mar 2015
Conditions to take into account/critical areas of concern with regard to toxicology		
Review Report/EFSA Conclusion for active substance	None related to toxicology	None related to toxicology

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for BAS 736 00 F 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 BAS 736 00 F

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference (BASF DocID)
Acute oral toxicity, predicted from composition [100%]	LD_{50} > 2000 mg/kg bw	Yes	**none**	CLP 1272/2008 **Appendix 2**
LD_{50} oral, rat (OECD 423)	500 < LD_{50} < 2000 mg/kg; ATE = 1848 mg/kg bw	Yes	**Acute Tox. 4; H302**	(2020/2080214) **Appendix 2**
Acute dermal toxicity, predicted from composition [69%] and supported by oral-to dermal extrapolation	LD_{50} > 2000 mg/kg bw	Yes	**No classification**	CLP 1272/2008 **Appendix 2**
Acute inhalation toxicity, predicted from composition [61%]	LC_{50} > 5 mg/L	Yes	none	CLP 1272/2008 **Appendix 2**
LC_{50} inhalation, rat (OECD 436)	LC_{50} = 5 mg/L	Yes	**Acute Tox. 4; H322**	(2021/2000826) **Appendix 2**
Skin corrosion / irritation, predicted from composition [100%]	Skin irritant	Yes	**Skin Irrit. 2; H315**	CLP 1272/2008 **Appendix 2**
In vitro Skin corrosion / irritation, EpiDerm tests (OECD 431/439)	Not corrosive but skin irritant (1+24h viability: 2.4%)	Yes	**Skin Irrit. 2; H315**	(2020/2028460) **Appendix 2**
Eye corrosion / irritation, predicted from composition [100%]	Eye corrosive	Yes	**Eye Dam. 1; H318**	CLP 1272/2008 ~~1172/2008~~ **Appendix 2**
In vitro Eye irritation, EpiOcular (OECD 492)	Eye corrosive or irritant	Yes	**Eye Dam. 1; H318**	(2020/2027869 **Appendix 2**)
Skin sensitisation predicted from composition [83%]	Skin sensitiser	Yes	**Skin Sens 1, H317**	CLP 1272/2008 ~~1172/2008~~ **Appendix 2**
Supplementary studies for combinations of plant protection products	No data – not required	Yes / No / Supplementary	-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of BAS 736 00 F

	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)	Fluxapyroxad (4.64 %)	Lact.; H362 (≥ 0.3%)	Reg. 1272/2008	Lact; H362
Toxicological properties of non-active substance(s) (relevant for classification of product)	Octabenzone (1.39%)	Skin Sens 1B; H317 (≥ 1%)	MSDS**	Skin Sens 1; H317
	iPoly50 (19.57%)	Skin Irrit. 2; H315 Skin Sens. 1; H317 (≥ 1%) Eye Dam. 1 H318 (≥ 3%)	MSDS**	Skin Irrit. 2; H315 Skin Sens 1; H317 Eye Dam. 1; H318
	N,N-dimethyldecan-1-amide (<20%)	Skin Irrit 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335	MSDS**	Skin Irrit 2; H315
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

zRMS:
The concentration of Fluxapyroxad in the product (4.64 %) is above 0.3% thus above a generic concentration limit of ingredients of a mixture classified for effects on or via lactation that trigger classification of the mixture according to Regulation 1272/2008 (Table 3.7.2) therefore product BAS 736 00 F (Miralon) require classification Lact., H362: May cause harm to breast-fed children.

6.4 Toxicological Evaluation of Groundwater Metabolites

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

6.4.1 M700F001 (Reg.No. 5069089; Soil metabolite metabolite of BAS 700 F)

An overview of the results of the accepted toxicological studies for groundwater metabolite M700F001 is given in the following table. All studies have previously been considered within an EU peer review process (EFSA conclusion). There are no studies on the metabolite that have not previously been considered within an EU peer review process.

Table 6.4-1: Summary of the results of toxicity studies for M700F001

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity, rat (OECD 423)	Rat oral LD50 > 2000 mg/kg bw	Yes	*2009/1072502
Repeated-dose 90-day oral toxicity study, rat (OECD 408) 0, 100, 300, 1000 mg/kg bw/day	NOAEL 1000 mg/kg bw/day	Yes	*2009/1072503
Salmonella typhimurium/Escheria coli reverse mutation assay (OECD 471; EPA 870.5100)	Non-mutagenic	Yes	*2009/1072504
In vitro chromosome aberration assay in Chinese hamster V79 cells; (OECD 473, EPA 870.5375)	Not clastogenic	Yes	*2009/1072505
In vitro gene mutation test in CHO cells (HPRT locus assay) (OECD 476, EPA 870.5300)	Not mutagenic	Yes	*2009/1072392 *2009/1081058
In vivo micronucleus test in bone marrow cells of the mouse (OECD 474, EPA 870.5395)	Not clastogenic or aneugenic	Yes	*2009/1072506
Rabbit prenatal developmental toxicity, oral gavage during days 6-28 of gestation 0, 40, 100, 250 mg/kg bw/day (OECD 414, EPA 870.3700)	Developmental & maternal NOAEL: 250 mg/kg bw/day No adverse effects observed. LOAEL > 250 mg/kg bw/day	Yes	*2009/1072507

* indicates that a study was reviewed at EU level; for details see BAS 700 F - Volume 3, Annex B.6a: Toxicology and Metabolism; B.6.8 Further toxicological studies (IIA 5.8) p.351ff

6.4.2 M700F002 (Reg.No. 5435595, Soil metabolite of BAS 700 F)

An overview of the results of the accepted toxicological studies for groundwater metabolite M700F002 is given in the following table. All studies have previously been considered within an EU peer review process (EFSA conclusion). There are no studies on the metabolite that have not previously been considered within an EU peer review process.

Table 6.4-2: Summary of the results of toxicity studies for M700F002

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity, rat (OECD 423)	Rat oral LD50 > 2000 mg/kg bw	Yes	*2009/1018501
Repeated-dose 28-day oral toxicity study, rat (OECD 407)	NOAEL 15 000 ppm (equivalent to 1165 and 1253 mg/kg bw/day in males and females)	Yes	*(2008/1052054
Repeated-dose 90-day oral toxicity study, rat (OECD 408)	NOAEL 1000 mg/kg bw/day	Yes	*2009/1012026
Salmonella typhimurium/Escheria coli reverse mutation assay (OECD 471; EPA 870.5100)	Non-mutagenic	Yes	*2007/1051931
In vitro chromosome aberration assay in Chinese hamster V79 cells (OECD 473, EPA 870.5375)	Not clastogenic	Yes	*2008/1002741
In vitro gene mutation test in CHO cells (HPRT locus assay) (OECD 476, EPA 870.5300)	Not mutagenic	Yes	*2008/1014199
In vivo micronucleus test in bone marrow cells of the mouse (OECD 474, EPA 870.5395)	Not clastogenic or aneugenic	Yes	*2008/1002421
Rabbit prenatal developmental toxicity, oral gavage during days 6-28 of gestation 0, 100, 300 and 1000 mg/kg bw/d (OECD 414, EPA 870.3700)	Developmental NOAEL: 1000 mg/kg bw/day Maternal NOAEL 300 mg/kg bw/day LOAEL 1000 mg/kg/bw/day, clinical signs, mortality, abortions, decreased food consumption and body weight gain	Yes	*2009/1072509

* indicates that a study was reviewed at EU level; for details see BAS 700 F - Volume 3, Annex B.6a: Toxicology and Metabolism; B.6.8Further toxicological studies (IIA 5.8) p.365ff

6.4.3 R234886 (plant and soil metabolite of azoxystrobin)

An overview of the results of the accepted toxicological studies for groundwater metabolite R234886 is given in the following table. All studies have previously been considered within an EU peer review process (EFSA conclusion). There are no studies on the metabolite that have not previously been considered within an EU peer review process.

Compound R234886 is a major plant metabolite and the main groundwater metabolite. It is the free acid form of the glucuronidated rat metabolite V of azoxystrobin. Metabolite V is found at over 25% of the azoxystrobin administered dose. The repeat dose toxicity of R234886 is considered to have been addressed adequately by in situ production from the administration of azoxystrobin (see DAR, 2009; Vol. 3 Annex B, B 6.14 (p. 81). During the azoxystrobin peer review (PRAPeR 71 meeting), the experts concluded that R234886 is not a relevant groundwater metabolite.

Table 6.4-3: Summary of the results of toxicity studies for R234886

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity, rat (OECD 423)	Rat oral LD50 > 5000 mg/kg bw	Yes	EFSA Journal 2010; 8(4); 1542*
Ames test (OECD 471)	Non-mutagenic	Yes	EFSA Journal 2010; 8(4); 1542*

* indicates that a study was reviewed at EU level; for details see Azoxystrobin - Volume 3, Annex B.6a: Toxicology and Metabolism; B.6.8 Further toxicological studies (IIA 5.8) p.155-160)

6.5 Dermal Absorption (KCP 7.3)

Dermal absorption studies performed with BAS 736 00 F are not available. Default dermal absorption estimates will therefore be applied for model estimations of non-dietary exposure to the active ingredients contained in BAS 736 00 F. Following the Guidance on Dermal absorption (EFSA Journal 2017; 15(6):4873), default estimate values will be used in the absence of experimental data. BAS 736 00 F is a solvent-based emulsion concentrate (EC), therefore the default values to be used for the active ingredients are 25% for the undiluted concentrate and 70% for the spray-strength dilutions.

A summary of the dermal absorption rates for the active substances in BAS 736 00 F are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in BAS 736 00 F

	Fluxapyroxad		Azoxystrobin	
	Value	**Reference**	**Value**	**Reference**
Concentrate	~~25 % (default)~~ 70 % (default)	EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)	25 % (default)	EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)
Dilutions (all dilutions)	70 % (default)	EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)	70 % (default)	EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)

6.5.1 Justification for proposed values - Fluxapyroxad

No data on dermal absorption for fluxapyroxad in BAS 736 00 F is available. Justifications for default values according to Guidance on Dermal Absorption (~~EFSA Journal 2012; 10(4):2665~~ EFSA Journal 2017;15(6):4873)) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for fluxapyroxad

	Value	Justification for value	Acceptability of justification
Concentrate	~~25 %~~ 70%	BAS 736 00 F is a emulsion concentrate (EC) type formulation. Therefore, the default value for solvent-based formulation types was selected. The concentration of fluxapyroxad in product BAS 736 00 F is below or equal 5% therefore in line with the EU guidance (SANTE/2018/10591 rev.1 of 24 October 2018) a plant protection product is considered as a "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to than to 50 g/L (or 50g/Kg or 5%).	Acceptable EFSA Journal 2017; 15(6):4873 Table 2 (p. 19) with a corrigendum (minor modification) has been adopted in the Standing Committee on Plants, Animals, Food and Feed on 24 October 2018.
Dilution	70 %	See justification above.	Acceptable EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)

6.5.2 Justification for proposed values - Azoxystrobin

No data on dermal absorption for fluxapyroxad in BAS 736 00 F is available. Justifications for default values according to Guidance on Dermal Absorption (~~EFSA Journal 2012; 10(4):2665~~ 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	25 %	BAS 736 00 F is a emulsion concentrate (EC) type formulation. Therefore, the default value for solvent-based formulation types was selected.	Acceptable EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)
Dilution	70 %	See justification above.	Acceptable EFSA Journal 2017; 15(6):4873 Table 2 (p. 19)

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	BAS 736 00 F	
Formulation type	EC	
Category	Fungicide	
Active substance(s) (incl. content)	**Fluxapyroxad (BAS 700 F)** 50 g/L	**Azoxystrobin (BAS 9164 F)** 75 g/L
AOEL systemic	0.04 mg/kg bw/d	0.2 mg/kg bw/d
Acute AOEL systemic	Not assigned	Not assigned
Inhalation absorption	100%	100%
Oral absorption	68%	100%
Dermal absorption	~~Concentrate (50 g/L): 25% (default)~~ Concentrate (50 g/L): 70% (default Dilutions (1:50 – 1:300): 70% (default)	Concentrate (75 g/L): 25% (default) Dilutions (1:50 – 1:300): 70% (default)

6.6.1 Selection of critical use(s) and justification

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

Justification

BAS 736 00 F is intended to be used in cereals; therefore, vehicle-mounted downward spraying to field crops is the only application equipment to be considered. The product is to be applied at a rate range of 1.0 – 2.0 L/ha and at a water application range of 100 – 300 L/ha.

Within the uses proposed for countries of the Central Zone, the GAP in cereals selected for exposure assessment of BAS 736 00 F yields the highest exposure based on two applications at the maximum application rate of 2 L product/ha and thus identified as “Critical GAP”. Other proposed uses involve only single applications or allow two applications but with a lower application rate.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Cereals, outdoor spraying (2 L product/ha. 2 applications within 21-days)
Model(s)	EFSA guidance AOEM [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874.]

Table 6.6-3: Estimated operator exposure

Application to cereals: vehicle-mounted, outdoor downward spraying		**Fluxapyroxad (BAS 700 F)**		**Azoxystrobin (BAS 9164 F)**	
Application rate: 2 L product/ha		0.1 kg a.s./ha		0.15 kg a.s./ha	
Longer-term exposure					
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of RVNAS (AOEL)**	**Total absorbed dose (mg/kg/day)**	**% of RVNAS (AOEL)**
EFSA AOEM 75th percentile Body weight: 60 kg	no PPE work wear - arms, body and legs covered concentrate dermal absorption 25%	0.0805	201	0.1113	56
	no PPE work wear - arms, body and legs covered concentrate dermal absorption 70%	0.2089	522	-	-
	work wear - arms, body and legs covered during mixing/loading and application PPE: gloves during mixing/loading concentrate dermal absorption 25%	0.0111	28	0.0164	8.2
	work wear - arms, body and legs covered during mixing/loading and application PPE: gloves during mixing/loading. concentrate dermal absorption 70%	0.01448	36.2%	-	-

6.6.3 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 considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

zRMS:
The exposure to Fluxapyroxad (BAS 700 F) of operator wearing a work clothing (long sleeved shirt, long trousers) during loading/mixing and application but no PPE and applying a product BAS 736 00 F (Miralon) on cereals at maximal dose of 2.0 L product/ha (0.1 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 522 % of AOEL. In case the operator is using protective gloves during mixing and loading the exposure to Fluxapyroxad (BAS 700 F) is reduced to 36.2% of AOEL..

The exposure to Azoxystrobin (BAS 9164 F) of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying a product BAS 736 00 F (Miralon) on cereals at maximal dose of 2.0 L product/ha (0.15 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 56 % of AOEL. In case the operator is using protective gloves during mixing and loading the exposure to Fluxapyroxad (BAS 700 F) is reduced to 8.2% of AOEL..

The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) and using protective gloves during mixing and loading to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product BAS 736 00 F (Miralon) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator

Summing up the application of product BAS 736 00 F (Miralon) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves during mixing and loading. Since the product classified as Skin Irrit. 2, Eye Dam. 1 and Skin Sens.1 the operator should wear protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BAS 736 00 F according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Cereals (2 L product/ha, outdoor spraying. 2 applications within 21 days)
Model	EFSA guidance [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874]

Table 6.6-5: Estimated worker exposure

Model data	Level of PPE	Fluxapyroxad (BAS 700 F)		Azoxystrobin (BAS 9164 F)	
		Total absorbed dose (mg/kg bw/day)	% of RVNAS (sys. AOEL)	Total absorbed dose (mg/kg bw/day)	% of RVNAS (sys. AOEL)
Number of applications and application rate: 2 applications, 2 L product/ha, 21-day treatment interval		2 x 0.10 kg a.s./ha		2 x 0.15 kg a.s./ha	
2 hours/day(1) TC [cm²/person/h] (2) - potential exposure: 12500 - no PPE: 1400 - PPE: not assigned Body weight: 60 kg concentrate dermal absorption 25%	Potential exposure	0.141	353	0.212	106
	workwear(3)	0.0158	40	0.024	12
	… plus gloves (4)	n.a.	n.a.	n.a.	n.a.
2 hours/day(1) TC [cm²/person/h] (2) - potential exposure: 12500 - no PPE: 1400 - PPE: not assigned Body weight: 60 kg concentrate dermal absorption 70%	Potential exposure	0.141	353		
	workwear(3)	0.0158328	39.58		
	… plus gloves (4)	n.a	n.a		

(1) 2 h/day for professional applications for maintenance or scouting of cereals;
(2) EFSA guidance model
(3) no PPE: Workwear - Arm, body and legs covered
(4) with PPE: Work wear and gloves - Hands, arm, body and legs covered
n.a. = not assigned, since no TC available for this exposure scenario

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

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 dislodgeable foliar residues was therefore not performed.

6.6.4.3 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.

zRMS:
The exposure to Fluxapyroxad (BAS 700 F), an active substance of a product BAS 736 00 F (Miralon) of

worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product BAS 736 00 F (Miralon) at maximal dose of 2.0 L product/ha (0.1 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 40 % of respective AOEL.

The exposure to Azoxystrobin (BAS 9164 F), an active substance of a product BAS 736 00 F (Miralon), of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product BAS 736 00 F (Miralon) at maximal dose of 2.0 L product/ha ((0.15 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 12 % of respective AOEL.

The sum of exposures of worker wearing a work clothing (long sleeved shirt, long trousers) to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product BAS 736 00 F (Miralon) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of worker.

Thus, it is concluded that the application of a product BAS 736 00 F (Miralon)does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers).

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to fluxapyroxad and azoxystrobin. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Cereals, outdoor spraying (max. 2 L product/ha)
Model	EFSA guidance [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874 .]

Table 6.6-7: Estimated bystander and resident exposure

Cereal application: vehicle-mounted, outdoor downward spraying		**Fluxapyroxad (BAS 700 F)**		**Azoxystrobin (BAS 9164 F)**	
Application rate: 2 L product/ha		**2 x 0.1 kg a.s./ha**		**2 x 0.15 kg a.s./ha**	
Model data for residents: Drift rate: 5.60% (2-3 m buffer) 75th percentile data		**Total absorbed dose (mg/kg/day)**	**% of RVNAS (AOEL)**	**Total absorbed dose (mg/kg/day)**	**% of RVNAS (AOEL)**
1-3 year old child Body weight: 10 kg	Spray drift	0.0188	47	0.0282	14
	Vapour	0.0011	2.7	0.0011	0.5
	Surface deposits	0.0017	4.3	0.0027	1.3
	Entry into treated crops	0.0191	48	0.0286	14
	All pathways (mean)	0.0279	70 (69.84)	0.0414	21
Adults Body weight: 60 kg	Spray drift	0.0045	11	0.0068	3.4
	Vapour	0.0002	0.58	0.0002	0.12
	Surface deposits	0.0008	1.9	0.0012	0.58
	Entry into treated crops	0.0106	27	0.0159	8.0
	All pathways (mean)	0.0114	29 (28.46)	0.0170	8.5

6.6.5.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for fluxapyroxad and azoxystrobin 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 and was therefore not performed.

zRMS:
The exposure estimation of resident (adult and child) to both active substances of a product BAS 736 00 F (Miralon) applied on a field of cereals at dose of 2.0 L product/ha, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident is equal respectively to 29% and to 70% of AOEL for Fluxapyroxad (BAS 700 F), and to 8.5% and to 21% of AOEL for Azoxystrobin (BAS 9164 F) and a sum of exposures of adult or child resident to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product product BAS 736 00 F (Miralon) does not pose an unacceptable risk to the health of adult and child resident for its intended use within good agricultural practice.

No bystander acute exposure estimation for Fluxapyroxad (BAS 700 F) and for Azoxystrobin (BAS 9164 F) is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Fluxapyroxad (BAS 700 F) and to Azoxystrobin (BAS 9164 F) as a result of application of a product BAS 736 00 F (Miralon) with accordance with intended use within good agricultural practice.

Summing up application of a product a product BAS 736 00 F (Miralon) on a field of cereals at dose of 2.0 L product/ha, using tractor-mounted/trailed boom sprayer in line with GAP does not pose an unacceptable health risk for residents and bystanders.

6.6.6 Combined exposure

The product is a mixture of two active substances.

6.6.6.1 Exposure Assessment of fluxapyroxad and azoxystrobin in BAS 736 00 F

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 from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-8: Acute risk assessment from combined exposure

Application scenario	Active Ingredient	Estimated exposure / RVNAS or RVAAS (HQ)
Operators – vehicle-mounted outdoor downward spraying with PPE [longer-term exposure]	fluxapyroxad	~~0.28~~ 0.36
	azoxystrobin	0.082
	Cumulative risk Operators (HI)	**~~0.362~~ 0.442**
Workers – crop inspection (worst case)	fluxapyroxad	0.40
	azoxystrobin	0.12
	Cumulative risk Workers (HI)	**0.36**
Resident – Child (all pathways)	fluxapyroxad	0.70
	azoxystrobin	0.21
	Cumulative risk Resident – Child (HI)	**0.91**
Resident – Adult (all pathways)	fluxapyroxad	0.29
	azoxystrobin	0.085
	Cumulative risk Resident – Adult (HI)	**0.375**

The Hazard Index is < 1. Thus combined exposure to all active substances in BAS 736 00 F is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

zRMS:
Since hazard index of combined exposure, calculated as sum of exposures to both active substances expressed as a decimal fraction of respective AOEL for each active substance of product BAS 736 00 F (Miralon), is below 1, the combined exposures of operator, worker and residents to both substances are considered as not posing an unacceptable risk.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.1.1/1	xxx	2020	BAS 736 00 F - Acute oral toxicity study in rats 2020/2080214 xxx	Yes	BASF
KCP 7.1.3/1	xxx	2015	BAS 736 00 F - Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure (nose-only) 2021/2000826 xxx	Yes	BASF
KCP 7.1.4/1	Remmele M.	2020	BAS 736 00 F - In vitro skin irritation and corrosion turnkey testing strategy 2020/2028460 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 7.1.5/1	Remmele M.	2020	BAS 736 00 F in vitro eye irritation test (EIT) in reconstructed human cornea 2020/2027869 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	BASF

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

BAS 736 00 F is a new product, no product data have been evaluated previously

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

BAS 736 00 F is an EC (emulsion concentrate) type formulation containing the active substances fluxapyroxad (50 g/L) and azoxystrobin (75 g/L).

For toxicological evaluation of this product, alternatives to vertebrate animal testing were taken into consideration as far as could be scientifically justified. A weight-of-evidence approach was pursued to provide a sufficiently reliable assessment of the product's acute toxicity by oral, dermal and inhalation routes of exposure, and of its potential to cause skin irritation, eye irritation and skin sensitization:

a) Prediction of toxicity, based on toxicity data from active ingredient and co-formulants, as far as available
b) results of in-vitro studies, and
c) in the absence of available similar EC-type products containing both active substances, limited (acute oral and inhalation toxicity) testing of the product in vertebrate animals to verify if the additivity assumption applies for predicting the health hazards from the product's composition according to CLP Regulation 1272/2008 (GHS calculating approaches) – and as prerequisite for waiving the acute dermal toxicity study.

Availability of acute toxicity data of BAS 736 00 F components

An overview of the available safety data sheet information on acute toxicity classification of the individual components contained in BAS 736 00 F is given in the following table. For confidentiality reasons, the co-formulants are coded (see Confidential Document Part C, Appendix 2 for corresponding table with extra column disclosing the co-formulant identity).

Table A 1: Overview of BAS 736 00 F ingredient MSDS information concerning acute toxicity C&L (CLP)

Ingredient	Conc [% w/w] (rounded)	Acute tox. C&L (MSDS)	Acute oral toxicity	Acute dermal toxicity	Acute inhalation toxicity	Skin Corr / Irrit	Eye Dam / Irrit	Skin Sens
Fluxapyroxad	4.64	–	no	no	no	no	no	no
Azoxystrobin	6.96	Acute (INH) 3	no	no	H331	no	no	no
#3	20.40	Acute (ORL) 4	H302	no data	no data	no	no	no
#4	19.57	Eye Irrit. 2	no	no	no	no	H319	no
#5	13.45	Skin Irrit.2 Eye Irrit. 2	no	no	no	H315	H319	no
#6	9.55	–	no	no	no data	no	no	no data
#7	9.28	Eye Dam. 1 Skin Irrit. 2 Skin Sens. 1	no	no	no	H315	H318	H317
#8	4.64	–	no	no data	no data	no	no	no data
#9	3.25	Eye Irrit. 2	no	no data	no data	no	H319	no data
#10	2.60	–	no	no	no	no	no	no
#11	2.50	–	no	no data	no	no	no	no
#12	1.76	–	no	no	no	no	no	no
#13	1.39	Skin Sens 1B	no	no	no data	no	no	H317
% of product with acute toxicity data			100	69	61	100	100	83

The weight-of-evidence approach used to predict the classification of BAS 736 00 F for a certain acute toxicity endpoint is described at the beginning of the corresponding sub-sections of this Appendix.

A 2.1 Statement on bridging possibilities

For the solvent-based EC-type formulation BAS 736 00 F, products of similar composition containing both active ingredients fluxapyroxad and azoxystrobin were not identified that appeared sufficiently useful for bridging. Therefore, the likelihood for non-additive toxicity phenomena and thus the reliability of the acute toxicity prediction via the GHS calculation approach could not be validated against in-vivo data from similar products. Consequently, and since azoxystrobin is classified as toxic by inhalation, acute toxicity studies by oral and inhalation routes of exposure were carried out with BAS 736 00 F.

Comments of zRMS:	The statement on the bridging possibilities is acceptable.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Data for assessment of acute oral toxicity is available for all 13 ingredients of the product. Only ingredient #3 (contained 20.4% in the product) with an acute oral LD_{50} of 1625 mg/kg bw is classified in Acute Tox. Cat. 4; H302 (harmful if swallowed); the active ingredients or other co-formulants are not classified for acute oral toxicity (see Table A 1).

Applying the calculation algorithm …

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i} = \frac{20.35}{1625}; \qquad ATE_{mix} = 100 \times \frac{1625}{20.35} = 7985 \text{ mg/kg bw}$$

an acute oral toxicity ATE_{mix} (LD_{50}) of 7985 mg/kg bw is calculated. Hence, a classification for acute oral toxicity is not indicated for BAS 736 00 F on the basis of its composition.

Since BAS 736 00 F represents a currently unique combination of active ingredients, an acute oral toxicity study in rats was performed to investigate if higher-than-expected toxicity occurs. In the study, 2 of 3 rats administered a dose of 2000 mg/kg bw died. No deaths occurred in two groups of three rats at a dose of 500 mg/kg bw. By Probit analysis according to Finney, an oral LD_{50} of 1848 mg/kg bw could be calculated. A study summary is provided at the end of this chapter.

In conclusion, based on the available data, BAS 736 00 F is classified in Acute Tox. Cat. 4; H302 (harmful if swallowed) according to Regulation (EC) No. 1272/2008, with an ATE = 1848 mg/kg bw.

A 2.2.1 Acute oral toxicity study with BAS 736 00 F in rats

Reference:	CP 7.1.1/1
Report	BAS 736 00 F - Acute oral toxicity study in rats xxx, 2020 xxx
Guideline(s):	OECD 423 (2001), Comm. Reg. (EC) No 440/2008, JMAFF 8147, EPA 870.1100
Deviations:	No
GLP:	Yes (certified by Landesanstalt fuer Umwelt, Messungen und Naturschutz Baden-Wuerttemberg, Karlsruhe, Germany)

Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	BAS 736 00 F Batch No. FD-190220-0002 Purity/Content: - Fluxapyroxad (BAS 700 F): 49.4 g/L - Azoxystrobin (BAS 9164 F): 73.9 g/L
Species	Wistar rat (Crl:WI (Han) SPF)
No. of animals (group size)	3 female rats/group
Dose(s)	2000 mg/kg bw (one group) 500 mg/kg bw (two groups)
Exposure	Once by oral gavage
Vehicle/Dilution	Undiluted
Post exposure observation period	14 days
Remarks	None

Results and discussions

- Mortality was observed in two of three animals in the first test group receiving 2000 mg/kg bw of the formulation; the animals died at hour 2 after treatment. Therefore, a second test group of three animals received a dose of 500 mg/kg bw of the formulation. In the absence of mortality, a third test group of three rats was administered the same dose of 500 mg/kg bw, and again no mortality was observed [see Table A 2]. An ATE of 1848 mg/kg bw was calculated by Probit analysis (according to Finney) on account of 6/6 survivors at 500 mg/kg bw and 1/3 survivors at 2000 mg/kg bw.
- At the dose of 2000 mg/kg bw, impaired general state and piloerection was observed from hour 2 until day 1 after administration in the animal that survived treatment. No clinical signs of toxicity were observed in two rats that died at hour 2. At the dose of 500 mg/kg bw, all animals of the first and second group showed impaired general state and piloerection on the day of treatment, and one rat of the first group additionally was found with dyspnea (hour 3-4) and in a cowering position (hour 4).
- All animals gained weight in a normal range throughout the study period.
- In the two animals that died on the day of treatment, gross necropsy showed yellowish discoloration of the stomach contents, red discoloration of the small intestine and dark discoloration of the liver. There were no macroscopic pathological findings in the animals sacrificed at the end of the observation period.

Table A 2: Results of acute oral toxicity study in rats of BAS 736 00 F

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Female rats				

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
2000	2 / 1 / 3	h2 – d1	h2	1848**
500	0 / 3/ 3	h2 – h4	No deaths	
500	0 / 3 / 3	h2 – h5	No deaths	

***** Number of animals which died/number of animals with clinical signs/number of animals used
hx: hours after administration at day 0; dx: days after administration
** LD_{50} 1848.398 mg/kg bw calculated by Probit Analysis according to Finney (SAS v9.4; intercept: -41.10, slope: 5.464).

Conclusion

Under the study conditions, the acute oral LD_{50} of BAS 736 00 F in rats was approx. 1848 mg/kg bw.

Comments of zRMS:	The study performed according to relevant OECD guidelines and in GLP conditions is acceptable. The results indicate that LD50 of 1848 mg/kg bw is within classification criteria for category 4 (300 < Category 4 ≤ 2 000 mg/kg bw), therefore the formulation BAS 736 00 F (Miralon) require classification for acute oral toxicity according to criteria of the Regulation 1272/2008 as Acute Tox. H302. The study revealed that the acute oral toxicity of BAS 736 00 F (Miralon) is much greater than that that predicted by calculation method based on content and classification of all ingredients of the formulation.

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

Data for assessment of acute dermal toxicity is available for 69% of the product's composition (for 9 out of 13 ingredients, see Table A 1). Since oral toxicity data is available for all ingredients, oral-to-dermal extrapolation could be applied either at product or ingredient level to finally predict the acute dermal toxicity of the product thereby considering data from all ingredients. The acute dermal toxicity of ingredient #3 (classified harmful if swallowed) might be derived by oral-to-dermal extrapolation: considering its oral ATE of 1625 mg/kg bw and assuming worst-case dermal absorption for oral-to-dermal extrapolation, it is evident that the resulting calculated dermal ATEmix for BAS 736 00 F containing 20.35% of this ingredient would by higher than 2000 mg/kg bw and therefore not require classification. Also applying oral-to-dermal extrapolation from the available acute oral toxicity test with BAS 736 00 F (oral LD_{50} 1848 mg/kg bw, no deaths at 500 mg/kg bw) does not give rise to any relevant concern for acute dermal toxicity (even if unrealistic systemic bioavailability is assumed), due to the predicted low acute oral toxicity of the product.

Thus, based on weight-of-evidence (composition and oral-to-dermal extrapolation), it is concluded BAS 736 00 F does not require classification for acute dermal toxicity according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	The provided weight-of-evidence analysis of acute dermal toxicity (composition and oral-to-dermal extrapolation), of Miralon is acceptable. Formulation BAS 736 00 F (Miralon) does not require classification for acute dermal toxicity.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Data for assessment of acute inhalation toxicity is available for 8 of 13 ingredients comprising approx. 61% of the total composition (see Table A 1). The active ingredient azoxystrobin (6.96% w/w) is classified as toxic by inhalation (Cat. 3; H331 with an ATE of 0.7 mg/L). None of the other ingredients with data indicate a concern for acute inhalation toxicity.

A calculation approach using the modified GHS algorithm for mixtures containing >10% relevant ingredients with unknown acute inhalation toxicity …

$$\frac{100-(\sum C_{unknown\ if\ >10\%})}{ATE_{mix}} = \sum_{n}\frac{C_i}{ATE_i}$$

$$\frac{61}{ATE_{mix}} = \sum_{n}\frac{C_i}{ATE_i} = \frac{6.96}{0.7}$$

$$ATE_{mix} = 61 \times \frac{0.7}{6.96} = 6.1 \text{ mg/L}$$

… predicts the product BAS 736 00 F to be of low acute toxicity by the inhalation route, with no need for acute toxicity classification (because LC_{50} > 5 mg/L).

However, there is some doubt whether the additivity prerequisite for using the GHS calculation approach applies in the case of BAS 736 00 F, since it under-predicted the acute oral toxicity of the product, when compared to results of the acute oral toxicity study in rats. Behind this background and for reasons of caution, it was considered necessary to perform an acute inhalation toxicity test with BAS 736 00 F in rats.

Comments of zRMS:	The study of acute inhalation toxicity study in Wistar rats of BAS 736 00 F -performed according to relevant OECD guidelines and in GLP conditions is acceptable. The results indicate that LC_{50} - 2.002 mg/L air for male rats and 2.335 mg/L air for female rats, is within classification criteria for category 4 of acute inhalation toxicity (1,0 < Category 4 ≤ 5,0 mg/L) therefore the formulation BAS 736 00 F (Miralon) require classification for acute inhalation toxicity according to criteria of the Regulation 1272/2008 as Acute Tox. 4, H332: Harmful if inhaled The study has revealed that BAS 736 00 F (Miralon) acute inhalation toxicity is greater than that predicted by calculation method based on content and classification of all ingredients of the formulation

A 2.4.1 Acute inhalation toxicity in rats with BAS 736 00 F

Reference:	CP 7.1.3/1
Report	BAS 736 00 F - Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure (nose-only) xxx
Guideline(s):	OECD 436 (2009), (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to (EC) No 1907/2006 of European Parliament and of Council on the REACH - Part B No. L 142
Deviations:	No
GLP:	Yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und

Gewerbeaufsicht, Mainz, Germany)

Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	BAS 736 00 F Batch No. FD-190220-0002 Purity/Content: - Fluxapyroxad (BAS 700 F): 49.4 g/L - Azoxystrobin (BAS 9164 F): 73.9 g/L
Species	Rat, Wistar (Crl:WI (Han) SPF)
No. of animals (group size)	3 male and 3 female rats per dose
Concentration(s)	1.132 and 5.622 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Concentration(s) and exposure conditions

Nominal conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
2.9	1.132	0.76 – 0.78	3.85 – 3.92
23.7	5.622	1.28 – 1.45	3.85 – 4.01

* MMAD = Mass Median Aerodynamic Diameter; ** GSD = Geometric Standard Deviation

Table A 4: Results of acute inhalation toxicity study in rats of BAS 736 00 F

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC_{50} (mg/L air) (14 days)
Male rats				
1.132	0 / / ~~5~~ 3	h1 – d5	No deaths	2.002
5.622	~~5~~ 3 / / ~~5~~ 3			
Female rats				
1.132	0 / / ~~5~~ 3		No deaths	2.335
5.622	~~5~~ 3 / / ~~5 3~~	h1 – d5		

* Number of animals which died/number of animals with clinical signs/number of animals used
h(x): hours after start of exposure; d(y): day of observation; d1 = day of application

Table A 5: Summary of findings of acute inhalation toxicity study in rats of BAS 736 00 F.

Mortality:	None of the animals died at 1.132 mg/L. At the high dose of 5.622 mg/L, 2 males and 3 females died after exposure on Day 0 and one male died on Day 1.
Clinical signs:	Clinical signs of toxicity in animals exposed to 1.132 mg/L comprised accelerated respiration, intermittent respiration, respiration sounds, piloerection and substance contaminated fur. At 5.622 mg/L, both male and female rats displayed intermittent respiration during exposure (h2-h4). No further clinical signs were noted in female rats. Male rats showed poor general condition, hunched posture, semi-closed eyelid, red-encrusted nose, impaired respiration (gasping, labored, sounds), no defacation, piloerection and substance-contaminated fur, observed up to day 1.
Body weight:	At 1.132 mg/L the mean body weights of the animals decreased on the first post-exposure day but increased thereafter. At 5.622 mg/L the body weight of the surviving male animal decreased on the first post-exposure observation day. No body weight data were available from Day 1 onward because all animals died or were sacrificed in a moribund state on Days 0 or 1.
Macroscopic examination:	At 5.266 mg/L, 1 female with blood nose. No other observations were noted at this dose or at 1.132 mg/L upon gross necropsy in animals that died or were sacrificed in a moribund state or at termination of the post exposure period.

Conclusion

Under the experimental conditions, the calculated inhalation LC_{50} of BAS 736 00 F was approx. 5 mg/L (cut-off value derived in accordance with OECD test guideline 436, Annex 3d) in male and female Wistar rats after 4-hour inhalation exposure to liquid aerosol of BAS 736 00 F. Thus, BAS 736 00 F is to be classified as ‘Harmful if inhaled’, Cat 4, H332 according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Data for assessment of skin irritation is available for all 13 ingredients of the product (see Table A 1). Ingredients #5 (13.45%) and #7 (9.28%) are classified as skin irritants (Skin Irrit.2; H315). The remaining components are not classified as skin irritant.
Based on skin irritation data available for the components, product classification as skin irritant is triggered for BAS 736 00 F according to GHS/CLP criteria, because the total product concentration of skin irritating ingredients is above the 10% trigger for classification.
When the product was tested in-vitro in the EpiDerm™ test (OECD 431 and OECD 439), BAS 736 00 F showed evidence for a relevant skin irritation potential (viability 2.4% after 1-h exposure followed by 42-h incubation period, compared to the negative control). However, based on published literature, a false-positive rate of 40% was identified for agrochemical formulations in this in-vitro skin irritation test (Kolle et al. (Regul. Toxicol. Pharmacol. 89, 125-130, 2017). Therefore, some doubt remains regarding the reliability of the study result.

However, in absence of bridging opportunities for read-across to similar products, the overall data available points to a skin-irritating hazard of BAS 736 00 F. For reasons of precaution, and to avoid vertebrate testing, it is proposed to classify BAS 736 00 F on the basis of the in-vitro study results as skin irritant.

Comments of zRMS:	The combined concentration of ingredients of product BAS 736 00 F (Miralon) classified as Skin Irrit. 2, H 315 amounted to 22,73% , which above 10% a generic concentration limit of ingredients classified for skin irritant hazard (Category 2) that trigger classification of the mixture as irritant to skin set in Regulation 1272/2008 (Table 3.2.3). This conclusion is further supported be the results of the acceptable in vitro study done according to relevant OECD guidelines (OECD 439) and in GLP conditions. The mean relative viability of the tissues treated with BAS 736 00 F after an exposure period of 1 hour with an about 42-hour post-incubation period was 2.32% (well below 50%), while it was 100% in the negative control group. The results indicate that a product should be classified as Skin Irrit. 2, H 315 The Skin Corrosivity test (SCT) OECD 431 did not provide an evidence for BAS 736 00 F skin corrosivity since mean tissue viability was 85.5% after 3 min exposure and 74.6% after 1 hour exposure(in % of negative control), thus well above 50%. Based on this evidence, the formulation BAS 736 00 F (Miralon) require classification for skin irritation according to criteria of the Regulation 1272/2008 as Skin Irrit. 2, H 315: Causes skin irritation.

A 2.5.1 In-vitro skin corrosion and skin irritation study with BAS 736 00 F

Reference:	CP 7.1.4/1
Report	BAS 736 00 F - In vitro skin irritation and corrosion turnkey testing strategy Remmele M., 2010 Report No: 69V0415/18A084 BASF DocID 2020/2028460
Guideline(s):	OECD 431, OECD 439, Commission Regulation (EC) No 440/2008 - Part B No. B.40 bis, Commission Regulation EU No. 640/2012 of 06 July 2012 - B.46
Deviations:	No

GLP:	Yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	BAS 736 00 F Batch No. FD-190220-0002 Purity/Content: - Fluxapyroxad (BAS 700 F): 49.4 g/L - Azoxystrobin (BAS 9164 F): 73.9 g/L pH value: ca. 5.0 (undiluted, determined in test facility)	
Test system	Reconstructed in vitro human skin model, EpiDerm™	
Principle of the method	Induced cytotoxicity (loss of viability) is expressed as the reduction of mitochondrial dehydrogenase activity measured by reduction of MTT conversion to blue-colored formazan, in comparison to a negative control. The test substance's ability of direct MTT reduction was minimal and did not impair the study result in a relevant way as demonstrated by the concurrently performed exposure of control tissues inactivated by freezing	
	Skin Corrosivity test (SCT) OECD 431	***Skin Irritation test (SIT) OECD 439***
No. of tissues per exposure and group	2	3
Exposure	50 µL (3 min), 50 µL (1 h)	30 µL (1 h)
Vehicle / dilution	Tested undiluted	Tested undiluted
Post-exposure incubation period	Not applicable	42 h
Positive control	8 N potassium hydroxide	5% (w/v) sodium dodecyl sulfate (SDS)
Negative control	De-ionized water	Phosphate-buffered saline (PBS)
Assessment	***Mean tissue viability (% of negative control)***	
Corrosive (optional subcategory 1A) [a]	3 min: < 50	–
Corrosive (opt. subcategory 1B and 1C) [a]	3 min: ≥ 50 and 1 hour: < 15	–
Non-corrosive	3 min: ≥ 50 and 1 hour: ≥ 15	–
Irritant	–	1 +42 hours: ≤ 50
Non-Irritant	–	1 +42 hours: > 50

[a] According to the current OECD Guideline 431 a sub-categorization is possible based on the results. However, the sub-

categorization into 1A is highly over-predictive as stated in the guideline and differentiation into sub-category 1B or 1C is not possible. If the test substance is identified to be corrosive by SCT and a transport classification is needed, the Corrositex® test (OECD 435) should be performed, if applicable, to confirm classification as 1A or to differentiate between 1B and 1C.

Results and discussions

Results of the skin corrosion and skin irritation tests are summarized in the table below.

Table A 6: in-vitro skin corrosion / irritation of BAS 736 00 F

Parameter	Negative control (NC)	Test item	Positive control
	viable tissue	viable tissue	viable tissue
Exposure: 3 min			
OD_{570} tissue I	2.150	1.853	0.188
OD_{570} tissue II	2.014	1.708	0.151
mean OD_{570}	2.082	1.781	0.169
Viability (% of NC)	**100.0 ± 4.6**	**85.5 ± 4.9**	**8.1 ± 1.3**
Exposure: 1 h			
OD_{570} tissue I	2.030	1.719	0.083
OD_{570} tissue II	1.965	1.262	0.086
mean OD_{570}	1.997	1.491	0.085
Viability (% of NC)	**100.0 ± 2.3**	**74.6 ± 16.2**	**4.2 ± 0.1**
Exposure:1 h + post-exposure incubation: 42 h			
OD_{570} tissue I	1.928	0.048	0.056
OD_{570} tissue II	1.961	0.048	0.056
OD_{570} tissue III	1.873	0.046	0.053
mean OD_{570}	1.920	0.047	0.055
Viability (% of NC)	**100.0 ± 2.3**	**2.46 ± 0.08**	**2.8 ± 0.1**
Mn viability of KC tissues (% of NC)	*2.8 ± 0.2*	*0.14 ± 0.18*	–
Final mean viability after KC correction (% of NC)	**–**	**2.32**	**–**

NC = negative control (deionised water), PC = positive control (8 N KOH); OD_{570} = optical density by λ = 570 nm

BAS 736 00 F was not corrosive to skin under the in-vitro study conditions. The mean relative viability of the tissues treated with the test substance determined after an exposure period of 3 minutes was 85.5%, and it was 74.6% after an 1-hour exposure period.

In the skin irritation test (SIT), the mean relative viability of the tissues treated with the test substance determined after an exposure period of 1 hour with an about 42-hour post-incubation period was about 2.46%. If the value is corrected for the minimal ability of the test substance to interfere with the detection method, the final mean viability is calculated to be 2.32%.

Conclusion

Based on the results obtained BAS 736 00 F was found to be skin irritant in the in vitro test with human reconstituted epidermis (mean tissue viability 2.32% of the negative control, thus clearly below the 50% viability threshold). In the corrosivity assay, mean tissue viability values at 3 minutes of ≥ 50% of the negative control and at one hour of ≥ 15% of the negative control indicated that BAS 736 00 F was not corrosive under the conditions of this assay. On the basis of these results, the product meets the criteria for classification as skin irritant.

A 2.6 Eye irritation (KCP 7.1.5)

Data for assessment of eye irritation is available for all 13 ingredients of the product (see Table A 1). Nine of the 13 ingredients are classified as non-irritants (ca. 54.5%). Co-formulants #4 (19.57%), #5 (13.45%) and #9 (3.25%) are classified as eye irritants (Eye Irrit 2; H319). Ingredient #7 (9.28%) is classified with Eye Dam. 1; H318. According to mixture classification algorithms of GHS/CLP, the concentration of the eye damaging ingredient #7 is already above the 3% classification trigger and consequently the product requires classification with Eye Dam. 1; H318.

A pH value of ca. 5.0 was determined for undiluted BAS 736 00 F, indicating no concern for corrosivity (see KCP 7.4.1 DocID 2019/2073795).

When BAS 736 00 F was investigated in-vitro, the EpiOcular™ test (OECD 492) gave evidence for an eye corrosive or irritating potential. This test method has been shown to be sufficiently reliable for predicting true negative in-vivo study outcomes in tests with agrochemical formulations (Kolle et al. 2017), but the test method cannot specify the Category of a test substance that is positive in the EpiOcular™test.

Based on the overall weight- of evidence (classification as Eye Dam. 1; H318 based on the composition / GHS calculation approach, and evidence for an eye irritation or corrosion potential in the EpiOcular™ Test, the available data indicates that classification as eye corrosive (Eye Dam. 1; H318) is warranted for BAS 736 00 F according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	The concentration of ingredient classified as Eye Dam. 1, H318 is 9.28%, which above 3%, a generic concentration limits of ingredients of a mixture classified as Category 1 for effects on the eye that trigger classification of the mixture for effects on the eye to Category 1 set in Regulation 1272/2008 (Table 3.3.3). The strong effects on eyes are supported by the combined concentration of ingredients of product BAS 736 00 F (Miralon) classified as Eye Irrit. 2, H 319 amounted to 36,27%. The serious eye damage/eye irritation by BAS 736 00 F is further supported be the results of the acceptable *in vitro* study which was carried out according to relevant OECD guidelines (Reconstructed Human Cornea-Like Epithelium (RhCE) Test Method OECS TG 492) for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage) and done in GLP conditions. The viability of reconstructed corneal tissues following exposure to BAS 736 00 F was 14.8% of the negative control value (thus lower than 60%), what indicates eye irritating or corrosive properties. Based on this evidence, the formulation BAS 736 00 F (Miralon) require classification for serious eye damage/eye irritation according to criteria of the Regulation 1272/2008 as Eye Dam. 1, H318: Causes serious eye damage

A 2.6.1 EpiOcular in-vitro eye irritation test (OECD 492)

Reference:	CP 7.1.5/1
Report	BAS 736 00 F – In Vitro Eye Irritation Test (EIT) in Reconstructed Human Cornea Remmele M., 2020 Report No: 62V0415/18A085 BASF DocID 2020/2027869
Guideline(s):	OECD 492 (2018) IATA for serious eye damage and eye irritation, Series on Testing and Assessment No. 263, 20 July 2017
Deviations:	No
GLP:	Yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	BAS 736 00 F Batch No. FD-190220-0002 Purity/Content: - Fluxapyroxad (BAS 700 F): 49.4 g/L - Azoxystrobin (BAS 9164 F): 73.9 g/L pH value: ca. 5.0 (undiluted, determined in test facility)

EpiOcular™ Test

Test system	Reconstructed in vitro human ocular model, EpiOcular™
Principle of the method	The test substance is administered to the surface of the EpiOcular™ tissue. Induced cytotoxicity (loss of viability) is expressed as the reduction of mitochondrial dehydrogenase activity measured by reduction of MTT conversion to blue-colored formazan, in comparison to a negative control.

No. of tissues per test group	2
Pretest for detection of direct (= non-enzymatic) MTT reduction	In a pre-test, the test substance is incubated with the substrate MTT and checked for formazan formation, indicating "direct" MTT reduction. In this event, two additional "freeze-killed" tissues each for the test substance group and the negative control group are added to the standard test protocol.
Exposure	50 µL: 30 min
Vehicle / dilution	Tested undiluted
Post-exposure wash solution	Phosphate-buffered saline (PBS)
Post-exposure incubation period	2 hours
Positive control	Methyl acetate
Negative control	De-ionized water
Assessment	***Mean tissue viability*** *(% of negative control)*
Irritant	≤ 60
Non-irritant	> 60

Results and discussions

Table A 7: in-vitro eye corrosion / irritation of BAS 736 00 F (EpiOcular™ Assay)

Test substance		Tissue 1	Tissue 2	**Mean**	Inter-tissue variability [%]
Neg. control (NC)	mean OD_{570}	2.279	2.335	2.307	
	Viability [% of NC]	98.8	101.2	**100.0**	2.4
BAS 736 00 F	mean OD_{570}	0.361	0.324	0.342	
	Viability [% of NC]	15.6	14.0	**14.8**	1.6
Positive control (PC)	mean OD_{570}	0.560	0.521	0.540	
	Viability [% of NC]	24.3	22.6	**23.4**	1.7

NC = negative control (de-ionized water), PC = positive control (methyl acetate); OD_{570} = optical density by λ = 570 nm

The viability of reconstructed corneal tissues following exposure to BAS 736 00 F was 14.8% of the negative control value (thus lower than 60%), indicating eye irritating or corrosive properties. In parallel incubations using KC tissues, the test substance showed minimal ability to reduce MTT directly (relative mean viability 0.07% of NC, data not tabulated here); However, the final relative mean viability of the test substance was not affected by KC correction (14.8% – 0.07% ≈ 14.8%).

Conclusion

Based on the results observed and the assessment criteria, BAS 736 00 F shows an eye corrosion/irritation potential in the EpiOcular™ test. For final assignment of a classification according to GHS/CLP criteria, additional data are required.

A 2.7 Skin sensitisation (KCP 7.1.6)

No skin sensitisation test was performed for the product BAS 736 00 F.

Data for assessment of skin sensitization is available for 83% of the product's composition (see Table A 1). Skin sensitization information is missing for ingredients #6, #8 and #9. Two ingredients, #7 (9.28%) and #13 (1.39%) are classified as skin sensitiser in Cat. 1 and Cat 1B, respectively. The active ingredients and the remaining co-formulants (#3, #4, #5, #10, #11 and #12) are not classified as skin sensitisers.

Overall, the content of both skin sensitising co-formulants #7 and #13 exceed the default 1% threshold concentration for skin sensitization classification applying GHS criteria. On this basis, classification with Skin Sens. 1; H317 is required for BAS 736 00 F according to classification criteria of Commission Reg. No. 1172/2008.

Comments of zRMS:	The concentration of ingredient of a product BAS 736 00 F (Miralon) classified as Skin Sens. 1 amounts 9.28% and as Skin Sens. 1B 1.39%, which well above 1 %, which is a generic concentration limit of ingredients of a mixture classified as skin sensitisers that trigger classification of the mixture as Skin Sens. 1 according to Regulation 1272/2008 (Table 3.4.3). Thus, a product BAS 736 00 F (Miralon) warrants classification as Skin Sens. 1, H317: May cause an allergic skin reaction

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

None available.

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 studies on dermal absorption are available for active ingredients formulated in BAS 736 00 F.

Non-dietary exposure estimations were conducted using default dermal absorption studies as recommended by the EFSA guidance on dermal absorption (EFSA Journal 2017; 15(6):4873) – see Chapter 6.5.

A 2.11 Other/Special Studies

None available.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for fluxapyroxad

Table A 8: Input parameters considered for the estimation of operator exposure (AOEM according to EFSA guidance) – no PPE: workwear

Application rate of active substance	**0.1**	kg a.s./ha	*i_AppRate*
Assumed area treated	**50**	ha/day	*d_AreaTreated*
Amount of active substance applied	**5**	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	**25%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**70%**		*i_AbsorInuse*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		
Indoor or Outdoor application	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Season	**not relevant**		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	**16767**	**62314**	AOEM	
	Body	**11058**	**114960**	AOEM	
	Head	**259**	**1423**	AOEM	
	Protected hands (gloves)	**98**	**990**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**99**	**731**	AOEM	
	Protected head (hood and face shield)	**4**	**81**	AOEM	
	Inhalation	**6**	**30**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**			
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Table A 8: Input parameters considered for the estimation of operator exposure (AOEM according to EFSA guidance) – no PPE: workwear (cont'd)

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	**742**	**7449**	AOEM	
	Body	**415**	**2138**	AOEM	
	Head	**20**	**59**	AOEM	
	Protected hands (gloves)	**102**	**4021**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**11**	**28**	AOEM	
	Inhalation	**2**	**7**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**			
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 9: Fluxapyroxad: Estimation of operator exposure using the EFSA model – no PPE: workwear

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	**7.852**	**4.830**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.1309**	**0.0805**
% of RVNAS	**327%**	**201%**

Table A 9: Fluxapyroxad: Estimation of operator exposure using the EFSA model – no PPE: workwear (cont'd)

2. DETAILS - Longer-term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**4191.680**	**69.861**	*D15*i_AbsorpProduct*
Body	**2764.375**	**46.073**	*D16*i_AbsorpProduct*
Head	**64.854**	**1.081**	*D17*i_AbsorpProduct*
Inhalation	**5.976**	**0.100**	*D21*i_AbsorpInhalation*
Sum	**7026.885**	**117.115**	
With RPE/PPE (as selected above)			
Hands	**4191.680**	**69.861**	*D18*i_AbsorpProduct*
Body	**24.744**	**0.412**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**64.854**	**1.081**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**5.976**	**0.100**	*D21*i_AbsorpInhalation*G25*
Sum	**4287.255**	**71.454**	
Water soluble bag	**4287.255**	**71.454**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**519.132**	**8.652**	*D30*i_AbsorpInuse*
Body	**290.264**	**4.838**	*D31*i_AbsorpInuse*
Head	**13.719**	**0.229**	*D32*i_AbsorpInuse*
Inhalation	**2.319**	**0.039**	*D35*i_AbsorpInhalation*
Sum	**825.434**	**13.757**	
With RPE/PPE (as selected above)			
Hands	**519.132**	**8.652**	*D33*i_AbsorpInuse*
Body	**7.962**	**0.133**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**13.719**	**0.229**	*D32*i_AbsorpInuse*F39*
Inhalation	**2.319**	**0.039**	*D35*i_AbsorpInuse*G39*
Sum	**543.133**	**9.052**	

Table A 10: Fluxapyroxad: Input parameters for estimation of operator exposure (AOEM according to EFSA guidance) – PPE level: gloves (mixing/loading), workwear

Application rate of active substance	**0.1**	kg a.s./ha	*i_AppRate*
Assumed area treated	**50**	ha/day	*d_AreaTreated*
Amount of active substance applied	**5**	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	**25%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**70%**		*i_AbsorInuse*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		
Indoor or Outdoor application	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Season	**not relevant**		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	**16767**	**62314**	AOEM	
	Body	**11058**	**114960**	AOEM	
	Head	**259**	**1423**	AOEM	
	Protected hands (gloves)	**98**	**990**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**99**	**731**	AOEM	
	Protected head (hood and face shield)	**4**	**81**	AOEM	
	Inhalation	**6**	**30**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**Yes**		Incl. in AOEM model	
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Table A 10: Fluxapyroxad: Input parameters for estimation of operator exposure (AOEM according to EFSA guidance) – PPE level: gloves (mixing/loading), workwear (cont'd)

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	**742**	**7449**	AOEM	
	Body	**415**	**2138**	AOEM	
	Head	**20**	**59**	AOEM	
	Protected hands (gloves)	**102**	**4021**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**11**	**28**	AOEM	
	Inhalation	**2**	**7**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**		Incl. in AOEM model	
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 11: Fluxapyroxad: Estimation of operator exposure using the EFSA model PPE level: gloves (mixing/loading), workwear

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	**7.852**	**0.663**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.1309**	**0.0111**
% of RVNAS	**327%**	**28%**

Table A 11: Fluxapyroxad: Estimation of operator exposure using the EFSA model
PPE level: gloves (mixing/loading), workwear (cont'd)

2. DETAILS - Longer-term exposure
2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**4191.680**	**69.861**	*D15*i_AbsorpProduct*
Body	**2764.375**	**46.073**	*D16*i_AbsorpProduct*
Head	**64.854**	**1.081**	*D17*i_AbsorpProduct*
Inhalation	**5.976**	**0.100**	*D21*i_AbsorpInhalation*
Sum	**7026.885**	**117.115**	
With RPE/PPE (as selected above)			
Hands	**24.537**	**0.409**	*D18*i_AbsorpProduct*
Body	**24.744**	**0.412**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**64.854**	**1.081**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**5.976**	**0.100**	*D21*i_AbsorpInhalation*G25*
Sum	**120.112**	**2.002**	
Water soluble bag	**120.112**	**2.002**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**519.132**	**8.652**	*D30*i_AbsorpInuse*
Body	**290.264**	**4.838**	*D31*i_AbsorpInuse*
Head	**13.719**	**0.229**	*D32*i_AbsorpInuse*
Inhalation	**2.319**	**0.039**	*D35*i_AbsorpInhalation*
Sum	**825.434**	**13.757**	
With RPE/PPE (as selected above)			
Hands	**519.132**	**8.652**	*D33*i_AbsorpInuse*
Body	**7.962**	**0.133**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**13.719**	**0.229**	*D32*i_AbsorpInuse*F39*
Inhalation	**2.319**	**0.039**	*D35*i_AbsorpInuse*G39*
Sum	**543.133**	**9.052**	

Calculations of operator exposure performed by zRMS

zRMS Fluxapyroxad: Estimation of operator exposure using the EFSA model and concentrate dermal absorption 70% – no PPE: workwear

Operator exposure for Miralon outdoor spray applications

Application rate of active substance	0,1	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	70,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

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

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	16767	62314	AOEM	
	Body	11058	114960	AOEM	
	Head	259	1423	AOEM	
	Protected hands (gloves)	98	990	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	99	731	AOEM	
	Protected head (hood and face shield)	4	81	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	742	7449	AOEM	
	Body	415	2138	AOEM	
	Head	20	59	AOEM	
	Protected hands (gloves)	102	4021	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	11	28	AOEM	
	Inhalation	2	7	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	20,4899568	12,5366884
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,3414993	0,2089448
% of RVNAS	853,75%	522,36%

zRMS: Fluxapyroxad: Estimation of operator exposure using the EFSA model and concentrate dermal absorption 70% – gloves during mixing and loading , workwear during mixing/loading and application

Operator exposure for Miralon outdoor spray applications

Application rate of active substance	0,1	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	70,00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70,00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

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

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	16767	62314	AOEM	
	Body	11058	114960	AOEM	
	Head	259	1423	AOEM	
	Protected hands (gloves)	98	990	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	99	731	AOEM	
	Protected head (hood and face shield)	4	81	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Incl. in AOEM model	
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	742	7449	AOEM	
	Body	415	2138	AOEM	
	Head	20	59	AOEM	
	Protected hands (gloves)	102	4021	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	11	28	AOEM	
	Inhalation	2	7	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	20,4899568	0,8686896
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,3414993	0,0144782
% of RVNAS	853,75%	36,20%

A 3.1.2 Calculations for azoxystrobin

Table A 12: Input parameters considered for the estimation of operator exposure (AOEM according to EFSA guidance) – no PPE: workwear

Application rate of active substance	**0.15**	kg a.s./ha	*i_AppRate*
Assumed area treated	**50**	ha/day	*d_AreaTreated*
Amount of active substance applied	**7.5**	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	**25%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**70%**		*i_AbsorInuse*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		
Indoor or Outdoor application	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Season	**not relevant**		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	**22909**	**85448**	AOEM	
	Body	**14704**	**129332**	AOEM	
	Head	**389**	**2134**	AOEM	
	Protected hands (gloves)	**128**	**1486**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**142**	**1097**	AOEM	
	Protected head (hood and face shield)	**6**	**121**	AOEM	
	Inhalation	**7**	**30**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**			
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Table A 12: Input parameters considered for the estimation of operator exposure (AOEM according to EFSA guidance) – no PPE: workwear (cont'd)

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	**1112**	**10024**	AOEM	
	Body	**622**	**3206**	AOEM	
	Head	**29**	**89**	AOEM	
	Protected hands (gloves)	**127**	**4216**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**17**	**42**	AOEM	
	Inhalation	**3**	**9**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**			
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 13: Azoxystrobin: Estimation of operator exposure using the EFSA model – no PPE: workwear

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	**10.745**	**6.681**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.1791**	**0.1113**
% of RVNAS	**89.5%**	**56%**

Table A 13: Azoxystrobin: Estimation of operator exposure using the EFSA model – no PPE: workwear (cont'd)

2. DETAILS - Longer-term exposure

2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**5727.280**	**95.455**	*D15*i_AbsorpProduct*
Body	**3676.011**	**61.267**	*D16*i_AbsorpProduct*
Head	**97.282**	**1.621**	*D17*i_AbsorpProduct*
Inhalation	**6.742**	**0.112**	*D21*i_AbsorpInhalation*
Sum	**9507.315**	**158.455**	
With RPE/PPE (as selected above)			
Hands	**5727.280**	**95.455**	*D18*i_AbsorpProduct*
Body	**35.445**	**0.591**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**97.282**	**1.621**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**6.742**	**0.112**	*D21*i_AbsorpInhalation*G25*
Sum	**5866.750**	**97.779**	
Water soluble bag	**5866.750**	**97.779**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**778.698**	**12.978**	*D30*i_AbsorpInuse*
Body	**435.397**	**7.257**	*D31*i_AbsorpInuse*
Head	**20.578**	**0.343**	*D32*i_AbsorpInuse*
Inhalation	**2.842**	**0.047**	*D35*i_AbsorpInhalation*
Sum	**1237.514**	**20.625**	
With RPE/PPE (as selected above)			
Hands	**778.698**	**12.978**	*D33*i_AbsorpInuse*
Body	**11.944**	**0.199**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**20.578**	**0.343**	*D32*i_AbsorpInuse*F39*
Inhalation	**2.842**	**0.047**	*D35*i_AbsorpInuse*G39*
Sum	**814.062**	**13.568**	

Table A 14: Azoxystrobin: Input parameters for estimation of operator exposure (AOEM according to EFSA guidance) – PPE level: gloves (mixing/loading), workwear

Application rate of active substance	**0.15**	kg a.s./ha	*i_AppRate*
Assumed area treated	**50**	ha/day	*d_AreaTreated*
Amount of active substance applied	**7.5**	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	**25%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**70%**		*i_AbsorInuse*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		
Indoor or Outdoor application	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Season	**not relevant**		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	**22909**	**85448**	AOEM	
	Body	**14704**	**129332**	AOEM	
	Head	**389**	**2134**	AOEM	
	Protected hands (gloves)	**128**	**1486**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**142**	**1097**	AOEM	
	Protected head (hood and face shield)	**6**	**121**	AOEM	
	Inhalation	**7**	**30**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**Yes**		Incl. in AOEM model	
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Table A 14: Azoxystrobin: Input parameters for estimation of operator exposure (AOEM according to EFSA guidance) – PPE level: gloves (mixing/loading), workwear (cont'd)

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	**1112**	**10024**	AOEM	
	Body	**622**	**3206**	AOEM	
	Head	**29**	**89**	AOEM	
	Protected hands (gloves)	**127**	**4216**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**17**	**42**	AOEM	
	Inhalation	**3**	**9**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**		Incl. in AOEM model	
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

Table A 15: Azoxystrobin: Estimation of operator exposure using the EFSA model PPE level: gloves (mixing/loading), workwear

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	**10.745**	**0.985**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.1791**	**0.0164**
% of RVNAS	**89.5%**	**8.2%**

Table A 15: Azoxystrobin: Estimation of operator exposure using the EFSA model PPE level: gloves (mixing/loading), workwear (cont'd)

2. DETAILS - Longer-term exposure
2.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula

Without RPE/PPE			
Hands	**5727.280**	**95.455**	*D15*i_AbsorpProduct*
Body	**3676.011**	**61.267**	*D16*i_AbsorpProduct*
Head	**97.282**	**1.621**	*D17*i_AbsorpProduct*
Inhalation	**6.742**	**0.112**	*D21*i_AbsorpInhalation*
Sum	**9507.315**	**158.455**	
With RPE/PPE (as selected above)			
Hands	**31.948**	**0.532**	*D18*i_AbsorpProduct*
Body	**35.445**	**0.591**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**97.282**	**1.621**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**6.742**	**0.112**	*D21*i_AbsorpInhalation*G25*
Sum	**171.417**	**2.857**	
Water soluble bag	**171.417**	**2.857**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**778.698**	**12.978**	*D30*i_AbsorpInuse*
Body	**435.397**	**7.257**	*D31*i_AbsorpInuse*
Head	**20.578**	**0.343**	*D32*i_AbsorpInuse*
Inhalation	**2.842**	**0.047**	*D35*i_AbsorpInhalation*
Sum	**1237.514**	**20.625**	
With RPE/PPE (as selected above)			
Hands	**778.698**	**12.978**	*D33*i_AbsorpInuse*
Body	**11.944**	**0.199**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**20.578**	**0.343**	*D32*i_AbsorpInuse*F39*
Inhalation	**2.842**	**0.047**	*D35*i_AbsorpInuse*G39*
Sum	**814.062**	**13.568**	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for fluxapyroxad

Table A 16: Input parameters considered for the estimation of worker exposure

Crop type	**Cereals**		
Indoor or outdoor	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Worker's task	**Inspection, irrigation**		
Main body parts in contact with foliage	**Hand and body**		
Application rate of active substance	**0.1**	kg a.s./ha	*i_AppRate*
Number of applications	**2**		*i_AppNo*
Interval between multiple applications	**21**	days	*i_AppInt*
Half-life of active substance	**30**	days	*d_HalflifeAS*
Multiple application factor	**1.6**		*d_MAF*
Dermal absorption of the product	**25%**		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	**70%**		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.3**	µg a.s./cm^2	*d_DFR*
Working hours	**2**	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	**12500**	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	**1400**	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	**no TC available for this assessment**	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	**NA**	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	**NA**	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	**NA**	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 17: Fluxapyroxad: Estimation of worker exposure using the EFSA guidance model

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	**8.482**	**0.950**	**no TC available for this assessment**
Total systemic exposure per kg body weight (mg/kg bw/day)	**0.141**	**0.0158**	
% of RVNAS	**353%**	**40%**	

2. Details

	Systemic exposure [mg a.s./day]	[mg a.s./kg bw/day]	Formula
Dermal - Potential	**8.482**	**0.141**	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*
Dermal - Work wear - arms, body and legs covered	**0.950**	**0.0158**	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*
Dermal - Working wear and gloves	**no TC available for this assessment**		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*
Inhalation	NA for outdoor activities		

Calculations of worker exposure to **Fluxapyroxad** performed by zRMS

Worker exposure from residues on foliage for Miralon		
Crop type	Cereals	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0,1	kg a.s./ha
Number of applications	2	
Interval between multiple applications	21	days
Half-life of active substance	30	days
Multiple application factor	1,6	
Dermal absorption of the product	70,00%	
Dermal absorption of the in-use dilution	70,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	8,4817541	0,9499565	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1413626	0,0158326	
% of RVNAS	353,41%	39,58%	

A 3.2.2 Calculations for azoxystrobin

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

Crop type	**Cereals**		
Indoor or outdoor	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Worker's task	**Inspection, irrigation**		
Main body parts in contact with foliage	**Hand and body**		
Application rate of active substance	**0.15**	kg a.s./ha	*i_AppRate*
Number of applications	**2**		*i_AppNo*
Interval between multiple applications	**21**	days	*i_AppInt*
Half-life of active substance	**30**	days	*d_HalflifeAS*
Multiple application factor	**1.6**		*d_MAF*
Dermal absorption of the product	**25%**		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	**70%**		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.45**	µg a.s./cm^2	*d_DFR*
Working hours	**2**	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	**12500**	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	**1400**	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	**no TC available for this assessment**	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	**NA**	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	**NA**	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	**NA**	ha/hr*10^(-3)	*d_InhalTcSort*

Table A 19: Azoxystrobin: Estimation of worker exposure using the EFSA guidance model

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	**12.723**	**1.425**	**no TC available for this assessment**
Total systemic exposure per kg body weight (mg/kg bw/day)	**0.212**	**0.024**	
% of RVNAS	**106%**	**12%**	

2. Details

	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Dermal - Potential	**12.723**	**0.212**	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*
Dermal - Work wear - arms, body and legs covered	**1.425**	**0.0237**	*d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*
Dermal - Working wear and gloves	**no TC available for this assessment**		*d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_AbsorpInuse*
Inhalation	NA for outdoor activities		

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for fluxapyroxad

Table A 20: Fluxapyroxad: Resident exposure: Input parameters for the estimation (EFSA guidance model)

Crop type	**Cereals**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		*i_AppEquip*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		*i_FormVal*
Buffer strip	**2-3**	m	*i_Buffer*
Application rate of the product	**0.1**	kg a.s./ha	*i_AppRate*
Conc.a.s. (in-use dilution for liquid applications)	**1.0**	g a.s./l	*d_ConcAS*
Dermal absorption of product	**25%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**70%**		*i_AbsorpInuse*
Oral absorption	**68%**		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.3**	µg a.s./cm2	*d_DFR*
Vapour pressure of in-use dilution	**low volatile substances having a vapour pressure of <5*10-3Pa**	Pa	*i_Volat*
Concentration in air	**0.001**	mg/m3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile – adult	**0.47**	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile – child	**0.327**	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile – adult	**0.00010**	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile – child	**0.00022**	ml spray dilution/person	
Resident dermal spray drift exposure mean – adult	**0.22318**	ml spray dilution/person	
Resident dermal spray drift exposure mean – child	**0.18**	ml spray dilution/person	
Resident inhal. spray drift exposure mean – adult	**0.00009**	ml spray dilution/person	
Resident inhal. spray drift exposure mean – child	**0.00017**	ml spray dilution/person	
Exposure duration dermal	**2**	hours	*d_ReExpDur*
Exposure duration inhalation	**24**	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	**0.25**	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	**18.0%**		*d_ClothAF*
Breathing rate adult	**0.23**	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	**1.07**	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	**5.60%**		
Drift percentage on surface (mean)	**4.10%**		
Turf transferable residues percentage	**5.00%**		*d_Turf*
Transfer coeff. of surface deposits-adult	**7300**	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 yr old)	**2600**	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	**50.00%**		*d_SalExt*
Surface area of hands mouthed	**20**	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	**9.5**	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	**25**	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	**20.00%**		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	**7500**	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	**2250**	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	**5980**	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	**1794**	cm^2/h	*d_TcEntryCh*

Table A 21: Fluxapyroxad: Estimation of resident exposure

1. Total

1-3 year old child	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways
	– 75th percentile –				– mean –
Total systemic exposure (mg a.s./day)	**0.1879**	**0.0107**	**0.0174**	**0.1908**	**0.2791**
Total systemic exposure (mg/kg bw/day)	**0.0188**	**0.0011**	**0.0017**	**0.0191**	**0.0279**
% of RVNAS	**47%**	**2.7%**	**4.3%**	**48%**	**70%**
Adult	**Spray drift**	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All pathways**
	– 75th percentile –				– mean –
Total systemic exposure (mg a.s./day)	**0.2699**	**0.0138**	**0.0462**	**0.6361**	**0.6831**
Total systemic exposure (mg/kg bw/day)	**0.0045**	**0.0002**	**0.0008**	**0.0106**	**0.0114**
% of RVNAS	**11%**	**0.58%**	**1.9%**	**27%**	**29%**

Table A 21: Fluxapyroxad: Estimation of resident exposure (cont'd)

2. Details – Resident exposure 75th percentile data

1-3 year old child	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Spray drift	**0.1879**	**0.01879**	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*
Vapour	**0.0107**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.0165**	**0.00165**	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*
Hand to mouth	**0.0006**	**0.00006**	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.0003**	**0.00003**	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.1908**	**0.01908**	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*
Hand to mouth*	–	–	*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*
Object to mouth*	–	–	*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*

Adult	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Spray drift	**0.2699**	**0.00450**	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*
Vapour	**0.0138**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.0462**	**0.00077**	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*
Entry into treated crops (dermal)	**0.6361**	**0.01060**	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*

*Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.

Table A 21: Fluxapyroxad: Estimation of resident exposure (cont'd)

3. Details – Resident exposure– Summing up all resident exposure pathways – mean data

1-3 year old child	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Spray drift	**0.1035**	**0.01035**	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*
Vapour	**0.0107**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.0121**	**0.00121**	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur *MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_ AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*
Hand to mouth	**0.0004**	**0.00004**	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.0002**	**0.00002**	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_Absor pOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.1522**	**0.01522**	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*
Hand to mouth*	–	–	*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaH M*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*
Object to mouth*	–	–	*(i_AppRate/100)*1*d_DRP*d_MouthGrass *i_AbsorpOralInuse*d_MAF*
Adult	**Systemic exposure [mg a.s./day]**	**Systemic exposure [mg a.s./kg bw/day]**	**Formula**
Spray drift	**0.1282**	**0.00214**	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*
Vapour	**0.0138**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.0338**	**0.00056**	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur *MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_ AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*
Entry into treated crops (dermal)	**0.5072**	**0.00845**	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*

Calculations of residents exposure to **Fluxapyroxad p**erformed by zRMS

Resident exposure for Miralon

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

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1879180	0,0107000	0,0177778	0,1908395	0,2793685
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0187918	0,0010700	0,0017778	0,0190839	0,0279369
% of RVNAS	46,98%	2,68%	4,44%	47,71%	69,84%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,2698800	0,0138000	0,0462312	0,6361316	0,6830521
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0044980	0,0002300	0,0007705	0,0106022	0,0113842
% of RVNAS	11,25%	0,58%	1,93%	26,51%	28,46%

A 3.3.2 Calculations for azoxystrobin

Table A 22: Azoxystrobin: Resident exposure: Input parameters for the estimation (EFSA guidance model)

Crop type	**Cereals**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		*i_AppEquip*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		*i_FormVal*
Buffer strip	**2-3**	m	*i_Buffer*
Application rate of the product	**0.15**	kg a.s./ha	*i_AppRate*
Conc.a.s. (in-use dilution for liquid applications)	**1.5**	g a.s./l	*d_ConcAS*
Dermal absorption of product	**25%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**70%**		*i_AbsorpInuse*
Oral absorption	**100%**		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.45**	µg a.s./cm2	*d_DFR*
Vapour pressure of in-use dilution	**low volatile substances having a vapour pressure of <5*10-3Pa**	Pa	*i_Volat*
Concentration in air	**0.001**	mg/m3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile – adult	**0.47**	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile – child	**0.327**	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile – adult	**0.00010**	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile – child	**0.00022**	ml spray dilution/person	
Resident dermal spray drift exposure mean – adult	**0.22318**	ml spray dilution/person	
Resident dermal spray drift exposure mean – child	**0.18**	ml spray dilution/person	
Resident inhal. spray drift exposure mean – adult	**0.00009**	ml spray dilution/person	
Resident inhal. spray drift exposure mean – child	**0.00017**	ml spray dilution/person	
Exposure duration dermal	**2**	hours	*d_ReExpDur*
Exposure duration inhalation	**24**	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	**0.25**	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	**18.0%**		*d_ClothAF*
Breathing rate adult	**0.23**	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	**1.07**	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	**5.60%**		
Drift percentage on surface (mean)	**4.10%**		
Turf transferable residues percentage	**5.00%**		*d_Turf*
Transfer coeff. of surface deposits-adult	**7300**	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 yr old)	**2600**	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	**50.00%**		*d_SalExt*
Surface area of hands mouthed	**20**	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	**9.5**	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	**25**	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	**20.00%**		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - adult	**7500**	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - child	**2250**	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	**5980**	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	**1794**	cm^2/h	*d_TcEntryCh*

Table A 23: Azoxystrobin: Estimation of resident exposure

1. Total

1-3 year old child	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways
	– 75th percentile –				– mean –
Total systemic exposure (mg a.s./day)	**0.2819**	**0.0107**	**0.0267**	**0.2863**	**0.4137**
Total systemic exposure (mg/kg bw/day)	**0.0282**	**0.0011**	**0.0027**	**0.0286**	**0.0414**
% of RVNAS	**14%**	**0.5%**	**1.3%**	**14%**	**21%**
Adult	**Spray drift**	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All pathways**
	– 75th percentile –				– mean –
Total systemic exposure (mg a.s./day)	**0.4048**	**0.0138**	**0.0693**	**0.9542**	**1.0177**
Total systemic exposure (mg/kg bw/day)	**0.0068**	**0.0002**	**0.0012**	**0.0159**	**0.0170**
% of RVNAS	**3.4%**	**0.12%**	**0.58%**	**8.0%**	**8.5%**

Table A 23: Azoxystrobin: Estimation of resident exposure (cont'd)

2. Details – Resident exposure 75th percentile data

1-3 year old child	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Spray drift	**0.2819**	**0.02819**	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*
Vapour	**0.0107**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.0247**	**0.00247**	*(i_AppRate/100)*C29*d_Turf*d_ReTCCh*d_ReExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*
Hand to mouth	**0.0013**	**0.00013**	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.0007**	**0.00007**	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.2863**	**0.02863**	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*
Hand to mouth*	–	–	*(i_AppRate/100)*d_Turf*d_MAF*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*
Object to mouth*	–	–	*(i_AppRate/100)*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*

Adult	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Spray drift	**0.4048**	**0.00675**	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*
Vapour	**0.0138**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.0693**	**0.00116**	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*
Entry into treated crops (dermal)	**0.9542**	**0.01590**	*(d_TcEntryAd*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*

*Considered only for application on grassland and lawns and for application on golf course, turf or other sports lawns.

Table A 23: Azoxystrobin: Estimation of resident exposure (cont'd)

3. Details – Resident exposure– Summing up all resident exposure pathways – mean data

1-3 year old child	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Spray drift	**0.1552**	**0.01552**	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*
Vapour	**0.0107**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.0181**	**0.00181**	*(i_AppRate/100)*C30*d_Turf*d_ReTCCh*d_ReExpDur *MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_ AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1))*
Hand to mouth	**0.0009**	**0.00009**	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.0005**	**0.00005**	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_Absor pOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.2282**	**0.02282**	*(d_TcEntryMeanCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse))*
Hand to mouth*	–	–	*(i_AppRate/100)*1*d_Turf*d_MAF*d_SalExt*d_AreaH M*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*
Object to mouth*	–	–	*(i_AppRate/100)*1*d_DRP*d_MouthGrass *i_AbsorpOralInuse*d_MAF*
Adult	**Systemic exposure [mg a.s./day]**	**Systemic exposure [mg a.s./kg bw/day]**	**Formula**
Spray drift	**0.1923**	**0.00320**	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*
Vapour	**0.0138**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.0508**	**0.00085**	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur *MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_ AppEquip = "Vehicle-mounted-Drift Reduction",0.5,1)*
Entry into treated crops (dermal)	**0.7608**	**0.01268**	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*

A 3.4 Combined exposure calculations for fluxapyroxad and azoxystrobin

The estimates are presented in section 6.6.5 above based on the calculation for the individual compounds as presented under A 3.1 to A 3.3.

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

No exposure or DFR studies relied upon.