REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: BAS 762 02 F

Product name(s): Revydas

Chemical active substance(s):

Mefentrifluconazole, 100 g/L
Boscalid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2021

MS Finalisation date: October 2021 (initial Core Assessment)

April 2022 (final Core Assessment)

Version history

When	What
03/2021	Applicant Initial dRR – BASF DocID 2021/2003414
October 2021	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
April 2022	Final report (Core Assessment after the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow, while not agreed use pattern is ~~struck through and shaded~~.

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Reviewer comments:

This part of dossier summarizes data related to the toxicological assessment and exposure data for the plant protection product BAS 762 02 F / Revydas and has been submitted to support registration according art. art. 33 of 1107/2009 in Poland.
Product was not a representative formulation reviewed during the Annex I inclusion/renewal of active substance(s) and has not been previously evaluated in any EU countries according to the Uniform Principles.
For the current product registration, applicant provided relevant data on the plant protection product BAS 762 02 F/Revydas regarding toxicological potential of the product, based on toxicity predicted from composition also substantiated with *in vivo* and *in vitro* tests. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable (please refer Appendix 2 to this dossier).
Due to fact that predictions for eye and skin corrosion/irritation based on composition of the product, results in different outcome than *in vivo* and *in vitro* studies, for this particular case (eye and skin corrosion/irritation) ZRMS decided to take into account only information obtained from *in vivo* and *in vitro* studies. ZRMS consider the other results as complete data package relevant to conclude hazard assessment. Product classification has been agreed using all accepted end-points considering weight of evidence.
ZRMS accepted already existing *in vivo* studies and do not request for the new one. Since there are *in vivo* tests already exist the information gained on animal studies are more than just a classification. Existing animal studies allow to identify of effects following a single exposure to the plant protection product can be established. The data is sufficient to indicate the time course and characteristics of the effect with full details of behavioral changes and possible gross pathological findings at post-mortem. These studies are valid for hazard classification and toxicological risk assessment.

NDE assessment and combined exposure calculations provided for operator, workers and B&R resulting from use of BAS 762 02 F / Revydas (*SC formulation, containing 100 g/L mefentrifluconazole and 200 g/L boscalid for use as a fungicide; refer dRR part B0*) considering critical use(s), identify safe use of the product BAS 762 02 F / Revydas.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on BAS 762 02 F

Product name and code	BAS 762 02 F
Formulation type	SC
Active substance(s) (incl. content)	Mefentrifluconazole, 100 g/L Boscalid, 200 g/L
Function	fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of BAS 762 02 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 762 02 F according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1
Hazard pictograms or Code(s) for hazard pictogram(s):	 GHS07
Signal word:	Warning
Hazard statement(s):	H315: Causes skin irritation H317: May cause an allergic skin reaction H319: Causes serious eye irritation
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 carefully and follow all instructions P261: Avoid breathing mist. P264: Wash contaminated body parts thoroughly after handling P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/clothing and eye/face protection P302+ P352: IF ON SKIN (or hair): Wash with plenty of soap and water P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P337 + P313: If eye irritation persists: ~~Call a POISON CENTER or physician.~~ 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 human health and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for BAS 762 02 F

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Gloves during mixing/loading
Workers	Acceptable	Workwear
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.
Note: additional indication of gloves using, has been based on hazardous properties of the product, thus gloves should be worn.

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:**	**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)** mefentrifluconazole **b)** boscalid	**Water L/ha min / max**			**Operator**	**Worker**	**Bystander**	**Residents**
1,2,3	Oilseed Rape, winter and spring (BBCH 57-75)	F	Spraying, LCTM	a) 1 b) 1	a) 0.06 - 0.10 b) ~~0.18~~ 0.12-0.20	100 - 400	F					
4,5	Sunflower (BBCH 31-69)	F	Spraying, LCTM	a) 2 (7d) b) 2 (7d)	a) 0.06 - 0.10 b) ~~0.18~~ 0.12-0.20	100 - 400	F	critical gap for operator, worker, bystander or resident exposure based on EFSA AOEM				
6	Sunflower (BBCH 31-69)	F	Spraying, LCTM	a) 1 b) 1	a) 0.06 - 0.10 b) ~~0.18~~ 0.12-0.20	100 - 400	F					
7,8	Wheat (BBCH 30-49)	F	Spraying, LCTM	a) 1 b) 1	a) 0.06 - 0.10 b) ~~0.18~~ 0.12-0.20	100 - 300	56					

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

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

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

$ if first application after BBCH 49; min. 21 days spray interval.

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: no applicable.

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 750 F	**BAS 510 F**
Common Name	Mefentrifluconazole	Boscalid
CAS-No.	1417782-03-6	188425-85-6
Classification and proposed labelling With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)		
Hazard classes (s), categories:	Skin Sens. 1 Aquatic Acute 1 (M=1) Aquatic Chronic 1 (M=1)	Aquatic Chronic 2
Code(s) for hazard pictogram(s):	 (GHS07 & GHS09)	 (GHS09)
Signal word:	Warning	
Hazard statement(s):	H317: May cause an allergic skin reaction H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects..	H411: Toxic to aquatic life with long lasting effects
Precautionary statement(s):	P261: Avoid breathing mist or vapour P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves P303 + P352: IF ON SKIN (or hair): Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage P501: Dispose of contents/container to hazardous or special waste collection point.	P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of contents/container to hazardous or special waste collection point.
Reference:	RAC Opinion (2018) Harmonized classification EC Reg. 2020/1182 15th ATP	ECHA C&L inventory
Additional C&L proposal	None.	None.
Agreed EU endpoints		
AOEL systemic	0.035 mg/kg bw/d (no correction for oral absorption required)	0.1 mg/kg bw/d (corrected for 44% oral absorption)
AAOEL	0.15 mg/kg bw/d	Not allocated
Reference	EFSA Journal 2018; 16(7):5379	EU Review Report for the active substance SANCO/3919/2007-rev.5, 21. January 2008
Conditions to take into account/critical areas of concern with regard to toxicology		
Review Report/EFSA Conclusion for active substance	None related to toxicology	Operator safety

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for BAS 762 02 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 762 02 F

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Acute oral toxicity, predicted from composition	LD_{50} > 2000 mg/kg bw	Yes		CLP 1272/2008
LD_{50} oral, rat (OECD 423)	LD_{50} > 5000 mg/kg bw	Yes	No classification	XXX & XXX, 2019
Acute dermal toxicity, predicted from composition and supported by oral-to dermal extrapolation)	LD_{50} > 2000 mg/kg bw	Yes	No classification	CLP 1272/2008
Acute inhalation toxicity, predicted from composition and supported by oral-to-inhalation extrapolation)	LC_{50} > 5 mg/L	Yes	No classification	CLP 1272/2008
~~Skin corrosion / irritation, predicted from composition)~~	~~Non-irritant (calculation see Appendix 2)~~	~~Yes / No / Supplementary~~		~~CLP 1272/2008~~
In vitro Skin irritation, EpiDerm (OECD 439)	1+24h viability: 20.2% skin irritant in-vitro	Yes	**Skin Irrit. 2; H315**	XXX, 2019a
~~Eye corrosion / irritation, predicted from composition)~~	~~Non-irritant (calculation see Appendix 2)~~	~~Yes / No / Supplementary~~		~~CLP 1172/2008~~
In vitro Eye irritation, EpiOcular (OECD 492)	Irritant	Yes	Eye Irrit. 2; H319	XXX, 2019b
In vitro Eye irritation, ICE test (OECD 438)	Inconclusive	Yes		XXX, 2019
Eye irritation, Overall weight-of-evidence	Irritant	Yes	**Eye Irrit. 2; H319**	See Appendix 2
Skin sensitisation predicted from composition)	Skin sensitizer	Yes	**Skin Sens 1, H317**	CLP 1172/2008
Supplementary studies for combinations of plant protection products	No data – not required	--	--	--

Table 6.3-2: Additional toxicological information relevant for classification/labelling of BAS 762 02 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)	Mefentrifluconazole (9.17% (w/w)) (CAS. No. 1417782-03-6)	Skin Sens 1; H317 (criteria ≥ 1%)	RAC Opinion, 2018 Harmonized classification EC Reg. 2020/1182 15th ATP	Skin Sens 1; H317 (criteria ≥ 1%)
Toxicological properties of non-active substance(s) (relevant for classification of product)	~~2-Methyl-2H-isothiazol-3-one (CAS-No. 2682-20-4) ≤ 0.0045% in product~~	~~Skin Sens 1; H317 (criteria ≥ 0.0015%)~~	~~Reg. 1272/2008~~	~~Skin Sens 1; H317 (criteria ≥ 0.0015%)~~
	~~Reaction mass of 5-chloro-2-methyl-4-iso-thiazolin-3-one and 2-methyl-2H-isothiazol-3-one < 0.0015% but >0.00015% in product~~	~~Skin Sens 1; H317 (criteria ≥ 0.0015%)~~	~~Reg. 1272/2008~~	~~To be added on the label~~
	~~1,2-benzisothiazolin-3-one (0.036% (w/w))~~	~~Skin Sens 1; H317 (criteria ≥ 0.05%)~~	~~Reg. 1272/2008~~	~~To be added on the label~~
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

RMS note: According information's retrieved from applicant, Table 6.3.2 has been corrected as follow:

a) The entry for "reaction mass of 5-chloro-2-methyl-4-iso-thiazolin-3-one and 2-methyl-2H-isothiazol-3-one" was a copy&paste typo from another dRR thus it has been deleted.

b) The BIT concentration is : ≤ 0.0048% in product. Based on current SCL of 0.05%, mentioning on the label is not required, thus entry for BIT has been deleted.

c) In section A2.7/Table A6 the information regarding the contents of MIT and BIT is correct.

The correct MIT and BIT concentrations are:
MIT: ≤ 0.0047%
BIT: ≤ 0.0048%

6.4 Toxicological Evaluation of Groundwater Metabolites

All concentrations for metabolites mefentrifluconazole and boscalid are predicted to stay below 0.1 µg/L – no groundwater assessment is required (see Section 8.8 of this dossier).

6.5 Dermal Absorption (KCP 7.3)

Summary of the dermal absorption rates for the active substances in BAS 762 02 F are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in BAS 762 02 F

	Mefentrifluconazole (BAS 750 F)		Boscalid (BAS 510 F)	
	Value	**Reference**	**Value**	**Reference**
Concentrate	0.031% [100 g/L]	New study reported in Appendix 2Appendix 2	0.026% [200 g/L]	New study reported in Appendix 2Appendix 2
Dilution (1:400)	1.8% [0.25 g/L]	New study reported in Appendix 2Appendix 2	0.86% [0.50 g/L]	New study reported in Appendix 2Appendix 2

6.5.1 Justification for proposed values - mefentrifluconazole (BAS 750 F)

Proposed dermal absorption rates for mefentrifluconazole (BAS 750 F) are based on dermal absorption studies with BAS 762 02 F (identical to the product applied for registration). The estimates were derived in accordance to latest EFSA Guidance (2017). The study has not previously been evaluated within an EU peer review process, therefore a full summary of the study on the dermal absorption of BAS 750 F/BAS 762 02 F is described in detail in Appendix 2. A corresponding excel evaluation file (EFSA Version 3) is provided separately with this dossier submission. The study results are summarized in the following table.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for BAS 750 F

Test	Dermal absorption Concentrate [g/L]	Dermal absorption Spray dilution (dilution factor)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	0.031% [100 g/L]	1.8% (1:400) *Pro rata: 3.0%* *(1:667)***	BAS 762 02 F	Yes	Yes (see Appendix 2)	Justification accepted. Endpoint can be used for current product	XXX et al., 2019 (CA 7.3/1 DoclD 2019/2038144)

* indicates that a study was reviewed at EU level; ** see justification in section 6.6

6.5.2 Justification for proposed values - Boscalid (BAS 510 F)

Proposed dermal absorption rates for boscalid (BAS 510 F) are based on dermal absorption studies with BAS 762 02 F (identical to the product applied for registration). The estimates were derived in accordance to latest EFSA Guidance (2017). The study has not previously been evaluated within an EU peer review process, therefore a full summary of the study on the dermal absorption of BAS 750 F/BAS 762 02 F is described in detail in Appendix 2. A corresponding excel evaluation file (EFSA Version 3) is provided separately with this dossier submission. The study results are summarized in the following table.

Table 6.5-3: Summary of the results of submitted dermal absorption studies for BAS 510 F

Test	Dermal absorption Concentrate [g/L]	Dermal absorption Spray dilution (dilution factor)	Formulation in study	Acceptability of study	Justification provided on representativity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	0.026% [200 g/L]	0.86% (1:400) *Pro rata: 1.43%* *(1:667)***	BAS 762 02 F	Yes	Yes (see Appendix 2)	Justification accepted. Endpoint can be used for current product	XXX and XXX, 2019 (CA 7.3/3 DoclD 2019/2040354)

* indicates that a study was reviewed at EU level; ** see justification in section 6.6

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

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

Product name and code	BAS 762 02 F	
Formulation type	SC	
Category	Fungicide	
Container size(s), short description	0.15, 0.25, 0.5, 1 L PA/PE (Coex) or f-HDPE bottles, opening 42 mm inner Ø 1, 3, 5, 10, 20, 50 L PA/PE (Coex) or f-HDPE containers, opening 52-54 mm inner Ø	
Active substance(s) (incl. content)	**Mefentrifluconazole (BAS 750 F)** 100 g/L	**Boscalid (BAS 510 F)** 200 g/L
AOEL systemic	0.035 mg/kg bw/d	0.1 mg/kg bw/d
Acute AOEL systemic	0.15 mg/kg bw/d	Not assigned
Vapour pressure	3.2 x 10^{-6} Pa (20 °C)	7.0 x 10^{-7} Pa (20 °C)
Inhalation absorption	100%	100%
Oral absorption	100%	44%
Dermal absorption	Concentrate (100 g/L): 0.031% 1:400 Dilution (0.25 g/L): 1.8% (new study summarized in Appendix 2)	Concentrate (200 g/L): 0.026% 1:400 Dilution (0.5 g/L): 0.86% (new study summarized in Appendix 2)

6.6.1 Selection of critical use(s) and justification

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

Justification

BAS 762 02 F is intended to be used in oilseed rape, sunflower and wheat; 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 0.6 – 1.0 L/ha and at a water application range of 100 – 400 L/ha.

Within the uses proposed for countries of the Central Zone, the GAP in sunflower selected for exposure assessment of BAS 762 02 F yields the highest exposure based on two applications at the maximum application rate of 1 L product/ha and thus identified as “Critical GAP” (uses #4 and #5) Other proposed uses involve only single applications.

Product- and use-specific dermal absorption estimates for the active ingredients are available for the undiluted product and for the 1:400 dilution. These study-derived estimates are applicable for exposure estimations considering the maximum product application rate of 1 L/ha. Exposure estimations for the lower product application rate of 0.6 L/ha require a corresponding pro-rata increase of the dermal absorption estimate for the maximum in-use dilution of the product’s active ingredients by a factor of 1.67 (= 1.0/0.6). Comparative exposure calculations (summarized in
Table 6.6-2) demonstrate that the higher dermal absorption estimate in combination with the lower product application rate, yields, if at all, decimal point differences in exposure estimates for the different application scenarios. Highest exposure estimates were almost always obtained at the maximum product application rate, except for the acute exposure estimation for operators, which was minimally higher at the low-application rate scenario (2.1% vs 1.9% of the AAOEL). In view of the practically negligible differences, additional detailed calculations for this low-application rate use scenario were not included in Appendix 3, but can be provided at request.

Table 6.6-2: Comparison of exposure estimates for different application scenarios considered for selection of the critical GAP for proposed uses in sunflower

	BAS 750 F		BAS 510 F	
- Number of applications	2	2	2	2
- Product appl. rate	1 L/ha	0.6 L/ha	1 L/ha	0.6 L/ha
- Active ingredient appl. rate	100 g/ha	60 g/ha	200 g/ha	120 g/ha
- Water volume	100 – 400 L/ha		100 – 400 L/ha	
Dermal absorption - Concentrate - Max. Dilution	 0.031% 1.8%	 0.031% 3.0%*	 0.026% 0.86%	 0.026% 1.43%*
Exposure estimates (% AOEL or AAOEL)				
Operator, PPE during M&L				
- long-term exposure	1.06	1.00	0.40	0.37
- acute exposure	1.93	**2.12**	–	–
Worker	1.33	1.33	0.45	0.44
Bystander, child, wort-case	0.80	0.77	–	–
Resident, child, worst -case	5.56	5.42	1.92	1.86

* pro rata extrapolated value from study-derived data at 1:400 dilution

Reviewer comment:

Discussion and justification (see above) reflecting selection of key parameters used for NDE assessment (Table 6.6-2) are accepted by the ZRMS, thus exposure calculation summarized below is relevant for risk assessment. In our opinion separate NDE calculation considering lower AR with Pro-rata DA values correction will not have impact on final risk assessment. In both cases, scenarios which considers high AR with lower DA and lower AR with DA pro-rata adjustment, estimated exposure is significantly below the AOEL / AAOEL.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of BAS 762 02 F according to the critical use(s) is presented in Table 6.6-3. Outcome of the estimation is presented in Table 6.6-4. Detailed calculations are in Appendix 3.

Table 6.6-3: Exposure models for intended uses

Critical use(s)	Sunflower, outdoor spraying (1 L product/ha. 2 applications within 7-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 6.6-4: Estimated operator exposure

Application to oilseed-type crop: vehicle-mounted, outdoor downward spraying		**Mefentrifluconazole (BAS 750 F)**		**Boscalid (BAS 510 F)**	
Application rate: 1 L product/ha		0.1 kg a.s./ha		0.2 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	0.0005	1.31	0.00053	0.53
	PPE gloves and work wear - arms, body and legs covered during mixing/loading and work wear - arms, body and legs covered during application.	0.0004	1.06	0.00040	0.40
Acute exposure					
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of RVAAS (AAOEL)**	**Total absorbed dose (mg/kg/day)**	**% of RVAAS (AAOEL)***
EFSA AOEM 75th percentile Body weight: 60 kg	no PPE work wear - arms, body and legs covered	0.0032	2.14	n.a.	n.a.
	PPE gloves and work wear - arms, body and legs covered during mixing/loading and work wear - arms, body and legs covered during application.	0.0029	1.93	n.a.	n.a.
* AAOEL not assigned (n.a.) for boscalid at EU level					

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.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BAS 762 02 F according to the critical use(s). Outcome of the estimation is presented in
Table 6.6-6. Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Sunflower (1 L product/ha, 2 applications within 7 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 6.6-6: Estimated worker exposure

Model data	Level of PPE	Mefentrifluconazole (BAS 750 F)		Boscalid (BAS 510 F)	
		Total absorbed dose (mg/kg bw/day)	**% of RVNAS (sys. AOEL)**	**Total absorbed dose (mg/kg bw/day)**	**% of RVNAS (sys. AOEL)**
2 applications to oilseed-type crop, 1 L product/ha, 7-day treatment interval		2 x 0.10 kg a.s./ha		2 x 0.2 kg a.s./ha	
2 hours/day(1) TC [cm^2/person/h] (2) - potential exposure: 12500 - no PPE: 1400 - PPE: not assigned Body weight: 60 kg	Potential exposure	0.00416	11.9	0.00398	4.0
	workwear(3)	0.00047	1.33	0.00045	0.45
	… plus gloves (4)	n.a.	n.a.	n.a.	n.a.

(1) 2 h/day for professional applications for maintenance or scouting;
(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.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-7 shows the exposure model(s) used for estimation of bystander and resident exposure to mefentrifluconazole and boscalid. Outcome of the estimation is presented in Table 6.6-8. Detailed calculations are in Appendix 3.

Table 6.6-7: Exposure models for intended uses

Critical use(s)	Sunflower (max. 1 L product/ha, 2 applications within 7 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 6.6-8: Estimated bystander and resident exposure

2 applications to oilseed-type crop: vehicle-mounted, outdoor downward spraying		**Mefentrifluconazole (BAS 750 F)**		**Boscalid (BAS 510 F)**	
Application rate: 1 L product/ha		**2 x 0.1 kg a.s./ha**		**2 x 0.2 kg a.s./ha**	
Model data for bystander: Drift rate: 8.50% (2-3 m buffer) 95th percentile data		**Total absorbed dose (mg/kg bw/day)**	**% of RVAAS (Acute AOEL)**	**Total absorbed dose (mg/kg bw/day)**	**% of RVAAS (Acute AOEL)***
1-3 year old child Body weight: 10 kg	Spray drift	0.00120	0.80	n.a.	n.a.
	Vapour	0.00107	0.71	n.a.	n.a.
	Surface deposits	0.00054	0.36	n.a.	n.a.
	Entry into treated crops	0.00056	0.37	n.a.	n.a.
Adults Body weight: 60 kg	Spray drift	0.0031	0.20	n.a.	n.a.
	Vapour	0.00023	0.15	n.a.	n.a.
	Surface deposits	0.00007	0.05	n.a.	n.a.
	Entry into treated crops	0.00031	0.21	n.a.	n.a.
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	0.00050	1.44	0.00051	0.51
	Vapour	0.00107	3.06	0.00107	1.07
	Surface deposits	0.00020	0.57	0.00018	0.18
	Entry into treated crops	0.00056	1.61	0.00054	0.54
	All pathways (mean)	0.00195	5.56	0.00177	1.92
Adults Body weight: 60 kg	Spray drift	0.00012	0.34	0.00011	0.11
	Vapour	0.00023	0.66	0.00023	0.23
	Surface deposits	0.00002	0.06	0.00002	0.02
	Entry into treated crops	0.00031	0.89	0.00030	0.30
	All pathways (mean)	0.00055	1.58	0.00051	0.54

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 mefentrifluconazole and boscalid 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.

6.6.6 Combined exposure

The product is a mixture of two active substances.

6.6.6.1 Exposure Assessment of mefentrifluconazole and boscalid in BAS 762 02 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 6.6-9: 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]	mefentrifluconazole	~~0.0053~~ 0.0106
	boscalid	0.0040
	Cumulative risk Op erators (HI)	~~0.0093~~ **0.0146**
Workers – crop inspection with workwear (worst case)	mefentrifluconazole	0.0133
	boscalid	0.0045
	Cumulative risk Workers (HI)	**0.0178**
Bystander (worst-case: child exposure resulting from spray drift)	mefentrifluconazole	0.0080
	boscalid	n.a.*
	Cumulative risk Bystander – Child (HI)	**n.a.***
Resident – Child (all pathways)	mefentrifluconazole	0.0556
	boscalid	0.0192
	Cumulative risk Resident – Child (HI)	**0.0748**
Resident – Adult (all pathways)	mefentrifluconazole	0.0158
	boscalid	0.0054
	Cumulative risk Resident – Adult (HI)	**0.0212**

* No AAOEL was assigned for boscalid; risk assessment for long-term exposure of residents is used for bystander risk assessment

The Hazard Index is < 1. Thus combined exposure to all active substances in BAS 762 02 F is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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, S., XXX, S.	2019	BAS 762 02 F - Acute oral toxicity study in rats 2019/2034516 Bioassay - Labor fuer biologische Analytik GmbH, Heidelberg, Germany Fed.Rep. yes Unpublished	Yes	BASF
KCP 7.1.4/1	XXX, A.	2019	BAS 762 02 F - In vitro skin irritation and corrosion Turnkey Testing Strategy 2019/2034428 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 7.1.5/1	XXX, A.	2019	BAS 762 02 F in vitro eye irritation test (EIT) in reconstructed human cornea 2019/2034409 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 7.1.5/2	XXX, T.	2019	BAS 762 02 F: Isolated chicken eye test method for identifying (i) chemicals inducing serious eye damage and (ii) chemicals not requiring classification for eye Irritation or serious eye damage 2019/2040543 Phycher Bio Developpement, Martillac, France yes Unpublished	No	BASF
KCP 7.3/1	XXX, S., XXX, E., XXX, R.	2019	14C-BAS 750 F in BAS 762 02 F - Study of penetration through human skin in vitro BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2019/2038144 yes Unpublished	No	BASF

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 7.3/2	XXX, S., XXX, A.	2020	Excel file using "efs24873-sup-0001-supinfo_1.xlsx" (version 3) to support dermal absorption calculations according to EFSA Guidance on Dermal Absorption [EFSA Journal 2017;15(6):4873)] - For Study BASF DocID 2019/2038144 2020/2097030 BASF SE No Unpublished	No	BASF
KCP 7.3/3	XXX, S., XXX, R.	2019	14C-BAS 510 F in BAS 762 02 F - Study of penetration through human skin in vitro 2019/2040354 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 7.3/4	XXX, S.	2020	Excel file using "efs24873-sup-0001-supinfo_1.xlsx" (version 3) to support dermal absorption calculations according to EFSA Guidance on Dermal Absorption [EFSA Journal 2017;15(6):4873)] - For Study BASF DocID 2019/2040354 2020/2110168 BASF SE No Unpublished	No	BASF

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

BAS 762 02 F is a new product, no product studies have been evaluated previously.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

BAS 762 02 F is an SC (suspension concentrate) that contains the active substances mefentrifluconazole (100 g/L) and boscalid (200 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 SC-type products containing both active substances, limited (acute oral toxicity) testing of the product in vertebrate animals to verify if the additivity assumption for predicting the health hazards from the product's composition according to CLP Regulation 1272/2008 (GHS approaches) – and as prerequisite for waiving acute dermal and acute inhalation toxicity studies.

Availability of acute toxicity data of BAS 762 02 F components

An overview of the available safety data sheet information on acute toxicity classification of the individual components contained in BAS 762 02 F is given in the following table (co-formulants are number-coded corresponding to the numbering of co-formulants listed in Table 1.2-1 in Confidential Document Part C. Components that do not require consideration for product hazard classification according to the GHS mixture calculation approach (CLP Reg 1272/2008, because present below cut-off concentration) are in grey ink.

Table A 1: Overview of BAS 762 02 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
BAS 750 F	9.07	H317	no	no	no	no	no	H317
BAS 510 F	18.34	–	no	no	no	no	no	no
#3	6.16	–	no	no	no data	no	no	No
#4	5.25	H319	no	No (od) (2)	no data	no data	H319	no data
#5	0.88	H315, H318	no	No (od)	no data	H315	H318	No
#6	4.40	H302	H302	no data	no data	no	H319	no data
#7	1.10	–	no	No (od)	no data	no	no	no
#8	0.66	–	no	No	no data	No (r-a)	No (r-a)	No (r-a)
#9	0.66	–	no	No	no data	no	no	no
#10	0.26	–	no	No (od)	no	no	No	no
#11 (1)	0.18	H315,H317, H318	no (r-a)	no (r-a)	no (r-a)	H315	H318	H317 (BIT+MIT)
#12	0.44	EUH208	no (r-a)	no (r-a)	no (r-a)	no (r-a)	no (r-a)	no
Water	52.77	–	no	no	no	no	no	no
% of product with acute toxicity data			100	96	83	100	100	95

(1) contains up to 2.65% BIT (CAS No. 2634-33-5) and 2.60% MIT (2682-20-4) , resulting in product concentration of 0.0047% BIT and 0.0048% MIT. The SCL for skin sensitization: is 0.05% for BIT and 0.0015% for MIT.
(2) No (od) =Classification not required based on oral-to-dermal extrapolation;
(3) no (r-a) = classification not required based on read-across

The weight-of-evidence approach used to predict the classification of BAS 762 02 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 water-based BAS 762 02 F (suspension concentrate), products of similar composition were not identified that appeared sufficiently useful for bridging. BAS 762 02 F is currently the only product developed that contains both active ingredients mefentrifluconazole and boscalid.

In general, no evidence for increased toxicity is suggested from water-based formulations containing mefentrifluconazole at concentrations comparable or higher than in BAS 762 02 F. However, since the combination of mefentrifluconazole with boscalid is unique, bridging to water-based mefentrifluconazole formulations was not considered useful.

In order to assess the likelihood for non-additive toxicity phenomena, an acute oral toxicity study was therefore performed with the BAS 762 02 F.

Comments of zRMS:	Accepted. Data package has been generated on the product applied for the current registration

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	Acute oral toxicity assessment based on product composition is relevant and sufficient for hazard evaluation. Calculation is accepted.

Data for assessment of acute oral toxicity is available for all 13 ingredients of the product. Only ingredient #6 (contained 4.4% in the product) 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:
$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i} = \frac{4.4}{500}$; $ATE_{mix} = 100 \times \frac{500}{4.4}$ =11,364 mg/kg bw

Based on the calculated acute oral toxicity ATE_{mix} (LD_{50}) of 11,364 mg/kg bw, a classification for acute oral toxicity is not indicated for BAS 762 02 F on the basis of its composition.

Since BAS 762 02 F represents a currently unique combination of active ingredients, an acute oral toxicity study in rats was performed to check if higher-than-expected toxicity occurs. The acute oral LD_{50} was higher than 5000 mg/kg bw. No mortality or clinical signs was observed in any of the six treated animals. A study summary is provided at the end of this chapter.

In conclusion, based on the weight-of-evidence taking into account the toxicological properties of the product's ingredients and their concentration, BAS 762 02 F does not require classification for acute oral toxicity according to Regulation (EC) No. 1272/2008.

A 2.2.1 Acute oral toxicity study with BAS 762 02 F in rats

Comments of zRMS:	Study has been reviewed for compliance with the current guidelines, resulting from scientific progress. There is no deviation from studies protocol. The OECD 423 procedure implements the 3R rules thus study is in line with the suggestions of point 5 of Regulation 284/2013. Results of the study and conclusions are adequate for risk assessment and classification purpose. Study accepted.

Reference:	CP 7.1.1/1
Report	BAS 762 02 F - Acute oral toxicity study in rats
	XXX S., XXX S., 2019

	Report No 10A0057/19X034
	BASF DocID 2019/2034516
	Authority registration No
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 762 02 F Batch No. FD-190207-0001 Purity/Content: - Mefentrifluconazole (BAS 750 F): 96.2 g/L - Boscalid (BAS 510 F): 205.2 g/L
Species	Wistar rat (Crl:WI (Han) SPF)
No. of animals (group size)	3 female rats/group
Dose(s)	5000 mg/kg bw (two groups)
Exposure	Once by oral gavage
Vehicle/Dilution	Undiluted
Post exposure observation period	14 days
Remarks	None

Results and discussions

- No mortality was observed in the first test group receiving 5000 mg/kg bw of the formulation. Therefore, a second test group of three animals received a dose of 5000 mg/kg bw of the formulation. Again no mortality was observed [see **Table A 2**]. According to the test scheme of the OECD guideline no further dosing was necessary.
- No clinical signs of toxicity were observed.
- All animals gained weight in a normal range throughout the study period.
- 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 762 02 F

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD_{50} (mg/kg bw) (14 days)
Female rats				
5000	0/0/3	No clinical signs	No deaths	>5000
5000	0/0/3	No clinical signs	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

Conclusion

Under the study conditions, the acute oral LD_{50} of BAS 762 02 F in rats was higher than 5000 mg/kg bw.

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

Comments of zRMS:	Acute dermal toxicity assessment based on product composition is relevant and sufficient for hazard evaluation. Calculation is accepted.

Data for assessment of acute dermal toxicity is available for 96% of the product's composition (for 12 out of 13 ingredients), either actual data or based on oral-to-dermal extrapolation. The acute dermal toxicity of ingredient #6 (classified harmful if swallowed) might be derived by oral-to-dermal extrapolation: taking into account the oral ATE of 500 mg/kg bw and assuming worst-case 100% dermal absorption for oral-to-dermal extrapolation, it is evident that the resulting calculated dermal ATEmix for BAS 762 02 F containing 4.4% 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 762 02 F (oral LD_{50} > 5000 mg/kg bw) does not give rise to any concern (even if unrealistic systemic bioavailability is assumed), due to the predicted low acute oral toxicity of the product.

Thus, BAS 762 02 F does not require classification for acute dermal toxicity according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	Acute inhalation toxicity assessment based on product composition is relevant and sufficient for hazard evaluation. Calculation is accepted.

Data for assessment of acute inhalation toxicity is available for 4 product ingredients (including water) comprising approx. 80% of the total composition (see **Table A 1**). None of the co-formulants with data indicate a concern for acute inhalation toxicity. Four of the remaining nine co-formulants without acute inhalation data are present at concentrations above the cut-off concentration 1% (w/w): co-formulants #3 (6.16%), #4 (5.25%), #6 (4.4%) and #7 (1.1%). Thus, based on available composition data, there is no indication of an acute inhalation toxicity hazard of BAS 762 02 F.

The available acute oral toxicity study with BAS 762 02 F clearly demonstrated the product is non-toxic in rats (oral LD_{50} >5000 mg/kg bw), confirming the additivity assumption from the product composition is valid. The exposed rats showed no clinical signs of toxicity during the post-exposure period following oral treatment. This fact provides reassurance that the additivity algorithm of GHS can be applied to predict the classification based on its composition in general.

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

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

… is triggered only if ingredients with an acute inhalation toxicity classification are present in the product. Otherwise, the calculation output would generally be a no-classification result.

In view of missing acute inhalation toxicity data for four BAS 762 02 F co-formulants, two further

approaches are proposed for assessing the acute inhalation toxicity hazard of the product.

1. Calculation approach applying the standard GHS algorithm for mixtures and using extrapolated acute inhalation LC_{50} values for ingredients with missing acute toxicity data (via oral-to-inhalation route extrapolation)
2. Calculation approach using the standard GHS algorithm for mixtures and assuming that all ingredients with missing data show increased toxicity by inhalation than by oral route by one hazard category (i.e. Cat 4 for ingredients with no classification for oral toxicity, and Cat.3 for ingredient #6, which is classified in oral toxicity Cat. 4 thus harmful if swallowed). Thus, the standard ATE value for Category 3 of 0.5 mg/L is used as input value for ingredient #6, and the ATE value for Category 4 of 1.5 mg/L is used as input values for the ingredients #3. #4, and #7.

Ad. 1

Only ingredient #6 is classified for acute oral toxicity in Category 4 (harmful if swallowed). The other ingredients in BAS 762 02 F are not classified for oral toxicity. Applying oral-to-inhalation extrapolation as suggested according to the CLP Guidance Document of ECHA (1 mg/kg bw = 0.0052 mg/l/4h; Guidance on the application of CLP criteria, Version 5.0, July 2017, section 3.1.3.3.5), the resulting inhalation ATE value for ingredient #6 would be 2.6 mg/L and would necessarily be greater than 5 mg/L for the remaining co-formulants #3, #4 and #6 (even if assuming worst-case acute oral toxicity category 5 (UN GHS), ATE= 2500 mg/kg bw an LC_{50} of 13 mg/L would be calculated). Consequently, ingredients #3, #4, and #7 do not need to be considered in the GHS calculation algorithm.

Thus using oral-to-inhalation extrapolation for the ingredients #3, #4, #6 and #7 to close data gaps in combination with the GHS mixture calculation algorithm, only the calculated LC_{50} of 2.6 mg/L for ingredient #6 (4.4%) needs to be considered for calculating the product ATEmix (inhalation) for BAS 762 02 F. The calclulated LC_{50} for BAS 762 02 F obtained via this approach is 59 mg/L.

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i} = \frac{4.4}{2.6}; \qquad ATE_{mix} = 100 \times \frac{2.6}{4.4} = 59 \text{ mg/L}$$

Ad 2.

Assuming worst case that all 4 ingredients with missing acute inhalation toxicity data have a more severe category than by the oral route of exposure, i.e. co-formulants #3, #4 and #6 are all classified as “harmful if inhaled” (Cat 4; ATE 1.5 mg/L) and ingredient #6 as toxic by inhalation (Cat 3; ATE = 0.5 mg/L), the calculation approach yields a calculated LC_{50} of 5.83 mg/L for BAS 762 02 F:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i} = \frac{6.16}{1.5} + \frac{5.25}{1.5} + \frac{4.4}{0.5} + \frac{1.1}{1.5} = \frac{12.51}{1.5} + \frac{4.4 \times 3}{0.5 \times 3}; \qquad ATE_{mix} = 100 \times \frac{1.5}{25.7} = 5.83 \text{ mg/L}$$

Overall, by both additional approaches the estimated acute inhalation toxicity LC_{50} for BAS 762 02 F remains greater than 5 mg/L and thus does not indicate an acute inhalation hazard of the product. The available data is considered sufficient to justify that vertebrate testing of BAS 762 02 F for acute inhalation toxicity hazard assessment is not required.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Skin irritation assessment based on product composition has not been considered for hazard evaluation due to different outcome reached in *in vitro* study (irritant). ZRMS agree with proposed precautionary approach to classify BAS 762 02 F on the basis of the *in-vitro* study results as skin irritant.

Safety Data sheet information for assessment of skin irritation is available for 12 of 13 ingredients of the product, comprising about 95% of the composition. Ingredient #5 (0.88%) and #11 (0.18%) are classified as skin irritants. According to the supplier's safety data sheet, co-formulant #4 (5.25%) is not classified for skin corrosion/irritation "based on available information"; however more details are not presented for this hazard endpoint (BASF DocID 2020/2081109). Consultation of ECHA's C&L inventory database (https://echa.europa.eu/information-on-chemicals/cl-inventory-database) revealed that the majority of notifiers have classified coformulant #4 as skin irritant (Skin Irrit.2; H315).

Thus, for prediction of the skin irritation hazard according to GHS calculation approach, co-formulant #4 (5.25%) would be the only ingredient present in BAS 762 02 F above the cut-off concentration of 1% (w/w) that would potentially need to be considered (not based on MSDS but considering information from the ECHA website). The total product concentration of skin irritating ingredients is below the 10% trigger for classification. Thus, based on skin irritation data available for the components, product classification as skin irritant would not be triggered for BAS 762 02 F according to GHS/CLP criteria.

When the product was tested in-vitro in the EpiDerm™ test (OECD 431 and OECD 439), BAS 762 02 F showed evidence for a relevant skin irritation potential (viability 20.2% 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.

In absence of bridging opportunities for read-across to similar products, the overall data available points to a borderline situation. For reasons of precaution, and to avoid vertebrate testing, it is proposed to classify BAS 762 02 F on the basis of the in-vitro study results as skin irritant.

A 2.5.1 In-vitro skin corrosion and skin irritation study

Comments of zRMS:	Study has been reviewed for compliance with the current requirements. There are no deviation from testing protocol. I*n vitro* procedure fully implements the 3R rules thus study is in line with the suggestions of point 5 of Regulation 284/2013. Studies accepted. Prediction can be made regarding the classification of the test product BAS 762 02 F / Revydas according to the evaluation criteria. Therefore, an *in vivo* follow up study was not performed.

Reference:	CP 7.1.4/1
Report	BAS 762 02 F - In vitro skin irritation and corrosion Turnkey Testing Strategy XXX A., 2019 Report No: 69V0057/19A007 BASF DocID 2019/2034428 Authority registration No
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 762 02 F Batch No. FD-190207-0001 Purity/Content: - Mefentrifluconazole (BAS 750 F): 96.2 g/L - Boscalid (BAS 510 F): 205.2 g/L pH value: ca. 7.0 (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 did not impair the study result as demonstrated by the concurrently performed exposure of control tissues inactivated by freezing (performed with corrosion test, only).	
	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.

RMS note: The proficiency of the laboratory to conduct the study is guaranteed via the ISO certification of the test facility also BASF SE Experimental Toxicology and Ecology is accredited as an inspection body according to DIN EN ISO/IEC 17020:2012 "Conformity assessment – requirement for the operation of various types of bodies performing inspection" by the national accreditation body of Germany (DAkkS; Deutsche Akkreditierungsstelle.

Results and discussions

OECD 431
Run and Test Acceptance Criteria:
- Positive and negative control mean values and acceptance ranges based on historical data;
- Acceptable variability between tissue replicates for positive and negative controls;
- Acceptable variability between tissue replicates for test chemical

OECD 439
Run and Test Acceptance Criteria:

• Positive and negative control mean values and acceptance ranges based on historical data; Acceptable variability between tissue replicates for positive and negative controls;
• Acceptable variability between tissue replicates for test chemical.

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

Table A 3: in-vitro skin corrosion / irritation of BAS 762 02 F

Parameter	Negative control (NC)	Test item	Positive control
	viable tissue	viable tissue	viable tissue
Exposure: 3 min			
OD_{570} tissue I	1.909	1.977	0.185
OD_{570} tissue II	1.626	1.957	0.164
mean OD_{570}	1.768	1.967	0.174
Viability (% of NC)	**100.0 ± 11.3**	**111.3 ± 0.8**	**9.9 ± 0.8**
Exposure: 1 h			
OD_{570} tissue I	1.968	1.541	0.118
OD_{570} tissue II	1.895	1.647	0.140
mean OD_{570}	1.932	1.594	0.129
Viability (% of NC)	**100.0 ± 2.7**	**82.5 ± 3.9**	**6.7 ± 0.8**
Exposure:1 h + post-exposure incubation: 42 h			
OD_{570} tissue I	1.687	0.363	0.059
OD_{570} tissue II	1.812	0.289	0.061
OD_{570} tissue III	1.687	0.396	0.068
mean OD_{570}	1.729	0.349	0.062
Viability (% of NC)	**100.0 ± 4.2**	**20.2 ± 3.2**	**3.6 ± 0.3**

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

BAS 762 02 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 111.3%, and it was 82.5% 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 20.2%.

Conclusion

Based on the results obtained BAS 762 02 F was found to be skin irritant in the in vitro test with human reconstituted epidermis (mean tissue viability 20.2% of the negative control, thus 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 762 02 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)

Comments of zRMS:	Eye irritation assessment based on product composition has not been considered for hazard evaluation due to different outcome reached in *in vitro* study (irritant). ZRMS agree with weight of evidence assessment and supports classification of the product BAS 762 02 F on the basis of the *in-vitro* study results as eye irritant.

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. 89.5%). Co-formulants #4 (5.25%) and #6 (4.40%) are classified as eye irritants (Eye Irrit 2; H319). Ingredients #5 (0.88%) and #11 (0.18%) are classified with Eye Dam. 1; H318. ~~According to mixture classification algorithms of GHS/CLP, the concentrations of the eye damaging ingredients #5 and #11 are each below the 1% trigger and therefore would not need to be considered further.~~ The total concentration of eye irritant / eye corrosive ingredients is above the 10%

trigger for classification of the mixture as eye irritant: (10x Eye Dam. Cat. 1 + Eye Irrit. Cat. 2) = 10x(0.88%+0.18%) + 5.25%+4.40%)= 20.25%.

A pH value of ca. 7.4-7.8 was determined for undiluted BAS 762 02 F, indicating no concern for corrosivity (see KCP 2.4.2; Keller, 2019; DocID 2019/2073795). Thus, based on eye damage/irritation data available for the components, and pH value of BAS 762 02 F, product classification as serious eye irritant would be triggered according to GHS/CLP criteria.

When BAS 762 02 F was investigated in-vitro, the EpiOcular™ test (OECD 492) gave evidence for an eye 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.

In the Isolated Chicken Eye test (ICE, OECD 438), treatment with BAS 762 02 F caused marked retention of fluorescein (Category IV) but only slight effects on cornea opacity (Category II) and cornea swelling (Category II); microscopic examination of the corneas did not reveal any morphological changes. Based on the results, the test substance could not be placed in the Category Eye Dam. 1 or categorized as non-irritant to the eye. Thus, a prediction of eye irritation potential could not be made based on this study outcome following OECD Guideline criteria.

Based on the overall weight- of evidence (evidence for an eye irritation potential based on the composition / GHS calculation approach, evidence for an eye irritation or eye damaging potential in the EpiOcular™ Test, and insufficient evidence from results of the ICE test to categorize the test substance to cause eye damage), the available data indicates that classification as eye irritant (Eye Irrit 2; H319) is warranted for BAS 762 02 F according to Regulation (EC) No. 1272/2008.

Comments of zRMS:	Study has been reviewed for compliance with the current requirements. There are no deviation from testing protocol. Base on study outcome ZRMS agree that I*n vitro* procedure is sufficiently reliable for predicting negative *in-vivo* study outcomes in tests with agrochemical formulations, but the test method cannot specify the Category. Therefore, additional an *in vitro* follow up study was performed.

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

Reference:	CP 7.1.5/1
Report	BAS 762 02 F – In Vitro Eye Irritation Test (EIT) in Reconstructed Human Cornea XXX A., 2019 Report No: 62V0057/19A006 BASF DocID 2019/2034409 Authority registration No
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 762 02 F Batch No. FD-190207-0001 Purity/Content: - Mefentrifluconazole (BAS 750 F): 96.2 g/L - Boscalid (BAS 510 F): 205.2 g/L pH value: ca. 7.0 (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. Based on the result of the pretest, it was judged that application of killed control tissues is not necessary.
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

RMS note: The proficiency of the laboratory to conduct the study is guaranteed via the ISO certification of the test facility also BASF SE Experimental Toxicology and Ecology is accredited as an inspection body according to DIN EN ISO/IEC 17020:2012 "Conformity assessment – requirement for the operation of various types of bodies performing inspection" by the national accreditation body of Germany (DAkkS; Deutsche Akkreditierungsstelle.

Results and discussions

Run and Test Acceptance Criteria

- Positive and negative control means and acceptance ranges based on historical data;
- Acceptable variability between tissue replicates for positive and negative controls;
- Acceptable variability between tissue replicates for the test chemical;

Table A 4: in-vitro eye corrosion / irritation of BAS 762 02 F (EpiOcular™ Assay)

Test substance		Tissue 1	Tissue 2	**Mean**	Inter-tissue variability [%]
Neg. control (NC)	mean OD_{570}	1.816	1.911	1.864	
	Viability [% of NC]	97.5	102.5	**100.0**	5.1
BAS 762 02 F	mean OD_{570}	0.329	0.284	0.307	
	Viability [% of NC]	17.7	15.2	**16.4**	2.4
Positive control (PC)	mean OD_{570}	0.556	0.361	0.459	
	Viability [% of NC]	29.8	19.4	**24.6**	10.5

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 762 02 F was 16.4% of the negative control value (thus lower than 60%), indicating eye irritating properties of the test substance.

Conclusion

Based on the results observed and the assessment criteria, BAS 762 02 F shows an eye irritation potential in the EpiOcular™ test. For final assignment of a classification according to GHS/CLP criteria, additional data are required.

A 2.6.2 Isolated Chicken Eye test (OECD 438)

Comments of zRMS:	Study has been reviewed for compliance with the current requirements. There are no deviation from testing protocol. I*n vitro* procedure fully implements the 3R rules. Studies accepted. Base on study outcome ZRMS agree that test substance could not be placed in the Category Eye Dam. 1 or categorized as non-irritant to the eye. Thus, a prediction of eye irritation potential could not be made based on this study results following OECD Guideline criteria. Final proposal regarding eye irritation potential: ZRMS agree that considering overall weight- of evidence (positive outcome for an eye irritation potential in the EpiOcular™ Test, and insufficient evidence from results of the ICE test to categorize the test substance to cause eye damage), the available data indicates **that classification as eye irritant (Eye Irrit 2; H319) is warranted for BAS 762 02 F** according to Regulation (EC) No. 1272/2008.

Reference:	CP 7.1.5/2
Report	BAS 762 02 F - Isolated chicken eye test method for identifying (i) chemicals including serious eye damage and (ii) chemicals not requiring classification for eye Irritation or serious eye damage XXX T., XXX 2019 Report No: 62V0057/19A006 BASF DocID 2019/2040543 Authority registration No
Guideline(s):	OECD 438 (2018) Commission Regulation (EU) 1152/2010 – Test method B.48 of 8 December 2008 Council Regulation 440/2008 of 30 May 2008
Deviations:	No
GLP:	Yes (certified by Groupe Interministeriel des Produits Chimiques, Ivry-sur-Seine CEDEX, France)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	BAS 762 02 F Batch No. FD-190207-0001 Purity/Content: - Mefentrifluconazole (BAS 750 F): 96.2 g/L - Boscalid (BAS 510 F): 205.2 g/L
Test system	Chicken eyes obtained from slaughter animals (ca. 7 wk old male or female chickens) used for human consumption
Principle of the method	The test substance is administered to the surface of the isolated chicken eye, so that the total surface of the cornea is evenly covered. After 10-second exposure, the eye is rinsed with saline. Corneal thickness (expressed as corneal swelling), corneal opacity and fluorescein retention are determined before (t=0) and after exposure, and histopathology of the corneas is performed.
No. of tissues per test group	3
Pre- and post-exposure incubation	The dissected eye ball was placed in a stainless steel clamp and transferred into a chamber kept at 32 °C. The entire cornea was continuously rinsed with physiological saline (ca. 32 °C) supplied by a peristaltic pump at a target rate of 0.1 – 0.15 mL/min. Eyes were removed from the chamber for treatment and post-treatment rinse and subsequently returned to the chamber.
Exposure	30 µL: 10 seconds
Vehicle / dilution	Tested undiluted
Post-exposure rinse	2x 10 mL physiological saline (0.9% aqueous NaCl solution)
Post-exposure assessment time point	0, 30, 75, 120, 180, 240 minutes
Negative control	0.9% aqueous NaCl (physiological saline) – 1 eye
Positive control	5% Benzalkonium chloride in physiological saline (BAC) – 2 eyes

RMS note: The proficiency of the laboratory to conduct the study is guaranteed via the ISO certification of the test facility also BASF SE Experimental Toxicology and Ecology is accredited as an inspection body according to DIN EN ISO/IEC 17020:2012 “Conformity assessment – requirement for the operation of various types of bodies performing inspection” by the national accreditation body of Germany (DAkkS; Deutsche Akkreditierungsstelle.

Assessment

The three effect parameters corneal swelling, corneal opacity and fluorescein retention are scored at designated time points using an effect severity classification in one of four categories **I-IV** (not irritating; slightly irritating; moderately irritating; severely irritating). A prediction model assigns a final classification based on the combination of severity scores determined for the different parameters.

Endpoint	**Severity Category**
Corneal thickness / swelling Determined at each time-point according to following formula: $\frac{\text{corneal thickness t - corneal thickness } t0}{\text{corneal thickness } t0} \times 100$ The highest mean score determined from different time points taken for assessment.	**I** (0-5%), **II** (>5-12% or >75 minutes: >12-18%), **III** (< 75 minutes: 12-18% or >75 minutes: 26-32%), **IV** (< 75 minutes: 26-32% or >32%)
Corneal opacity score time point with area most densely opacified was taken for scoring. The highest mean score determined from different time points taken for assessment. Scores (comparable to Draize): 0 (no opacity) 0.5 (very faint opacity) 1 (scattered or diffuse area; iris details clearly visible) 2 (easily discernable translucent area, iris details slightly obscured) 3 (severe opacity, iris details not visible, pupil size barely discernable 4 (complete corneal opacity, iris invisible)	**I** (0.0-0.5), **II** (0.6-1.5), **III** (1.6-2.5), **IV** (2.6-4.0)
Fluorescein retention (at 30 min only) Scores: 0 (no fluorescein retention) 0.5 (very minor single cell staining) 1 (single cell staining scattered throughout the cornea area 2 (Focal or confluent dense single cell staining) 3 (Confluent large areas of the cornea retaining fluorescein)	**I** (0.0-0.5), **II** (0.6-1.5), **III** (1.6-2.5), **IV** (2.6-3.0)
Morphological effects (reported but not used for classification due to lack of established criteria)	These include "pitting" of corneal epithelial cells, "loosening" of epithelium, "roughening" of the corneal surface and "sticking" of the test substance to the cornea. These findings can vary in severity and may occur simultaneously. The classification of these findings is subject to the interpretation of the investigator.

Proposed criteria for classification according to UN GHS

Eye Dam. 1 (H318)	3x **IV** 2x **IV** 2x IV, 1 x III 2x IV, 1 x II* 2x IV, 1 x I*
No Category	3x **I** 2x **I** and 1x **II** 2x **II** and 1x **I**
Other combinations	***No prediction can be made***

Results and discussions

Table A 5: Results of slit-lamp examination in in-vitro isolated chicken eye (ICE) test

Test material	Maximum mean score for: Swelling % (Irritation category)	Opacity (Irritation category)	Fluorescein retention (Irritation category)	Classification (CLP)
BAS 762 02 F	7 (**II**)	1.0* (**II**)	3.0 (**IV**)	**No prediction can be made.**
Positive ctrl (5% BAC)	39 (**IV**)	3.0** (**IV**)	3.0 (**IV**)	Eye Dam. 1
Negative ctrl	0 (**I**)	0.0* (**I**)	0.5 (**I**)	No classification

*no morphological effects were noted in exposed corneas of the negative control and of the test substance groups regardless of the examination time point.
** Blisters on the cornea were noted from 30 min post-dose with the positive control substance in eyes #1, #2 and #3.

BAS 762 02 F caused slight corneal swelling and corneal opacity (each Category II) and marked fluorescein retention (maximum mean score of 3.0, corresponding to Category IV). Microscopic examination of the corneas generally did not reveal morphological effects.

The negative control eye did not show any corneal effect and demonstrated that the general conditions during the tests were adequate. Microscopic examination of the cornea did not reveal any abnormalities.

The positive control BAC 5% caused severe corneal effects and demonstrated the validity of the ICE test to detect severe eye irritants.

Conclusion

The results obtained for BAS 762 02 F under the experimental conditions of the Isolated Chicken Eye test – 2x Category II + 1x Category IV – lead to the outcome "no prediction can be made" according to assessment criteria of OECD Guideline 438. Additional data is required to establish a definitive classification.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Skin sensitisation assessment based on product composition is relevant and sufficient for hazard evaluation. Calculation is accepted.

No skin sensitisation test was performed for the product BAS 762 02 F.

Data for assessment of skin sensitization is available for >95% of the product's composition (see **Table A 1**). Skin sensitization information is missing for two co-formulants #4 (5.25%), and #6 (#4.40%).

The active ingredient mefentrifluconazole (9.07%) was found to be a skin sensitizer in the GPMT.

Low concentrations of the isothiazolinones MIT and BIT are contained in BAS 762 02 F due to their presence in co-formulant #11 (see Confidential Document Part C for details). The total concentrations of MIT and BIT are presented in Table A 6 below. The BIT content in BAS 762 02 F is below 10% of the specific concentration limit (0.05%), and therefore does not need to be mentioned on the product label. The SCL of MIT (0.0015%) as stipulated in the CLP Regulation, is however exceeded.

Table A 6: Isothiazolinone content in BAS 762 02 F

Isothiazolinone	In components	Total concentration in components	Component concentration in BAS 762 02 F	Concentration in BAS 762 02 F
MIT	#11	Up to 2.60%	0.18%	0.0048%
BIT	#11	Up to 2.65%	0.18%	0.0047%

Overall, the content of mefentrifluconazole exceeds the default 1% threshold concentration for skin sensitization classification applying GHS criteria. Also, the MIT concentration in BAS 762 02 F is above the SCL of 0.0015%. On this basis, classification with Skin Sens. 1; H317 is required for BAS 762 02 F according to classification criteria of Commission Reg. No. 1172/2008.

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

No study 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)

In-vitro dermal penetration studies with human skin membranes have been carried out, to investigate the dermal absorption of active ingredients formulated in BAS 762 02 F. The studies have not undergone a previous EU peer-review, therefore full summaries are presented in detail below. Assessments were carried out according to the revised EFSA Guidance (2017) and using the Excel data entry sheets ("efs24873-sup-0001-supinfo_1.xlsx" (version 3), released 20 August 2018).

A 2.10.1 ^{14}C-mefentrifluconazole (BAS 750 F) in BAS 762 02 F

Comments of zRMS:	Study is considered to be acceptable and dermal absorption for mefentrifluconazol is covered by this study. DA values obtained from the study are reliable and can be used for risk assessment. Pro-rata assessment has been performed reflecting applications rate (spray dilution) proposed in the GAP. For additional information please refer point *6.6.1 Selection of critical use(s) and justification.* Testing dilution: (1:400) DA 1.8% Dilution proposed in the GAP (1:667) DA Pro rata: 3.0%

Reference:	CP 7.3/1
Report	^{14}C-BAS 750 F in BAS 762 02 F - Study of penetration through human skin in vitro XXX S., XXX E., XXX R., BASF DocID 2019/2038144 Authority registration No
Guideline(s):	OECD 428, OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany, Germany)
Acceptability:	yes
Duplication (if vertebrate study)	No
Reference:	CP 7.3/2
Report	Excel file using "efs24873-sup-0001-supinfo_1.xlsx" (version 3) to support dermal absorption calculations according to EFSA Guidance on Dermal Absorption [EFSA Journal 2017;15(6):4873)] for study … BASF DocID 2019/2038144 XXX, S., XXX A., 2020 BASF DocID 2020/2097030 Authority registration No

Materials and methods

^{14}C-BAS 750 F formulated as a suspension concentrate (SC) formulation BAS 762 02 F was applied to dermatomed human skin membranes at two nominal dose levels (“concentrate” and 1:400 dilution). The “concentrate” was a radiolabeled formulation concentrate with a nominal concentration of BAS 750 F of 104.0 mg/mL. The 1:400 dilution was prepared by diluting the radiolabeled formulation concentrate 1:400 with tap water, which resulted in a nominal concentration of BAS 750 F of 0.26 mg/mL. For details see Table A 7.

Table A 7: General information on the test system and test material used

Test system	Species	Human		
	Method	In vitro		
Test material				
Active substance	Name (Lot/Batch No.)	^{14}C-BAS 750 F (1075-2101)		
	Test preparation	Radioformulation		
	Radiochemical purity		>98	%
Product	Name (Lot/Batch No.)	^{14}C-BAS 762 02 F (19/0205-1)		
	Company code	BAS 762 02 F		
	Concentration a.s.		100	g/L
	Type of formulation	SC		
	Vehicle used (if any)	tap water (for dilutions 1 and 2)		
Blank product	Name (Lot/Batch No.)	N/A		
	Concentration a.s.	N/A		g/L
	Type of formulation	N/A		

The dermal penetration study used a flow-through system with cells having an exposed skin area of 1 cm². Eight cells were placed in an apparatus connected with a water bath for maintaining a skin temperature of 32 °C. Skin sections of 221 – 400 µm thickness from 4 human donors per dose were used (for details see Table A 8). Prior to the application of the test substance the integrity of the skin samples was investigated via TEER measurements. Measured values above 1 kΩ were expected for intact skin preparations.

Ethanol/tap water (1:9) and physiological saline with 0.01% NaN_3 were used as receptor fluids for the concentrate and the spray dilution, respectively. The flow rate of the receptor was approx. 2.3 mL/h. The receptor fluid was sampled at hourly intervals during the first 8 hours, bi-hourly thereafter up to 18 hours and after 21 and 24 hours. The solubility of Mefentrifluconazole in the receptor fluids was determined to be 46 and 15 mg/L in the receptors used for the concentrate and the spray dilution, respectively. Taking into account the solubility, the actual applied doses and the total receptor volume of approx. 55.2 mL (over 24 hours), no rate limiting effects on the diffusion process by saturation of the receptor fluid was expected as 18.50 and 0.05 mg/L would have been the theoretically maximum achievable concentrations for the concentrate and spray dilution in the receptor fluid, respectively (for more details see Table A 8 and Table A 10). Furthermore, less than 2% of the applied test item were absorbed at both doses, excluding any rate limiting effect of the receptor media.

A volume of 10 µL per chamber was applied to the skin. A first skin wash was performed after the 8-hour exposure. At the end of the study period of 24 hours a second skin wash was performed. Thereafter the diffusion cells were dismantled, and the skin samples removed and consecutively stripped with an adhesive tape. A total of 20 tape strips were performed. The tapes were pooled into five samples (2, 4, 4, 4 and 6 tape strips for samples 1-5, respectively) for analysis. More details are given in Table A 8.

Table A 8: Details on the test system and test material used (Excerpt from EFSA excel sheet)

Diffusion cell	Type of diffusion cell	Flow-through	
	(If dynamic) Flow rate	2.3	mL/h
	Exposed skin area	1	cm^2
	Cover	Semi-occluded	
Skin sample	Skin type	Dermatomed	
	Skin thickness range	221-400	µm
	Skin donor age	32-63	years
	Skin donor sex	Female	
	Site	Abdomen	
	Source	Surgery	
	Integrity test	yes (TEER)	
Receptor	Receptor medium	undiluted: ethanol/tap water (1:9); dilution: physiological saline with 0.01% NaN_3	
	Solubility in receptor medium	undiluted: 46 mg/L; dilution: 15 mg/L	
Sampling	Exposure time	8	hours
	Sampling duration	24	hours
	Sample intervals	(pre-dose, -15 min); 1; 2; 3; 4; 5; 6; 7; 8; 10; 12; 14; 16; 18; 21; 24 h after application	hours
	Skin wash/Swabbing	post exposure 8 hours and at termination 24 hours [#]	
Tape strips	Tape stripping	Yes	
	Type of tape strips used	Scotch Crystal Tape 600 (3M, France)	
	TS 1-2 analysed separately?	Yes	

[#] Skin wash: 8-h post exposure: 2x with washing fluid (3% w/v Estesol® HAIR&BODY in tap water), gently swabbed 2x with cotton swabs soaked with washing fluid, 1x rinse with tap water, skin swabbed 1x with cotton swab soaked with tap water, dried with 1 dry cotton swab; at study termination skin was swabbed with washing fluid and thereafter with tap water.

Results and discussion

The preliminary permeability test (TEER) yielded resistances of above 1 kΩ for all cells which were consequently considered acceptable for the dermal absorption study.

The achieved actual concentrations of the application suspensions and the skin loading with the active substance was in good agreement with the calculated target values (see Table A 10).

Table A 9: Preliminary permeability test (TEER)

Dose group 1 (concentrate)								
- Cell	1	2	3	4	5	6	7	8
- Donor	TRA002200G001 to G023	TRA002200G001 to G023	0991-01-0119	0991-01-0119	19-02-10022	19-02-10022	AAB1902	AAB1902
- Resistance [kΩ]	8.1	21.3	8.3	11.0	18.4	15.5	12.6	8.3
Dose group 2 (1:400)								
- Cell	9	10	11	12	13	14	15	16
- Donor	TRA002200G001 to G023	TRA002200G001 to G023	0991-01-0119	0991-01-0119	19-02-10022	19-02-10022	AAB1902	AAB1902
- Resistance [kΩ]	16.2	23.0	10.1	14.0	23.5	15.2	16.9	7.8

Table A 10: Technical parameters of the dermal absorption study

Tested doses	Concentrate	Dilution 1 (1:400)
Target concentration [mg/mL]	100	0.25
Surface area dose [µg/cm^2]	1000	2.5
Total dose [µg/cell]	1000	2.5
Mean actual applied dose [µg/cm^2]	1021	2.6
Specific activity [kBq/mL]	412000 #	1000
No. of donors	4	4
No. of replicates used/valid replicates*	8 / 8	8 / 8

The specific activity of the undiluted product of 365 MBq/g corresponds to 412 MBq/mL (density 1.13 g/mL)

The mean total recovery at both dose groups was greater than 95%. Therefore, no correction of the dermal penetration values was necessary. For the spray dilution, dermal penetration was essentially complete after 12 hours as indicated by the mean lower limit of confidence (LLC) of 100.0%, while it was not essentially complete for the concentrate with a mean LLC of 61.2%. Therefore, the dose recovered from the 3rd to 20th tape strip was added to the absorbed dose for the concentrate only. The dermal penetration estimates to be used for risk assessment were set at 0.031% and 1.8% for the formulation concentrate and the 1:400 spray dilution, respectively. For details see Table A 11 .

Table A 11: Dermal penetration of Mefentrifluconazole formulated as BAS 762 02 F through human skin *in vitro*

	Concentrate (undiluted)		Dilution 1 (1:400)	
Target concentration [mg/mL]	100		0.25	
Target dose [µg/cm^2]	1000		2.5	
Mean actual applied dose [µg/cm^2]	1021		2.6	
Recovery [%]	Mean	SD	Mean	SD
Dislodgeable dose				
Skin wash after **8** and **24** hours	99.91	1.17	97.17	1.79
Donor chamber wash	0.16	0.12	1.22	0.38
Skin associated dose				
Tape strips 1-2	0.00	0.00	0.04	0.03
Tape strips 3-6	0.01	0.00	0.17	0.09
Skin preparation	0.00	0.00	0.20	0.30
Absorbed dose				
Receptor fluid	0.00	0.00	0.01	0.01
Receptor chamber wash	0.01	0.01	0.77	0.71
Total recovery	100.10	1.15	99.55	1.89
Absorbed at t_0.5 #	61.20	6.88	100.00	0.00
Absorption complete?	No		Yes	
Measured absorption, if t_0.5<=75%	0.02	0.01	N/A	N/A
Measured absorption, if t_0.5>75%	N/A	N/A	0.97	1.00
Measured absorption corrected	0.02	0.01	0.97	1.00
Relevant absorption estimate	0.031		1.818	
Final estimate (rounded)	**0.031**		**1.8**	

Remarks: Dilution1: T0.5 values for cells with zero or close-to-zero cumulative absorption at both 12h and 24h time points were set to "100.00" (cells 2, 3, 4, 5 and 7).

Conclusion:

The dermal penetration of ^{14}C-mefentrifluconazole (BAS 750 F) formulated as BAS 762 02 F through human dermatomed skin was determined in vitro. The % amount of applied dose (AD) considered absorbable within 24 hours was determined to be 0.02 ± 0.01% AD and 0.97 ± 1.00% AD for the formulation concentrate and the 1:400 spray dilution, respectively. **The dermal penetration estimates to be used for risk assessment were set at 0.031% and 1.8% for the formulation concentrate and the ~~1:200~~ 1:400 spray dilution based on current EFSA guidance criteria (2017).**

A 2.10.2 ^{14}C-Boscalid (BAS 510 F) in BAS 762 02 F

Comments of zRMS:	Some adjustments in the study summary have been made by a Reviewer (e.g. name of the test substance was entered incorrectly in the material and methods section). Remaining information and the results in the tables are consistent with the original laboratory report. These changes has no impact on the final study outcome, thus study is considered to be acceptable and the dermal absorption for boscalid is covered by this study. DA values obtained from the study are reliable and can be used for risk assessment. Pro-rata assessment has been performed reflecting applications rate (spray dilution) proposed in the GAP. For additional information please refer point *6.6.1 Selection of critical use(s) and justification.* Testing dilution: (1:400) DA 0.86% Dilution proposed in the GAP (1:667) DA Pro rata: 1.43%

Reference:	CP 7.3/3
Report	^{14}C-BAS 510 F in BAS 762 02 F - Study of penetration through human skin in vitro XXX S., XXX R., 2019 BASF DocID 2019/2040354 Authority registration No
Guideline(s):	OECD 428, OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)
Deviations:	No
GLP:	Yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Reference:	CP 7.3/4
Report	Excel file using "efs24873-sup-0001-supinfo_1.xlsx" (version 3) to support dermal absorption calculations according to EFSA Guidance on Dermal Absorption [EFSA Journal 2017;15(6):4873)] XXX, S., 2020 BASF DocID 2020/2110168 Authority registration No

Materials and methods

^{14}C-BAS 750 F formulated as a suspension concentrate (SC) formulation BAS 762 02 F was applied to dermatomed human skin membranes at two nominal dose levels ("concentrate" and 1:400 dilution). The "concentrate" was a radiolabeled formulation concentrate with a nominal concentration of BAS 750 F of 104.0 mg/mL. The 1:400 dilution was prepared by diluting the radiolabeled formulation concentrate 1:400 with tap water, which resulted in a nominal concentration of BAS 750 F of 0.26 mg/mL.

Test-substance preparations corresponding to a formulation concentrate (target concentration of BAS 510 F = 200 g/L (corresponding to about 177 mg/g, density 1.130 g/mL); analyzed content = 177.2 mg/g) and one representative aqueous spray dilution for field use (1:400 / v:v aqueous dilution with a target concentration of 0.5 mg/mL of BAS 510 F (supposed to have the density of water)) were applied.
For details see Table A 12.

Table A 12: General information on the test system and test material used

Test system	Species	Human		
	Method	In vitro		
Test material				
Active substance	Name (Lot/Batch No.)	^{14}C-BAS 510 F (640-2501)		
	Test preparation	Radioformulation		
	Radiochemical purity		>98	%
Product	Name (Lot/Batch No.)	^{14}C-BAS 762 02 F (19/0204-1)		
	Company code	BAS 762 02 F		
	Concentration a.s.		200	g/L
	Type of formulation	SC		
	Vehicle used (if any)	tap water (for dilutions 1 and 2)		
Blank product	Name (Lot/Batch No.)	N/A		
	Concentration a.s.	N/A		g/L
	Type of formulation	N/A		

The dermal penetration study used a flow-through system with cells having an exposed skin area of 1 cm². Eight cells were placed in an apparatus connected with a water bath for maintaining a skin temperature of 32 °C. Skin sections of 239 – 400 µm thickness from 4 human donors per dose were used (for details see Table A 13). Prior to the application of the test substance the integrity of the skin samples was investigated via TEER measurements. Measured values above 1 kΩ were expected for intact skin preparations (Table A 14).

Ethanol/tap water (1:9) and physiological saline with 0.01% NaN_3 were used as receptor fluids for the concentrate and the spray dilution, respectively. The flow rate of the receptor was approx. 2.3 mL/h. The receptor fluid was sampled at hourly intervals during the first 8 hours, bi-hourly thereafter up to 18 hours and after 21 and 24 hours. The solubility of ~~Mefentrifluconazole~~ Boscalid in the receptor fluids was determined to be 44 and 4.6 mg/L in the receptors used for the concentrate and the spray dilution, respectively. Taking into account the solubility, the actual applied doses and the total receptor volume of approx. 55.2 mL (over 24 hours), no rate limiting effects on the diffusion process by saturation of the receptor fluid was expected as 35.7 and 0.09 mg/L would have been the theoretically maximum achievable concentrations for the concentrate and spray dilution in the receptor fluid, respectively, assuming 100% dermal absorption (for more details see Table A 13 and Table A 15). Furthermore, less than 1% of the applied test item were absorbed at both doses, excluding any rate limiting effect of the receptor media.

A volume of 10 µL per chamber was applied to the skin. A first skin wash was performed after the 8-hour exposure. At the end of the study period of 24 hours a second skin wash was performed. Thereafter the diffusion cells were dismantled, and the skin samples removed and consecutively stripped with an adhesive tape. A total of 20 tape strips were performed. The tapes were pooled into five samples (2, 4, 4, 4 and 6 tape strips for samples 1-5, respectively) for analysis. More details are given in Table A 13.

Table A 13: Details on the test system and test material used (Excerpt from EFSA excel sheet)

Diffusion cell	Type of diffusion cell	Flow-through	
	(If dynamic) Flow rate	2.3	mL/h
	Exposed skin area	1	cm^2
	Cover	Semi-occluded	
Skin sample	Skin type	Dermatomed	
	Skin thickness range	239-400	µm
	Skin donor age	32-54	years
	Skin donor sex	Female	
	Site	Abdomen	
	Source	Surgery	
	Integrity test	yes (TEER)	
Receptor	Receptor medium	undiluted: ethanol/tap water (1:9); dilution: physiological saline with 0.01% NaN_3	
	Solubility in receptor medium	undiluted: 44 mg/L; dilution: 4.6 mg/L	
Sampling	Exposure time	8	hours
	Sampling duration	24	hours
	Sample intervals	(pre-dose, -15 min); 1; 2; 3; 4; 5; 6; 7; 8; 10; 12; 14; 16; 18; 21; 24 h after application	hours
	Skin wash/Swabbing	post exposure 8 hours and at termination 24 hours [#]	
Tape strips	Tape stripping	Yes	
	Type of tape strips used	Scotch Crystal Tape 600 (3M, France)	
	TS 1-2 analysed separately?	Yes	

[#] Skin wash: 8-h post exposure: 2x with washing fluid (3% w/v Estesol® HAIR&BODY in tap water), gently swabbed 2x with cotton swabs soaked with washing fluid, 1x rinse with tap water, skin swabbed 1x with cotton swab soaked with tap water, dried with 1 dry cotton swab; at study termination skin was swabbed with washing fluid and thereafter with tap water.

Results and discussion

The preliminary permeability test (TEER) yielded resistances of above 1 kΩ for all cells which were consequently considered acceptable for the dermal absorption study (see Table A 14).

The achieved actual concentrations of the application suspensions and the skin loading with the active substance was in good agreement with the calculated target values (see Table A 15).

Table A 14: Preliminary permeability test (TEER)

Dose group 1 (concentrate)								
- Cell	1	2	3	4	5	6	7	8
- Donor	AHD1905	AHD1905	19-02-10022	19-02-10022	0991-01-0119	0991-01-0119	AAB1902	TRA002200F046 - F048
- Resistance [kΩ]	5.7	5.0	2.1	2.6	1.7	2.9	2.0	1.7
Dose group 2 (1:400)								
- Cell	9	10	11	12	13	14	15	16
- Donor	AHD1905	AHD1905	19-02-10022	19-02-10022	0991-01-0119	0991-01-0119	TRA002200F046 - F048	TRA002200F046 - F048
- Resistance [kΩ]	7.5	9.5	4.0	3.9	2.5	2.4	1.8	1.9

Table A 15: Technical parameters of the dermal absorption study

Tested doses	Concentrate	Dilution 1 (1:400)
Target concentration [mg/mL]	200	0.5
Surface area dose [µg/cm²]	2000	5.0
Total dose [µg/cell]	2000	5.0
Mean actual applied dose [µg/cm²]	1972	5.0
Specific activity [kBq/mL]	411000 #	1100
No. of donors	4	4
No. of replicates used/valid replicates	8 / 8	8 / 8

The specific activity of the undiluted product of 364 MBq/g corresponds to 412 MBq/mL (density 1.13 g/mL)

The mean total recovery at both dose groups was greater than 95%. Therefore, no correction of the dermal penetration values was necessary. For the spray dilution, dermal penetration was essentially complete after 12 hours as indicated by the mean lower limit of confidence (LLC) of 100.0%, while it was not essentially complete for the concentrate with a mean LLC of 68%. Therefore, the dose recovered from the 3rd to 20th tape strip was added to the absorbed dose for the concentrate only. The dermal penetration estimates to be used for risk assessment were set at 0.026% and 0.86% for the formulation concentrate and the 1:400 spray dilution, respectively. For details see Table A 16.

Table A 16: Dermal penetration of ~~Mefentrifluconazole~~ boskalid formulated as BAS 762 02 F through human skin *in vitro*

	Concentrate (undiluted)		Dilution 1 (1:400)	
Target concentration [mg/mL]	200		0.5	
Target dose [µg/cm^2]	2000		5	
Mean actual applied dose [µg/cm^2]	1972		5.0	
Recovery [%]	Mean	SD	Mean	SD
Dislodgeable dose				
Skin wash after **8** and **24** hours	97.82	1.32	99.11	1.59
Donor chamber wash	0.05	0.04	0.34	0.29
Skin associated dose				
Tape strips 1-2	0.00	0.00	0.05	0.06
Tape strips 3-6	0.00	0.00	0.14	0.16
Skin preparation	0.01	0.01	0.15	0.16
Absorbed dose				
Receptor fluid	0.00	0.00	0.00	N/A
Receptor chamber wash	0.01	0.00	0.54	0.23
Total recovery	100.10	1.15	99.55	1.89
Absorbed at t_0.5 #	97.89	1.33	100.16	1.54
Absorption complete?	No		Yes	
Measured absorption, if t_0.5<=75%	0.02	0.01	N/A	N/A
Measured absorption, if t_0.5>75%	N/A	N/A	0.62	0.29
Measured absorption corrected	0.02	0.01	0.62	0.29
Relevant absorption estimate	0.026		0.861	
Final estimate (rounded)	**0.026**		**0.86**	

Remarks Dilution1: T0.5 and T1 receptor fluid were zero in 7 out of 8 cells(#9-16). In cell #15, maximum cumulative absorption of 0.00027% was obtained after 3 hours. Zero-values of cells at both 12h and 24h time points were replaced by the double background value of 0.006% to avoid division by zero in the calculation, which effectively corresponded to T0.5 of "100" in these cells.

Conclusion:

The dermal penetration of ^{14}C-boscalid (BAS 510 F) formulated as BAS 762 02 F through human dermatomed skin was determined in vitro. The % amount of applied dose (AD) considered absorbable within 24 hours was determined to be 0.02 ± 0.01% AD and 0.62 ± 0.29% AD for the formulation concentrate and the 1:400 spray dilution, respectively. **The dermal penetration estimates to be used for risk assessment were set at 0.026% and 0.86% for the formulation concentrate and the ~~1:200~~ 1:400 spray dilution based on current EFSA guidance criteria (2017).**

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 mefentrifluconazole

Table A 17: 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	**0.031%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**1.80%**		*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 17: 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 18: Mefentrifluconazole: 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)	**0.0382**	**0.0275**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.0006**	**0.0005**
% of RVNAS	**1.82%**	**1.31%**
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	**0.2662**	**0.1928**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.0044**	**0.0032**
% of RVAAS	**2.96%**	**2.14%**

Table A 18: Mefentrifluconazole: 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	**5.1977**	**0.0866**	*D15*i_AbsorpProduct*
Body	**3.4278**	**0.0571**	*D16*i_AbsorpProduct*
Head	**0.0804**	**0.0013**	*D17*i_AbsorpProduct*
Inhalation	**5.9760**	**0.0996**	*D21*i_AbsorpInhalation*
Sum	**14.6820**	**0.2447**	
With RPE/PPE (as selected above)			
Hands	**5.1977**	**0.0866**	*D18*i_AbsorpProduct*
Body	**0.0307**	**0.0005**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**0.0804**	**0.0013**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**5.9760**	**0.0996**	*D21*i_AbsorpInhalation*G25*
Sum	**11.2848**	**0.1881**	
Water soluble bag	**11.2848**	**0.1881**	*C70*F26*

2.2 Application

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

Without RPE/PPE			
Hands	**13.3491**	**0.2225**	*D30*i_AbsorpInuse*
Body	**7.4639**	**0.1244**	*D31*i_AbsorpInuse*
Head	**0.3528**	**0.0059**	*D32*i_AbsorpInuse*
Inhalation	**2.3194**	**0.0387**	*D35*i_AbsorpInhalation*
Sum	**23.4852**	**0.3914**	
With RPE/PPE (as selected above)			
Hands	**13.3491**	**0.2225**	*D33*i_AbsorpInuse*
Body	**0.2047**	**0.0034**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**0.3528**	**0.0059**	*D32*i_AbsorpInuse*F39*
Inhalation	**2.3194**	**0.0387**	*D35*i_AbsorpInuse*G39*
Sum	**16.2260**	**0.2704**	

Table A 18: Mefentrifluconazole: Estimation of operator exposure using the EFSA model – no PPE: workwear (cont'd)

3. DETAILS - Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**19.3174**	**0.3220**	*E15*i_AbsorpProduct*
Body	**35.6376**	**0.5940**	*E16*i_AbsorpProduct*
Head	**0.4411**	**0.0074**	*E17*i_AbsorpProduct*
Inhalation	**29.8370**	**0.4973**	*E21*i_AbsorpInhalation*
Sum	**85.2330**	**1.4206**	
With RPE/PPE (as selected above)			
Hands	**19.3174**	**0.3220**	*E18*i_AbsorpProduct*
Body	**0.2267**	**0.0038**	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	**0.4411**	**0.0074**	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	**29.8370**	**0.4973**	*E21*i_AbsorpInhalation*G25*
Sum	**49.8221**	**0.8304**	
Water soluble bag	**49.8221**	**0.8304**	*C104*F26*

3.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**134.0786**	**2.2346**	*E30*i_AbsorpInuse*
Body	**38.4764**	**0.6413**	*E31*i_AbsorpInuse*
Head	**1.0638**	**0.0177**	*E32*i_AbsorpInuse*
Inhalation	**7.3427**	**0.1224**	*E35*i_AbsorpInhalation*
Sum	**180.9616**	**3.0160**	
With RPE/PPE (as selected above)			
Hands	**134.0786**	**2.2346**	*E33*i_AbsorpInuse*
Body	**0.5022**	**0.0084**	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	**1.0638**	**0.0177**	*E32*i_AbsorpInuse*F39*
Inhalation	**7.3427**	**0.1224**	*E35*i_AbsorpInuse*G39*
Sum	**142.9874**	**2.3831**	

Table A 19: Mefentrifluconazole: 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	**0.031%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**1.80%**		*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 19: Mefentrifluconazole: 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 20: Mefentrifluconazole: 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)	**0.0382**	**0.0223**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.0006**	**0.0004**
% of RVNAS	**1.82%**	**1.06%**
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	**0.2662**	**0.1738**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.0044**	**0.0029**
% of RVAAS	**2.96%**	**1.93%**

Table A 20: Mefentrifluconazole: 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	**5.1977**	**0.0866**	*D15*i_AbsorpProduct*
Body	**3.4278**	**0.0571**	*D16*i_AbsorpProduct*
Head	**0.0804**	**0.0013**	*D17*i_AbsorpProduct*
Inhalation	**5.9760**	**0.0996**	*D21*i_AbsorpInhalation*
Sum	**14.6820**	**0.2447**	
With RPE/PPE (as selected above)			
Hands	**0.0304**	**0.0005**	*D18*i_AbsorpProduct*
Body	**0.0307**	**0.0005**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**0.0804**	**0.0013**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**5.9760**	**0.0996**	*D21*i_AbsorpInhalation*G25*
Sum	**6.1176**	**0.1020**	
Water soluble bag	**6.1176**	**0.1020**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**13.3491**	**0.2225**	*D30*i_AbsorpInuse*
Body	**7.4639**	**0.1244**	*D31*i_AbsorpInuse*
Head	**0.3528**	**0.0059**	*D32*i_AbsorpInuse*
Inhalation	**2.3194**	**0.0387**	*D35*i_AbsorpInhalation*
Sum	**23.4852**	**0.3914**	
With RPE/PPE (as selected above)			
Hands	**13.3491**	**0.2225**	*D33*i_AbsorpInuse*
Body	**0.2047**	**0.0034**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**0.3528**	**0.0059**	*D32*i_AbsorpInuse*F39*
Inhalation	**2.3194**	**0.0387**	*D35*i_AbsorpInuse*G39*
Sum	**16.2260**	**0.2704**	

Table A 20: Mefentrifluconazole: Estimation of operator exposure using the EFSA model PPE level: gloves (mixing/loading), workwear (cont'd)

3. DETAILS - Acute exposure

3.1 Mixing and loading

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**19.3174**	**0.3220**	*E15*i_AbsorpProduct*
Body	**35.6376**	**0.5940**	*E16*i_AbsorpProduct*
Head	**0.4411**	**0.0074**	*E17*i_AbsorpProduct*
Inhalation	**29.8370**	**0.4973**	*E21*i_AbsorpInhalation*
Sum	**85.2330**	**1.4206**	
With RPE/PPE (as selected above)			
Hands	**0.3070**	**0.0051**	*E18*i_AbsorpProduct*
Body	**0.2267**	**0.0038**	*E19*i_AbsorpProduct or E16*i_AbsorpProduct*F24*
Head	**0.4411**	**0.0074**	*E20*i_AbsorpProduct or E17*i_AbsorpProduct*F25*
Inhalation	**29.8370**	**0.4973**	*E21*i_AbsorpInhalation*G25*
Sum	**30.8118**	**0.5135**	
Water soluble bag	**30.8118**	**0.5135**	*C104*F26*

3.2 Application

	Systemic exposure [µg a.s. /day]	Systemic exposure [µg a.s./kg bw/day]	Formula
Without RPE/PPE			
Hands	**134.0786**	**2.2346**	*E30*i_AbsorpInuse*
Body	**38.4764**	**0.6413**	*E31*i_AbsorpInuse*
Head	**1.0638**	**0.0177**	*E32*i_AbsorpInuse*
Inhalation	**7.3427**	**0.1224**	*E35*i_AbsorpInhalation*
Sum	**180.9616**	**3.0160**	
With RPE/PPE (as selected above)			
Hands	**134.0786**	**2.2346**	*E33*i_AbsorpInuse*
Body	**0.5022**	**0.0084**	*E34*i_AbsorpInuse or E31*i_AbsorpInuse*F38*
Head	**1.0638**	**0.0177**	*E32*i_AbsorpInuse*F39*
Inhalation	**7.3427**	**0.1224**	*E35*i_AbsorpInuse*G39*
Sum	**142.9874**	**2.3831**	

A 3.1.2 Calculations for boscalid

Table A 21: Input parameters considered for the estimation of operator exposure (AOEM according to EFSA guidance) – no PPE: workwear

Application rate of active substance	**0.2**	kg a.s./ha	*i_AppRate*
Assumed area treated	**50**	ha/day	*d_AreaTreated*
Amount of active substance applied	**10**	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	**0.026%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**0.86%**		*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	**28588**	**106902**	AOEM	
	Body	**17999**	**140606**	AOEM	
	Head	**519**	**2846**	AOEM	
	Protected hands (gloves)	**154**	**1981**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**183**	**1463**	AOEM	
	Protected head (hood and face shield)	**8**	**161**	AOEM	
	Inhalation	**7**	**30**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**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 21: 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	**1483**	**12376**	AOEM	
	Body	**829**	**4275**	AOEM	
	Head	**39**	**118**	AOEM	
	Protected hands (gloves)	**148**	**4360**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**23**	**56**	AOEM	
	Inhalation	**3**	**11**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**			
	Clothing	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 22: Boscalid: 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)	**0.04310**	**0.03153**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.00072**	**0.00053**
% of RVNAS	**0.72%**	**0.53%**

Table A 22: Boscalid: 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	**7.43299**	**0.12388**	*D15*i_AbsorpProduct*
Body	**4.67987**	**0.07800**	*D16*i_AbsorpProduct*
Head	**0.13490**	**0.00225**	*D17*i_AbsorpProduct*
Inhalation	**7.34514**	**0.12242**	*D21*i_AbsorpInhalation*

Sum	**19.59289**	**0.32655**	
With RPE/PPE (as selected above)			
Hands	**7.43299**	**0.12388**	*D18*i_AbsorpProduct*
Body	**0.04757**	**0.00079**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**0.13490**	**0.00225**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**7.34514**	**0.12242**	*D21*i_AbsorpInhalation*G25*
Sum	**14.96059**	**0.24934**	
Water soluble bag	**14.96059**	**0.24934**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	**Systemic exposure [µg a.s./kg bw/day]**	**Formula**
Without RPE/PPE			
Hands	**12.75581**	**0.21260**	*D30*i_AbsorpInuse*
Body	**7.13221**	**0.11887**	*D31*i_AbsorpInuse*
Head	**0.33709**	**0.00562**	*D32*i_AbsorpInuse*
Inhalation	**3.28240**	**0.05471**	*D35*i_AbsorpInhalation*
Sum	**23.50751**	**0.39179**	
With RPE/PPE (as selected above)			
Hands	**12.75581**	**0.21260**	*D33*i_AbsorpInuse*
Body	**0.19565**	**0.00326**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**0.33709**	**0.00562**	*D32*i_AbsorpInuse*F39*
Inhalation	**3.28240**	**0.05471**	*D35*i_AbsorpInuse*G39*
Sum	**16.57095**	**0.27618**	

Table A 23: Boscalid: Input parameters for estimation of operator exposure (AOEM according to EFSA guidance) – PPE level: gloves (mixing/loading), workwear

Application rate of active substance	**0.2**	kg a.s./ha	*i_AppRate*
Assumed area treated	**50**	ha/day	*d_AreaTreated*
Amount of active substance applied	**5**	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	**0.026%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**0.86%**		*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	**28588**	**106902**	AOEM	
	Body	**17999**	**140606**	AOEM	
	Head	**519**	**2846**	AOEM	
	Protected hands (gloves)	**154**	**1981**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**183**	**1463**	AOEM	
	Protected head (hood and face shield)	**8**	**161**	AOEM	
	Inhalation	**7**	**30**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**Yes**		Incl. in AOEM model	
	Clothing	work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Table A 23: Boscalid: 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	**1483**	**12376**	AOEM	
	Body	**829**	**4275**	AOEM	
	Head	**39**	**118**	AOEM	
	Protected hands (gloves)	**148**	**4360**	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	**23**	**56**	AOEM	
	Inhalation	**3**	**11**	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	**No**		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 24: Boscalid: 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)	**0.04310**	**0.02414**
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	**0.00072**	**0.00040**
% of RVNAS	**0.72%**	**0.40%**

Table A 24: Boscalid: 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	**7.43299**	**0.12388**	*D15*i_AbsorpProduct*
Body	**4.67987**	**0.07800**	*D16*i_AbsorpProduct*

Head	**0.13490**	**0.00225**	*D17*i_AbsorpProduct*
Inhalation	**7.34514**	**0.12242**	*D21*i_AbsorpInhalation*
Sum	**19.59289**	**0.32655**	
With RPE/PPE (as selected above)			
Hands	**0.04007**	**0.00067**	*D18*i_AbsorpProduct*
Body	**0.04757**	**0.00079**	*D19*i_AbsorpProduct or D15*i_AbsorpProduct*F24*
Head	**0.13490**	**0.00225**	*D20*i_AbsorpProduct or D17*i_AbsorpProduct*F25*
Inhalation	**7.34514**	**0.12242**	*D21*i_AbsorpInhalation*G25*
Sum	**7.56767**	**0.12613**	
Water soluble bag	**7.56767**	**0.12613**	*C70*F26*

2.2 Application

	Systemic exposure [µg a.s. /day]	**Systemic exposure [µg a.s./kg bw/day]**	**Formula**
Without RPE/PPE			
Hands	**12.75581**	**0.21260**	*D30*i_AbsorpInuse*
Body	**7.13221**	**0.11887**	*D31*i_AbsorpInuse*
Head	**0.33709**	**0.00562**	*D32*i_AbsorpInuse*
Inhalation	**3.28240**	**0.05471**	*D35*i_AbsorpInhalation*
Sum	**23.50751**	**0.39179**	
With RPE/PPE (as selected above)			
Hands	**12.75581**	**0.21260**	*D33*i_AbsorpInuse*
Body	**0.19565**	**0.00326**	*D34*i_AbsorpInuse or D31*i_AbsorpInuse*F38*
Head	**0.33709**	**0.00562**	*D32*i_AbsorpInuse*F39*
Inhalation	**3.28240**	**0.05471**	*D35*i_AbsorpInuse*G39*
Sum	**16.57095**	**0.27618**	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for mefentrifluconazole

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

Crop type	**Oilseeds**		
Indoor or outdoor	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Worker's task	**Inspection, irrigation**		
Main body parts in contact with foliage	**Hand and body**		
Application rate of active substance	**0.1**	kg a.s./ha	*i_AppRate*
Number of applications	**2**		*i_AppNo*
Interval between multiple applications	**7**	days	*i_AppInt*
Half-life of active substance	**30**	days	*d_HalflifeAS*
Multiple application factor	**1.9**		*d_MAF*
Dermal absorption of the product	**0.031%**		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	**1.80%**		*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 26: Mefentrifluconazole: 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)	**0.24984**	**0.02798**	**no TC available for this assessment**
Total systemic exposure per kg body weight (mg/kg bw/day)	**0.00416**	**0.00047**	
% of RVNAS	**11.9%**	**1.33%**	

2. Details

	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Dermal - Potential	**0.24984**	**0.00416**	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*
Dermal - Work wear - arms, body and legs covered	**0.02798**	**0.00047**	*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 3.2.2 Calculations for boscalid

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

Crop type	**Oilseeds**		
Indoor or outdoor	**Outdoor**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		
Worker's task	**Inspection, irrigation**		
Main body parts in contact with foliage	**Hand and body**		
Application rate of active substance	**0.2**	kg a.s./ha	*i_AppRate*
Number of applications	**2**		*i_AppNo*
Interval between multiple applications	**7**	days	*i_AppInt*
Half-life of active substance	**30**	days	*d_HalflifeAS*
Multiple application factor	**1.9**		*d_MAF*
Dermal absorption of the product	**0.026%**		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	**0.86%**		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.6**	µg a.s./cm^2	*d_DFR*
Working hours	**2**	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	**12500**	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	**1400**	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	**no TC available for this assessment**	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 28: Boscalid: 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)	**0.23874**	**0.02674**	**no TC available for this assessment**
Total systemic exposure per kg body weight (mg/kg bw/day)	**0.00398**	**0.00045**	
% of RVNAS	**4.0%**	**0.45%**	

2. Details

	Systemic exposure [mg a.s./day]	Systemic exposure [mg a.s./kg bw/day]	Formula
Dermal - Potential	**0.23874**	**0.00398**	*d_DermTcUCV*d_WorkHr*i_DFR*i_MAF/1000*i_AbsorpInuse*
Dermal - Work wear - arms, body and legs covered	**0.02674**	**0.00045**	*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 mefentrifluconazole

Table A 29: Bystander exposure: Input parameters considered for the estimation

Crop type	**Oilseeds**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		*i_AppEquip*
Formulation type	**Emulsifiable concentrate**		
Application rate of the product	**0.1**	kg a.s./ha	*i_AppRate*
Buffer strip	**2-3**	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	**1**	g a.s./l	*d_ConcAS*
Dermal absorption of product	**0.031%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**1.8%**		*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 substanceshaving a vapour pressure of <5*10-3Pa**	Pa	*i_Volat*
Concentration in air	**0.001**	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	**1.21**	ml spray dilut./person	
Bystander dermal spray drift exposure - child	**0.74**	ml spray dilut./person	
Bystander inhal. spray drift exposure - adult	**0.00050**	ml spray dilut./person	
Bystander inhal. spray drift exposure - child	**0.00112**	ml spray dilution/person	
Exposure duration	**2**	hours	*d_ByExpDur*
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/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	**1.07**	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	**8.50%**		
Turf transferable residues percentage	**5.00%**		*d_Turf*
Transfer coeff. of surface deposits-adult	**14500**	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits -child (1-3 year old)	**5200**	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	**50.00%**		*d_SalExt*
Surface area of hands mouthed	**20**	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	**20**	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	**25**	cm^2	*d_MouthGrass*
Dislodgeable residues % transferability for object to mouth	**20.00%**		*d_DRP*
Transfer coefficient for entry into treated crops - adult	**7500**	cm^2/hour	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - child	**2250**	cm^2/hour	*d_TcEntryCh*

Table A 30: Mefentrifluconazole: Estimation of bystander exposure

1. Total

1-3 year old child	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	**0.01204**	**0.01070**	**0.00541**	**0.00562**
Total systemic exposure (mg/kg bw/day)	**0.00120**	**0.00107**	**0.00054**	**0.00056**
% of RVAAS	**0.80%**	**0.71%**	**0.36%**	**0.37%**
Adult	**Spray drift**	**Vapour**	**Surface deposits**	**Entry into treated crops**
Total systemic exposure (mg a.s./day)	**0.01836**	**0.01380**	**0.00411**	**0.01874**
Total systemic exposure (mg/kg bw/day)	**0.00031**	**0.00023**	**0.00007**	**0.00031**
% of RVAAS	**0.20%**	**0.15%**	**0.05%**	**0.21%**

Table A 30: Mefentrifluconazole: Estimation of bystander exposure (cont'd)

2. Details

1-3 year old child	**Systemic exposure [mg a.s. /day]**	**Systemic exposure [mg a.s./kg bw/day]**	**Formula**
Spray drift	**0.01204**	**0.00120**	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS")*
Vapour	**0.01070**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.00147**	**0.00015**	*(i_AppRate/100)*C24*d_Turf*d_ByTCCh*d_ByExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip="Vehicle-mounted-Drift Reduction",0.5,1)*
Hand to mouth	**0.00315**	**0.00031**	*(i_AppRate/100)*C25*d_Turf*d_SalExt*d_AreaHM*d_ByFreqHM*d_ByExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.00079**	**0.00008**	*(i_AppRate/100)*C25*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.00562**	**0.00056**	*(d_TcEntryCh*0.25*d_DFR*d_MAF)/1000*MAX(i_AbsorpProduct,i_AbsorpInuse)*
Hand to mouth*	–	–	*(i_AppRate/100)*d_MAF*d_Turf*d_SalExt*d_AreaHM*d_ByFreqHM*d_ByExpDur*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	**0.01836**	**0.00031**	*((C15*i_AbsorpInuse*(1-d_ClothAF)t)+C17)*d_ConcAS*
Vapour	**0.01380**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.00411**	**0.00007**	*(i_AppRate/100)*C24*d_Turf*d_ByTCAd*d_ByExpDur*MAX(i_AbsorpProduct,i_AbsorpInuse)*d_MAF*IF(i_AppEquip="Vehicle-mounted-Drift Reduction",0.5,1)*
Entry into treated crops (dermal)	**0.01874**	**0.00031**	*(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 31: Mefentrifluconazole: Resident exposure: Input parameters for the estimation (EFSA guidance model)

Crop type	**Oilseeds**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		*i_AppEquip*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		*i_FormVal*
Buffer strip	**2-3**	m	*i_Buffer*
Application rate of the product	**0.1**	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	**0.031%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**1.8%**		*i_AbsorpInuse*
Oral absorption	**100.00%**		*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 32: Mefentrifluconazole: 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)	0.00505	0.01070	0.00199	0.00562	0.01946
Total systemic exposure (mg/kg bw/day)	0.00050	0.00107	0.00020	0.00056	0.00195
% of RVNAS	1.44%	3.06%	0.57%	1.61%	5.56%
Adult	**Spray drift**	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All pathways**
	– 75th percentile –				– mean –
Total systemic exposure (mg a.s./day)	0.00704	0.01380	0.00136	0.01874	0.03312
Total systemic exposure (mg/kg bw/day)	0.00012	0.00023	0.00002	0.00031	0.00055
% of RVNAS	0.34%	0.66%	0.06%	0.89%	1.58%

Table A 32: Mefentrifluconazole: 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	**0.00505**	**0.00050**	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*
Vapour	**0.01070**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.00049**	**0.00005**	*(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	**0.00098**	**0.00010**	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.00052**	**0.00005**	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.00562**	**0.00056**	*(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	**0.00704**	**0.00012**	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*
Vapour	**0.01380**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.00136**	**0.00002**	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*
Entry into treated crops (dermal)	**0.01874**	**0.00031**	*(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 32: Mefentrifluconazole: 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	**0.00283**	**0.00028**	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*
Vapour	**0.01070**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.00036**	**0.00004**	*(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	**0.00072**	**0.00007**	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.00038**	**0.00004**	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_Absor pOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.00448**	**0.00045**	*(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	**0.00338**	**0.00006**	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*
Vapour	**0.01380**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.00100**	**0.00002**	*(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)	**0.01494**	**0.00025**	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*

A 3.3.2 Calculations for boscalid

Table A 33: Boscalid: Resident exposure: Input parameters for the estimation (EFSA guidance model)

Crop type	**Oilseeds**		
Application method	**Downward spraying**		
Application equipment	**Vehicle-mounted**		*i_AppEquip*
Formulation type	**Soluble concentrates, emulsifiable concentrate, etc.**		*i_FormVal*
Buffer strip	**2-3**	m	*i_Buffer*
Application rate of the product	**0.2**	kg a.s./ha	*i_AppRate*
Conc.a.s. (in-use dilution for liquid applications)	**2.0**	g a.s./l	*d_ConcAS*
Dermal absorption of product	**0.026%**		*i_AbsorpProduct*
Dermal absorption of in-use dilution	**0.86%**		*i_AbsorpInuse*
Oral absorption	**44.00%**		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	**0.6**	µg a.s./cm2	*d_DFR*
Vapour pressure of in-use dilution	**low volatile substances having a vapour pressure of <5*10-3Pa**	Pa	*i_Volat*
Concentration in air	**0.001**	mg/m3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile – adult	**0.47**	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile – child	**0.327**	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile – adult	**0.00010**	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile – child	**0.00022**	ml spray dilution/person	
Resident dermal spray drift exposure mean – adult	**0.22318**	ml spray dilution/person	
Resident dermal spray drift exposure mean – child	**0.18**	ml spray dilution/person	
Resident inhal. spray drift exposure mean – adult	**0.00009**	ml spray dilution/person	
Resident inhal. spray drift exposure mean – child	**0.00017**	ml spray dilution/person	
Exposure duration dermal	**2**	hours	*d_ReExpDur*
Exposure duration inhalation	**24**	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	**0.25**	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	**18.0%**		*d_ClothAF*
Breathing rate adult	**0.23**	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 34: Boscalid: 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)	**0.00505**	**0.01070**	**0.00179**	**0.00537**	**0.01917**
Total systemic exposure (mg/kg bw/day)	**0.00051**	**0.00107**	**0.00018**	**0.00054**	**0.00192**
% of RVNAS	**0.51%**	**1.07%**	**0.18%**	**0.54%**	**1.92%**
Adult	**Spray drift**	**Vapour**	**Surface deposits**	**Entry into treated crops**	**All pathways**
	– 75th percentile –				– mean –
Total systemic exposure (mg a.s./day)	**0.00683**	**0.01380**	**0.00130**	**0.01791**	**0.03236**
Total systemic exposure (mg/kg bw/day)	**0.00011**	**0.00023**	**0.00002**	**0.00030**	**0.00054**
% of RVNAS	**0.11%**	**0.23%**	**0.02%**	**0.30%**	**0.54%**

Table A 34: Boscalid: 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	**0.00505**	**0.00051**	*((C16*i_AbsorpInuse*(1-d_ClothAF))+C18)*d_ConcAS*
Vapour	**0.01070**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.00046**	**0.00005**	*(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	**0.00087**	**0.00009**	*(i_AppRate/100)*C29*d_Turf*d_SalExt*d_AreaHM*d_ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.00046**	**0.00005**	*(i_AppRate/100)*C29*d_DRP*d_MouthGrass*i_AbsorpOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.00537**	**0.00054**	*(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	**0.00683**	**0.00011**	*(C15*i_AbsorpInuse*(1-d_ClothAF))+C17)*d_ConcAS*
Vapour	**0.01380**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.00130**	**0.00002**	*(i_AppRate/100)*C30*d_Turf*d_ReTCAd*d_ReExpDur*i_AbsorpInuse*
Entry into treated crops (dermal)	**0.01791**	**0.00030**	*(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 34: Boscalid: 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	**0.00288**	**0.00029**	*((C20*i_AbsorpInuse*(1-d_ClothAF))+C22)*d_ConcAS*
Vapour	**0.01070**	**0.00107**	*d_AirCon*d_BreathRCh*d_BwChild*
Surface deposits			
Dermal	**0.00034**	**0.00003**	*(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	**0.00063**	**0.00006**	*(i_AppRate/100)*C30*d_Turf*d_SalExt*d_AreaHM*d_ ReFreqHM*d_ReExpDur*i_AbsorpOralInuse*d_MAF*
Object to mouth	**0.00033**	**0.00003**	*(i_AppRate/100)*C30*d_DRP*d_MouthGrass*i_Absor pOralInuse*d_MAF*
Entry into treated crops			
Dermal	**0.00428**	**0.00043**	*(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	**0.00333**	**0.00006**	*"(C19*i_AbsorpInuse*(1-d_ClothAF))+C21)*d_ConcAS"*
Vapour	**0.01380**	**0.00023**	*d_AirCon*d_BreathRAd*d_BwAdult*
Surface deposits (dermal)	**0.00095**	**0.00002**	*(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)	**0.01428**	**0.00024**	*(d_TcEntryMeanAd*0.25*d_DFR*d_MAF)/1000 *MAX(i_AbsorpProduct,i_AbsorpInuse)*

A 3.4 Combined exposure calculations for mefentrifluconazole and boscalid

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.