

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: FGG01

Product name: Lozzare Pro, Miller Pro, Palator Pro

Chemical active substance:

Boscalid, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

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November 2024	zRMS assessment
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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on FGG01 / LOZZARE PRO *

Product name and code	FGG01 / LOZZARE PRO
Formulation type	WG
Active substance(s) (incl. content)	Boscalid; 500 g/kg
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 - This submission is for a new product registration

* Information on the detailed composition of FGG01 / LOZZARE PRO 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 FGG01 / LOZZARE PRO according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Not classified (regarding human health)
Hazard pictograms or Code(s) for hazard pictogram(s)	None (regarding human health)
Signal word	None (regarding human health)
Hazard statement(s)	None (regarding human health)
Precautionary statement(s)	None (regarding human health)
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	None

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for FGG01 / LOZZARE PRO

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Normal work wear, no PPE required.
Workers	Acceptable	Normal work wear, no PPE required.
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is

used as intended. No specific PPE is necessary.

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

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

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safen- er/synergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion technique ****)	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. applica- tion rate kg as/ha a) a.s. 1	Water L/ha min / max			Operator	Worker	Residents	Bystander
#1	Grapevine, wine & table (BBCH 60-85)	F	Spraying, HCTM HCHH	a) 1 b) 1	a) 0.500	100 - 1000	21	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				
#6	Fresh beans and peas (BBCH 60-69)	F	Spraying, LCTM LCHH	a) 2 (7 d) b) 2 (7 d)	a) 0.500	150 - 600	7	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				
#7	Oilseed rape (BBCH 13-71)	F	Spraying, LCTM	a) 1 b) 1	a) 0.250	100 - 300	35	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032				

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

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

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

Explanation for column 10 "Acceptability of exposure assessment"

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

Data gaps

No data gaps identified.

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

	Boscalid
Common Name	Boscalid
CAS-No.	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: Not classified Code(s) for hazard pictogram(s): None Signal word: None Hazard statement(s): None Precautionary statement(s): None
Additional C&L proposal	Not required
Agreed EU endpoints	
AOEL systemic	0.1 mg/kg bw/d (corrected for 44% oral absorption)
Reference	Review Report SANCO/3919 /2007-rev. 5, 21 January 2008
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report	Operator safety

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for FGG01 / LOZZARE PRO 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 6.3-1a: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for FGG01 / LOZZARE PRO

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	Not submitted, not necessary. Justification presented in Appendix 2			
LD ₅₀ dermal, rat	Not submitted, not necessary. Justification presented in Appendix 2			
LC ₅₀ inhalation, rat	Not submitted, not necessary. Justification presented in Appendix 2			
Skin irritation	Not submitted, not necessary. Justification presented in Appendix 2			
Eye irritation	Not submitted, not necessary. Justification presented in Appendix 2			
Skin sensitisation	Not submitted, not necessary. Justification presented in Appendix 2			

Skin sensitisation, mouse (OECD 429/LLNA)	Not submitted, not necessary. Justification presented in Appendix 2			
Supplementary studies for combinations of plant protection products	No data – not required			

It should be noted that following studies with Boscalid 500 WG / FGG01 were performed for use in regions outside of Europe. A report of these studies is not submitted. The results of these studies confirm the classification that is presented in **Table 6.1-2** and which is based on calculation, in accordance with Regulation (EU) 1272/2008. (Please refer to **Table 6.3-1b**)

Table 6.3-2b: Summary of results of studies (not submitted) on acute toxicity including irritancy and skin sensitisation for FGG01 / LOZZARE PRO

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 425 (2001))	> 5000 mg/kg bw	Yes	None	(2023a)
LD ₅₀ dermal, rat (OECD 402 (1987))	>2000 mg/kg bw	Yes	None	(2023b)
LC ₅₀ inhalation, rat (OECD 403 (1981))	>5.33 mg/L air	Yes	None	(2023a)
Skin irritation, rabbit (OECD 404 (2002))	Non-irritant	Yes	None	(2023c)
Eye irritation, rabbit (OECD 405 (2002))	Non-irritant	Yes	None	(2023d)
Skin sensitisation, mouse (OECD 429 (2010), LLNA)	Non-sensitising	Yes	None	(2023b)

Table 6.3-3: Additional toxicological information relevant for classification/labelling of FGG01 / LOZZARE PRO

	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)	Boscalid (50% (w/w))	Not classified	Reg. 1272/2008 / MSDS** / EFSA conclusion	None
Toxicological properties of non-active substance(s) (relevant for classification of product)	None	Not applicable (n.a.)	n.a.	n.a.
Further toxicological information	No data – not required			

- * Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

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

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substance in FGG01 / LOZZARE PRO is presented in the following table.

Table 6.5-1: Dermal absorption rates for Boscalid in FGG01 / LOZZARE PRO

	Boscalid	
	Value	Reference
Concentrate	0.21%	New study reported in Appendix 2 (Desai, 2023)
Dilution (1:83)	0.6%	New study reported in Appendix 2 (Desai, 2023)
Dilution (1:2670)	3.4%	New study reported in Appendix 2 (Desai, 2023)

6.5.1 Justification for proposed values - Boscalid

Proposed dermal absorption rates for Boscalid are based on dermal absorption study on the formulation FGG01 / LOZZARE PRO. The study results are summarised in the following table. Full summaries of studies on the dermal absorption of Boscalid/FGG01 / LOZZARE PRO that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for Boscalid

Test	Concentrate	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)	0.21%	0.6% (1:83) 3.4% (1:2670)	FGG01 / LOZZARE PRO	Yes	Not required as the test item is the current formulation.	Justification accepted. Endpoint can be used for current product / Justification not accepted. Endpoint cannot be used for current product.	██████ (2023)

Boscalid 500 g/kg WG (FGG01) was tested at three target concentrations of Boscalid:

- Test preparation I - as the commercial concentrate. The concentrate formulation was mixed with water in a 1:1 ratio (w/w) to generate a 'paste' which was applied to the skin. This exposure scenario was considered to be representative of a person being exposed to the concentrate formulation which in turn mixes with sweat. Therefore, the concentration of Boscalid in the 1:1 mixture was ≈ 250 g Boscalid/kg,
- Test preparation II - as an aqueous spray dilution-1 representing the lowest in-use dilution (highest concentration) of 1.2 L product in 100 L water allowed in the GAP [Boscalid: 5.93 g/L],
- Test preparation III - as an aqueous spray dilution-2 representing the highest in-use dilution (lowest concentration) of 0.375 L product in 1000 L water allowed in the GAP [Boscalid: 0.19 g/L].

The concentrate represents the concentration encountered when handling the undiluted formulation (e.g., during mixing and loading), while the dilutions reflect the lowest (lower concentration) and highest (lowest concentration) in-use spray dilutions recommended for use on the label.

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	FGG01 / LOZZARE PRO
Formulation type	WG
Category	Fungicide
Active substance(s) (incl. content)	Boscalid 500 g/kg
AOEL systemic	0.1 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	44%
Dermal absorption	Concentrate: 0.21% Dilution 1: 0.6% (1.2 g product/L, 0. 5 kg/ha 6 g Boscalid/L) Dilution 2: 3.4% (0.375 g product/L, 0.2 g Boscalid/L) (Based on FGG01 (formulation))

6.6.1 Selection of critical use(s) and justification

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

Justification

Use #1 in grapevines represents the worst case for viticulture uses as regards operator, worker, resident and bystander for tractor-mounted and hand-held (knapsack) application in view of application rate and in-use dilution in water revealing the highest dermal absorption. Grapevine use #2 (3×0.2 kg a.s./ha) is covered by this having a five times lower application rate and a 10 day-interval between applications. Operator (TM and HH) and resident/bystander exposure from use in high vegetables (i.e. runner beans, uses #6/7) will also be covered by these calculations.

Uses #3, 4, 5 in winter and spring oilseed rape are similar, representing the worst case in respect of operator, worker, resident and bystander exposure for field crops in view of application rate and lowest Boscalid concentration in the spray dilution.

For use in low vegetables, i.e. fresh beans and peas, use #6/7 represents the worst case as regards operator, worker, resident and bystander for tractor-mounted and hand-held (knapsack) applications with max-

imum application rate and lowest concentration in water. Worker exposure from use in high vegetables is covered by these estimations, too.

6.6.2 Operator exposure (KCP 7.2.1)

Please note, as no acute reference value (AAOEL) for non-dietary human exposure is set, no acute exposure calculations are necessary.

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of FGG01 / LOZZARE PRO according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Viticulture, 1 kg product/ha, field crops, 0.5 kg product/ha, low vegetables, 1 kg product/ha.
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products; EFSA Journal 2022;20(1):7032 Online calculator version: 1.0.1

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Tractor mounted broadcast-assisted application outdoors to high crops (viticulture)			
Application rate		0.5 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure M/L and A	0.04	38.2
	Work wear (arms, body and legs covered) M/L and A no PPE/RPE	0.01	13.2
Tractor mounted boom spray application outdoors to field crops (OSR)			
Application rate		0.25 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure M/L and A	0.003	3.4
	Work wear (arms, body and legs covered) M/L and A no PPE/RPE	0.003	2.5
Tractor mounted boom spray application outdoors to low vegetables (beans & peas)			
Application rate		0.5 kg a.s./ha	
Spray application	Work wear (arms, body and	0.006	5.7

(AOEM; 95 th percentile) Body weight: 60 kg	legs covered) M/L and A		
	Work wear (arms, body and legs covered) M/L and A no PPE/RPE	0.004	4.2
Hand-held (knapsack sprayer) application outdoors to high crops (viticulture)			
Application rate		0.5 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure M/L and A	0.03	33.9
	Work wear (arms, body and legs covered) M/L and A no PPE/RPE	0.003	3.2
Hand-held (knapsack sprayer) application outdoors to low vegetables (beans & peas)			
Application rate		1 kg a.s./ha	
Spray application (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure M/L and A	0.05	52.6
	Work wear (arms, body and legs covered) M/L and A no PPE/RPE	0.007	7.3

Using the AOEM model, operator exposure is predicted to be in a range of 0.003 mg/kg bw/d to 0.01 mg/kg bw/d equal to approximately 3% and 13% of the AOEL for Boscalid for tractor-mounted spraying to low and high crops incl. viticulture and high vegetables, respectively, if normal work wear is worn by the operator. Similarly, for hand-held spraying using a knapsack sprayer, exposure is estimated to range from 0.003 to 0.007 mg/kg bw/d for low and high crops, equal to ca. 7.3 to 7% of the AOEL. Please note, use of hand-held spraying equipment is considered to be safe as well, as results are within the range of results (risk envelope) presented.

No risk for the operator using FGG01 / LOZZARE PRO is anticipated for all intended uses even without personal protective equipment(PPE) but should be use work wear (arms, body and legs covered) M/L and A

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with FGG01 / LOZZARE PRO according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical uses	Viticulture (max. 1 kg product/ha) Field crops (max. 1 × 0.5 kg product/ha) Low vegetables max. 2 × 1 kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products; EFSA Journal 2022;20(1):7032 Online calculator version: 1.0.1

Table 6.6-5: Estimated worker exposure (longer term exposure)

		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Viticulture – hand harvesting Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: N/A			
Number of applications and application rate		1 × 0.5 kg a.s./ha	
Body weight: 60 kg	Potential TC: 30000 cm ² /person/h	0.2	204
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.07	68.7
Field crops – inspection/irrigation (OSR) Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: N/A			
Number of applications and application rate		1 × 0.25 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.01	10.6
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.001	1.2
Low vegetables – reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.5 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.07	73
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.03	31.5

Potential worker exposure is estimated to range from 0.01 to 0.07 mg/kg bw/d equal to approximately 11 to 73% of the AOEL for re-entry activities in field crops and low vegetables such as inspection/irrigation, searching and reaching/picking. For hand harvesting of grapevines, worker exposure is estimated to be 0.07 mg/kg bw/d equal to ca. 69% of the AOEL if normal work wear is worn.

No risk for workers upon re-entry is anticipated for all intended outdoor uses of FGG01 / LOZZARE PRO if use work wear (arms, body and legs covered)

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

In view of worker exposure assessment results, no studies were deemed necessary.

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

Table 6.6-6 shows the exposure models used for estimation of resident and bystander exposure to Boscalid. The outcome of the estimation is presented in [Table 6.6-69](#) (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical uses	Viticulture (max. 1 kg product/ha) Field crops (max. 1°× 0.5 kg product/ha) Low vegetables (max. 2 × 1 kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products; EFSA Journal 2022;20(1):7032 Online calculator version: 1.0.1

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

		Boscalid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted broadcast-assisted application outdoors to high crops (viticulture)			

		Boscalid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<u>Buffer zone: 5 m</u> Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: N/A			
Number of applications and application rate		1 × 0.5 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.02	24.1
	Vapour (75 th perc.)	8 × 10 ⁻⁵	0.08
	Deposits (75 th perc.)	0.0002	0.2
	Re-entry (75 th perc.)	0.003	2.9
	Sum (mean)	0.02	18.4
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.01	13.3
	Vapour (75 th perc.)	3 × 10 ⁻⁵	0.03
	Deposits (75 th perc.)	6 × 10 ⁻⁵	0.06
	Re-entry (75 th perc.)	0.002	1.6
	Sum (mean)	0.01	10
Tractor mounted boom spray application outdoors to low crops (OSR) <u>Buffer zone: 2-3 m</u> Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: N/A			
Number of applications and application rate		1 × 0.25 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.002	2.3
	Vapour (75 th perc.)	8 × 10 ⁻⁵	0.08
	Deposits (75 th perc.)	0.0002	0.2
	Re-entry (75 th perc.)	0.001	1.4
	Sum (mean)	0.003	2.7
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0006	0.6
	Vapour (75 th perc.)	3 × 10 ⁻⁵	0.03
	Deposits (75 th perc.)	6 × 10 ⁻⁵	0.06
	Re-entry (75 th perc.)	0.0008	0.8
	Sum (mean)	0.001	1.0
Tractor mounted boom spray application outdoors to low vegetables (beans & peas) <u>Buffer zone: 2-3 m</u> Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.5 kg a.s./ha	
Resident child	Drift (75 th perc.)	0.003	3.1

		Boscalid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Body weight: 10 kg	Vapour (75 th perc.)	8×10^{-5}	0.08
	Deposits (75 th perc.)	0.0008	0.8
	Re-entry (75 th perc.)	0.005	5.3
	Sum (mean)	0.007	6.6
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.007	0.7
	Vapour (75 th perc.)	3×10^{-5}	0.03
	Deposits (75 th perc.)	0.0002	0.2
	Re-entry (75 th perc.)	0.003	2.9
	Sum (mean)	0.003	2.9

Resident exposure for children is estimated to range from 0.003 to 0.02 mg/kg bw/d equal to approximately 3 to 18% of the AOEL for Boscalid. Resident exposure of adults is predicted to range from 0.001 to 0.01 mg/kg bw/d equal to approximately 1 - 10% of the AOEL.

No risk for residents and bystanders is anticipated for all intended uses of FGG01/LOZZARE PRO and buffer zone 2-3m except for viticulture where the buffer zone is 5m.

6.6.4.2 Measurement of resident and/or bystander exposure

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

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.3/01	Desai, KR	2023	Boscalid 500 g/kg WG: In vitro dermal absorption of Boscalid using human split-thickness skin in a flow through diffusion system Report No: 617-1-06-33435 (study no. UPL/2023/0583) Jai Research Foundation, Valvada - 396105, Dist. Valsad, Gujarat, India GLP Published	N	UPL Europe

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

No bridging of data for other formulations was necessary.

Comments of zRMS:	N/A
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The acute toxicological profile of FGG01 / LOZZARE PRO was assessed according to the principles laid down in Regulation (EC) No 1272/2008.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The acute oral LD ₅₀ was shown to be higher than 5000 mg/bw in rats. And then FGG01 / LOZZARE PRO is not classified
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The acute oral toxicity of FGG01 / LOZZARE PRO was assessed according to the rules laid down in Regulation (EC) No 1272/2008.

It is considered scientifically acceptable to use the calculation method for classification of FGG01 / LOZZARE PRO because the toxicological profiles of Boscalid and the co-formulants are well characterized.

Due to the confidential nature of the formulation, for details on the calculation, please refer to Part C.

The plant protection product FGG01 / LOZZARE PRO does not contain any component classified for acute oral toxicity, thus, it's reasonable to assume that the oral LD₅₀ of the formulation will be higher than 2000 mg/kg bw and no classification is warranted according to Regulation (EC) No. 1272/2008.

This is also confirmed by the following study, which was performed for other regions than Europe and that will not be submitted as part of this application:

Rani P. (2023a). Acute oral toxicity study of Boscalid 500 g/kg WG in rats. Jai Research Foundation, India. Report no. 401-1-01-33919.

The acute oral LD₅₀ was shown to be higher than 5000 mg/bw in rats.

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

Comments of zRMS:	The acute dermal LD ₅₀ was shown to be higher than 2000 mg/bw in rats. And then FGG01 / LOZZARE PRO is not classified
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The acute dermal toxicity of FGG01 / LOZZARE PRO was assessed according to the rules laid down in Regulation (EC) No 1272/2008.

It is considered scientifically acceptable to use the calculation method for classification of FGG01 /

LOZZARE PRO because the toxicological profiles of Boscalid and the co-formulants are well characterized.

Due to the confidential nature of the formulation, for details on the calculation, please refer to Part C.

The plant protection product FGG01 / LOZZARE PRO does not contain any component classified for acute dermal toxicity, thus, it's reasonable to assume that the dermal LD₅₀ of the formulation will be higher than 2000 mg/kg bw and no classification is warranted according to Regulation (EC) No. 1272/2008.

This is also confirmed by the following study, which was performed for other regions than Europe and that will not be submitted as part of this application:

Rani P. (2023b). Acute dermal toxicity study of Boscalid 500 g/kg WG in rats. Jai Research Foundation, India. Report no. 403-1-01-33920.

The acute dermal LD₅₀ was shown to be higher than 2000 mg/bw in rats.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	The acute inhalation LC₅₀ was shown to be higher than 5.33 mg/L in rats. And then FGG01 / LOZZARE PRO is not classified
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The acute inhalation toxicity of FGG01 / LOZZARE PRO was assessed according to the rules laid down in Regulation (EC) No 1272/2008.

It is considered scientifically acceptable to use the calculation method for classification of FGG01 / LOZZARE PRO because the toxicological profiles of Boscalid and the co-formulants are well characterized.

Due to the confidential nature of the formulation, for details on the calculation, please refer to Part C.

The plant protection product FGG01 / LOZZARE PRO does not contain any component classified for acute inhalation toxicity, thus, it's reasonable to assume that the oral LC₅₀ of the formulation will be higher than the trigger value of 5 mg/L for dusts and mists and no classification is warranted according to Regulation (EC) No. 1272/2008.

This is also confirmed by the following study, which was performed for other regions than Europe and that will not be submitted as part of this application:

Panpatil NA. (2023a). Acute inhalation toxicity study of Boscalid 500 g/kg WG in rats. Jai Research Foundation, India. Report no. 405-1-01-33921.

The acute inhalation LC₅₀ was shown to be higher than 5.33 mg/L in rats.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Boscalid 500 g/kg WG was shown to be not irritating to the skin of rabbits.
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The skin irritating properties of FGG01 / LOZZARE PRO were assessed according to the rules laid down

in Regulation (EC) No 1272/2008.

It is considered scientifically acceptable to use the calculation method for classification of FGG01 / LOZZARE PRO because the toxicological profiles of Boscalid and the co-formulants are well characterized.

Due to the confidential nature of the formulation, for details on the calculation, please refer to Part C.

The plant protection product FGG01 / LOZZARE PRO does not contain any component classified for skin corrosion or irritation, thus, it's reasonable to assume that the formulation is not irritating to skin and no classification is warranted according to Regulation (EC) No. 1272/2008.

This is also confirmed by the following study, which was performed for other regions than Europe and that will not be submitted as part of this application:

Rani P. (2023c). Acute dermal irritation study of Boscalid 500 g/kg WG in rats. Jai Research Foundation, India. Report no. 406-1-01-33922.

Boscalid 500 g/kg WG was shown to be not irritating to the skin of rabbits.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Boscalid 500 g/kg WG was shown to be not irritating to the eyes of rabbits.
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The eye irritating properties of FGG01 / LOZZARE PRO were assessed according to the rules laid down in Regulation (EC) No 1272/2008.

It is considered scientifically acceptable to use the calculation method for classification of FGG01 / LOZZARE PRO because the toxicological profiles of Boscalid and the co-formulants are well characterized.

Due to the confidential nature of the formulation, for details on the calculation, please refer to Part C.

The plant protection product FGG01 / LOZZARE PRO does not contain any component classified for eye corrosion or irritation, thus, it's reasonable to assume that the formulation is not irritating to eyes and no classification is warranted according to Regulation (EC) No. 1272/2008.

This is also confirmed by the following study, which was performed for other regions than Europe and that will not be submitted as part of this application:

Rani P. (2023d). Acute eye irritation study of Boscalid 500 g/kg WG in rats. Jai Research Foundation, India. Report no. 407-1-01-33923.

Boscalid 500 g/kg WG was shown to be not irritating to the eyes of rabbits.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Boscalid 500 g/kg WG was shown to be no skin sensitizer in mice.
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The skin sensitising properties of FGG01 / LOZZARE PRO were assessed according to the rules laid down in Regulation (EC) No 1272/2008.

It is considered scientifically acceptable to use the calculation method for classification of FGG01 / LOZZARE PRO because the toxicological profiles of Boscalid and the co-formulants are well characterized.

Due to the confidential nature of the formulation, for details on the calculation, please refer to Part C.

The plant protection product FGG01 / LOZZARE PRO does not contain any component classified for skin sensitisation, thus, it's reasonable to assume that the formulation is not sensitising to skin and no classification is warranted according to Regulation (EC) No. 1272/2008.

This is also confirmed by the following study, which was performed for other regions than Europe and that will not be submitted as part of this application:

Panpatil NA. (2023b). Skin sensitisation study of Boscalid 500 g/Kg WG by Local Lymph Node Assay in mice. Jai Research Foundation, India. Report no. 409-1-01-33924.

Boscalid 500 g/kg WG was shown to be no skin sensitiser in mice.

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

Not required. No use in combination with other plant protection products is intended.

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)

A 2.10.1 Study 1 – Boscalid in FGG01 / LOZZARE PRO

Dermal absorption, in vitro using human skin

Comments of zRMS:	The dermal penetration estimates to be used for risk assessment were set at 0.21%, 0.6% and 3.4% for the formulation concentrate and spray dilutions 1 and 2 based on the EFSA guidance criteria and the BfR calculation sheet
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Reference	KCP 7.3/01
Report	<div style="background-color: black; width: 100px; height: 1.2em; display: inline-block;"></div> (2023) Boscalid 500 g/kg WG: In vitro dermal absorption of Boscalid using human split-thickness skin in a flow through diffusion system. Report no.: 617-1-06-33435
Guideline(s)	Yes (OECD 428)
Deviations	None
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	Not applicable

Materials and methods

Test material	Name (Lot/Batch No.)	Boscalid (batch no. 12745JDG012-3)
	Test preparation	spiking
	Specific activity	1821 MBq/mmol
	Radiochemical purity	99.5
Product	Name (Lot/Batch No.)	Boscalid 500 g/kg WG (batch no. ARD/BD364/50/WG/0422/59)
	Company code	GPF516/FGG01
	Concentration a.s.	[g/L or g/kg]
	Formulation type	WG
Blank product	Name (Lot/Batch No.)	Blank for Boscalid 500 g/kg WG (batch no. ARD/BD364/50/WG/0422/BLK)
	Concentration a.s.	0 g/kg

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.6 ml/h
	Exposed skin area	0.64 cm ²
	Cover	open
Membrane	Skin type	dermatomed epidermis
	Skin thickness range	200 - 400 µm
	Skin donors age	27 - 48
	Skin donors sex	Female
	Location	abdomen
	Source	ex vivo
	Integrity test	Permeability coefficient
Receptor	Receptor medium	Dulbecco's phosphate-buffered saline, pH 7.4, 6% PEG) plus antibiotics
	Solubility in receptor medium	Y, 100 µg/mL
Sample Time	Exposure time	8 h
	Observation time	24 h
Sampling	Sample intervals	1, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 h

Washing		post exposure (8 h) / post observation (24 h)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	y
Remarks:None		

Tested doses	Concentrate	Spray dilution 1	Spray dilution 2
Target concentration [mg/ml]	250	5.93	0.19
Area dose [$\mu\text{g}/\text{cm}^2$]	2500	59.3	1.9
Total dose [$\mu\text{g}/\text{cell}$]	3200	6,4	6,4
Specific activity [kBq/ml]	5800	5800	1003
No. of donors	4	4	4
No of cells used/valid cells*	8/8	8/8	8/8

* Justification for excluded cells, if applicable

Results and discussions

In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) the study was evaluated using the Excel calculation sheet provided by BfR (efs24873-sup-0001-supinfo_1) as summarized below.

Table A 1: In-vitro dermal penetration of Boscalid formulated as FGG01 / LOZZARE PRO through human skin - Recovery data

Dose group	High dose		Mid dose		Low dose	
	(Formulation concentrate)		(Spray dilution 1:83)		(Spray dilution 1:2670)	
Target concentration [mg/mL]	250		5.93		0.19	
Target dose [$\mu\text{g}/\text{cm}^2$]	2500		59.3		1.9	
Mean actual applied dose [$\mu\text{g}/\text{cm}^2$]	2511		58.45		1.9	
	Recovery [%]		Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.	Mean	S.D.
Dislodgeable dose						
Skin washing after 8 h						
Skin washing after 24 h						
Donor chamber wash	0.02	0.02	0.07	0.06	0.22	0.12
Dose associated to skin						
Tape strips: 1 st sample, strips 1 + 2	0.01	0.00	0.01	0.01	0.06	0.06
Tape strips: 2 nd sample; strips 3 - 15	0.02	0.01	0.03	0.03	0.16	0.07
Skin preparation	0.13	0.02	0.19	0.08	1.07	0.48
Absorbed dose						
Receptor fluid	0.03	0.01	0.22	0.08	1.32	0.50
Receptor chamber wash	0.02	0.01	0.02	0.01	0.03	0.02
Total recovery¹						
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at $t_{0.5}$]	No [57.89% \pm 3.81]		No [66.94% \pm 8.27]		No [70.52% \pm 7.72]	
If no:	0.19	0.02	0.46	0.17	2.57	1.03

Absorption estimates = absorbed dose + skin preparation + tape strips sample 2) ²						
If yes: Absorption estimates = absorbed dose + skin preparation	N/A	N/A	N/A	N/A	N/A	N/A
Absorption estimate normalised ³	0.19		0.46		2.57	
Relevant absorption estimate ⁴	0.209		0.598		3.438	
Absorption estimates used for risk assessment⁵	0.21		0.6		3.4	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal [2017;15\(6\):4873](#)) [2012;10\(4\):2665](#)) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.

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

⁴ In accordance with the EFSA Guidance on Dermal Absorption, one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was ≥ 25% of the mean value.

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

N/A: not applicable

Remarks

No further remarks are considered necessary.

No cells were excluded.

Conclusion/endpoint:

The dermal penetration of Boscalid formulated as FGG01 / LOZZARE PRO through human dermatomed skin was determined *in vitro*. The amount of applied dose penetrating within 24 hours given as the sum of receptor fluid, receptor compartment wash, skin preparation and *stratum corneum* (as less than 75% of the absorption occurred in the first half of the study) was determined to be $0.19 \pm 0.02\%$ for the formulation concentrate, $0.46 \pm 0.17\%$ for spray dilution 1 (1:83) and $2.57 \pm 1.01\%$ for spray dilution 2 (1670) respectively according to the report.

The dermal penetration estimates to be used for risk assessment were set at **0.21%**, **0.6%** and **3.4%** for the formulation concentrate and spray dilutions 1 and 2 based on the EFSA guidance criteria and the BfR calculation sheet.

A 2.11 Other/Special Studies

No further studies were deemed necessary.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Boscalid

Table A 2: Input parameters considered for the estimation of operator exposure - grapevine (vehicle-mounted)

Formulation type	WG		Crop type	Viticulture
Application rate (AR)	0.5	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.21	% (concentr.)	Indoor/outdoor	Outdoor
	3.4	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.1	mg/kg bw/d	Water soluble bag	No
AAOEL	N/A	mg/kg bw/d		

Table A 3: Estimation of longer-term operator exposure towards active substance according to EFSA guidance - grapevine (vehicle-mounted)

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			No protective gloves	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.2	µg/kg bw/d
Body			Work wear	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.004	µg/kg bw/d
Head			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.005	µg/kg bw/d
Inhalation			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.7	µg/kg bw/d
Application				
Hands			No protective gloves	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	6	µg/kg bw/d
Body			Work wear	

Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.3	µg/kg bw/d
<u>Head</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	3.3	µg/kg bw/d
<u>Inhalation</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	2.7	µg/kg bw/d
Total				
Total systemic exposure		mg/kg bw/d	0.01	mg/kg bw/d
% of AAOEL		%	13.2	%

Table A 4: Input parameters considered for the estimation of operator exposure - grapevine (hand-held)

Formulation type	WG		Crop type	Viticulture
Application rate (AR)	0.5	kg a.s./ha	Application method	Upward spraying
Area treated per day (A)	1	ha	Application equipment	Manual-knapsack
Dermal absorption (DA)	0.21	% (concentr.)	Indoor/outdoor	Outdoor
	3.4	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.1	mg/kg bw/d	Water soluble bag	No
AAOEL	N/A	mg/kg bw/d		

Table A 5: Estimation of longer-term operator exposure towards Boscalid according to EFSA guidance - grapevine (hand-held)

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			No protective gloves	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.3	µg/kg bw/d
Body			Work wear	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.0009	µg/kg bw/d
Head			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.0002	µg/kg bw/d
Inhalation			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.6	µg/kg bw/d
Application				

<u>Hands</u>		No protective gloves	
Specific exposure value	µg/person		µg/person
Systemic exposure	mg/kg bw/d	0.9	µg/kg bw/d
<u>Body</u>		Work wear	
Specific exposure value	µg/person		µg/person
Systemic exposure	mg/kg bw/d	0.6	µg/kg bw/d
<u>Head</u>		No protection	
Specific exposure value	µg/person		µg/person
Systemic exposure	mg/kg bw/d	0.07	µg/kg bw/d
<u>Inhalation</u>		No protection	
Specific exposure value	µg/person		µg/person
Systemic exposure	mg/kg bw/d	0.8	µg/kg bw/d
Total			
Total systemic exposure	mg/kg bw/d	0.003	mg/kg bw/d
% of AOEL	%	3.2	%

Table A 6: Input parameters considered for the estimation of operator exposure - OSR (vehicle-mounted)

Formulation type	WG	Crop type	Field crops
Application rate (AR)	0.25 kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50 ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.21 % (concentr.)	Indoor/outdoor	Outdoor
	3.4 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal
AOEL	0.1 mg/kg bw/d	Water soluble bag	No
AAOEL	N/A mg/kg bw/d		

Table A 7: Estimation of longer-term operator exposure towards active substance according to EFSA guidance – OSR (vehicle-mounted)

	Potential	With work wear + PPE/RPE
Mixing and loading		
<u>Hands</u>		No protective gloves
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.3 µg/kg bw/d
<u>Body</u>		Work wear
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.006 µg/kg bw/d
<u>Head</u>		No protection
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.01 µg/kg bw/d

<u>Inhalation</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	1.0	µg/kg bw/d
Application				
<u>Hands</u>			No protective gloves	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	1.0	µg/kg bw/d
<u>Body</u>			Work wear	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.02	µg/kg bw/d
<u>Head</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.03	µg/kg bw/d
<u>Inhalation</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.06	µg/kg bw/d
Total				
Total systemic exposure		mg/kg bw/d	0.003	mg/kg bw/d
% of AAOEL		%	2.5	%

Table A 8: Input parameters considered for the estimation of operator exposure - beans & peas (vehicle-mounted)

Formulation type	WG		Crop type	Low vegetables
Application rate (AR)	0.5	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	0.21	% (concentr.)	Indoor/outdoor	Outdoor
	3.4	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.1	mg/kg bw/d	Water soluble bag	No
AAOEL	N/A	mg/kg bw/d		

Table A 9: Estimation of longer-term operator exposure towards active substance according to EFSA guidance - beans & peas (vehicle-mounted)

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			No protective gloves	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.5	µg/kg bw/d
Body			Work wear	
Specific exposure value		µg/person		µg/person

Systemic exposure		mg/kg bw/d	0.01	µg/kg bw/d
<u>Head</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.03	µg/kg bw/d
<u>Inhalation</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	1.4	µg/kg bw/d
Application				
<u>Hands</u>			No protective gloves	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	2.1	µg/kg bw/d
<u>Body</u>			Work wear	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.03	µg/kg bw/d
<u>Head</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.06	µg/kg bw/d
<u>Inhalation</u>			No protection	
Specific exposure value		µg/person		µg/person
Systemic exposure		mg/kg bw/d	0.09	µg/kg bw/d
Total				
Total systemic exposure		mg/kg bw/d	0.004	mg/kg bw/d
% of AAOEL		%	4.2	%

Table A 10: Input parameters considered for the estimation of operator exposure - beans & peas (hand-held)

Formulation type	WG		Crop type	Low vegetables
Application rate (AR)	0.5	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	1	ha	Application equipment	Manual-knapsack
Dermal absorption (DA)	0.21	% (concentr.)	Indoor/outdoor	Outdoor
	3.4	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.1	mg/kg bw/d	Water soluble bag	No
AAOEL	N/A	mg/kg bw/d		

Table A 11: Estimation of longer-term operator exposure towards Boscalid according to EFSA guidance - beans & peas (hand-held)

	Potential	With work wear + PPE/RPE
Mixing and loading		
<u>Hands</u>		No protective gloves
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.3 µg/kg bw/d
<u>Body</u>		Work wear
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.0009 µg/kg bw/d
<u>Head</u>		No protection
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.0002 µg/kg bw/d
<u>Inhalation</u>		No protection
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.6 µg/kg bw/d
Application		
<u>Hands</u>		No protective gloves
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.9 µg/kg bw/d
<u>Body</u>		Work wear
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	5 µg/kg bw/d
<u>Head</u>		No protection
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.007 µg/kg bw/d
<u>Inhalation</u>		No protection
Specific exposure value	µg/person	µg/person
Systemic exposure	mg/kg bw/d	0.4 µg/kg bw/d
Total		
Total systemic exposure	mg/kg bw/d	0.007 mg/kg bw/d
% of AOEL	%	7.3 %

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Boscalid

Table A 12: Input parameters considered for the estimation of worker exposure - grapevine

Intended use(s)	Viticulture, hand harvesting, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.5	kg a.s./ha	Dermal absorption (DA)	3.4	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	30000	cm ² /h
Multiple application factor (MAF)	1		TC dermal (work wear)	10100	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	N/A	cm ² /h
AOEL	0.1	mg/kg bw/d	Task specific factor inhalation	N/A	ha/h x 10 ⁻³
AAOEL	N/A	mg/kg bw/d			

Table A 133: Estimation of longer-term worker exposure towards Boscalid according to EFSA guidance - grapevine

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.203	mg/kg bw/d	0.068	mg/kg bw/d	N/A	mg/kg bw/d
Worker (re-entry): Total						
Systemic exposure	0.2	mg/kg bw/d	0.07	mg/kg bw/d	N/A	mg/kg bw/d
% of AOEL	204	%	68.7	%	N/A	%

Table A 24: Input parameters considered for the estimation of worker exposure -OSR

Intended use(s)	Field crops, inspection/irrigation, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.25	kg a.s./ha	Dermal absorption (DA)	3.4	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	2	h/d
Half-life of active substance	30	days	TC dermal (potential)	12500	cm ² /h
Multiple application factor (MAF)	1		TC dermal (work wear)	1400	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	1250	cm ² /h
AOEL	0.1	mg/kg bw/d	Task specific factor inhalation	N/A	ha/h x 10 ⁻³
AAOEL	N/A	mg/kg bw/d			

Table A 145: Estimation of longer-term worker exposure towards Boscalid according to EFSA guidance - OSR

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.6	mg/kg bw/d	0.07	mg/kg bw/d	0.06	mg/kg bw/d
Worker (re-entry): Total						
Systemic exposure	0.01	mg/kg bw/d	0.001	mg/kg bw/d	0.001	mg/kg bw/d
% of AOEL	10.6	%	1.2	%	1.1	%

Table A 26: Input parameters considered for the estimation of worker exposure -peas & beans

Intended use(s)	Low vegetables, reaching/picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.5	kg a.s./ha	Dermal absorption (DA)	3.4	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	7	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.85		TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.1	mg/kg bw/d	Task specific factor inhalation	N/A	ha/h x 10 ⁻³
AAOEL	N/A	mg/kg bw/d			

Table A 15: Estimation of longer-term worker exposure towards Boscalid according to EFSA guidance – peas & beans

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.07	mg/kg bw/d	0.03	mg/kg bw/d	0.007	mg/kg bw/d
Worker (re-entry): Total						
Systemic exposure	0.07	mg/kg bw/d	0.03	mg/kg bw/d	0.007	mg/kg bw/d
% of AOEL	73	%	31.5	%	7.3	%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Boscalid

Table A 16: Input parameters considered for the estimation of longer-term resident exposure - grapevine

Intended use(s)	Viticulture, outdoor		Drift reduction (DR)	0	%
Application rate (AR)	0.5	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	100	L/ha	Drift on surface (D) - 75 th perc.	-	%
Buffer strip	5	m	Drift on surface (D) - mean	-	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	-	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	3.4	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	44	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.1	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	-	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	-	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	-	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	-	mL spray dilution (child)			
Spray drift dermal (SD) - mean	-	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	-	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	-	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	-	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	0.27	m ³ /d/kg (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	0.8	m ³ /d/kg (child)		1794	cm ² /h (child)

Table A 29: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance - grapevine

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.01	mg/kg bw/d	Systemic exposure	0.02	mg/kg bw/d
% of AOEL:	13.3	%	% of AOEL:	24.1	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	3 × 10 ⁻⁵	mg/kg bw/d	Systemic exposure	8 × 10 ⁻⁵	mg/kg bw/d
% of AOEL:	0.03	%	% of AOEL:	0.08	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	-	mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	6 × 10 ⁻⁵	mg/kg bw/d	Systemic exposure	0.0002	mg/kg bw/d
% of AOEL:	0.06	%	% of AOEL:	0.2	%
Entry into treated crops (75 th perc.)					
<u>Dermal</u>					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure		mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.002	mg/kg bw/d	Systemic exposure	0.003	mg/kg bw/d
% of AOEL:	1.6	%	% of AOEL:	2.9	%
All pathways (mean)					
Systemic exposure	0.01	mg/kg bw/d	Systemic exposure	0.02	mg/kg bw/d
% of AOEL:	10	%	% of AOEL:	18.4	%

Table A 30: Input parameters considered for the estimation of longer-term resident exposure - OSR

Intended use(s)	Field crops, outdoor		Drift reduction (DR)	0	%
Application rate (AR)	0.25	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	100	L/ha	Drift on surface (D) - 75 th perc.	-	%
Buffer strip	2-3	m	Drift on surface (D) - mean	-	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	N/A	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	-	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	3.4	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	44	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.1	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	-	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	-	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	-	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	-	mL spray dilution (child)			
Spray drift dermal (SD) - mean	-	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	-	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	-	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	-	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	0.27	m ³ /d/kg (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	0.8	m ³ /d/kg (child)		1794	cm ² /h (child)

Table A 17: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance - OSR

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0006	mg/kg bw/d	Systemic exposure	0.002	mg/kg bw/d
% of AOEL:	0.6	%	% of AOEL:	2.3	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	3 × 10 ⁻⁵	mg/kg bw/d	Systemic exposure	8 × 10 ⁻⁵	mg/kg bw/d
% of AOEL:	0.03	%	% of AOEL:	0.08	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	-	mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	6 × 10 ⁻⁵	mg/kg bw/d	Systemic exposure	0.0002	mg/kg bw/d
% of AOEL:	0.06	%	% of AOEL:	0.2	%
Entry into treated crops (75 th perc.)					
<u>Dermal</u>					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure		mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0008	mg/kg bw/d	Systemic exposure	0.001	mg/kg bw/d
% of AOEL:	1.5	%	% of AOEL:	1.4	%
All pathways (mean)					
Systemic exposure	0.001	mg/kg bw/d	Systemic exposure	0.003	mg/kg bw/d
% of AOEL:	1.0	%	% of AOEL:	2.7	%

Table A 18: Input parameters considered for the estimation of longer-term resident exposure - peas & beans

Intended use(s)	Low vegetables, outdoor		Drift reduction (DR)	0	%
Application rate (AR)	0.5	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	150	L/ha	Drift on surface (D) - 75 th perc.	-	%
Buffer strip	2-3	m	Drift on surface (D) - mean	-	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	7	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.85		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	-	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	3.4	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	44	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.1	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	-	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	-	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	-	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	-	mL spray dilution (child)			
Spray drift dermal (SD) - mean	-	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	-	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	-	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	-	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	0.27	m ³ /d/kg (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	0.8	m ³ /d/kg (child)		1794	cm ² /h (child)

Table A 19: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance – peas & beans

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0007	mg/kg bw/d	Systemic exposure	0.003	mg/kg bw/d
% of AOEL:	0.7	%	% of AOEL:	3.1	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	3 × 10 ⁻⁵	mg/kg bw/d	Systemic exposure	8 × 10 ⁻⁵	mg/kg bw/d
% of AOEL:	0.03	%	% of AOEL:	0.08	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	-	mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0002	mg/kg bw/d	Systemic exposure	0.0008	mg/kg bw/d
% of AOEL:	0.2	%	% of AOEL:	0.8	%
Entry into treated crops (75 th perc.)					
<u>Dermal</u>					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure		mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.003	mg/kg bw/d	Systemic exposure	0.005	mg/kg bw/d
% of AOEL:	2.9	%	% of AOEL:	5.3	%
All pathways (mean)					
Systemic exposure	0.003	mg/kg bw/d	Systemic exposure	0.007	mg/kg bw/d
% of AOEL:	2.9	%	% of AOEL:	6.6	%

Table A 20: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance – peas & beans

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.003	mg/kg bw/d	Systemic exposure	0.005	mg/kg bw/d
% of AOEL:	2.7	%	% of AOEL:	4.8	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	3 × 10 ⁻⁵	mg/kg bw/d	Systemic exposure	8 × 10 ⁻⁵	mg/kg bw/d
% of AOEL:	0.03	%	% of AOEL:	0.08	%
Surface deposits (75 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	-	mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
	-		Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0001	mg/kg bw/d	Systemic exposure	0.0005	mg/kg bw/d
% of AOEL:	0.1	%	% of AOEL:	0.5	%
Entry into treated crops (75 th perc.)					
<u>Dermal</u>					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure		mg/kg bw/d	Systemic exposure		mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.002	mg/kg bw/d	Systemic exposure	0.003	mg/kg bw/d
% of AOEL:	1.6	%	% of AOEL:	2.9	%
All pathways (mean)					
Systemic exposure	0.003	mg/kg bw/d	Systemic exposure	0.006	mg/kg bw/d
% of AOEL:	3.2	%	% of AOEL:	5.9	%

A 3.4 Combined exposure calculations for Boscalid and active substance 2

Not required. The plant protection product contains one active substance only.

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

Not relevant. No DFR studies were necessary.

Appendix 5 EFSA Online Calculator output

Please note: As there is currently no guidance how to present the results of the EFSA OPEX online calculator, the report as generated by this tool without modifications is copied below.

Exposure assessment for operator, worker, resident and bystander

Product: Boscalid 500 WG - dossier_central zone

OPEX version: 1.0.1

20 March 2024

1 Information on product and active substance(s)

Product name	Boscalid 500 WG - dossier_central zone
Formulation type	Wettable granules, soluble granules
Product category	Other
Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	500
AOEL [mg/kg bw/day]	0.1
AAOEL [mg/kg bw]	
Inhalation absorption [%]	100
Oral absorption [%]	44
Dermal absorption [%] (concentrate)	0.21
Dermal absorption [%] (dilution) 6 [g a.s./l or kg]	0.6
Dermal absorption [%] (dilution) 0.2 [g a.s./l or kg]	3.4





2 Assessed uses

Use	Crops	Max. appli- cation rate of the prod- uct [l or kg/ha]	Unit	Max. no. of appli- cations	Interval be- tween multi- ple ap- plica- tions [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	In- door/o utdoor	Appli- cation method	Type of cultiva- tion	Appli- cation tech- nique	Buffer strip [m]	Drift reduc- tion [%]
Use 1	Viticul- ture	1.0	kg/ha	1	7	100	1000	Outdoor	Upward spray- ing	Normal	Vehicle- mount- ed	5	0
Use 1	Viticul- ture	1.0	kg/ha	1	7	100	1000	Outdoor	Upward spray- ing	Normal	Manual- knap- sack	5	0
Use 2	Field crops	0.5	kg/ha	1	7	100	300	Outdoor	Down- ward spray- ing	Normal	Vehicle- mount- ed	2-3	0
Use 3	Low vegeta- bles	1.0	kg/ha	2	7	150	600	Outdoor	Down- ward spray- ing	Normal	Vehicle- mount- ed	2-3	0
Use 3	Low vegeta- bles	1.0	kg/ha	2	7	150	600	Outdoor	Down- ward spray- ing	Normal	Manual- knap- sack	2-3	0





3 Operator

3.1 Use 1 : Viticulture

Short term exposure

Mixing/loading Application		Boscalid (% AOEL)	
 	 	Normal & vehicle-mounted	Normal & manual-knapsack
		38.2	33.9
		13.2	3.2

Acute exposure

Mixing/loading Application		Boscalid (% AOEL)	
 	 	Normal & vehicle-mounted	Normal & manual-knapsack

3.1.1 Scenario 1 : Outdoor, normal, upward spraying, vehicle-mounted

3.1.1.1 Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOE L
Viticulture/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.5 kg a.s./ha Dermal absorption (concentrate): 0.21 % Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear App: Workwear	0.01	13.2

3.1.1.2 Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AA-OEL
Viticulture/Outdoor/Upward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.5 kg a.s./ha Dermal absorption (concentrate): 0.21 % Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear + Protected hands + FP2, P2 and similar App: Closed cabin + workwear		No results!

3.1.2 Scenario 2 : Outdoor, normal, upward spraying, manual-knapsack

3.1.2.1 Summary data - Short term exposure





Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOE L
Viticulture/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.5 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear App: Workwear	0.003	3.2

3.1.2.2 Summary data - Acute exposure





Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AA-OEL
Viticulture/Outdoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.5 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear + Protected hands + FP2, P2 and similar App: Closed cabin + workwear		No results!

3.2 Use 2 : Field crops

Short term exposure

Mixing/loading Application		Boscalid (% AOEL) Normal & ve- hicle-mounted
		3.4
		2.5

Acute exposure

Mixing/loading Application		Boscalid (% AOEL) Normal & ve- hicle-mounted
		
		

3.2.1 Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

3.2.1.1 Summary data - Short term exposure





Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOE L
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.25 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear App: Workwear	0.003	2.5

3.2.1.2 Summary data - Acute exposure





Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AA-OEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.25 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear + Protected hands + FP2, P2 and similar App: Workwear + Protected hands + FP2, P2 and similar		No results!

3.3 Use 3 : Low vegetables

Short term exposure

Mixing/loading Application		Boscalid (% AOEL)	
		Normal & vehicle-mounted	Normal & manual-knapsack
		5.7	52.6
		4.2	7.3

Acute exposure

Mixing/loading Application		Boscalid (% AOEL)	
		Normal & vehicle-mounted	Normal & manual-knapsack
			
			

3.3.1 Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

3.3.1.1 Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of sys-temic AOEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 2 x 0.5 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
Boscalid	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear App: Workwear	0.004	4.2

3.3.1.2 Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of sys-temic AA-OEL
Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/95th percentile Crop density: Normal			

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AA-OEL
Boscalid	Number of applications and application rate: 2 x 0.5 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear + Protected hands + FP2, P2 and similar		No re-
	App: Workwear + Protected hands + FP2, P2 and similar		sults!

3.3.2 Scenario 2 : Outdoor, normal, downward spraying, manual-knapsack

3.3.2.1 Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of sys-temic AOEL
Low vegetables/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 2 x 0.5 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		
	M/L: Workwear App: Workwear	0.007	7.3

3.3.2.2 Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of sys-temic AA-OEL
Low vegetables/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/95th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 2 x 0.5 kg a.s./ha		
	Dermal absorption (concentrate): 0.21 %		
	Dermal absorption (in-use dilution): 3.4 %		

Model data	Level of PPE	Total ab-sorbed dose [mg/kg bw]	% of sys-temic AA-OEL
M/L: Workwear + Protected hands + FP2, P2 and similar			No re-sults!
App: Workwear + Protected hands + FP2, P2 and similar			

4 Worker

4.1 Use 1 : Viticulture

4.1.1 Scenario 1 : Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Hand harvesting / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 30000 cm ² /h TC (workwear (arms, body and legs covered)): 10100 cm ² /h TC (workwear (arms, body and legs covered) and gloves): NA cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 1 x 0.5 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.2	204	31
Workwear	0.07	68.7	0
Workwear and gloves			
Hands covered, no workwear			

4.2 Use 2 : Field crops

4.2.1 Scenario 1 : Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 12500 cm ² /h TC (workwear (arms, body and legs covered)): 1400 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 1250 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 1 x 0.25 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Potential	0.01	10.6	0
Workwear	0.001	1.2	0
Workwear and gloves	0.001	1.1	0
Hands covered, no workwear			

4.3 Use 3 : Low vegetables

4.3.1 Scenario 1 : Outdoor, normal

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: 7 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 2500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 580 cm ² /h TC (gloves): NA cm ² /h			
Number of applications & application rate: 2 x 0.5 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.07	73	0
Workwear	0.03	31.5	0
Workwear and gloves	0.007	7.3	0
Hands covered, no workwear			

5 Resident

5.1 Use 1 : Viticulture

5.1.1 Scenario 1 : Outdoor, season not relevant

Model data		Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
			Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 l	
Boscalid			Number of applications and application rate: 1 x 0.5 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)		0.02	24.1
	Vapour (75th perc.)		8e-05	0.08
	Deposits (75th perc.)		0.0002	0.2
	Re-entry (75th perc.)		0.003	2.9
	Sum (mean)		0.02	18.4
Resident adult Body weight: 60 kg	Drift (75th perc.)		0.01	13.3
	Vapour (75th perc.)		3e-05	0.03
	Deposits (75th perc.)		6e-05	0.06
	Re-entry (75th perc.)		0.002	1.6
	Sum (mean)		0.01	10

5.2 Use 2 : Field crops

5.2.1 Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 l			
Number of applications and application rate: 1 x 0.25 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.002	2.3
	Vapour (75th perc.)	8e-05	0.08
	Deposits (75th perc.)	0.0002	0.2
	Re-entry (75th perc.)	0.001	1.4
	Sum (mean)	0.003	2.7
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0006	0.6
	Vapour (75th perc.)	3e-05	0.03
	Deposits (75th perc.)	6e-05	0.06
	Re-entry (75th perc.)	0.0008	0.8
	Sum (mean)	0.001	1

5.3 Use 3 : Low vegetables

5.3.1 Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 150 l			
Number of applications and application rate: 2 x 0.5 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.003	3.1
	Vapour (75th perc.)	8e-05	0.08
	Deposits (75th perc.)	0.0008	0.8
	Re-entry (75th perc.)	0.005	5.3
	Sum (mean)	0.007	6.6
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0007	0.7
	Vapour (75th perc.)	3e-05	0.03
	Deposits (75th perc.)	0.0002	0.2
	Re-entry (75th perc.)	0.003	2.9
	Sum (mean)	0.003	2.9

6 Bystander

6.1 Use 1 : Viticulture

6.1.1 Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 l			
Number of applications and application rate: 1 x 0.5 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.06	
	Vapour (95th perc.)	8e-05	
	Deposits (95th perc.)	0.0005	
	Re-entry (95th perc.)	0.003	
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.03	
	Vapour (95th perc.)	3e-05	
	Deposits (95th perc.)	0.0001	
	Re-entry (95th perc.)	0.002	

6.2 Use 2 : Field crops

6.2.1 Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 100 l			
Number of applications and application rate: 1 x 0.25 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.005	
	Vapour (95th perc.)	8e-05	
	Deposits (95th perc.)	0.0006	
	Re-entry (95th perc.)	0.001	
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.001	
	Vapour (95th perc.)	3e-05	
	Deposits (95th perc.)	0.0002	
	Re-entry (95th perc.)	0.0008	

6.3 Use 3 : Low vegetables

6.3.1 Scenario 1 : Outdoor, season not relevant

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AAOEL
Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 7 days Minimum volume of water: 150 l			
Number of applications and application rate: 2 x 0.5 kg a.s./ha Dermal absorption: 3.4 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.007	
	Vapour (95th perc.)	8e-05	
	Deposits (95th perc.)	0.002	
	Re-entry (95th perc.)	0.005	
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.002	
	Vapour (95th perc.)	3e-05	
	Deposits (95th perc.)	0.0006	
	Re-entry (95th perc.)	0.003	

7 Appendix

7.1 Operator

7.1.1 Use 1 : Viticulture

7.1.1.1 Scenario 1 : Outdoor, normal, upward spraying, vehicle-mounted

Boscalid , Input Data

Formulation type	Wettable granules, soluble granules	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	500	Crops	Viticulture
Area treated [ha/day]	10	Application method	Upward spraying
Dermal absorption [%] (concentrate)	0.21	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	3.4	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.2	0.2
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.004	0.004
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.005	0.005
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.7	0.7
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	6	6
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.3	0.3
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	3.3	3.3
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	2.7	2.7
Total	Total systemic exposure [mg/kg bw per day]	0.01	0.01
	% of AOEL	13.2	13.2

7.1.1.2 Scenario 2 : Outdoor, normal, upward spraying, manual-knapsack

Boscalid , Input Data

Formulation type	Wettable granules, soluble granules	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	500	Crops	Viticulture
Area treated [ha/day]	1	Application method	Upward spraying
Dermal absorption [%] (concentrate)	0.21	Application technique	Manual-knapsack
Dermal absorption [%] (dilution)	3.4	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.3	0.3
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.0009	0.0009
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.0002	0.0002
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.6	0.6
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.9	0.9
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.6	0.6
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.07	0.07
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.8	0.8
Total	Total systemic exposure [mg/kg bw per day]	0.003	0.003
	% of AOEL	3.2	3.2

7.1.2 Use 2 : Field crops

7.1.2.1 Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

Boscalid , Input Data

Formulation type	Wettable granules, soluble granules	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	500	Crops	Field crops
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0.21	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	3.4	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.3	0.3
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.006	0.006
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.01	0.01
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	1	1
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	1	1
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.02	0.02
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.03	0.03
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.06	0.06
Total	Total systemic exposure [mg/kg bw per day]	0.003	0.003
	% of AOEL	2.5	2.5

7.1.3 Use 3 : Low vegetables

7.1.3.1 Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

Boscalid , Input Data

Formulation type	Wettable granules, soluble granules	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	500	Crops	Low vegetables
Area treated [ha/day]	50	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0.21	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	3.4	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.5	0.5
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.01	0.01
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.03	0.03
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	1.4	1.4
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	2.1	2.1
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.03	0.03
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.06	0.06
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.09	0.09
Total	Total systemic exposure [mg/kg bw per day]	0.004	0.004
	% of AOEL	4.2	4.2

7.1.3.2 Scenario 2 : Outdoor, normal, downward spraying, manual-knapsack

Boscalid , Input Data

Formulation type	Wettable granules, soluble granules	Name of active substance	Boscalid
Concentration of active substance [g a.s./l or kg]	500	Crops	Low vegetables
Area treated [ha/day]	1	Application method	Downward spraying
Dermal absorption [%] (concentrate)	0.21	Application technique	Manual-knapsack
Dermal absorption [%] (dilution)	3.4	Indoor/outdoor	Outdoor
Oral absorption [%]	44	Drift reduction [%]	0
Inhalation absorption [%]	100	Type of cultivation	Normal
Body weight (kg)	60		
AOEL [mg/kg bw/day]	0.1		
AAOEL [mg/kg bw]			

Boscalid , Per body part - Short term exposure

Activity	Systemic exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.3	0.3
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	0.0009	0.0009
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.0002	0.0002
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.6	0.6
Application (µg/kg bw per day)	<i>Hand protection</i>	<i>None</i>	<i>None</i>
	Hands exposure	0.9	0.9
	<i>Body protection</i>	<i>Workwear</i>	<i>Workwear</i>
	Body exposure	5	5
	<i>Head protection</i>	<i>None</i>	<i>None</i>
	Head exposure	0.007	0.007
	<i>Inhalation protection</i>	<i>None</i>	<i>None</i>
	Inhalation exposure	0.4	0.4
Total	Total systemic exposure [mg/kg bw per day]	0.007	0.007
	% of AOEL	7.3	7.3

7.2 Worker

7.2.1 : Viticulture

7.2.1.1 Scenario 1 : Outdoor, normal

Boscalid , Input data

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Hand harvesting	Dermal transfer coefficient - Total potential exposure [cm²/h]	30000
Crops	Viticulture	Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	10100
Application method	Upward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	
Application technique	Vehicle-mounted; manual-knapsack	Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]	1	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30

Interval between multiple applications [days]	7
Multiple application factor	1
Body weight (kg)	60
Name of active substance	Boscalid
Dermal absorption [%] (dilution)	3.4
Inhalation absorption [%]	100
Time [hours per day]	8

Boscalid , Exposure per body part

Exposure route	Description	Poten- tial	Work- wear	Workwear and gloves	Glove s
Dermal	Systemic dermal exposure [mg a.s. per day]	12.2	4.1	NA	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]			NA	NA
	Total systemic exposure [mg a.s. per day]	12.2	4.1	NA	NA
Total	Total systemic exposure [mg/kg bw per day]	0.2	0.07	NA	NA
	% of AOEL	204	68.7	NA	NA

7.2.2 : Field crops

7.2.2.1 Scenario 1 : Outdoor, normal

Boscalid , Input data

Indoor/outdoor		Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Inspection, irrigation		Dermal transfer coefficient - Total potential exposure [cm²/h]	12500
Crops	Field crops		Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	1400
Application method	Downward spraying		Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	1250
Application technique	Vehicle-mounted		Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]		0.5	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications		1	DT50 foliar worker [days]	30
Interval between multiple applications [days]		7		
Multiple application factor		1		

Body weight (kg)	60
Name of active substance	Boscalid
Dermal absorption [%] (dilution)	3.4
Inhalation absorption [%]	100
Time [hours per day]	2

Boscalid , Exposure per body part

Exposure route	Description	Poten- tial	Work- wear	Workwear and gloves	Glove s
Dermal	Systemic dermal exposure [mg a.s. per day]	0.6	0.07	0.06	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	0.6	0.07	0.06	NA
Total	Total systemic exposure [mg/kg bw per day]	0.01	0.001	0.001	NA
	% of AOEL	10.6	1.2	1.1	NA

7.2.3 : Low vegetables

7.2.3.1 Scenario 1 : Outdoor, normal

Boscalid , Input data

Indoor/outdoor		Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Reaching, picking (all except Brassica)		Dermal transfer coefficient - Total potential exposure [cm²/h]	5800
Crops	Low vegetables		Dermal transfer coefficient - Arm, body and legs covered [cm²/h]	2500
Application method	Downward spraying		Dermal transfer coefficient - Hands, arm, body and legs covered [cm²/h]	580
Application technique	Vehicle-mounted; manual-knapsack		Dermal transfer coefficient - Hands covered, no workwear [cm²/h]	
Max. application rate of the product [l or kg/ha]		1	DFR refined worker [µg/cm² foliage per kg a.s./ha]	3
Max. no. of applications		2	DT50 foliar worker [days]	30
Interval between multiple applications [days]		7	Inhalation task specific factor [ha/h*10 ⁻³]	0.1
Multiple application factor		1.85		

Body weight (kg)	60
Name of active substance	Boscalid
Dermal absorption [%] (dilution)	3.4
Inhalation absorption [%]	100
Time [hours per day]	8

Boscalid , Exposure per body part

Exposure route	Description	Poten- tial	Work- wear	Workwear and gloves	Glove s
Dermal	Systemic dermal exposure [mg a.s. per day]	4.4	1.9	0.4	NA
Inhalation	Systemic inhalation exposure [mg a.s. per day]				NA
	Total systemic exposure [mg a.s. per day]	4.4	1.9	0.4	NA
Total	Total systemic exposure [mg/kg bw per day]	0.07	0.03	0.007	NA
	% of AOEL	73	31.5	7.3	NA