

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: BSK-FUN 500 SC

Product name(s): -

Chemical active substance:

boscalid, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Sp. z o. o. and ProAgri International Sp. z o. o.

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Version history

When	What
09/2024	ZRMS assessment
02/2025	The final Registration Report.
06/2025	Corrections made after the commenting period.

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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on BSK-FUN 500 SC *

Product name and code	BSK-FUN 500 SC
Formulation type	Suspension concentrate [SC]
Active substance(s) (incl. content)	Boscalid; 500 g/L
Function	fungicide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of BSK-FUN 500 SC 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 BSK-FUN 500 SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories	None
Hazard pictograms or Code(s) for hazard pictogram(s)	None
Signal word	None
Hazard statement(s)	None
Precautionary statement(s)	None
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-one and methylisothiazolone. May produce an allergic reaction. [EUH208]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for BSK-FUN 500 SCc

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Workwear and gloves during mixing/loading and during application.
Workers	Acceptable	Workwear.
Residents	Acceptable	None.
Bystanders		Buffer zone: 2-3 m.

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

used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.
A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 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. num- ber (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg as/ha boscalid	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Field crops: Winter wheat (BBCH 30-49)	F	Spraying, LCTM	a) 1 b) 1	a) 0.350 kg as/ha b) 0.350 kg as/ha	100 - 300 L/ha	56 d	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				
8	Field crops: Winter oilseed rape (BBCH 31-57)	F	Spraying, LCTM	a) 1 b) 2 (14 days)	a) 0.250 kg as/ha b) 0.500 kg as/ha	100 - 400 L/ha	N/A					

* 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

N/A

Noticed data gaps are:

6.2 Toxicological Information on Active Substance(s)

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

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

	boscalid
Common Name	boscalid
CAS-No.	188425-85-6
Classification and proposed labelling	

	boscalid
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: None Code(s) for hazard pictogram(s): None Signal word: None Hazard statement(s): None Precautionary statement(s): None
Additional C&L proposal	Not relevant
Agreed EU endpoints	
AOEL systemic	0.1 mg/kg bw/d (corrected for 44% oral absorption)
Reference	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	The operator safety

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for BSK-FUN 500 SC is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for BSK-FUN 500 SC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Oral acute toxicity	Estimation based on composition of the product	Yes	None	dRR Part C
Dermal acute toxicity	Estimation based on composition of the product	Yes	None	dRR Part C
Inhalation acute toxicity	Estimation based on composition of the product	Yes	None	dRR Part C
Skin irritation	Estimation based on composition of the product	Yes	None	dRR Part C
Eye irritation	Estimation based on composition of the product	Yes	None	dRR Part C
Skin sensitisation	Estimation based on composition of the product	Yes	None	dRR Part C
Supplementary studies for combinations of plant protection products	-	-	-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of BSK-FUN 500 SC

	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)	Not applicable	-	-	-
Toxicological properties of non-active substance(s) (relevant for classification of product)	Not applicable	-	-	-
Further toxicological information	Not applicable	-	-	-

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 substances in BSK-FUN 500 SC are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in BSK-FUN 500 SC

boscalid		
	Value	Reference
Concentrate	10 %	EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption and SANTE/2018/10591 rev.1 of 24 October 2018.
Dilution	50 %	

6.5.1 Justification for proposed values - boscalid

No data on dermal absorption for boscalid in BSK-FUN 500 SC is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) and SANTE/2018/10591 rev.1 of 24 October 2018 (a corrigendum (minor modification) on EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for boscalid

	Value	Justification for value	Acceptability of justification
Concentrate	10 %	According to EFSA Journal 2017;15(6):4873 a default	Yes

	Value	Justification for value	Acceptability of justification
		dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed ^(c) or solid-formulated ^(d) . According to SANTE/2018/10591 rev.1 of 24 October 2018 a "concentrate" when the active substance is present in the plant protection product at a concentration higher than 50 g/L (or 50g/Kg or 5%).	
Dilution	50 %	According to EFSA Journal 2017;15(6):4873 a default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed ^(c) or solid-formulated ^(d) . According to SANTE/2018/10591 rev.1 of 24 October 2018 a "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%).	Yes

(c): Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (=SC).

(d): Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

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	BSK-FUN 500 SC
Formulation type	SC
Category	Fungicide
Active substance(s) (incl. content)	boscalid 500 g/L
AOEL systemic	0.1 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	44%
Dermal absorption	Concentrate: 10 % Dilution: 50 % (Default)

6.6.1 Selection of critical use(s) and justification

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

Justification

The critical GAP was selected on a worst-case assumption.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of BSK-FUN 500 SC according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (short term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Wheat (max. 1x 0.7 L product/ha) Oilseed rape (max. 2x 0.5 L product/ha)
Model	AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

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

boscalid			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Wheat Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		1 x 0.35 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential exposure	0.2	171
	M/L: Workwear App: Workwear	0.1	110
	M/L: Workwear + Protected hands App: Workwear	0.03	25.4
Oilseed rape Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Application rate		2 x 0.25 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential exposure	0.1	133
	M/L: Workwear App: Workwear	0.09	86.2

Conclusion

According to the model calculations it can be concluded that the risk for the operator using BSK-FUN 500 SC on intended uses presented in GAP table is acceptable when operator is equipped with work wear (arms, body and legs covered) and protective gloves during mixing/loading and during application.

6.6.2.2 Measurement of operator exposure

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

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BSK-FUN 500 SC according to the critical uses. Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical uses	Wheat (max. 1x 0.7 L product/ha) Oilseed rape (max. 2x 0.5 L product/ha)
Model	AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1

Table 6.6-5: Estimated worker exposure

boscalid			
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Wheat (<i>Field crops</i>) Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA 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			
Application rate		1x 0.35 kg a.s./ha	
Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential	0.2	219
	Workwear	0.02	24.5
	Workwear and gloves	0.02	21.9
Oilseed rape (<i>Field crops</i>) Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: 14 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			
Application rate		2x 0.25 kg a.s./ha	

Body weight: 60 kg <i>OPEX version: 1.0.1</i>	Potential	0.3	269
	Workwear	0.03	30.1
	Workwear and gloves	0.03	26.9

Conclusion

The results of the performed exposure calculations show that the use of BSK-FUN 500 SC according to the list of intended uses presented in GAP Table, causes no health risk for the worker equipped with workwear (arms, body and legs covered) during field activities. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not relevant.

6.6.3.3 Measurement of worker exposure

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

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

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

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

Table 6.6-6 shows the exposure model used for estimation of resident and bystander exposure to boscalid. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Wheat (max. 1x 0.7 L product/ha) Oilseed rape (max. 2x 0.5 L product/ha)
Model	AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX 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
Wheat (<i>Field crops</i>) Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 L Number of applications and application rate: 1 x 0.35 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days			
Number of applications and application rate		1x 0.35 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.05	47.4
	Vapour (75 th perc.)	0.0008	0.8
	Deposits (75 th perc.)	0.003	2.7
	Re-entry (75 th perc.)	0.03	29.5
	Sum (mean)	0.05	52.2
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.01	11.2
	Vapour (75 th perc.)	0.0003	0.3
	Deposits (75 th perc.)	0.001	1.2
	Re-entry (75 th perc.)	0.02	16.4
	Sum (mean)	0.02	19.5
Oilseed rape (<i>Field crops</i>) Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 14 days Minimum volume of water: 100 L Number of applications and application rate: 2 x 0.25 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT ₅₀ : 30 days			
Number of applications and application rate		2x 0.25 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.03	33.9
	Vapour (75 th perc.)	0.0008	0.8
	Deposits (75 th perc.)	0.003	3.3
	Re-entry (75 th perc.)	0.04	36.3
	Sum (mean)	0.05	50.6
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.008	8
	Vapour (75 th perc.)	0.0003	0.3
	Deposits (75 th perc.)	0.001	1.5
	Re-entry (75 th perc.)	0.02	20.2

	Sum (mean)	0.02	21.2
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Conclusion

The reference value acutely toxic active substance (RVAAS) for boscalid is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

All estimated values are below the systemic AOEL for boscalid. It can be concluded that the exposure of bystander and resident (children and adult) to boscalid contained in the formulation BSK-FUN 500 SC causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP Table. Buffer zone 2-3m.

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
-	-	-	-	-	-

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Not relevant.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of Evaluator:	According to Regulation (EC) No. 1272/2008 BSK-FUN 500 SC is unclassified
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of BSK-FUN 500 SC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

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

Comments of Evaluator:	According to Regulation (EC) No. 1272/2008 BSK-FUN 500 SC is unclassified
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of BSK-FUN 500 SC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of Evaluator:	According to Regulation (EC) No. 1272/2008 BSK-FUN 500 SC is unclassified
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of BSK-FUN 500 SC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of Evaluator:	According to Regulation (EC) No. 1272/2008 BSK-FUN 500 SC is unclassified
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of BSK-FUN 500 SC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of Evaluator:	According to Regulation (EC) No. 1272/2008 BSK-FUN 500 SC is unclassified
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of BSK-FUN 500 SC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of Evaluator:	According to Regulation (EC) No. 1272/2008 BSK-FUN 500 SC is unclassified
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No studies submitted with this application. Classification based on composition of the product.

According to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006* classification of BSK-FUN 500 SC for toxicological part was based on ingredients of the mixture (Additivity formula) and concentration limits. The CLP calculation method is an alternative method based on the concentration addition of all adverse substances in a mixture. The additivity approach is often accepted as a worst-case estimation of chemical interaction.

On the label should be written EUH208: Contains 1,2-benzisothiazol-3(2H)-one and methylisothiazolone. May produce an allergic reaction

According to Regulation (EC) No. 1272/2008 no classification is required. For more details, please refer to dRR Part C.

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

Not relevant.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

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

A 2.9.2 Available toxicological data for each co-formulant

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

A 2.10 Studies on dermal absorption (KCP 7.3)

Not relevant.

A 2.11 Other/Special Studies

Not relevant.

Appendix 3 Exposure calculations







A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for boscalid

Wheat

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	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)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	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]			

Table A 1: Estimation of operator exposure towards boscalid according to EFSA guidance (OPEX version: 1.0.1)

Short term exposure		Boscalid (% AOEL) Normal & vehicle- mounted
Mixing/loading	Application	
		171
		110
		25.4

3.1.1. Scenario 1 : Outdoor, normal, downward 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 AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 1 x 0.35 kg a.s./ha		
	Dermal absorption (concentrate): 10 %		
	Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear + Protected hands App: Workwear	0.03	25.4

Oilseed rape

Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	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)	10	Application technique	Vehicle-mounted
Dermal absorption [%] (dilution)	50	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]			

Table A 2: Estimation of operator exposure towards boscalid according to EFSA guidance (OPEX version: 1.0.1)

Short term exposure		Boscalid (% AOEL) Normal & vehicle- mounted
Mixing/loading	Application	
		133
		86.2

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 AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal			
Boscalid	Number of applications and application rate: 2 x 0.25 kg a.s./ha		
	Dermal absorption (concentrate): 10 %		
	Dermal absorption (in-use dilution): 50 %		
	M/L: Workwear	0.09	86.2
	App: Workwear		

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for boscalid

Table A 3: Estimation of worker exposure towards boscalid according to EFSA guidance (OPEX version: 1.0.1)

Wheat

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm ² /h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm ² /h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm ² /h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm ² /h]	
Max. application rate of the product [l or kg/ha]	0.7	DFR refined worker [µg/cm ² foliage per kg a.s./ha]	3
Max. no. of applications	1	DT50 foliar worker [days]	30
Interval between multiple applications [days]	NA		
Multiple application factor	1		
Body weight (kg)	60		
Name of active substance	Boscalid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

4.1. Use 1 : Field crops

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]
Inspection, irrigation / Outdoor Work rate: 2 hours/day Interval: NA 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 0.35 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.2	219	34
Workwear	0.02	24.5	0
Workwear and gloves	0.02	21.9	0

Oilseed rape

Indoor/outdoor	Outdoor	AOEL [mg/kg bw/day]	0.1
Re-entry activity	Inspection, irrigation	Dermal transfer coefficient - Total potential exposure [cm ² /h]	12500
Crops	Field crops	Dermal transfer coefficient - Arm, body and legs covered [cm ² /h]	1400
Application method	Downward spraying	Dermal transfer coefficient - Hands, arm, body and legs covered [cm ² /h]	1250
Application technique	Vehicle-mounted	Dermal transfer coefficient - Hands covered, no workwear [cm ² /h]	
Max. application rate of the product [l or kg/ha]	0.5	DFR refined worker [µg/cm ² foliage per kg a.s./ha]	3
Max. no. of applications	2	DT50 foliar worker [days]	30
Interval between multiple applications [days]	14		
Multiple application factor	1.72		
Body weight (kg)	60		
Name of active substance	Boscalid		
Dermal absorption [%] (dilution)	50		
Inhalation absorption [%]	100		
Time [hours per day]	2		

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: 14 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: 2 x 0.25 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Potential	0.3	269	43
Workwear	0.03	30.1	0
Workwear and gloves	0.03	26.9	0

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for boscalid

Table A 4: Estimation of longer term resident exposure towards boscalid according to EFSA guidance (OPEX version: 1.0.1)

Wheat

5. Resident

5.1. Use 1 : Field crops

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: 2-3 m Drift reduction technology: 0 % Interval between treatments: NA Minimum volume of water: 100 l			
Number of applications and application rate: 1 x 0.35 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.05	47.4
	Vapour (75th perc.)	0.0008	0.8
	Deposits (75th perc.)	0.003	2.7
	Re-entry (75th perc.)	0.03	29.5
	Sum (mean)	0.05	52.2
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.01	11.2
	Vapour (75th perc.)	0.0003	0.3
	Deposits (75th perc.)	0.001	1.2
	Re-entry (75th perc.)	0.02	16.4
	Sum (mean)	0.02	19.5

Oilseed rape

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: 14 days Minimum volume of water: 100 l			
Number of applications and application rate: 2 x 0.25 kg a.s./ha Dermal absorption: 50 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days			
Boscalid			
Resident child Body weight: 10 kg	Drift (75th perc.)	0.03	33.9
	Vapour (75th perc.)	0.0008	0.8
	Deposits (75th perc.)	0.003	3.3
	Re-entry (75th perc.)	0.04	36.3
	Sum (mean)	0.05	50.6
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.008	8
	Vapour (75th perc.)	0.0003	0.3
	Deposits (75th perc.)	0.001	1.5
	Re-entry (75th perc.)	0.02	20.2
	Sum (mean)	0.02	21.2

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.