FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: BSK-FUN 500 SC

Product name(s): **Boskalid 500 SC**

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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10.2024	Update on evaluator request
12.2024	Updated assessment by zRMS
02.2025	The final Registration Report.
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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	Poland	Winter wheat	F	*Puccinia recondite* PUCCRE *Zymoseptoria tritic* SEPTTR *Oculimacula acuformis* PSDCHA	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	-	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	**A**	**A**
2	Poland	Spring wheat	F	*Zymoseptoria tritic* SEPTTR	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	-	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	**A**	**A**
3	Poland	Winter triticale	F	*Puccinia recondite* PUCCRE *Zymoseptoria tritic* SEPTTR	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	-	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	**A**	**A**
4	Poland	Spring triticale	F	*Puccinia recondite* PUCCRE *Zymoseptoria tritic* SEPTTR	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	-	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	**A**	**A**
5	Poland	Winter barley	F	*Pyrenophora teres* PYRNTE	broadcast spraying	BBCH 30-49	1 a) 1	-	0.7 L/ha a) 0.7 L/ha	350 g as/ha a) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	**A**	**A**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
							b) 1		b) 0.7 L/ha	b) 350 g as/ha										
6	Poland	Spring barley	F	*Pyrenophora teres* PYRNTE	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	-	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	A	**A**
7	Poland	Winter oilseed rape	F	*Leptospheria maculans* LEPTMA	broadcast spraying	Autumn BBCH 13-18 Spring BBCH 31-57	2 a) 1 b) 2	30 days	0.2 - 0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-400 L/ha	N/A	one in autumn, one in spring or 2 in spring, min. 14 days between applications	**A**	**A**	**A**	**A**	**A**	A	**A**
8	Poland	Winter oilseed rape	F	*Leptospheria maculans* LEPTMA	broadcast spraying	Spring BBCH 31-57	2 a) 1 b) 2	14 days	0.2 - 0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-400 L/ha	N/A	one in autumn, one in spring or 2 in spring, min. 14 days between applications	**A**	**A**	**A**	**A**	**A**	A	**A**
9	Poland	Winter oilseed rape	F	*Alternaria brassicae* ALTEBA *Sclerotinia sclerotiorum* SCLESC	broadcast spraying	BBCH 57-71	2 a) 1 b) 2	14 days	0.2 - 0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-400 L/ha	N/A	-	**A**	**A**	**A**	**A**	**A**	A	**A**
10	Poland	Winter rye	F	Leaf blotch of cereals *(Rhynchosporium secalis)* RHYNSE	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	-	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	-	**A**	**A**	**A**	**A**	**A**	A	**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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.,* fumigation of a structure)
(4) 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
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g., biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g., high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g., overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of as per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g., ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

zRMS comment:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes.

9.1.1.1 Overall conclusions

9.1.1.2 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Birds

Effects on birds for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. However further data on BSK-FUN 500 SC is not relevant as data for each active substance on toxicity to birds are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for BSK-FUN 500 SC with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of BSK-FUN 500 SC to birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with active substances, as well as SV_{90} and SV_m. The drinking water exposure and exposure for earthworm-eating birds and fish-eating birds via secondary poisoning was not required.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to birds from the proposed use of BSK-FUN 500 SC. No risk management measures are required.

Terrestrial vertebrates (other than birds)

Effects on mammals for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. However further data on BSK-FUN 500 SC is not relevant as data for each active substance on toxicity to mammals are considered essential. It is possible to extrapolate from data for each active substance. Therefore, all relevant data were assessed in the EU review. Risk assessments for BSK-FUN 500 SC with the proposed use pattern and EU agreed endpoints have been provided and are considered adequate.

The risk assessment for effects on terrestrial vertebrates other than birds was carried out according to the latest guidance for risk assessment for birds and mammals EFSA Journal 2009; 7(12): 1438.

The acute and reproductive risks of BSK-FUN 500 SC to terrestrial vertebrates other than birds were assessed from toxicity exposure ratios between EU agreed toxicity endpoints, estimated from studies with boscalid, as well as SV_{90} and SV_m. The drinking water exposure and exposure for earthworm-eating mammals and fish-eating mammals via secondary poisoning was not required.

The TER values where applicable exceed the trigger values of 10 for acute and 5 for reproductive and long-term risk, thus indicating no unacceptable risk to mammals from the proposed use. No risk mitigations are required.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

Effects on aquatic organisms for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. The studies on effects of BSK-FUN 500 SC on algae and *Daphnia magna* were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC.

Risk assessments for BSK-FUN 500 SC with the proposed use pattern was carried out according to the latest guidance for risk assessment for aquatic organisms in edge-of-field surface water EFSA Journal 2013; 11(7):3290.

PEC/RAC values were calculated on the basis of PECsw calculations as well as worst case toxicity endpoints from studies for active substance and formulation BSK-FUN 500 SC. On the basis of PEC/RAC values it was concluded that BSK-FUN 500 SC used in accordance with GAP does not pose unacceptable risk for aquatic organisms except scenario D2 for which further evaluation on national level is required. In case of D3, D4, D5, R1, R3 and R4 no risk mitigations measures are required.

For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that BSK-FUN 500 SC used according to proposed GAP does not pose unacceptable risk to aquatic organisms. No risk mitigations are required.

Classification of BSK-FUN 500 SC was done on the basis of formulation BSK-FUN 500 SC studies' results as well as active substance and co-formulants properties. The proposed classification of the product BSK-FUN 500 SC is:

Aquatic Acute 1, H400
Aquatic Chronic 2, H411
Labelling: H10

9.1.1.4

9.1.1.5 zRMS comments:

The surface water modelling has been performed using parameters for boscalid have been taken from SANCO/3919 /2007-rev. 5 21 January 2008.

Aquatic toxicity data for boscalid in Table 9.2-1 are in line with EU agreed endpoints reported in SANCO/3919/2007-rev. 5, January 2008.. Studies on effects of the formulated product on aquatic organisms listed in Table 9.5-2 were evaluated by the zRMS and considered acceptable. Summaries of the performed studies together with zRMS evaluation may be found in Appendix 2.

The Applicant haven't performed a *Lemna gibba* test with **BOSKALID 500 SC**. However, in this case, the test with formulation **BOSKALID 500 SC** with *Lemna gibba* is not necessary. **BOSKALID 500 SC** is not a herbicide. It is a fungicide applied at post-emergence of crops. Therefore, no toxic effects of **BOSKALID 500 SC** formulations on aquatic plants are expected.

~~The Applicant haven't performed a *fish test* with **BOSKALID 500 SC**.~~

~~- It is not necessary to present a study of the formulation for fish, as the formulation contains only one active ingredient, and the inert ingredients do not increase the toxicity of the formulation (COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013).~~
~~- Furthermore, the data presented for similar product ENTARGO (see part C) indicate that this formulation is significantly less toxic to fish than the active ingredient boscalid.~~
~~Hence, it can be considered that the risk assessment for fish can be carried out for the substance boscalid, which will cover the assessment for the formulation.~~
~~In the opinion of zRMS, there is no need to carry out tests for Boskalid 500 SC.~~
~~Conclusion based on additional data, e.g., document C.~~

~~For **BOSKALID 500 SC**, tests on invertebrates *Daphnia magna*, algae *Pseudokirchneriella subcapitata* were provided by Applicant, but no tests are reported for fish.~~
~~According to the Commission Regulation (EU) No 546/2011, point 10.2.1 Acute toxicity:~~
~~" *Test shall be carried out on one species from each of the three/four groups of aquatic organisms, that is to say fish, aquatic invertebrates, algae…*"~~
~~and~~
~~"*Testing shall be performed where:*~~
~~(a) *the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance*;.."~~
~~**In fact, the organisms can be organized in order of sensitivity to boscalid as follows:**~~
~~**Algae > Fish > Invertebrate**~~

Acute toxicity data for active substance and formulation

Species	**boscalid**	**Boskalid 500 SC**
	Endpoint	**Endpoint**
Oncorhynchus mykiss	2.7 mg a.s./L	-

Daphnia magna	5.33 mg a.s./L	EC_{50} = 7.914 mg/L (3.394 mg as/L) NOEC = 0.940 mg/L (0.403 mg as/L)
Pseudokirchneriella subcapitata	1.34 mg a.s./L	E_rC_{50} = 0.153 mg/L (0.066 mg as/L) E_yC_{50} = 0.012 mg/L (0.005 mg as/L)

Based on the aquatic acute data for active substance, algae is the most sensitive species.
Given that:

- results of studies performed with the formulation on daphnia and algae (the most sensitive species) did show higher or unexpected toxicity than predicted based on the results of the active substance, it can be assumed that acute toxicity to fish for formulation **Boskalid 500 SC** should not be required by zRMS.
- In addition, according to the Reg.284/2013, Point 10.2.1: Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes, testing for formulation shall be performed where:

(a) the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance; or
(b) the intended use includes direct application on water;
(c) extrapolation on the basis of available data for a similar plant protection product is not possible.
Based on that, the study for formulation **Boskalid 500 SC** is not required for PL as the toxicity of product can be predicted by the data of active substance.

~~Justification:~~
~~*Studies of the effect of Boskalid 500 SC on Daphnia magna and Pseudokirchneriella subcapitata (the most sensitive group of aquatic organisms) show an increase in the toxicity of the formulation compared to the toxicity of the active substance boscalid on these groups of organisms. In the case of algae, this is as much as 20 times greater toxicity of the formulation compared to the active substance boscalid. In the case of available data for the plant protection product Boskalid 500 SC, fish are not the most sensitive group of aquatic organisms, however, the endpoint of the acute toxicity test of the active substance for fish is higher than the endpoints for other groups of aquatic organisms by less than 10 times. In this case, according to EFSA (2013) guidelines, an appropriate acute toxicity test of the formulation for fish should be carried out (it is recommended to carry out a standard test for a limit concentration of 100 mg/L or the maximum concentration, selected based on available data for individual groups of aquatic organisms.*~~

~~*On the other hand, u*nprotected data on the representative product BAS 510 01 F from the RAR indicates even lower sensitivity of fish compared to other organism:~~

BAS 510 01 F	*O. mykiss*	96 h acute (static)	LC_{50}	≅ **100** (i.e. = 51.3 mg a.s./L) (nominal)	[redacted] 2000, 2000/1018528 AIIIA-10.2.1

☑ ~~**BAS 510 01 F** which contains only the active substance boscalid (formulation closely related to Boskalid 500 SC based on the same the amount of active substance contained in formulation 500 g boscalid/L). However, not the same formulation type. BAS 510 01 F is a water dispersible granule (WG) formulation containing 500 g/kg (50 % w/w) of the active substance boscalid. In the case of the BSK FUN 500 SC product, the substance content is approximately 50% but SC type of formulation. Both products are not comparable in terms of formulation type (WG) and their toxicity to aquatic organisms. Boskalid 500 SC is more toxic to *Daphnia magna* and *Pseudokirchneriella subcapitata*. However, this data should be treated as additional source of information of toxicity formulation with boscalid for fish. Unprotected data on the representative product BAS 510 01 F from the RAR indicates even **lower sensitivity to fish** compared to other~~

~~organism groups.~~

Acute toxicity data for active substance and formulation

Species	**boscalid**	**Boskalid 500 SC**	~~**BAS 510 01 F ENTARGO**~~
	Endpoint	**Endpoint**	~~**Endpoint**~~
Oncorhynchus mykiss	2.7 mg a.s./L	-	~~≥ 100 (i.e. ≥ 51.3 mg a.s./L) (nominal)~~
Daphnia magna	5.33 mg a.s./L	EC_{50} = 7.914 mg/L (3.394 mg as/L) NOEC = 0.940 mg/L (0.403 mg as/L)	~~50 (i.e. 25.65 mg a.s./L) (nominal)~~
Pseudokirchneriella subcapitata	1.34 mg a.s./L	E_rC_{50} = 0.153 mg/L (0.066 mg as/L) E_yC_{50} = 0.012 mg/L (0.005 mg as/L)	~~4.5 (i.e. 2.31 mg a.s./L) 3.37 (nominal)~~

~~**WG vs SC in Aquatic Toxicity (Fish):**~~

~~1. Water Dispersible Granules (WG):~~
   - ~~WGs are designed to disperse into water, and while they may initially be less bioavailable compared to SCs, once dissolved, the active ingredient (Boscalid in this case) becomes available to aquatic organisms.~~
   - ~~Potential Issue: WG formulations might cause localized toxicity near the site of release (like fish in a pond or river). The granules may settle, creating localized "hotspots" of contamination.~~

~~2. Suspension Concentrates (SC):~~
   - ~~SC formulations typically contain a higher concentration of active ingredient dissolved in a liquid carrier, which increases the immediate bioavailability of the active substance to aquatic organisms like fish.~~
   - ~~Potential Issue: SCs may result in higher acute toxicity to aquatic organisms because of the faster release and absorption of the active ingredient into the water column. This can lead to more immediate and widespread exposure.~~

~~SC formulations are often more toxic in the short term to aquatic organisms, including fish, due to the higher concentration of the active ingredient in a liquid form that is immediately bioavailable. WG formulations, while still potentially toxic, may have a more gradual release of the active ingredient into the water, leading to slower or more localized toxicity.~~

~~In the case of the BSK-FUN 500 SC product, the substance content is approximately 50%, so it can be assumed that the active substance will be the main component that will affect the toxicity of the product, and therefore extrapolate from the substance data can be considered. Furthermore, based on the acute toxicity data for the active substance, it can be concluded that fish are not the most sensitive aquatic organism to boscalid, so duplicating studies on vertebrate fish may not be necessary in the RMS assessment. On the other hand, unprotected data on the representative product BAS 510 01 F from the RAR indicates even lower sensitivity of fish compared to other organism groups. However, SC formulations are often more toxic in the short term to aquatic organisms, including fish. Due to many doubts the other MSs should be considered if the packed data in this case is sufficient.~~

~~It should be considered by MSs level.~~

Conclusion zRMS: For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that BSK-FUN 500 SC used according to proposed GAP does not pose unacceptable risk to aquatic organisms. No risk mitigations are required.

9.1.1.6 Effects on bees (KCP 10.3.1)

Effects on bees for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. The studies on effects of BSK-FUN 500 SC on bees were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC.

Risk assessments for BSK-FUN 500 SC with the proposed use pattern was carried out according to the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and the latest Draft EFSA Guidance for risk assessment for bees EFSA Journal 2013; 11(7):3295.

The risks of BSK-FUN 500 SC to honeybees was assessed from Hazard Quotients (HQ) and Exposure Toxicity Ratio (ETR) between toxicity endpoints, estimated from acute oral and contact studies with formulated product as well as the maximum single application rate.

All the Hazard Quotients and Exposure Toxicity Ratios were considerably less than the respective triggers, indicating BSK-FUN 500 SC used according to proposed GAP, does not pose unacceptable risk to bees. No risk management measures are required.

9.1.1.7 Effects on arthropods other than bees (KCP 10.3.2)

Effects on non-target arthropods for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. The studies on effects of BSK-FUN 500 SC on arthropods were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC.

Risk assessments for BSK-FUN 500 SC with the proposed use pattern was carried out according to the guidance for risk assessment for arthropods "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and in consideration of the recommendations of the guidance document ESCORT 2.

The in-field and off-field risk of BSK-FUN 500 SC to non-target arthropods was assessed from Hazard Quotients (HQ) between toxicity endpoints estimated from studies with the formulated product BSK-FUN 500 SC as well as in-field and off-field predicted environmental rate. No risk was determined in-field and off-field after application of BSK-FUN 500 SC according to proposed GAP. No risk management measures are required.

9.1.1.8 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

Effects on earthworms and other soil micro-organisms for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. The studies on effects of BSK-FUN 500 SC on earthworms and micro-organisms were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC.

Risk assessments for BSK-FUN 500 SC with the proposed use pattern was carried out according to the guidance for risk assessment for terrestrial ecotoxicology "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002).

Earthworms
The risk of BSK-FUN 500 SC to earthworms was assessed from toxicity exposure ratios (TERs) between the toxicity endpoint for the formulated product BSK-FUN 500 SC as well as the maximum soil PECs.

The chronic TER values were greater than the trigger of 5 indicating an acceptable risk to earthworms following application of BSK-FUN 500 SC according to proposed GAP. No risk management measures are required.

Folsomia candida* and *Hypoaspis aculeifer
Not relevant.

Micro-organisms
The risk of BSK-FUN 500 SC to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for the formulated product BSK-FUN 500 SC with predicted application concentrations (PECs).

Considering to the performed risk assessment it was assessed that the application of BSK-FUN 500 SC according to proposed GAP does not pose unacceptable risk to soil micro-organisms. No risk management measures are required.

9.1.1.9 Effects on non-target terrestrial plants (KCP 10.6)

Effects on non-target terrestrial plants for BSK-FUN 500 SC were not evaluated as part of the EU review of boscalid. The studies on seedling emergence and vegetative vigour for BSK-FUN 500 SC were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC.

The risk of BSK-FUN 500 SC to non-target plants was evaluated by comparison of toxicity endpoints derived from laboratory tests for the formulation BSK-FUN 500 SC with application rates. According to the performed risk assessment it was assessed that the application of BSK-FUN 500 SC in accordance with GAP does not pose unacceptable risk to non-target plants. No risk mitigation measures are required.

9.1.1.10 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of BSK-FUN 500 SC grouped according to criterion

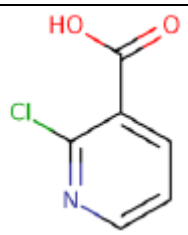
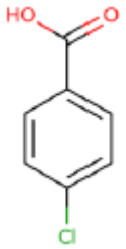
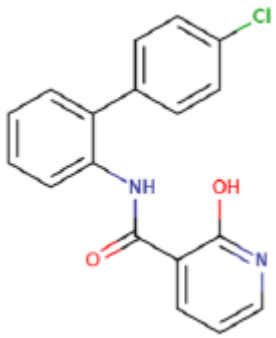
Grouping according to criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
1	cereals (uses no. 1-6, 10)	application rate: 350 g as/ha	NR

Grouping according to criterion			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
2	oilseed rape (uses no. 7-9)	application rate: 2 x 250 g as/ha	NR

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of BSK-FUN 500 SC is indicated in the table.

Table 9.1-3: Metabolites of boscalid

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M510F47	157.6		Soil: anaerobic conditions 2.6 % after 3 d, 6 % after 62 d, 5.9 % after 90 d, 6.7 % after 120 d	-
M510F64	156.56		Sediment: under outdoor conditions 7.3 % after 7 d 9 % after 14 d 9.4 % after 30 d 1.9 % after 120 d	-
M510F49	324.8		Soil: aerobic conditions 9% after 127d 9% after 181d 12.6% after 273d 14.5% after 371d	-

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with boscalid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid.

However, the provision of further data on the BSK-FUN 500 SC is not considered essential, because it is possible to extrapolate data from the active substance. Additionally, vertebrates' studies should be avoided.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	boscalid	Oral Acute	**LD_{50} > 2000 mg/kg bw**	SANCO/3919 /2007-rev. 5
Anas platyrhynchos L. *Colinus virginianus*	boscalid	Dietary Short-term	LC_{50} > 5000 mg/kg feed	SANCO/3919 /2007-rev. 5
Colinus virginianus	boscalid	Dietary Reproductive toxicity	**NOEL = 24.1 mg/kg bw/d**	SANCO/3919 /2007-rev. 5

zRMS comments:

Avian toxicity data for boscalid in Table 9.2-1 are in line with EU agreed endpoints reported in SANCO/3919/2007-rev. 5, January 2008.

9.2.1.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-2: Screening and first-tier assessment of the acute and long-term risk for birds due to the use of BSK-FUN 500 SC in cereals (uses no. 1, 2, 3, 4, 5, 6, 10)

Intended use	cereals (uses no. 1, 2, 3, 4, 5, 6, 10)				
Active substance	boscalid				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90}**	**TER_a**

Growth stage				**(mg/kg bw/d)**	
Screening assessment					
BBCH 30-49 350 g as/ha	small omnivorous bird	158.8	1	55.58	36
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening assessment					
BBCH 30-49 350 g as/ha	small omnivorous bird	64.8	1 x 0.53	12.02	**2**
First tier assessment					
BBCH 30-49 350 g as/ha	Small omnivorous bird "lark" Woodlark (*Lullula arborea*) BBCH 30-39	5.4	1 x 0.53	1.0	24.1
	Small omnivorous bird "lark" Woodlark (*Lullula arborea*) BBCH ≥ 40	3.3	1 x 0.53	0.61	39.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: Screening and first-tier assessment of the acute and long-term risk for birds due to the use of BSK-FUN 500 SC in oilseed rape (uses no. 7, 8, 9)

Intended use	oilseed rape (uses no. 7, 8, 9)				
Active substance	boscalid				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening assessment					
BBCH 13-71 2 x 250 g as/ha min. interval: 7d	small omnivorous bird	158.8	1.2	47.64	42
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening assessment					
BBCH 13-71 2 x 250 g as/ha min. interval: 7d	small omnivorous bird	64.8	1.4 x 0.53	12.02	**2**
First tier assessment					
BBCH 13-71	Small insectivorous bird	2.7	1.4 x 0.53	0.5	48.2

2 x 250 g as/ha min. interval: 7d	"dunnock" BBCH 30-99				
	Large herbivorous bird "goose" BBCH 10-19	15.9	1.4 x 0.53	2.95	8.2
	Small omnivorous bird "lark" BBCH BBCH 10 – 29	10.9	1.4 x 0.53	2.02	11.9
	Small omnivorous bird "lark" BBCH 30 - 39	3.3	1.4 x 0.53	0.61	39.5
	Small omnivorous bird "lark" BBCH ≥ 40	2.7	1.4 x 0.53	0.5	48.2
	medium herbivorous/granivorous bird "pigeon" BBCH 10 – 19	22.7	1.4 x 0.53	4.21	5.7
	medium herbivorous/granivorous bird "pigeon" BBCH 20 – 29	3.5	1.4 x 0.53	0.65	37.1
	medium herbivorous/granivorous bird "pigeon" BBCH 30 – 39	1.1	1.4 x 0.53	0.2	120.5
	medium herbivorous/granivorous bird "pigeon" BBCH ≥ 40	0.9	1.4 x 0.53	0.17	141.8
	Small insectivorous bird "wagtail" BBCH 10 - 19	5.9	1.4 x 0.53	1.09	22.1
	Small insectivorous bird "wagtail" BBCH 20 - 29	2.8	1.4 x 0.53	0.52	46.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

First step in the risk assessment

The first step risk assessment for active substance boscalid performed in cereals and oilseed rape is agreed by zRMS.

TER_A and TER_{LT} values for the exposure to the active substance when **BOSKALID 500 SC** is applied in cereals and oilseed rape are above the trigger of 10 and 5 for acute and long-term exposure, indicating acceptable risk for birds.

Overall, acceptable acute and long-term risk may be concluded for birds exposed to **BOSKALID 500 SC.**

9.2.2.2 Higher-tier risk assessment

Not relevant.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since BSK-FUN 500 SC is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). With a K(f)oc of 771.5, boscalid belongs to the group of more sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the oilseed rape (use no. 7) also covers the risk for birds from all other intended uses (see 9.1.2).

Effective application rate (g/ha)= 2 x 250				
Acute toxicity (mg/kg bw)	=	2000	quotient =	0.25
Reprod. toxicity (mg/kg bw/d)	=	24.1	quotient =	20.75

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000, a quantitative risk assessment (calculation of TER values) is not necessary.

zRMS comments: Agreed.

Overall, the risk to birds from drinking water from puddles is acceptable when **BOSKALID 500 SC** is used in all intended crops at the recommended rates.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} values of boscalid is 2.96 and it does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not relevant.

Risk assessment for fish-eating birds via secondary poisoning

Not relevant.

zRMS comments: Agreed.

The log P_{ow} values of boscalid is 2.96 and it does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

All the TER values exceed the trigger values of 10 for acute and 5 for reproductive/long-term risk. BSK-FUN 500 SC used in accordance with proposed GAP, does not pose unacceptable risk to birds.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with boscalid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. However, the provision of further data on the BSK-FUN 500 SC is not considered essential, because it is possible to extrapolate data from the active substance. Additionally, vertebrates' studies should be avoided.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Boscalid	Oral, 1 d Acute	**LD_{50} > 5000 mg/kg bw**	SANCO/3919/2007-rev. 5
Rat	Boscalid	Dietary Reproductive toxicity Two-generation study	NOELrepr = 667 mg/kg bw/d NOELparents = 6.7 mg/kg bw/d **NOELoffspring = 67 mg/kg bw/d**	SANCO/3919/2007-rev. 5
Rat	Boscalid	Oral Developmental toxicity	NOELmaternal = 1000 mg/kg bw/d NOELdevelopmental = 300 mg/kg bw/d	SANCO/3919/2007-rev. 5
Rat	Boscalid	Oral Developmental	NOELmaternal = 100 mg/kg bw/d	SANCO/3919/2007-rev. 5

Species	Substance	Exposure System	Results	Reference
		toxicity	NOELdevelopmental = 300 mg/kg bw/d	

zRMS comments:

Mammalian toxicity data for boscalid in Table 9.3-1 are in line with EU agreed endpoints reported in SANCO/3919/2007-rev. 5, January 2008.

9.3.1.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2: Screening and first-tier assessment of the acute and long-term risk for mammals due to the use of BSK-FUN 500 SC in cereals (uses no. 1, 2, 3, 4, 5, 6, 10)

Intended use **Active substance/product**	cereals (uses no. 1, 2, 3, 4, 5, 6, 10) boscalid				
Acute toxicity (mg/kg bw) **TER criterion**	5000 10				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**
Screening assessment					
BBCH 30-49 350 g as/ha	small herbivorous mammal	118.4	1	41.4	120.8
Reprod. toxicity (mg/kg bw/d) **TER criterion**	67 5				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Screening assessment					
BBCH 30-49 350 g as/ha	small herbivorous mammal	48.3	1 x 0.53	8.96	7.48

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: Screening and first-tier assessment of the acute and long-term risk for mammals due to the use of BSK-FUN 500 SC in oilseed rape (uses no. 7, 8, 9)

Intended use **Active substance/product**	oilseed rape (uses no. 7, 8, 9) boscalid				
Acute toxicity (mg/kg bw) **TER criterion**	5000 10				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90}** **(mg/kg bw/d)**	**TER_a**
Screening assessment					
BBCH 13-71 2 x 250 g as/ha min. interval: 7d	small herbivorous mammal	118.4	1.2	35.5	140.8
Reprod. toxicity (mg/kg bw/d) **TER criterion**	67 5				
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_m**	**MAF_m ×** **TWA**	**DDD_m** **(mg/kg bw/d)**	**TER_{lt}**
Screening assessment					
BBCH 13-71 2 x 250 g as/ha min. interval: 7d	small herbivorous mammal	48.3	1.4 x 0.53	8.96	7.48

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

Screening step in the risk assessment

The screening step risk assessment for active substance boscalid performed in the Table 9.3-2 and Table 9.3-3 is validated by zRMS. TER_A and TER_{LT} values for the exposure to the active substance when **BOSKALID 500 SC** is applied in cereals and oilseed rape are above the trigger of 10 and 5 for acute and long-term exposure, indicating acceptable risk for mammals.

Overall, acceptable acute and long-term risk may be concluded for mammals exposed to **BOSKALID 500 SC.**

9.3.2.2 Higher-tier risk assessment

Not relevant.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). With a K(f)oc of 771.5, boscalid belongs to the group of more sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for winter oilseed rape (use no. 7) also covers the risk for mammals from all other intended uses (see 9.1.2).

Effective application rate (g/ha)= 2 x 250					
Acute toxicity (mg/kg bw)	=	5000	quotient	=	0.1
Reprod. toxicity (mg/kg bw/d)	=	67	quotient	=	7.46

Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000, a quantitative risk assessment (calculation of TER values) is not necessary.

zRMS comments: Agreed.

Overall, the risk to mammals from drinking water from puddles is acceptable when **BOSKALID 500 SC** is used in all intended crops at the recommended rates.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} values of boscalid is 2.96 and it does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not relevant.

Risk assessment for fish-eating mammals via secondary poisoning

Not relevant.

zRMS comments: Agreed.

The log P_{ow} values of boscalid is 2.96 and it does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

All the TER values exceed the trigger values of 10 for acute and 5 for reproductive/long-term risk. BSK-FUN 500 SC used in accordance with proposed GAP, does not pose unacceptable risk to mammals.

zRMS comments: Agreed.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not relevant.

zRMS comments:

As currently there are no agreed rules or criteria for evaluation of the risk to other terrestrial vertebrates like reptiles and amphibians, this issue should be addressed once respective guidance is available and EU agreed endpoints concluded.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with boscalid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. The studies on effects of BSK-FUN 500 SC on *Daphnia* and algae *Pseudokirchneriella subcapitata* were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – boscalid and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	boscalid	96 h, s	**EC_{50} = 2.7 mg a.s./L**	SANCO/3919 /2007-rev. 5
Oncorhynchus mykiss	boscalid	97 d, f	**NOEC = 0.125 mg a.s./L**	SANCO/3919 /2007-rev. 5
Daphnia magna	boscalid	48 h, s	**EC_{50} = 5.33 mg a.s./L**	SANCO/3919 /2007-rev. 5
Daphnia magna	boscalid	21 d, ss	**NOEC = 1.31 mg a.s./L**	SANCO/3919 /2007-rev. 5
Chironomus riparius	boscalid	28 d, s	**NOEC = 1 mg a.s./L**	SANCO/3919 /2007-

		(spiked water)		rev. 5
Chironomus riparius	boscalid	28 d, s (spiked sediment)	NOEC = 23.26 mg a.s./kg	Addendum 2 to the DAR, Vol. 3, Annex B.9, May 2006
Pseudokirchneriella subcapitata	boscalid	96 h, s	**EC_{50} = 1.34 mg a.s./L**	SANCO/3919 /2007-rev. 5
Higher-tier studies (micro- or mesocosm studies)				
Not available.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – BSK-FUN 500 SC

Species	Substance	Exposure System	Results	Reference
Daphnia magna	BSK-FUN 500 SC	48 h, s	EC_{50} = 7.914 mg/L (3.394 ~~µg~~ mg as/L) NOEC = 0.940 mg/L (0.403 ~~µg~~ mg as/L)	KCP 10.2.1.2/01 Kolek L/ 2024 / ETOX-2023-20
Pseudokirchneriella subcapitata	BSK-FUN 500 SC	72 h, s	**E_rC_{50} = 0.153 mg/L (0.066 mg as/L)** E_yC_{50} = 0.012 mg/L (0.005 mg as/L)	KCP 10.2.1.3/01 Kolek L/ 2024 / ETOX-2023-21
Higher-tier studies (micro- or mesocosm studies)				
Not available.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

New endpoints are provided for the formulated product BSK-FUN 500 SC. Details of studies and results are included in Table 9.5-2. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below. Risk assessment was performed with active substance endpoints and formulation endpoints.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of BSK-FUN 500 SC to winter cereals BBCH 30-49 (1 × 350 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*	-
Endpoint **(µg/L)**		EC_{50} 2700	NOEC 125	EC_{50} 5330 3394*	NOEC 1310	E_rC_{50} 66*	NOEC 1000	EC_{50} -
AF		100	10	100	10	10	10	10
RAC (µg/L)		27	12.5	53.3 33.94	131	6.6	100	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1	61.8414	**2.29**	**4.95**	**1.16** **1.82**	0.47	**9.37**	0.62	-
Step 2	11.2027	0.41	0.90	0.21 0.33	0.09	**1.70**	0.11	-
Step 3								
D1/ditch	8.079	0.30	0.65	0.15 0.24	0.06	**1.22**	0.08	-
D1/stream	5.057	0.19	0.40	0.09 0.15	0.04	0.77	0.05	-
D2/ditch	9.565	0.35	0.77	0.18 0.28	0.07	**1.45**	0.10	-
D2/stream	5.962	0.35	0.77	0.18 0.18	0.07	**1.45**	0.10	-

D3/ditch	2.215	0.08	0.18	0.04 0.065	0.02	0.34	0.02	-
D4/pond	0.8997	0.03	0.07	0.02 0.027	0.01	0.14	0.01	-
D4/stream	1.637	0.06	0.13	0.03 0.05	0.01	0.25	0.02	-
D5/pond	0.7229	0.03	0.06	0.01 0.021	0.01	0.11	0.01	-
D5/stream	1.784	0.07	0.14	0.03 0.053	0.01	0.27	0.02	-
D6/ditch	2.802	0.10	0.22	0.05 0.083	0.02	0.42	0.03	-
R1/pond	0.3910	0.01	0.03	0.01 0.012	0.00	0.06	0.00	-
R1/stream	3.018	0.11	0.24	0.06 0.089	0.02	0.46	0.03	-
R3/stream	3.932	0.15	0.31	0.07 0.12	0.03	0.60	0.04	-
R4/stream	5.093	0.19	0.41	0.10 0.15	0.04	0.77	0.05	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoint for formulation

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of BSK-FUN 500 SC to spring cereals BBCH 30-49 (1 × 350 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	EC_{50}	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*	-
Endpoint **(µg/L)**		EC_{50} 2700	NOEC 125	5330 3394* EC_{50}	NOEC 1310	E_rC_{50} 66*	NOEC 1000	EC_{50} -
AF		100	10	100	10	10	10	10
RAC (µg/L)		27	12.5	53.3 33.94	131	6.6	100	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1	61.8414	**2.29**	**4.95**	**1.16** **1.82**	0.47	**9.37**	0.62	-
Step 2	11.2027	0.41	0.90	0.21 0.33	0.09	**1.70**	0.11	-
Step 3								
D1/ditch	6.573	0.24	0.53	0.12 0.19	0.05	**1.00**	0.07	-
D1/stream	4.134	0.15	0.33	0.08 0.12	0.03	0.63	0.04	-
D3/ditch	2.217	0.08	0.18	0.04 0.065	0.02	0.34	0.02	-

D4/pond	0.8809	0.08	0.18	0.04 0.026	0.02	K0.34	0.02	-
D4/stream	1.816	0.07	0.15	0.03 0.054	0.01	0.28	0.02	-
D5/pond	0.7333	0.03	0.06	0.01 0.022	0.01	0.11	0.01	-
D5/stream	1.871	0.07	0.15	0.04 0.055	0.01	0.28	0.02	-
R4/stream	5.719	0.21	0.46	0.11 0.17	0.04	0.87	0.06	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoint for formulation

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of BSK-FUN 500 SC to winter rape BBCH 13-57 (2 × 250 g/ha, interval 30 days)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	EC_{50}	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*	-
Endpoint **(µg/L)**		EC_{50} 2700	NOEC 125	5330 3394* EC_{50}	NOEC 1310	E_rC_{50} 66*	NOEC 1000	EC_{50} -
AF		100	10	100	10	10	10	10
RAC (µg/L)		27	12.5	53.3 33.94	131	6.6	100	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1	88.3448	**3.27**	**7.07**	**1.66** **2.6**	0.67	**13.39**	0.88	-
Step 2 NEU	11.9209	0.44	0.95	0.22 0.35	0.09	**1.81**	0.12	-
Step 3								
D2/ditch	22.37	0.83	1.79	0.42 0.66	0.17	**3.39**	0.22	-
D2/stream	14.00	0.52	1.12	0.26 0.41	0.11	**2.12**	0.14	-
D3/ditch	1.389	0.05	0.11	0.03 0.04	0.01	0.21	0.01	-
D4/pond	2.557	0.05	0.11	0.03 0.075	0.01	0.21	0.01	-

D4/stream	3.977	0.15	0.32	0.07 0.12	0.03	0.60	0.04	-
D5/pond	1.256	0.05	0.10	0.02 0.037	0.01	0.19	0.01	-
D5/stream	1.761	0.07	0.14	0.03 0.052	0.01	0.27	0.02	-
R1/stream	0.3813	0.01	0.03	0.01 0.011	0.00	0.06	0.00	-
R1/pond	3.801	0.14	0.30	0.07 0.11	0.03	0.58	0.04	-
R3/stream	3.685	0.14	0.29	0.07 0.11	0.03	0.56	0.04	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoint for formulation

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of BSK-FUN 500 SC to winter rape BBCH 31-57 (2 × 250 g/ha, interval 14 days)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	EC_{50}	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*	-
Endpoint **(µg/L)**		EC_{50} 2700	NOEC 125	5330 3394* EC_{50}	NOEC 1310	E_rC_{50} 66*	NOEC 1000	EC_{50} -
AF		100	10	100	10	10	10	10
RAC (µg/L)		27	12.5	53.3 33.94	131	6.6	100	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1	88.3448	**3.27**	**7.07**	**1.66** **2.6**	0.67	**13.39**	0.88	-
Step 2 NEU	12.1565	0.45	0.97	0.23 0.36	0.09	**1.84**	0.12	-
Step 3								
D2/ditch	13.14	0.49	1.05	0.25 0.39	0.10	**1.99**	0.13	-
D2/stream	8.207	0.30	0.66	0.15 0.24	0.06	**1.24**	0.08	-
D3/ditch	1.382	0.05	0.11	0.03 0.04	0.01	0.21	0.01	-
D4/pond	1.359	0.05	0.11	0.03 0.04	0.01	0.21	0.01	-

D4/stream	1.966	0.07	0.16	0.04 0.058	0.02	0.30	0.02	-
D5/pond	0.8733	0.03	0.07	0.02 0.026	0.01	0.13	0.01	-
D5/stream	1.335	0.05	0.11	0.03 0.039	0.01	0.20	0.01	-
R1/stream	0.5942	0.02	0.05	0.01 0.018	0.00	0.09	0.01	-
R1/pond	3.602	0.13	0.29	0.07 0.106	0.03	0.55	0.04	-
R3/stream	5.141	0.19	0.41	0.10 0.15	0.04	0.78	0.05	

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoint for formulation

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of BSK-FUN 500 SC to winter rape BBCH 57-71 (2 × 250 g/ha, interval 14 days)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Higher plants
Test species		*Oncorhynchus mykiss*	*Oncorhynchus mykiss*	EC_{50}	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*	-
Endpoint **(µg/L)**		EC_{50} 2700	NOEC 125	5330 3394* EC_{50}	NOEC 1310	E_rC_{50} 66*	NOEC 1000	EC_{50} -
AF		100	10	100	10	10	10	10
RAC (µg/L)		27	12.5	53.3 33.94	131	6.6	100	-
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 1	88.3448	**3.27**	**7.07**	**1.66** **2.6**	0.67	**13.39**	0.88	-
Step 2 NEU	7.2931	0.27	0.58	0.14 0.21	0.06	**1.11**	0.07	-
Step 3								
D2/ditch	2.905	0.11	0.23	0.05 0.086	0.02	0.44	0.03	-
D2/stream	2.387	0.09	0.19	0.04 0.07	0.02	0.36	0.02	-
D3/ditch	1.390	0.05	0.11	0.03 0.04	0.01	0.21	0.01	-
D4/pond	0.2162	0.05	0.11	0.03 0.006	0.01	0.21	0.01	-

D4/stream	1.184	0.04	0.09	0.02 0.03	0.01	0.18	0.01	-
D5/pond	0.2328	0.01	0.02	0.00 0.007	0.00	0.04	0.00	-
D5/stream	1.277	0.05	0.10	0.02 0.038	0.01	0.19	0.01	-
R1/stream	0.4440	0.02	0.04	0.01 0.013	0.00	0.07	0.00	-
R1/pond	4.906	0.18	0.39	0.09 0.14	0.04	0.74	0.05	-
R3/stream	3.473	0.13	0.28	0.07 0.102	0.03	0.53	0.03	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* endpoint for formulation

For the intended uses, calculated PEC/RAC ratios for boscalid did not indicate an acceptable risk for aquatic organisms in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios based on FOCUS Step 4 PECsw will be required at national level.

9.5.3 Overall conclusions

PEC/RAC values were calculated on the basis of PECsw calculations as well as worst case toxicity endpoints from studies for active substance and formulation BSK-FUN 500 SC. On the basis of PEC/RAC values it was concluded that BSK-FUN 500 SC used in accordance with GAP does not pose unacceptable risk for aquatic organisms except scenario D2 for which further evaluation on national level is required. In case of D3, D4, D5, R1, R3 and R4 no risk mitigation measures are required.

zRMS comments:

The surface water modelling has been performed using parameters for boscalid have been taken from SANCO/3919 /2007-rev. 5 21 January 2008.

Aquatic toxicity data for boscalid in Table 9.2-1 are in line with EU agreed endpoints reported in SANCO/3919/2007-rev. 5, January 2008.. Studies on effects of the formulated product on aquatic organisms listed in Table 9.5-2 were evaluated by the zRMS and considered acceptable. Summaries of the performed studies together with zRMS evaluation may be found in Appendix 2.

The Applicant haven't performed a *Lemna gibba* test with **BOSKALID 500 SC**. However, in this case, the test with formulation **BOSKALID 500 SC** with *Lemna gibba* is not necessary. **BOSKALID 500 SC** is not a herbicide. It is a fungicide applied at post-emergence of crops. Therefore, no toxic effects of **BOSKALID 500 SC** formulations on aquatic plants are expected.

~~The Applicant haven't performed a fish test with **BOSKALID 500 SC**.~~

- ~~It is not necessary to present a study of the formulation for fish, as the formulation contains only one active ingredient, and the inert ingredients do not increase the toxicity of the formulation (COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013).~~
- ~~Furthermore, the data presented for similar product ENTARGO (see part C) indicate that this formulation is significantly less toxic to fish than the active ingredient boscalid. Hence, it can be considered that the risk assessment for fish can be carried out for the substance boscalid, which will cover the assessment for the formulation.~~

~~In the opinion of zRMS, there is no need to carry out tests for Boskalid 500 SC.~~
~~Conclusion based on additional data, e.g., document C.~~

~~For **BOSKALID 500 SC**, tests on invertebrates *Daphnia magna*, algae *Pseudokirchneriella subcapitata* were provided by Applicant, but no tests are reported for fish.~~
~~According to the Commission Regulation (EU) No 546/2011, point 10.2.1 Acute toxicity:~~
~~" *Test shall be carried out on one species from each of the three/four groups of aquatic organisms, that is to say fish, aquatic invertebrates, algae…*"~~
~~and~~
~~"*Testing shall be performed where:*~~
~~(a) *the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance*;.."~~
~~**In fact, the organisms can be organized in order of sensitivity to boscalid as follows:**~~
~~**Algae > Fish > Invertebrate**~~

Acute toxicity data for active substance and formulation

Species	**boscalid**	**Boskalid 500 SC**
	Endpoint	**Endpoint**
Oncorhynchus mykiss	2.7 mg a.s./L	-
Daphnia magna	5.33 mg a.s./L	EC_{50} = 7.914 mg/L (3.394 mg as/L) NOEC = 0.940 mg/L (0.403 mg as/L)
Pseudokirchneriella subcapitata	1.34 mg a.s./L	E_rC_{50} = 0.153 mg/L (0.066 mg as/L) E_yC_{50} = 0.012 mg/L (0.005 mg as/L)

Based on the aquatic acute data for active substance, algae is the most sensitive species.
Given that:

- results of studies performed with the formulation on daphnia and algae (the most sensitive species) did show higher or unexpected toxicity than predicted based on the results of the active substance, it can be assumed that acute toxicity to fish for formulation **Boskalid 500 SC** should not be required by zRMS.
- In addition, according to the Reg.284/2013, Point 10.2.1: Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes, testing for formulation shall be performed where:

(a) the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance; or
(b) the intended use includes direct application on water;
(c) extrapolation on the basis of available data for a similar plant protection product is not possible.
Based on that, the study for formulation **Boskalid 500 SC** is not required for PL as the toxicity of product can be predicted by the data of active substance.

~~Justification:~~
~~*Studies of the effect of Boskalid 500 SC on Daphnia magna and Pseudokirchneriella subcapitata (the most sensitive group of aquatic organisms) show an increase in the toxicity of the formulation compared to the toxicity of the active substance boscalid on these groups of organisms. In the case of algae, this is as much as 20 times greater toxicity of the formulation compared to the active substance boscalid. In the case of available data for the plant protection product Boskalid 500 SC, fish are not the most sensitive group of aquatic organisms, however, the endpoint of the acute toxicity test of the active substance for fish is higher than the endpoints for other groups of aquatic organisms by less than 10 times. In this case, according to EFSA (2013) guidelines, an appropriate acute toxicity test of the formulation for fish should be carried out (it is recommended to carry out a standard test for a limit concentration of 100 mg/L or the maximum concentration, selected based on available data for individual groups of aquatic organisms.*~~

~~*On the other hand,* unprotected data on the representative product BAS 510 01 F from the RAR indicates even lower sensitivity of fish compared to other organism:~~

BAS 510 01 F	*O. mykiss*	96 h acute (static)	LC_{50}	≅ **100** (i.e. = 51.3 mg a.s./L) (nominal)	[redacted] 2000, 2000/1018528 AIIIA-10.2.1

☑ ~~**BAS 510 01 F** which contains only the active substance boscalid (formulation closely related to Boskalid 500 SC based on the same the amount of active substance contained in formulation 500 g boscalid/L). However, not the same formulation type. BAS 510 01 F is a water dispersible granule (WG) formulation containing 500 g/kg (50 % w/w) of the active substance boscalid. In the case of the BSK FUN 500 SC product, the substance content is approximately 50% but SC~~

~~type of formulation. Both products are not comparable in terms of formulation type (WG) and their toxicity to aquatic organisms. Boskalid 500 SC is more toxic to *Daphnia magna* and *Pseudokirchneriella subcapitata*. However, this data should be treated as additional source of information of toxicity formulation with boscalid for fish. Unprotected data on the representative product BAS 510 01 F from the RAR indicates even **lower sensitivity to fish** compared to other organism groups.~~

Acute toxicity data for active substance and formulation

Species	**boscalid**	**Boskalid 500 SC**	~~**BAS 510 01 F ENTARGO**~~
	Endpoint	**Endpoint**	~~**Endpoint**~~
Oncorhynchus mykiss	2.7 mg a.s./L	-	~~≥ 100 (i.e. ≥ 51.3 mg a.s./L) (nominal)~~
Daphnia magna	5.33 mg a.s./L	EC_{50} = 7.914 mg/L (3.394 mg as/L) NOEC = 0.940 mg/L (0.403 mg as/L)	~~50 (i.e. 25.65 mg a.s./L) (nominal)~~
Pseudokirchneriella subcapitata	1.34 mg a.s./L	E_rC_{50} = 0.153 mg/L (0.066 mg as/L) E_yC_{50} = 0.012 mg/L (0.005 mg as/L)	~~4.5 (i.e. 2.31 mg a.s./L) 3.37 (nominal)~~

~~**WG vs SC in Aquatic Toxicity (Fish):**~~

~~3. Water Dispersible Granules (WG):~~
- ~~WGs are designed to disperse into water, and while they may initially be less bioavailable compared to SCs, once dissolved, the active ingredient (Boscalid in this case) becomes available to aquatic organisms.~~
- ~~Potential Issue: WG formulations might cause localized toxicity near the site of release (like fish in a pond or river). The granules may settle, creating localized "hotspots" of contamination.~~

~~4. Suspension Concentrates (SC):~~
- ~~SC formulations typically contain a higher concentration of active ingredient dissolved in a liquid carrier, which increases the immediate bioavailability of the active substance to aquatic organisms like fish.~~
- ~~Potential Issue: SCs may result in higher acute toxicity to aquatic organisms because of the faster release and absorption of the active ingredient into the water column. This can lead to more immediate and widespread exposure.~~

~~SC formulations are often more toxic in the short term to aquatic organisms, including fish, due to the higher concentration of the active ingredient in a liquid form that is immediately bioavailable. WG formulations, while still potentially toxic, may have a more gradual release of the active ingredient into the water, leading to slower or more localized toxicity.~~

~~In the case of the BSK-FUN 500 SC product, the substance content is approximately 50%, so it can be assumed that the active substance will be the main component that will affect the toxicity of the product, and therefore extrapolate from the substance data can be considered. Furthermore, based on the acute toxicity data for the active substance, it can be concluded that fish are not the most sensitive aquatic organism to boscalid, so duplicating studies on vertebrate fish may not be necessary in the RMS assessment. On the other hand, unprotected data on the representative product BAS 510 01 F from the~~

~~RAR indicates even lower sensitivity of fish compared to other organism groups. However, SC formulations are often more toxic in the short term to aquatic organisms, including fish. Due to many doubts the other MSs should be considered if the packed data in this case is sufficient.~~

~~It should be considered by MSs level.~~

Conclusion zRMS: For Poland D3, D4 and R1 scenarios are relevant so it can be concluded that BSK-FUN 500 SC used according to proposed GAP does not pose unacceptable risk to aquatic organisms. No risk mitigations are required.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with boscalid and representative formulations. Full details of these studies are provided in the respective EU DAR and related documents. Since results for representative formulations are not relevant for BSK-FUN 500 SC evaluation, results have not been summarised here.

Effects on bees of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. The studies on effects of BSK-FUN 500 SC on bees were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	boscalid	acute, oral	48h LD_{50} = 166 µg as/bee	SANCO/3919 /2007-rev. 5
Apis mellifera	boscalid	acute, contact	48h LD_{50} = 200 µg as/bee	SANCO/3919 /2007-rev. 5
Apis mellifera	BSK-FUN 500 SC	Acute, Oral	**LD_{50} >0.2 µL/bee (99.72 µg as /bee)**	KCP 10.3.1.1.1/01 Mautino G/ 2024/ 1141.F.SAG23/r
Bombus spp.	BSK-FUN 500 SC	Acute, Oral	48h LD_{50} > 363.817 µg test item/bumblebee (156 µg as/bumblebee)	KCP 10.3.1.1.1/02 Szlauer S/2023/Study Code: ETOX-2023-22
Apis mellifera	BSK-FUN 500 SC	Acute, Contact	**LD_{50} >0.2 µL/bee (100 µg as /bee)**	KCP 10.3.1.1.2/01 Mautino G/ 2024/ 1141.F.SAG23/r
Bombus spp.	BSK-FUN 500 SC	Acute, Contact	48h LD_{50} > 400 µg test item/bumblebee (171.52 µg as/bumblebee)	KCP 10.3.1.1.2/02 Szlauer S/2023/Study Code: ETOX-2023-23
Apis mellifera	BSK-FUN 500 SC	Chronic, Oral	LC_{50} > 2.08 mL/kg (1027.7 mg as/kg) NOEC = 1.18 mL/kg (578 mg as/kg) **LDD_{50} > 0.041 µL/bee/day**	KCP 10.3.1.1.2/02 Mautino G/ 2024/ 1142.F.SAG23/r

Species	Substance	Exposure System	Results	Reference
			(20.55 µg as/bee/day) NOEDD = 0.023 mg/kg (11.56 mg as/kg)	
Apis mellifera	BSK-FUN 500 SC	Chronic, Larval	**ED_{50} = 0.15 µL/larva (76.99 µg as/larva)** NOED = 0.041 µL/larva (20.35 µg as/larva)	KCP 10.3.1.4/01 Mautino G/ 2024/ 1143.F.SAG23/r
Higher-tier studies (tunnel test, field studies)				
Not relevant.				

9.6.1.1 Justification for new endpoints

New endpoints are provided for the formulated product BSK-FUN 500 SC. Details of studies and results are included in Table 9.6-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.6.2 Risk assessment

9.6.2.1 Hazard quotients for bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and "EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)" (EFSA Journal 2013;11(7):3295).

<u>Risk assessment acc. to SANCO/10329/2002 rev.2 (final), October 17, 2002</u>

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the winter wheat (use no. 1) also covers the off-field risk for arthropods from all other intended uses (see 9.1.2).

Table 9.6-2: First-tier assessment of the risk for bees due to the use of BSK-FUN 500 SC in winter wheat (max. application rate 350 g as/ha)

Intended use	winter wheat (use no. 1)		
Product	BSK-FUN 500 SC		
Max. application rate (g/ha)	1 × 350		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: Q_H ≤ 50**
Acute oral toxicity	99.72	350	3.5
Acute contact toxicity	100		3.5

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

Risk assessment acc. to EFSA Journal 2013;11(7):3295

Table 9.6-3: Screening step assessment of the risk for bees due to the use of BSK-FUN 500 SC in winter wheat (max. application rate 350 g as/ha)

Intended use **Product** **Application rate (g/ha)**	winter wheat (use no. 1) BSK-FUN 500 SC 1 × 350				
Test design	**LD_{50} (µg/bee)** **LDD_{50} (µg/bee/day)** **NOED (µg/larva)**	**Single application rate (g/ha)**	**SV**	**HQ/ ETR**	**Trigger**
Contact exposure					
Bees - acute contact toxicity	100	350	-	3.5	42
Bumblebees - acute contact toxicity	156	350	-	2.0	7
Oral exposure					
Bees - acute oral toxicity	99.72	350	7.6	0.03	0.2
Bees - chronic adult oral toxicity	20.55	350	7.6	**0.129**	0.03
Bees - larval development oral toxicity	20.35	350	4.4	0.08	0.2
Bumblebees - acute oral toxicity	171.52	350	11.2	0.03	0.036

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure. HQ/ETR values shown in bold breach the relevant trigger.

The screening step risk assessment above has indicated a potential chronic adult oral risk and therefore a Tier 1 assessment for treated crop has been provided.

Table 9.6-4: First-tier assessment of the risk for bees due to the use of BSK-FUN 500 SC in winter wheat (max. application rate 350 g as/ha)

Intended use **Product** **Application rate (g/ha)**	winter wheat (use no. 1) BSK-FUN 500 SC 1 × 350						
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**SV**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Cereals – treated crop							
Bees - chronic adult oral toxicity	20.55	350	0.92	0.72	1	0.011	0.03
Cereals – weeds							
Bees - chronic adult oral toxicity	20.55	350	2.9	0.72	0.5	0.018	0.03
Cereals – field margin							

Bees - chronic adult oral toxicity	20.55	350	2.9	0.72	0.0092	0.000	0.03
Cereals – adjacent crop							
Bees - chronic adult oral toxicity	20.55	350	5.8	0.72	0.0033	0.000	0.03
Cereals – next crop							
Bees - chronic adult oral toxicity	20.55	350	0.54	0.72	1	0.007	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

The Tier I ETR values are less than the trigger for downward sprays, according to EFSA 2013, indicating that the risk to bees is acceptable following use of BSK-FUN 500 SC according to the proposed use pattern.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

The acute risk of BSK-FUN 500 SC to honeybees was assessed from HQ between toxicity endpoints, estimated from acute oral and contact studies with formulated product BSK-FUN 500 SC as well as the maximum single application rate. The HQ values were considerably less than 50. It can be concluded that BSK-FUN 500 SC used in accordance with GAP does not pose unacceptable risk to bees. No risk mitigations are required.

Review comments:

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).
The required study on oral and contact toxicity of the formulated product **BOSKALID 500 SC** to honeybees was conducted and considered to be valid.
The endpoints as proposed by the Notifier are considered acceptable and are used in the risk assessment. All hazard quotients for acute oral and acute contact exposure were below 50, the Commission Regulation (EU) No. 546/2011 criterion, indicating low risk to honey bees.
The chronic studies with formulation **BOSKALID 500 SC** were submitted. The studies were accepted by zRMS. The chronic risk assessment was performed based on EFSA 2013 guidance. The Tier I ETR values are less than the trigger for downward sprays, according to EFSA 2013, indicating that the risk to bees is acceptable following use of **BOSKALID 500 SC** according to the proposed use pattern.

~~The risk assessment should be considered by MSs level.~~

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with representative formulations. Full details of these studies are provided in the respective EU DAR and related documents. Since results for representative formulations are not relevant for BSK-FUN 500 SC evaluation, results have not been summarised here.
Effects on non-target arthropods of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. The studies on effects of BSK-FUN 500 SC on arthropods were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Aphidius rhopalosiphi	BSK-FUN 500 SC	Tier I plastic discs	Mortality **48h LR_{50} > 1 L/ha (503.4 a as/ha)** 48h NOER ≥ 1 L/ha (503.4 a as/ha) 0.25 L/ha 0.0% 0.5 L/ha 2.564% 1 L/ha 2.564% Reproduction 48h ER_{50} > 1 L/ha (503.4 a as/ha) 48h NOER ≥ 1 L/ha (503.4 a as/ha) 0.25 L/ha 10.204% 0.5 L/ha 4.592% 1 L/ha 15.306%	KCP 10.3.2.1/01 Wiktorek-Smagur A/2024/Study Code: ETOX-2023-25
Typhlodromus pyri	BSK-FUN 500 SC	Tier I glass plates	Mortality **48h LR_{50} > 1 L/ha (503.4 a as/ha)** 48h NOER ≥ 1 L/ha (503.4 a as/ha) 0.25 L/ha 5.660% 0.5 L/ha 9.434% 1 L/ha 13.208% Reproduction 48h ER_{50} > 1 L/ha (503.4 a as/ha) 48h NOER ≥ 1 L/ha (503.4 a as/ha) 0.25 L/ha 1.443% 0.5 L/ha 4.925% 1 L/ha 15.004%	KCP 10.3.2.1/02 Kulec-Płoszczyca E /2024/Study Code: ETOX-2023-24
Field or semi-field tests				
-				-

9.7.1.1 Justification for new endpoints

New endpoints are provided for the formulated product BSK-FUN 500 SC. Details of studies and results are included in Table 9.7-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the oilseed rape (use no. 8) also covers the in-field risk for arthropods from all other intended uses (see 9.1.2).

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of BSK-FUN 500 SC in oilseed rape (max. application rate 2 x 250 g as/ha)

Intended use	oilseed rape (use no. 8)		
Product	BSK-FUN 500 SC		
Application rate (g/ha)	2 × 250		
MAF	1.7		
Test species **Tier I**	**LR_{50} (lab.)** **(g/ha)**	**$PER_{in\text{-}field}$** **(g/ha)**	**$HQ_{in\text{-}field}$ criterion** **HQ ≤ 2**
Aphidius rhopalosiphi	> 503.4	425	0.84
Typhlodromus pyri	> 503.4		0.84

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the oilseed rape (use no. 8) also covers the off-field risk for arthropods from all other intended uses (see 9.1.2).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of BSK-FUN 500 SC oilseed rape (max. application rate 2 x 250 g as/ha)

Intended use	oilseed rape (use no. 8)
Active substance/product	BSK-FUN 500 SC
Application rate (g/ha)	2 × 250
MAF	1.7
VDF	5[1]

Test species Tier I	LR_{50} (lab.) (g/ha)	Drift rate	$PER_{off\text{-}field}$ (g/ha)	CF	$HQ_{off\text{-}field}$ criterion: HQ ≤ 2
Aphidius rhopalosiphi	> 503.4	2.77%	1.385	10	0.028
Typhlodromus pyri	> 503.4				0.028

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
[1] value for Tier I in accordance with EFSA Supporting publication 2019:EN-1673 and Working Document on Risk Assessment of Plant Protection Products in the Central Zone (Version 1.0, May 2021)

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The risk of BSK-FUN 500 SC to non-target arthropods was assessed from in-field and off-field HQ between toxicity endpoints, estimated from laboratory studies with formulated product BSK-FUN 500 SC as well as application rate. The HQ values were considerably less than 2, indicating that the product poses a low risk to non-target arthropods. It can be concluded that BSK-FUN 500 SC used in accordance with GAP does not pose unacceptable in-field and off-field risk to non-target arthropods. No risk mitigations are required.

zRMS comments: Agreed.

The calculations of the risk assessment for in – field and off-field for **BOSKALID 500 SC** for two indicator species were accepted by zRMS. HQ in - field and HQ-off field are below 2 based on laboratory studies (Tier1).
The PER-in and PER_{off}-field for *T.pyri* and *A.rhopalosiphi* (based on the laboratory studies) are below trigger value 2. Therefore, this assessment indicates that **BOSKALID 500 SC** poses low risk to in-field and off-field non-target arthropods following application according to the proposed use patterns.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the chronic toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with representative formulations. Full details of these studies are provided in the respective EU DAR and related documents. Since results for representative formulations are not relevant for BSK-FUN 500 SC evaluation, results have not been summarised here.

Effects on earthworms of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. The studies on effects of BSK-FUN 500 SC on earthworms were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC. New data submitted with this

application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	BSK-FUN 500 SC	56 d, chronic	Mortality: EC_{50}≥ 1000 mg/kg dw (500 mg/kg dw[1]) NOEC≥ 1000 mg/kg dw (500 mg/kg dw[1]) Reproduction: EC_{50}= 146.32 mg/kg dw (73.16 mg/kg dw[1]) **NOEC= 59.60 mg/kg dw (29.8 mg/kg dw[1])** Mortality: EC_{50}≥ 1000 mg/kg dw (~~500~~ 404.96 mg as/kg dw[1]) NOEC≥ 1000 mg/kg dw (~~500~~ 404.96 mg as/kg dw[1]) $EC_{50,corr}$[1]≥ 500 mg/kg dw (202.48 mg as/kg dw) $NOEC_{corr}$[1]≥ 500 mg/kg dw (202.48 mg as/kg dw Reproduction: EC_{50}= 146.32 mg/kg dw (~~73.16~~ 63.83 mg as/kg dw[1]) NOEC= 59.60 mg/kg dw (~~29.8~~ 11.75 mg as/kg dw[1]) $EC_{50,corr}$[1]= 73.16 mg/kg dw (31.92 mg as/kg dw) **$NOEC_{corr}$[1]= 29.8 mg/kg dw (5.89 mg as/kg dw[1])**	KCP 10.4.1.1/01/ Wesołowska K/ 2024/ ETOX-2023-26
Field studies				
Not relevant.				
Litter bag test				
No data.				

[1] corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 (substance with logPow of > 2)

9.8.1.1 Justification for new endpoints

New endpoints are provided for the formulated product BSK-FUN 500 SC. Details of studies and results are included in Table 9.8-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate).

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the oilseed rape (use no. 8) also covers the risk for soil organisms from all other intended uses (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of BSK-FUN 500 SC in oilseed rape (max. application rate 2 x 250 g as/ha)

Intended use	oilseed rape (use no. 8)		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg as/kg dw)**	**PEC_{soil} (mg as/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
boscalid as BSK-FUN 500 SC	~~29.8~~ 5.89	0.5612[1]	~~53.1~~ 10.5
Chronic effects on *Folsomia candida*			
NR	NR	NR	NR
Chronic effects on *Hypoaspis aculeifer*			
NR	NR	NR	NR

[1] $PECs_{accumulation}$

9.8.2.2 Higher-tier risk assessment

Not required.

9.8.3 Overall conclusions

The risk of BSK-FUN 500 SC to soil meso- and macrofauna was evaluated by comparison of toxicity endpoints derived from laboratory tests for the formulation BSK-FUN 500 SC with predicted concentrations in soil PECs. According to the performed risk assessment it was concluded that BSK-FUN 500 SC used in accordance with GAP does not pose unacceptable risk to soil meso- and macrofauna. No risk mitigations are required.

Review Comments:

As the maximum PEC_{soil} values for the active substance and **BOSKALID 500 SC** were corrected in Section 8, the TER calculations were revised accordingly by Evaluator in Table 9.8.2.

The acute risk assessment is no longer required, however the TER_A values for active substance is above the trigger value of 10 set by Commission Regulation (EU) No. 546/2011.
The long-term TER values for active substance and **BOSKALID 500 SC** are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011.

In conclusion, no unacceptable risk to non-target soil meso- and macrofauna is expected following the application of **BOSKALID 500 SC** according to the proposed use pattern.

The study for formulation of BOSKALID 500 SC for earthworms with risk assessment was accepted by zRMS only provisionally. The toxicity endpoints were based on nominal concentration. At the end on the studies concentration of substances active – boscalid fell under 80% of nominal. The TWA or geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. Please complete the calculation the toxicity endpoints based on geometric mean measured concentration.

It should be considered at MSs level.

Updated December 2024

The Applicant provided the new calculation the toxicity endpoints for earthworms study based on geometric mean measured concentration. The calculation was accepted by zRMS. The risk assessment for earthworms was updated by Applicant. Risk assessment based new calculation was accepted by zRMS. The long-term TER values for active substance and **BOSKALID 500 SC** are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011.

~~**No additional action required.**~~
~~**It should be considered at MSs level.**~~

Updated May 2025
Risk assessment for other non-target soil organisms
As stated in Commission Regulation EU No 284/2013 of 1 March 2013, "For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species might be taken into account for a preliminary risk assessment. If effects do occur on either species, testing on *Folsomia candida* and *Hypoaspis aculeifer* shall be required." The formulated product BSK-FUN 500 SC or Boskalid 500 SC product is applied as a foliar spray treatment. As demonstrated above, acceptable risks are expected towards the earthworms and a low in-field and off-field risk is demonstrated for non-target arthropods - such as - *Typhlodromus pyri*, *Aphidius rhopalosiphi*. On the other hand, all the long-term TER values are higher than the trigger value of 5 (TER = 10.5 - the risk envelope approach is applied), indicating that BSK-FUN 500 SC or Boskalid 500 SC poses low acute risk also for earthworms. Therefore, the risk assessment for macroorganisms other than earthworms is not required.
~~**It should be considered by MSs level.**~~

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on soil microorganisms have been carried out with representative formulations. Full details of these studies are provided in the respective EU DAR and related documents. Since results for representative formulations are not relevant for BSK-FUN 500 SC evaluation, results have not been summarised here.

Effects on soil microorganisms of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. The studies on effects of BSK-FUN 500 SC on microorganisms were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	BSK-FUN 500 SC	28 d	no significant effects of > 25 % on nitrogen transformation at: 2.0 and **10 mg/kg soil** dw (0.86 and **4.29 mg as/kg dw**)	KCP 10.5/01 Szlauer S/ 2024/ Study Code: ETOX-2023-27

9.9.1.1 Justification for new endpoints

New endpoints are provided for the formulated product BSK-FUN 500 SC. Details of studies and results are included in Table 9.9-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate).

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the oilseed rape (use no. 8) also covers the risk for soil microorganisms from all other intended uses (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of BSK-FUN 500 SC in oilseed rape (max. application rate 2 x 250 g as/ha)

Intended use	oilseed rape (use no. 8)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
boscalid as BSK-FUN 500 SC	4.29	0.5612[1]	yes

[1] $PECs_{accumulation}$

9.9.3 Overall conclusions

The risk of BSK-FUN 500 SC to soil micro-organisms was evaluated by comparison of no-effect concentration in soil, derived from laboratory tests for BSK-FUN 500 SC with appropriate predicted environmental concentrations in soil (PECs). According to the performed risk assessment it was

concluded that the application of BSK-FUN 500 SC in accordance with GAP does not pose unacceptable risk to soil micro-organisms. No risk mitigations are required.

zRMS comment: New study was submitted and accepted.
The EU agreed endpoints and relevant endpoint for formulation were used in risk assessment.
An acceptable risk to soil microorganisms is expected from the formulation application in accordance with proposed GAP.

The risk assessment for soil micro-organism after exposure of **BOSKALID 500 SC** has been verified and accepted by the zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PEC_s for the maximum application rate of the product **BOSKALID 500 SC**.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with representative formulations. Full details of these studies are provided in the respective EU DAR and related documents. Since results for representative formulations are not relevant for BSK-FUN 500 SC evaluation, results have not been summarised here.

Effects on non-target terrestrial plants of BSK-FUN 500 SC were not evaluated as part of the EU assessment of boscalid. The studies on seedling emergence and vegetative vigour for BSK-FUN 500 SC were submitted in this dossier and deemed acceptable for evaluation and authorisation of BSK-FUN 500 SC. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
cabbage carrot sunflower soybean onion perennial ryegrass	BSK-FUN 500 SC	21 d Seedling emergence	Plant emergence ER_{50} >7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha) Plant number ER_{50} 7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha) Shoot length ER_{50} 7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha) Plant weight ER_{50} 7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha) Phytotoxicity ER_{50} >7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha)	KCP 10.6.2/01/ Wesołowska K./ 2024/ Study Code: ETOX-2023-28
cabbage carrot sunflower	BSK-FUN 500 SC	21 d Vegetative vigour	Plant number ER_{50} 7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha)	KCP 10.6.2/02/ Wesołowska K./ 2024/ Study Code:

soybean onion perennial ryegrass			Shoot length ER_{50} 7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha) Plant weight ER_{50} 7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha) Phytotoxicity ER_{50} >7000 ml/ha (3524 g as/ha) NOER ≥7000 ml/ha (3524 g as/ha)	ETOX-2023-29

9.10.1.1 Justification for new endpoints

New endpoints are provided for the formulated product BSK-FUN 500 SC. Details of studies and results are included in Table 9.10-1. Summary of the studies is included in Appendix II. Additional studies are required according to Regulation (EC) No. 284/2013.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

To achieve a concise risk assessment, the risk envelope approach is applied. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the oilseed rape (use no. 8) also covers the risk for non-target plants from all other intended uses (see 9.1.2).

Table 9.10-2: Assessment of the risk for non-target plants due to the use of BSK-FUN 500 SC in oilseed rape (max. application rate 2 x 0.5 L/ha)

Intended use	oilseed rape (use no. 8)			
Product	BSK-FUN 500 SC			
Application rate (ml/ha)	1 × 500			
MAF	1.7			
Test species	**ER_{50} (ml/ha)**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (ml/ha)**	**TER criterion: TER ≥ 5**
Seedling emergence (Tier I)				
cabbage, carrot, sunflower, soybean, onion, perennial ryegrass	7000	2.77	23.55	297.2
Vegetative vigour (Tier I)				

cabbage, carrot, sunflower, soybean, onion, perennial ryegrass	7000	2.77	23.55	297.2

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

Not relevant.

9.10.3 Overall conclusions

The risk of BSK-FUN 500 SC to non-target plants was evaluated by comparison of toxicity endpoints derived from laboratory tests for the formulation BSK-FUN 500 SC with application rates. According to the performed risk assessment it was assessed that the application of BSK-FUN 500 SC in accordance with proposed GAP, does not pose unacceptable risk to non-target plants. No risk mitigations are required.

zRMS comment: The submitted information and data were accepted. New studies were submitted and accepted. The EU agreed endpoints and relevant endpoint for formulation were used in risk assessment.
The risk for seedling emergence and vegetative vigour was provided. The study's results for particular plants are presented in summary of the studies in Appendix 2. An acceptable risk to non-target terrestrial plant is expected from the formulation application.
No mitigation measure is required.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not available.

9.12 Monitoring data (KCP 10.8)

Not available.

9.13 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 ecotoxicological data is proposed for the formulation:

Table 9.13-1: Justified proposals for classification and labelling for BSK-FUN 500 SC according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Aquatic Acute 1, H400 Aquatic Chronic 2, H411

Hazard pictograms or Code(s) for hazard pictogram(s):	GHS09
Signal word:	Warning
Hazard statement(s):	Very toxic to aquatic life. [H400] Toxic to aquatic life with long lasting effects. [H411]
For formulation:	**H410**
Precautionary statement(s):	Collect spillage [P391]
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). [SP 1]

Table 9.13-2: Summary of evaluation of the ecotoxicological studies for BSK-FUN 500 SC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Acute toxicity to aquatic organisms (lowest value)	E_yC_{50} = 0.153 mg/L	A	Aquatic Acute 1, H400	KCP 10.2.1.3/01 Kolek L/ 2024 / ETOX-2023-21
Chronic toxicity to aquatic organisms	no data for formulation, classification based on composition	A	Aquatic Chronic 2, H411	Please refer to dRR Part C

zRMS comment: Agreed.

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 10.2.1.2/01	Kolek L.	2024	*Daphnia* sp., Acute Immobilisation Test Study Code: ETOX-2023-20 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
			Amendment No. 1 *Daphnia* sp., Acute Immobilisation Test Study Code: ETOX-2023-20 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.2.1.3/01	Kolek L.	2024	Freshwater Alga and Cyanobacteria, Growth Inhibition Test Study Code: ETOX-2023-21 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
			Amendment No. 1 Freshwater Alga and Cyanobacteria, Growth Inhibition Test Study Code: ETOX-2023-21 Source: EcoTox Alliance Sp. z o. o., Poland GLP	N	Pestila Sp. z o.o. and ProAgri International

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
			Unpublished		Sp. z o.o.
KCP 10.3.1.1.1/01 KCP 10.3.1.1.2/01	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees (*Apis mellifera* L.) in the laboratory – Acute Oral and Contact Toxicity Test Study code: 1141.F.SAG23/r Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.3.1.1.1/02	Szlauer S.	2023	Bumblebees (Bombus spp.), Acute Oral Toxicity Test Study code: ETOX-2023-22 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.3.1.1.2/02	Szlauer S.	2023	Bumblebees (Bombus spp.), Acute Contact Toxicity Test Study Code: ETOX-2023-23 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.3.1.2/01	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees (Apis mellifera L.) in the laboratory – Chronic Oral Toxicity Test Study Code: 1142.F.SAG23/ r Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.3.1.4/01	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees (*Apis mellifera* L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure Study Code: 1143.I.SAG23/r; Source: SAGEA Centro di Saggio s.r.l., Italy GLP	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.

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
			Unpublished		
KCP 10.3.2.1/01	Wiktorek-Smagur A.	2024	A laboratory test for evaluating the effects of BSK FUN 500 SC on the parasitic wasp, *Aphidius rhopalosiphi* Study Code: ETOX-2023-25 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.3.2.1/02	Kulec-Płoszczyca E.	2024	Laboratory residual contact test with the predatory mite *Typhlodromus pyri* for regulatory testing of BSK-FUN 500 SC Study Code: ETOX-2023-24 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.4.1.1/01	Wesołowska K.	2024	Earthworm Reproduction Test (Eisenia andrei); Study Code: ETOX-2023-26 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
	Wesołowska K.		STUDY REPORT AMENDMENT No. 1 Earthworm Reproduction Test (Eisenia andrei); Study Code: ETOX-2023-26 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished		
KCP 10.5/01	Szlauer S.	2024	Soil Microorganisms: Nitrogen Transformation Test Study Code: ETOX-2023-27 Source: EcoTox Alliance Sp. z o. o., Poland GLP	N	Pestila Sp. z o.o. and ProAgri International

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
			Unpublished		Sp. z o.o.
KCP 10.6.2/01	Wesołowska K.	2024	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study Code: ETOX-2023-28 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCP 10.6.2/02	Wesołowska K.	2024	Terrestrial Plant Test: Vegetative Vigour Test Study Code: ETOX-2023-29 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.

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 new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

Not relevant. No studies submitted. The formulation study is not considered essential, because active substance data on toxicity to birds are used. It is possible to extrapolate from active substance data. Additionally, duplication of vertebrate's studies should be avoided.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

Not relevant. No studies submitted. The formulation study is not considered essential, because active substance data on toxicity to mammals are used. It is possible to extrapolate from active substance data. Additionally, duplication of vertebrate's studies should be avoided.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

Not relevant. No studies submitted.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.1.1 KCP 10.2.1.1 Acute toxicity to fish

Not relevant. No studies submitted. The formulation study is not considered essential, because active substance data on toxicity to fish are used. It is possible to extrapolate from active substance data. Additionally, duplication of vertebrate's studies should be avoided.

A 2.2.1.2 KCP 10.2.1.2 Acute toxicity to aquatic invertebrates

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 202 of the test were met. **Validity criteria:**

VALIDITY OF THE STUDY

For the test to be valid, the following performance criteria specified in OECD Guideline No. 202 (2004) were met:

- In the control not more than 10% of daphnids were immobilised or showed signs of stress, for example: discoloration or unusual behaviour such as trapping at surface of water or other abnormalities.
- The concentration of dissolved oxygen in the test and control vessels was ≥ 3 mg/L at the end of the test.

Deviation of the study: none

Agreed toxicity endpoints:

Endpoint values and LOEC and NOEC values resulting from the number of immobilized daphnids with 95% confidence limits based on nominal test item concentrations and active ingredient content. The endpoint values for active ingredient were calculated on the basis of the actual content of boscalid in the test item, confirmed in the Certificate of Analysis

Nominal test item concentration		
Endpoint values [mg/L]	24h	48h
EC_{10}	2.004 *wm *(0.695 – 4.660)*	1.806 *wm *(0.824 – 2.776)*
EC_{20}	9.553 *wm *(4.200 – 74.912)*	3.254 *wm *(1.915 – 4.499)*
EC_{50}	> 15.000	7.914 *wm *(5.923 – 10.754)*
LOEC	> 15.000 *bf	1.880 *casd
NOEC	≥ 15.000 * bf	0.940 *casd
Active ingredient content		
Endpoint values [mg/L]	24h	48h
EC_{10}	0.860*wm *(0.299 – 1.998)*	0.775 *wm *(0.354 – 1.190)*
EC_{20}	4.094 *wm *(1.802-32.014)*	1.395 *wm *(0.821-1.929)*
EC_{50}	≥ 6.432	3.394 *wm *(2.544-4.611)*
LOEC	≥ 6.432 *bf	0.806 *casd
NOEC	≥ 6.432 * bf	0.403 *casd

*wm: Weibull analysis using linear max. likelihood regression;
*bf: Fisher`s exact binomial test with Bonferroni correction;
*casd: Step-down Cochran-Armitage test procedure; significance level was 0.05, one-sided greater.

Reference: KCP 10.2.1.2/01

Report *Daphnia* sp., Acute Immobilisation Test
Kolek L; 2024; Study code: ETOX-2023-20

Amendment no. 1 *Daphnia* sp., Acute Immobilisation Test
Kolek L; 2024; Study code: ETOX-2023-20

Guideline(s): Yes, OECD 202

Deviations:	In the study, an editing deviation occurred: for the chemical analysis the name of a sample was ETOX 2032 20 instead of ETOX 2023 20. This deviation did not affect the results and quality of the test.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control: vehicle control: test medium,
positive control: potassium dichromate

3. Test organism

Species:	*Daphnia magna*
Source:	The Institute of Ichthyobiology and Aquaculture of Polish Academy of Sciences in Golysz, 43-520 Zaborze, Kalinowa 2, Poland
Age:	less than 24-hour old
Feeding:	during the test daphnia were not fed
Test units:	-

4. Environmental conditions:

Medium:	The medium prepared according OECD Guideline No. 202, the growth medium was made up by adding specific amounts of reagents of recognized analytical grade to distilled water. The pH was in the range of 6-9 and hardness between 140-250 mg/L (as CaCO3)
pH:	control: 7.32 – 7.69
Dissolved oxygen:	4.06 – 5.64 mg/L
Temperature:	20. 62 2 1 48°C
Lighting:	D0 1310.975 lux, D1 1269.2 lux, D3 1329.325 lux

STUDY DESIGN AND METHOD

The impact of BSK-FUN 500 SC on *Daphnia magna* was investigated during a 48-hour toxicity study. Five daphnids in four replicates were exposed to the test item solutions. The test was performed using seven test item concentrations: 0.23, 0.47, 0.94, 1.88, 3.75, 7.5 and 15.0 mg/L, in four replicates each, determined during the preliminary experiments, plus four replicates of control. In relation to chemical determinations, 2 samples of concentrations (the lowest - 0.23 mg/L, and the highest concentration - 15.0 mg/L) and a control were collected at the beginning and end of the treatment. Test item concentrations were determined using an own validated liquid chromatography method with mass spectroscopy. Number of immobilised daphnids at 24 and 48 hours after the beginning of the test and any abnormal behavior or appearance were reported.

Test design:	4 replicates per each test item concentration and the control; 5 *Daphnia magna* in each replicate
Type of the exposure:	static
Exposure time:	48 hours
Tested concentrations, definitive test:	0.23, 0.47, 0.94, 1.88, 3.75, 7.5 and 15.0 mg/L plus the control
Dates:	start of the experimental part: 16.01.2024 end of the experimental part: 19.02.2024
Statistic:	Probit analysis using linear max. likelihood regression with immobility at 24 h and 48 h was used to determine the effects of the test item concentrations on immobility in Daphnia magna at 24 h and 48h. Bonferroni Fisher Test was used to determine the lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC). The ToxRat Professional computer software was used for the determined the endpoint values.
Validity of the test:	For the test to be valid, the following performance criteria specified in OECD Guideline No. 202 (2004) were met: − in the control not more than 10% of daphnids were immobilised or showed signs of stress, for example: discoloration or unusual behaviour such as trapping at surface of water or other abnormalities, − the concentration of dissolved oxygen in the test and control vessels was ≥ 3 mg/L at the end of the test.

Stability of test compound:	The concentration of boscalid in the test item sample was chemically determined using the validated method. The analysis were performed using a ultrahigh performance liquid chromatographic method with tandem mass spectrometry detection. The aim was to make sure that the solution was prepared properly. Analysis proved that the solutions were prepared correctly and the recovery was within an acceptable range.

RESULTS

Summary of daphnia immobilization presented below.

Table KCP 10.2.1.2-1 Definitive Test – Results on Daphnia Immobilization

Test item concentration [mg/L]	Test vessel	After 24 h		After 48 h	
		Number of immobilized organisms (x/5)	Behaviour and appearance	Number of immobilized organisms (x/5)	Behaviour and appearance
Control	01	0	Normal behaviour and appearance	0	Normal behaviour and appearance
	02	0		0	
	03	0		0	
	04	0		0	
0.23	1A	0	Normal behaviour and appearance	0	Normal behaviour and appearance
	1B	0		0	
	1C	0		0	
	1D	0		0	
0.47	2A	0	Normal behaviour and appearance	0	Normal behaviour and appearance
	2B	0		0	
	2C	0		0	
	2D	0		0	
0.94	3A	0	Normal behaviour and appearance	0	Normal behaviour and appearance
	3B	0		0	
	3C	0		0	
	3D	0		0	
1.88	4A	0	Normal behaviour and appearance	1	Normal behaviour and appearance
	4B	0		1	
	4C	0		0	
	4D	0		1	
3.75	5A	1	Normal behaviour and appearance	1	Normal behaviour and appearance
	5B	0		2	
	5C	1		1	
	5D	0		2	
7.50	6A	1	Normal behaviour and appearance	2	Slow swimming, most of the time stay on the bottom
	6B	0		3	
	6C	1		2	
	6D	1		3	
15.00	7A	2	Normal behaviour and appearance	4	Slow swimming, most of the time stay on the bottom, white colour
	7B	1		4	
	7C	2		3	
	7D	1		4	

Results of the analytical measurement

No	Day	Nominal concentration [µg/L]	Sample name	Area A	Sample volume [ml] V_{pi}	Volume after dilution [ml] Vk_i	Dilution $\prod_i^n \frac{V_{k,i}}{V_{p,i}}$	Measured concentration [µg/L]	Final concentration [µg/L]	Mean concentration [µg/L]	Recovery [%]	Recovery [%]	SD	RSD [%]
1	16.01.2024	0	ETOX-2023-20-0	4	1	1	1	<LOQ	<LOQ	<LOQ	-	-	-	-
				1				<LOQ	<LOQ		-			
				6				<LOQ	<LOQ		-			
2		98.6	ETOX-2023-20-1	19512	1	1	1	83.7	83.7	85.1	84.9	86.3	1.2	1.4
				20081				86.2	86.2		87.4			
				19865				85.3	85.3		86.5			
3		6432	ETOX-2023-20-7	17505	0.125	10	80	75.1	6011	6145	93.5	95.5	1.9	2.0
				18182				78.0	6243		97.1			
				18000				77.3	6181		96.1			
4	18.01.2024	0	ETOX-2023-20-0	1	1	1	1	<LOQ	<LOQ	<LOQ	-	-	-	-
				18				<LOQ	<LOQ		-			
				8				<LOQ	<LOQ		-			
5		98.6	ETOX-2023-20-1	19085	1	1	1	82.0	82.0	85.6	83.2	86.8	3.3	3.8
				20161				86.6	86.6		87.9			
				20524				88.2	88.2		89.4			
6		6432	ETOX-2023-20-7	17257	0.125	10	80	74.1	5931	6050	92.2	94.1	1.6	1.7
				17744				76.2	6099		94.8			
				17806				76.5	6120		95.2			

Used calibration curve: 16.01.2024: a = 233.1, b = -9.4; 18.01.2024: a = 232.2, b = 42.0;

CONCLUSION

The endpoint values and LOEC and NOEC values, determined on the basis of the nominal concentration of BSK-FUN 500 SC, resulting from the number of immobilized daphnids with 95% confidence limits are given below:

Table KCP 10.2.1.2-2 Endpoints based on nominal concentrations of test item

Endpoint values [mg/L]	24h	48h
EC_{10}	2.004 *wm *(0.695 – 4.660)*	1.806 *wm *(0.824 – 2.776)*
EC_{20}	9.553 *wm *(4.200 – 74.912)*	3.254 *wm *(1.915 – 4.499)*
EC_{50}	> 15.000	7.914 *wm *(5.923 – 10.754)*
LOEC	> 15.000 *bf	1.880 *casd
NOEC	≥ 15.000 * bf	0.940 *casd

The following endpoint values were calculated for the active ingredient which determined based on nominal concentration of the test item:

Table KCP 10.2.1.2-3 Endpoints based on nominal concentrations of active substance

Endpoint values [mg/L]	24h	48h
EC_{10}	0.860*wm *(0.299 – 1.998)*	0.775 *wm *(0.354 – 1.190)*
EC_{20}	4.094 *wm *(1.802-32.014)*	1.395 *wm *(0.821-1.929)*
EC_{50}	> 6.432	3.394 *wm *(2.544-4.611)*
LOEC	> 6.432 *bf	0.806 *casd
NOEC	≥ 6.432 * bf	0.403 *casd

A 2.2.1.3 KCP 10.2.1.3 Effects on aquatic algae

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 201 of the test were met. **Validity criteria:** **VALIDITY OF THE STUDY** The following validity criteria were met during the experiment [1]: – the biomass in the control increased by a factor of 133.6 within the 72-hour test period (criterion: at least a 16-fold growth), – the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation - exposure termination) in the control culture was 1.2% (criterion: it must not exceed 7%). – the mean coefficient of variation for the section-by-section growth rate in the control culture was 26.0% (criterion: it must not exceed 35%). Deviation of the study: No deviations occurred during the study. **Agreed toxicity endpoints:** Freshwater alga growth inhibition test – final results (test item endpoints)

Growth rate endpoint value [mg/L]	Time		
	24h	48h	72h
E_rC_{50}	n.d.	0.437 *pm	0.153 *
E_rC_{20}	0.294 *pm	0.141 *pm	0.016 *
E_rC_{10}	0.025 *pm	0.078 *pm	0.005 *
LOEC	0.012 *wl	0.012 *bw	0.012
NOEC	0.004 *wl	0.004 *bw	0.004
Yield endpoint value [mg/L]	**Time**		
	24h	**48h**	**72h**
E_yC_{50}	1.264 *pm	0.130 *pm	0.012 *
E_yC_{20}	0.029 *pm	0.034 *pm	0.006 *
E_yC_{10}	0.004 *pm	0.017 *pm	0.004 *
LOEC	0.012 *wl	0.012 *wl	0.012 *
NOEC	0.004 *wl	0.004 *wl	0.004 *

The following endpoint values were calculated for the active ingredient which was determined based on nominal concentration of the test item:

Freshwater alga growth inhibition test – final results (active substance endpoints)

Growth rate endpoint value [mg/L]	Time		
	24h	48h	72h
E_rC_{50}	n.d.	0.188 *pm	0.066 *
E_rC_{20}	0.126 *pm	0.061 *pm	0.007 *
E_rC_{10}	0.011 *pm	0.034 *pm	0.002 *
LOEC	0.005*wl	0.005 *bw	0.005

NOEC	0.002*wl	0.002 *bw	0.002
Yield endpoint value [mg/L]	Time		
	24h	48h	72h
E_yC_{50}	0.542*pm	0.055*pm	0.005*
E_yC_{20}	0.013*pm	0.015*pm	0.002*
E_yC_{10}	0.002*pm	0.007*pm	0.002*
LOEC	0.005 *wl	0.005 *wl	0.005 *
NOEC	0.002 *wl	0.002*wl	0.002 *

*pm - Probit analysis using linear max. likelihood regression; wl - Williams multiple sequential t-test proc bw- Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm; n.d – not determined; jtsd: Jonckheere-Terpstra test procedure; significance level was 0.05.

Reference:	KCP 10.2.1.3/01
Report	Freshwater Alga and Cyanobacteria, Growth Inhibition Test. Kolek L; 2024; Study Code: ETOX-2023-21 Amendment No 1 Freshwater Alga and Cyanobacteria, Growth Inhibition Test. Kolek L; 2024; Study Code: ETOX-2023-21
Guideline(s):	Yes, OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control: vehicle control: algal medium
positive control: 3,5-dichlorophenol

3. Test organism

Species:	*Raphidocelis subcapitata*
Source:	The Institute of Ichthyobiology and Aquaculture of Polish Academy of Sciences in Golysz, 43-520 Zaborze, Kalinowa 2, Poland
Age:	four days prior to the start of the test
Test units:	flask of a volume 250 mL

4. Environmental conditions:

Medium:	AAP medium (US EPA) recommended by OECD Guideline No. 201, medium was prepared on the basis of ultra-pure water by adding stock solutions of reagent grade chemicals
Medium temperature:	20.20 22. 26ºC
pH:	6.19 – 7.66
Lighting:	mean light intensity: 4400 to 8800 lux

DESIGN AND METHOD

The impact of BSK FUN 500 SC on the green algae growth was investigated during a 72-hour toxicity study. The initial density of the algae was 1·104 cells/mL. The test was performed using the following test item concentrations: 0.0037, 0.012, 0.038, 0.12, 0.39, 1.25 and 4.0 mg/L (separating factor 3.2) in three replicates each, determined based on the preliminary non-GLP study. Control was prepared in six replicates. The number of algae cells was determined by using the Bürker chamber with a microscope in each replicate after 24, 48 and 72 h of exposure. Morphology observations of the algae cells were performed on each day of algae biomass measurement. The impact of the test item on differences in the appearance of algae cells was observed. Differences in shape and size of algae cells were found in comparison with the control algae cells.

Test design:	tested concentrations in three replicates, control in six replicates
Type of the exposure:	static
Exposure time:	72 hours
Inoculum:	1 x 10^4 cells/mL
Tested concentrations, definitive test:	0.0037, 0.012, 0.038, 0.12, 0.39, 1.25 and 4.0 mg/L
Dates:	start of the experimental part: 09.01.2024 end of the experimental part: 19.02.2024
Statistic:	The ToxRat Professional computer software

Validity of the test:	The following validity criteria were met during the experiment: −the biomass in the control increased by a factor of 133.6 within the 72-hour test period (criterion: at least a 16-fold growth), −the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation - exposure termination) in the control culture was 1.2% (criterion: it must not exceed 7%). −the mean coefficient of variation for the section-by-section growth rate in the control culture was 26.0% (criterion: it must not exceed 35%).
Stability of test compound:	The concentration of Boscalid in the test item sample was chemically determined using the validated method. The analysis were performed using a ultrahigh performance liquid chromatographic method with tandem mass spectrometry detection. The aim was to make sure that the solution was prepared properly. Analysis proved that the solutions were prepared correctly and the recovery was within an acceptable range.

RESULTS

The average section-by-section specific growth rates and yield increase during exposure were calculated on the basis of the density of algae cells determined after 24, 48 and 72 hours of exposure. The specific growth rates, and the yield increase during exposure are provided below.

Table KCP 10.2.1.3-1: The specific growth rates, and the yield dependent on concentration and time of exposure.

Specific growth rates - test interval 0 - 24 h			
Test item concentration [mg/L]	**Mean**	**Std. Dev.**	**n**
Control	1.938	0.0865	6
0.0037	1.911	0.0449	3
0.0120	1.817	0.0819	3
0.0380	1.802	0.1428	3
0.1200	1.511	0.0335	3
0.3900	1.457	0.0699	3
1.2500	1.369	0.0386	3
4.0000	1.332	0.0938	3
Specific growth rates - test interval 0 - 48 h			
Test item concentration [mg/L]	**Mean**	**Std. Dev.**	**n**
Control	1.545	0.0198	6
0.0037	1.531	0.0149	3
0.0120	1.496	0.0144	3
0.0380	1.415	0.0094	3
0.1200	1.284	0.0583	3
0.3900	0.869	0.0496	3
1.2500	0.312	0.0156	3
4.0000	0.009	0.1062	3
Specific growth rates - test interval 0 - 72 h			
Test item concentration [mg/L]	**Mean**	**Std. Dev.**	**n**
Control	1.625	0.0203	6
0.0037	1.601	0.0202	3
0.0120	1.382	0.0106	3
0.0380	0.928	0.0245	3
0.1200	0.880	0.0397	3
0.3900	0.714	0.0319	3
1.2500	0.436	0.0235	3
4.0000	0.031	0.0304	3

Yield of *Raphidocelis subcapitata* cells at 72 h			
Test item concentration [mg/L]	**Mean**	**Std. Dev.**	**n**
Control	130.1	8.15	6
0.0037	121.2	7.29	3
0.0120	62.2	2.00	3
0.0380	15.2	1.17	3
0.1200	13.1	1.73	3
0.3900	7.5	0.84	3
1.2500	2.7	0.26	3
4.0000	0.1	0.1	3

The relationships between growth rate and yield inhibition and the nominal test item concentrations after 72 hours of exposure is shown below.

Table KCP 10.2.1.3-2: Growth rate and yield inhibition after 72 h of exposure to the test item

Nominal test item concentration [mg/L]	% inhibition of growth rate after 72 h of exposure	% inhibition of yield after 72 h of exposure
Control	0.0	0.0
0.0037	1.4	6.9
0.0120	14.9	52.2
0.0380	42.9	88.3
0.1200	45.8	89.9
0.3900	56.1	94.2
1.2500	73.2	97.9
4.0000	98.1	99.9

CONCLUSION

The endpoint values determined on the basis of the nominal concentration of BSK-FUN 500 SC in the test item are given below:

Table KCP 10.2.1.3-3: Freshwater alga growth inhibition test – final results (test item endpoints)

Growth rate endpoint value [mg/L]	Time		
	24h	48h	72h
E_rC_{50}	n.d.	0.437 *pm	0.153 *pm
E_rC_{20}	0.294 *pm	0.141 *pm	0.016 *pm
E_rC_{10}	0.025 *pm	0.078 *pm	0.005 *pm
LOEC	0.012 *wl	0.012 *bw	0.012 *wl
NOEC	0.004 *wl	0.004 *bw	0.004 *wl
Yield endpoint value [mg/L]	**Time**		
	24h	**48h**	**72h**
E_yC_{50}	1.264 *pm	0.130 *pm	0.012 *pm
E_yC_{20}	0.029 *pm	0.034 *pm	0.006 *pm
E_yC_{10}	0.004 *pm	0.017 *pm	0.004 *pm
LOEC	0.012 *wl	0.012 *wl	0.012 *jtsd
NOEC	0.004 *wl	0.004 *wl	0.004 *jtsd

The following endpoint values were calculated for the active ingredient which was determined based on nominal concentration of the test item:

Table KCP 10.2.1.3-4: Freshwater alga growth inhibition test – final results (active substance endpoints)

Growth rate endpoint value [mg/L]	Time		
	24h	48h	72h
E_rC_{50}	n.d.	0.188 *pm	0.066 *pm
E_rC_{20}	0.126 *pm	0.061 *pm	0.007 *pm
E_rC_{10}	0.011 *pm	0.034 *pm	0.002 *pm
LOEC	0.005*wl	0.005 *bw	0.005 *wl

NOEC	0.002*wl	0.002 *bw	0.002 *wl
Yield endpoint value [mg/L]	**Time**		
	24h	**48h**	**72h**
E_yC_{50}	0.542*pm	0.055*pm	0.005*pm
E_yC_{20}	0.013*pm	0.015*pm	0.002*pm
E_yC_{10}	0.002*pm	0.007*pm	0.002*pm
LOEC	0.005 *wl	0.005 *wl	0.005 *jtsd
NOEC	0.002 *wl	0.002*wl	0.002 *jtsd

*pm - Probit analysis using linear max. likelihood regression; wl - Williams multiple sequential t-test procedure; bw- Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm; n.d – not determined; jtsd: Step-down Jonckheere-Terpstra test procedure; significance level was 0.05.

A 2.2.1.4 KCP 10.2.1.4 Effects on aquatic macrophytes

Not relevant. No studies submitted. The long-term formulation study is not considered essential, because active substance data on long-term toxicity and acute formulation toxicity to aquatic organisms are used and deemed to be sufficient for evaluation and risk assessment.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Not relevant. No studies submitted. The long-term formulation study is not considered essential, because active substance data on long-term toxicity and acute formulation toxicity to aquatic organisms are used and deemed to be sufficient for evaluation and risk assessment.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not relevant. No studies submitted.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 213 of the test were met. **Validity criteria:**

Validity criteria of the study

Mortality in the control group after 48 HAA	In the control units, the mean value of dead bees was 3.33% for Limit test of the Acute Oral Toxicity and 0.00% for Limit test of the Acute Contact Toxicity, so the validity criterion was met.
24 HAA LD_{50} in the reference group	The 24-HAA LD_{50} for the Limit test of the Acute Oral test was 0.11 µg a.i./bee therefore, the validity criterion was met because in the range 0.10-0.35 µg a.i./bee. The 24-HAA LD_{50} for the Limit test of the Acute Contact test was 0.11 µg a.i./bee therefore, the validity criterion was met because in the range 0.10-0.30 µg a.i./bee.

Deviation of the study: No deviations occurred during the study.

Agreed toxicity endpoints:

Mortality at 4 HAA, 24-HAA and 48-HAA of exposure – Limit test (Acute Oral Toxicity)

Treatment number	Treatment	Test Item (Nominal intake)	Test Item (Actual intake#)	Mortality 4 HAA (%)	p[a]	Mortality 24 HAA (%)	p[a]	Mortality 48 HAA (%)	p[a]
T1	Control	-	-	0.00	-	0.00	-	3.33	-
T2	BSK-FUN 500 SC	0.20 µL f.p./bee (100 µg a.i./bee)	0.20 µL f.p./bee (99.72 µg a.i./bee)	0.00	n.a.	0.00	n.a.	0.00	n.s.
T3	ROGOR L 40 ST	0.00023 µL f.p./bee (0.090 µg a.i./bee)	0.00023 µL f.p./bee (0.091 µg a.i./bee)	13.33	*	40.00	***	40.00	***
T4	ROGOR L 40 ST	0.00045 µL f.p./bee (0.18 µg a.i./bee)	0.00044 µL f.p./bee (0.18 µg a.i./bee)	56.67	***	73.33	***	73.33	***
T5	ROGOR L 40 ST	0.00088 µL f.p./bee (0.35 µg a.i./bee)	0.00086 µL f.p./bee (0.35 µg a.i./bee)	76.67	***	96.67	***	96.67	***

Endpoints	Actual intake#	
	µL test item/bee	µg a.i./bee
4-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 99.72 µg a.i./bee [95%-CLs n.d.]
4-HAA NOED	≥ 0.20 µL f.p./bee	≥ 99.72 µg a.i./bee
4-HAA LOED	> 0.20 µL f.p./bee	> 99.72 µg a.i./bee
24-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 99.72 µg a.i./bee [95%-CLs n.d.]
24-HAA NOED	≥ 0.20 µL f.p./bee	≥ 99.72 µg a.i./bee
24-HAA LOED	> 0.20 µL f.p./bee	> 99.72 µg a.i./bee
48-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 99.72 µg a.i./bee [95%-CLs n.d.]
48-HAA NOED	≥ 0.20 µL f.p./bee	≥ 99.72 µg a.i./bee
48-HAA LOED	> 0.20 µL f.p./bee	> 99.72 µg a.i./bee

Note: Nominal intake according to the Study Plan
HAA: Hours after application
intake of µL f.p./µg a.i. calculated on the data feeding consumption obtained over the 6 hours exposure
[a], Fisher's Exact test and Cochran-Armitage test (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *
f.p., formulated product
a.i., active ingredient
n.a., not applicable: because no change in mortality was to be observed, no further computations have been performed
n.s., not significantly different compared to the control
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

Mortality at 4 HAA, 24 HAA and 48 HAA of exposure – Limit test (Acute Contact Toxicity)

Treatment number	Treatment	Application rate		Mortality 4 HAA (%)	p^a	Mortality 24 HAA (%)	p^a	Mortality 48 HAA (%)	p^a
		µL f.p./bee	µg a.i/bee						
T1	TRITON X-100	0.1%#	0.1%#	0.00	-	0.00	-	0.00	-
T2	BSK-FUN 500 SC	0.20 µL f.p./bee	100 µg a.i./bee	0.00	n.a.	0.00	n.a.	0.00	n.a.
T3	ROGOR L 40 ST	0.00019 µL f.p./bee	0.075 µg a.i./bee	13.33	*	30.00	***	30.00	***
T4	ROGOR L 40 ST	0.00038 µL f.p./bee	0.15 µg a.i./bee	43.33	***	70.00	***	70.00	***
T5	ROGOR L 40 ST	0.00075 µL f.p./bee	0.30 µg a.i./bee	83.33	***	93.33	***	93.33	***

Endpoints	µL test item/bee	µg a.i./bee
4-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 100 µg a.i./bee [95%-CLs n.d.]
4-HAA NOED	≥ 0.20µL f.p./bee	≥ 100 µg a.i./bee
4-HAA LOED	> 0.20 µL f.p./bee	> 100 µg a.i./bee
24-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 100 µg a.i./bee [95%-CLs n.d.]
24-HAA NOED	≥ 0.20µL f.p./bee	≥ 100 µg a.i./bee
24-HAA LOED	> 0.20 µL f.p./bee	> 100 µg a.i./bee
48-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 100 µg a.i./bee [95%-CLs n.d.]
48-HAA NOED	≥ 0.20µL f.p./bee	≥ 100 µg a.i./bee
48-HAA LOED	> 0.20 µL f.p./bee	> 100 µg a.i./bee

HAA: Hours after application
intake of µL f.p./µg a.i. calculated on the data feeding consumption obtained over the 6 hours exposure
a, Cochran-Armitage test, α≤0.001 ***, 0.01 **, 0.05 *
f.p., formulated product
a.i., active ingredient
n.a., not applicable: because no change in mortality was to be observed, no further computations have been performed
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

Reference:	KCP 10.3.1.1.1/01
Report	Effects of BSK-FUN 500 SC on Honeybees (*Apis mellifera L.*) in the laboratory – Acute Oral and Contact Toxicity Test; Mautino G; 2024; Study code: 1141.F.SAG23/r
Guideline(s):	Yes, OECD 213
Deviations:	Not relevant
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	SC (boscalid 500 g/L)
Description (physical state):	liquid
Batch no.:	1/BSK/2023
Production date:	18 April 2023
Expiration date:	18 April 2027

2. Vehicle and/or positive control:	vehicle: 50% sucrose solution in Milli-Q water positive control: dimethoate
Validity of the test:	The following criteria should be satisfied for a test result to be considered valid: - average mortality for the total number of control groups ≤ 10% at the end of the test. - LD50 value of the reference item meets the specified range.
3. Test organism	
Species:	honeybee *Apis mellifera,* Insecta, Hymenoptera
Source:	Beekeeper Marco Messa, via della colla 1, Pocapaglia (CN), 12060, three commercial beehives, queen-right, healthy (disease free) and adequately fed, with normal population of young adult worker individuals (approx. 2 weeks old)
Age:	adult female workers
Acclimation period:	the test units were placed into a climatic chamber and kept under darkness at the environmental conditions of the test (24.70 ºC and 60.5% RH) for 2 hours, until the beginning of the test. No food or water was supplied during acclimatisation
Diet:	sucrose solution in water with a final concentration of 500 g/L (50% w/v) was used as food
Test units:	ventilated stainless steel cages 8.5 cm x 6.5 cm x 4.5 cm (length x height x width) with removable glass panel and back side perforated with 50 ventilation holes; Ø 2 mm
4. Environmental conditions:	
Temperature:	25.48°C ± 0.165 °C (25.29 – 25.61 °C)
Relative humidity:	60.4 ± 0.1% (60.3 – 60.5%) RH
Photoperiod:	darkness (except during observation and food replacement)

STUDY DESIGN AND METHOD

Limit test of the Acute Oral Toxicity test

The study comprised 5 treatments (1 concentrations of the test item, 1 control group, 3 concentrations of the reference item) with 3 replicates; each test unit (stainless-steel cage) contained 10 individuals. Each cage was provided with a feeder containing 0.2 mL of tested doses dispersed in 50% w/v sucrose solution for maximum 6 hours. The amount of treated diet consumed per group was monitored. Then, feeders were replaced with ones containing sucrose solution only ad libitum. Mortality was recorded at 4, 24 and 48 hours after application and compared with that one of the control group. Since There was no significant increase in mortality between 24 and 48 HAA (< 10%) among the different treatments, the test was stopped at 48 HAA according to the OECD 213.

Limit test of the Acute Contact Toxicity test

The study included 5 treatments (1 concentrations of the test item, 1 control group, 3 concentrations of the reference item) with 3 replicates. Each test unit (stainless-steel cage) contained 10 individuals. The tested doses were dispersed in deionized water with a wetting agent and applied once to the thorax dorsal side of the bees. The bees were then fed ad libitum with 50% sucrose solution until the end of the test. Mortality was recorded at 4, 24 and 48 hours after application and compared with that one of the control group. Since There was no significant increase in mortality between 24 and 48 HAA (< 10%) among the different treatments, the test was stopped at 48 HAA+ according to the OECD 214.

At least the LD50 value for mortality at 4, 24 and 48 hours after application. Additionally, NOED and LOED values for mortality, where possible.

Test design:	tested doses and control in 3 replicates, 10 bees per replicate
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	limit test: 100 µg a.i./bee
Dates:	start of the study 07.09.2023 start of the experimental part: 09.10.2023 end of the experimental part: 11.10.2023 end of the study: 20.02.2024
Statistic:	Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using Cochran-Armitage test ($\alpha \leq 0.05$). Correction for control mortality was carried out using the Schneider-Orelli's formula. The LD50 values at different timing (4, 24 and 48-HAA) could not be calculated, because data were not appropriate for the computation, the number of responses was less than three. The No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC) values for mortality were determined, where possible.

RESULTS

All study validity criteria were met. The results are described in section 10 of this report and summarized in the following table.

Table KCP 10.3.1.1.1-1: ***Apis mellifera*** **- mortality at 4 HAA, 24-HAA and 48-HAA of exposure – Limit test (Acute Oral Toxicity)**

Treatment number	Treatment	Test Item (Nominal intake)	Test Item (Actual intake#)	Mortality 4 HAA (%)	p[a]	(%)	[a]	(%)	[a]
T1	Control	-	-	0.00	-	0.00	-	3.33	-
T2	BSK-FUN 500 SC	0.20 µL f.p./bee (100 µg a.i./bee)	0.20 µL f.p./bee (99.72 µg a.i./bee)	0.00	n.a.	0.00	n.a.	0.00	n.s.
T3	ROGOR L 40 ST	0.00023 µL f.p./bee (0.090 µg a.i./bee)	0.00023 µL f.p./bee (0.091 µg a.i./bee)	13.33	*	40.00	***	40.00	***
T4	ROGOR L 40 ST	0.00045 µL f.p./bee (0.18 µg a.i./bee)	0.00044 µL f.p./bee (0.18 µg a.i./bee)	56.67	***	73.33	***	73.33	***
T5	ROGOR L 40 ST	0.00088 µL f.p./bee (0.35 µg a.i./bee)	0.00086 µL f.p./bee (0.35 µg a.i./bee)	76.67	***	96.67	***	96.67	***

Endpoints	Actual intake#	
	µL test item/bee	µg a.i./bee
4-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 99.72 µg a.i./bee [95%-CLs n.d.]
4-HAA NOED	≥ 0.20 µL f.p./bee	≥ 99.72 µg a.i./bee
4-HAA LOED	> 0.20 µL f.p./bee	> 99.72 µg a.i./bee
24-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 99.72 µg a.i./bee [95%-CLs n.d.]
24-HAA NOED	≥ 0.20 µL f.p./bee	≥ 99.72 µg a.i./bee
24-HAA LOED	> 0.20 µL f.p./bee	> 99.72 µg a.i./bee
48-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 99.72 µg a.i./bee [95%-CLs n.d.]
48-HAA NOED	≥ 0.20 µL f.p./bee	≥ 99.72 µg a.i./bee
48-HAA LOED	> 0.20 µL f.p./bee	> 99.72 µg a.i./bee

Note: Nominal intake according to the Study Plan
HAA: Hours after application
intake of µL f.p./µg a.i. calculated on the data feeding consumption obtained over the 6 hours exposure
[a], Fisher's Exact test and Cochran-Armitage test (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *
f.p., formulated product
a.i., active ingredient
n.a., not applicable: because no change in mortality was to be observed, no further computations have been performed
n.s., not significantly different compared to the control
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

Table KCP 10.3.1.1.1-2: ***Apis mellifera* - mortality at 4 HAA, 24 HAA and 48 HAA of exposure – Limit test (Acute Contact Toxicity)**

Treatment number	Treatment	Application rate		Mortality 4 HAA (%)	p^a	Mortality 24 HAA (%)	p^a	Mortality 48 HAA (%)	p^a
		µL f.p./bee	µg a.i/bee						
T1	TRITON X-100	0.1%#	0.1%#	0.00	-	0.00	-	0.00	-
T2	BSK-FUN 500 SC	0.20 µL f.p./bee	100 µg a.i./bee	0.00	n.a.	0.00	n.a.	0.00	n.a.
T3	ROGOR L 40 ST	0.00019 µL f.p./bee	0.075 µg a.i./bee	13.33	*	30.00	***	30.00	***
T4	ROGOR L 40 ST	0.00038 µL f.p./bee	0.15 µg a.i./bee	43.33	***	70.00	***	70.00	***
T5	ROGOR L 40 ST	0.00075 µL f.p./bee	0.30 µg a.i./bee	83.33	***	93.33	***	93.33	***

Endpoints	µL test item/bee	µg a.i./bee
4-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 100 µg a.i./bee [95%-CLs n.d.]
4-HAA NOED	≥ 0.20µL f.p./bee	≥ 100 µg a.i./bee
4-HAA LOED	> 0.20 µL f.p./bee	> 100 µg a.i./bee
24-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 100 µg a.i./bee [95%-CLs n.d.]
24-HAA NOED	≥ 0.20µL f.p./bee	≥ 100 µg a.i./bee
24-HAA LOED	> 0.20 µL f.p./bee	> 100 µg a.i./bee
48-HAA LD_{50}	> 0.20 µL f.p./bee [95%-CLs n.d.]	> 100 µg a.i./bee [95%-CLs n.d.]
48-HAA NOED	≥ 0.20µL f.p./bee	≥ 100 µg a.i./bee
48-HAA LOED	> 0.20 µL f.p./bee	> 100 µg a.i./bee

HAA: Hours after application
intake of µL f.p./µg a.i. calculated on the data feeding consumption obtained over the 6 hours exposure
[a], Cochran-Armitage test, α≤0.001 ***, 0.01 **, 0.05 *
f.p., formulated product
a.i., active ingredient
n.a., not applicable: because no change in mortality was to be observed, no further computations have been performed
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

CONCLUSION

The 4-HAA NOED and 4-HAA LOED values couldn't be determined due to the absence of mortality, therefore, it can be estimated a LOED value > 100 µg a.i./honeybee and a LOED value ≥ 100 µg a.i./honeybee, respectively. The 4-HAA LD50 value for Acute Contact Toxicity test was estimated to be > 100 µg a.i./honeybee (95% confidence limits not determined).

The 48-HAA NOED and the 48-HAA LOED values were estimated to be > 100 µg a.i./honeybee and ≥ 100 µg a.i./honeybee, respectively. The 48-HAA LD50 value for Acute Contact Toxicity test was estimated to be > 100 µg a.i./bee (95% confidence limits not determined).

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 247 of the test were met. **Validity criteria:**

VALIDITY OF THE STUDY

The following validity criteria were met during the experiment [1]:

- mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%).
- mortality in the toxic reference item group (dimethoate) at the end of the test was 93.33% (criterion: ≥ 50%).

Deviation of the study:

DEVIATIONS IN THE STUDY

In the study, one temperature deviation occurred:

1. Temperature should meet the requirements specified in the OECD Guideline No. 247 and the Study Plan (25 ± 2ºC), however on 20.10.2023, on 9^{30} and 10^{15}, the temperature dropped below this range, and the lowest value were 22.7°C.
2. Dimethoate should be stored in the temperature 5 ± 4ºC according to the information included in the Certificate of Analysis (Appendix No. 5). However on 30.08.2023, on 14^{12} – 14^{20}, the temperature was above this range, and the highest value was 9.3 ºC.

Above deviation did not affect the study results, because validity criteria were met.

Agreed toxicity endpoints:

Dose [µg test item/ bumblebee]	Number of tested bumblebees [no.]	Number of dead bumblebees [no.]	LD_{50} [µg test item/bumblebee]	
			24 h	48 h
Control	50	0	–	–
363.817[1]	50	0	> 363.817	> 363.817
Active ingredient – Boscalid [µg/bumblebee]			> 156.00	> 156.00
NOED [µg test item/bumblebee]			≥ 363.817	
NOED Active ingredient – Boscalid [µg/bumblebee]			≥ 156.00	
Dimethoate	Number of tested bumblebees [no.]	Number of dead bumblebees [no.]	Mortality [%] after 48 h	
3.644[1]	30	28	93.33	

Reference: KCP 10.3.1.1.1/02

Report: Bumblebees (*Bombus* spp.), Acute Oral Toxicity Test; Szlauer S; 2023; Study Code: ETOX-2023-22

Guideline(s): Yes, OECD 247

Deviations: In the study, one temperature deviation occurred:
1. Temperature should meet the requirements specified in the OECD Guideline No. 24 7 and the Study Plan (25 ± 2ºC), however on 20.10.2023, on 9 30 and 10 15 , the temperature dropped below this range, and the lowest value were 22.7°C.
2. Dimethoate should be stored in the temperature 5 ± 4ºC according to the information included in the Certificate of Analysis (Appendix No. 5). However on 30.08.2023, on
14 12 14 20 , the temperature was above this range, and the highest value

	was 9.3 º Above deviation did not affect the study results, because validity criteria were met.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control:	vehicle: 50% sucrose solution positive control: dimethoat

3. Test organism

Species:	bumbleebee (*Bombus* spp.)
Source:	commercial supplier: Koppert Polska sp. z o.o.
Age:	adult worker bumblebees, medium sized bumblebee colonies with health certificate, having brood at all stages of development and a laying queen, containing ~ 60-80 bumblebee workers will be used to collect bumblebees for the study
Acclimation period:	before the main experiment, all bumblebees were acclimatized to the test conditions for 15 hours before the experiment with access to an untreated 50% (w/v) aqueous sucrose solution ad libitum
Diet:	50% sucrose solution
Test units:	easy to clean, made of plastic, passively ventilated cages were used, the size of the cages was appropriate to the size of the bumblebees

4. Environmental conditions:

Temperature:	22.7 – 25.7ºC
Relative humidity:	45.4 – 67.5%

Photoperiod:	dark

STUDY DESIGN AND METHOD

The aims of the study were to determine the acute oral toxicity of BSK-FUN 500SC to bumblebees (*Bombus* spp.) with a laboratory method and to demonstrate, that the LD50 and NOED values are greater than the dose used in the study. The oral toxicity study on BSK-FUN 500 SC was conducted to determine that the median lethal doses, i.e. the LD 50 values of the test item are higher than the highest dose used in the study. One concentration of the test item , i.e. 400 µg test item/bumblebee was used. It was performed as limit test. The bumblebees were exposed to the test item distributed in a 50% aqueous sucrose solution. The treated diet was provided in weighed syringes. Each syringe contained 40 µL of the sucrose solution with the test item at the tested dose. The insects were selected for the exposure in terms of their sizes. After that, the insects were kept individually in isolators. The sensitivity of the test bumblebees was verified using a reference item, i.e. dimethoate at the dose of 4.0 µg/bumblebee. The insects were observed for mortality and other signs of toxicity 4, 24, and 48 hours after the start of test/reference item administration. The acute oral toxicity experiment finished after 48-hour observation.

Test design:	the test item group was divided into 50 replicates (1 bumblebee/replicate), the control group (50 bumblebees)
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	400 µg test item/bumblebee
Stability of the test compound:	the concentration of Boscalid in the test item sample was chemically determined using the validated own chromatographic method, the aim was to make sure that the solution was prepared properly, the recovery of boscalid in the sample collected at exposure initiation was 100.0% of the nominal concentration, the results confirmed correct preparation of the test item concentration.
Dates:	start of the experimental part: 19.10.2023 end of the experimental part: 23.10.2023
Statistic:	due to the lack of mortality, statistical points have not been calculated
Validity of the test:	The following validity criteria were met: − Mortality of the control group was 0.0% at the end of the test (criterion: ≤ 10%). − Mortality in the toxic reference item group (dimethoate) at the end of the test was 93.33% (criterion: ≥ 50%).

RESULTS

Mortality of the treated insects is presented below. Mortality of the control group was 0.0% after 48 hours of exposure. The percentage of mortality after 48 hours of exposure to the test item at the dose of 400.0 µg test item/bumblebee was 0.0%.

Table KCP 10.3.1.1.1-3: ***Bombus* spp. mortality after 4 hours of exposure – main experiment**

Dose [µg test item/bumblebee]	Number of tested bumblebee [no.]	Mortality	
		Number of dead bumblebee [no.]	[%]
0.0 (Control)	50	0	0.00
363.817[1]	50	0	0.00
Reference item: dimethoate			
3.644[1]	30	11	36.67

Table KCP 10.3.1.1.1-4: ***Bombus* spp. mortality after 24 hours of exposure – main experiment**

Dose [µg test item/bumblebee]	Number of tested bumblebee [no.]	Mortality		LD_{50} [µg test item/bumblebee]
		Number of dead bumblebee [no.]	[%]	
0.0 (Control)	50	0	0.00	–
363.817[1]	50	0	0.00	> 363.817
NOED [µg test item/bumblebee]		≥ 363.817		
Reference item: dimethoate				
3.644[1]	30	28	93.33	–

Table KCP 10.3.1.1.1-5: ***Bombus* spp. mortality after 48 hours of exposure – main experiment**

Dose [µg/bumblebee]	Number of tested bumblebee [no.]	Mortality		LD_{50} [µg test item/bumblebee]
		Number of dead bumblebee [no.]	[%]	
0.0 (Control)	50	0	0.0	–
363.817[1]	50	0	0.0	> 363.817
NOED [µg test item/bumblebee]		≥ 363.817		
Reference item: dimethoate				
3.644[1]	30	28	93.33	–

During the experiment no sublethal effects (toxic symptoms) were observed. Toxic symptoms were observed in the reference item group.

Table KCP 10.3.1.1.1-6: *Bombus* spp. sublethal effects – main experiment

Dose [µg/bumblebee]	Mean body weight [g]	SD
0.0 (Control)	0.249	0.04
363.817[1]	0.258	0.02
Reference item: dimethoate		
3.644[1]	0.262	0.03

The mean weights of the bumblebees in each group were:
- 0.249 g for the control group;
- 0.258 g for the group treated with the test item at the dose 400.0 µg test item/bumblebee;
- 0.262 g for the group treated with the reference item.

The average consumption of the bumblebees in each group were:
- 35.482 µL/bumblebee in the control group;
- 36.382 µL/bumblebee for the group treated with the test item at the dose 400.0 µg test item/bumblebee;
- 36,439 µL/bumblebee for the group treated with the reference item.

CONCLUSION

The median lethal doses (**LD50) after 24 h and 48 h are higher than 363.817 µg test item/bumblebee**. The No Observed Effect Doses (NOED) value after 24 and 48 h are equal or above to 363.817 µg test item/bumblebee. The percentage of mortality after 24 and 48 h hours of exposure to the reference item at the dose of 4.0 µg/bumblebee was 93.33%.

Table KCP 10.3.1.1.1-7: *Bombus* spp. Acute oral study – final results

Dose [µg test item/ bumblebee]	Number of tested bumblebees [no.]	Number of dead bumblebees [no.]	LD_{50} [µg test item/bumblebee]	
			24 h	48 h
Control	50	0	–	–
363.817[1]	50	0	> 363.817	> 363.817
Active ingredient – Boscalid [µg/bumblebee]			> 156.00	> 156.00
NOED [µg test item/bumblebee]			≥ 363.817	
NOED Active ingredient – Boscalid [µg/bumblebee]			≥ 156.00	
Dimethoate	Number of tested bumblebees [no.]	Number of dead bumblebees [no.]	Mortality [%] after 48 h	
3.644[1]	30	28	93.33	

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:

The study is acceptable. The validity criteria according to OECD 247 of the test were met.

Validity criteria:

VALIDITY OF THE STUDY

The following validity criteria were met during the experiment [1]:

- mortality of the control group was 0.0% at the end of the test (criterion: ≤ 10%).
- mortality in the toxic reference item group (i.e. dimethoate) at the end of the test was 93.33% (criterion: ≥ 50%).

Deviation of the study:

DEVIATIONS IN THE STUDY

During the study, no deviations occurred. Validity criteria were met. In the study, one temperature deviation occurred:

1. Temperature should meet the requirements specified in the OECD Guideline No. 246 and the Study Plan (25 ± 2°C), however on 20.10.2023, on 9^{30} and 10^{15}, the temperature dropped below this range, and the lowest value were 22.7°C.
2. Dimethoate should be stored in the temperature 5 ± 4°C according to the information included in the Certificate of Analysis (Appendix No. 5). However on 30.08.2023, on 14^{12} – 14^{20}, the temperature was above this range, and the highest value was 9.3 °C.

Above deviation did not affect the study results, because validity criteria were met.

Agreed toxicity endpoints:

Dose [µg test item/bumblebee]	Number of tested bumblebees [no.]	Number of dead bumblebees[no.]	LD_{50} [µg test item/bumblebee]	
			24 h	48 h
Control	50	0	-	
400.0	50	0	> 400.0	> 400.0
Active ingredient – Boscalid [µg/bumblebee]			> 171.52	> 171.52
NOED [µg test item/bumblebee]			≥ 400.0	
NOED Active ingredient – Boscalid [µg/bumblebee]			≥ 171.52	
Dimethoate [µg/bumblebee]	Number of dead bumblebees [no.]	Number of tested bumblebees [no.]	Mortality [%] after 48 h	
10.0	28	30	93.33	

The No Observed Effect Doses (NOEDs) values after 24 and 48 h are ≥ 400.0 µg test item/bumblebee.

Reference: KCP 10.3.1.1.2/02

Report: Bumblebees (*Bombus* spp.), Acute Contact Toxicity Test; Szlauer S; 2023; Study Code: ETOX-2023-23

Guideline(s):	Yes, OECD 246
Deviations:	In the study, temperature deviation occurred: 1. Temperature should meet the requirements specified in the OECD Guideline No. 246 and the Study Plan (25 ± 2ºC), however on 20.10.2023, on 9 30 and 10 15 , the temperature dropped below this range, and the lowest value were 22.7°C. 2. Dimethoate should be stored in the temperature 5 4 ºC according to the information included in the Certificate of Analysis (Appendix No. 5). However on 30.08.2023, on 14 12 14 20 , the temperature was above this range, and the highest value was 9.3 ºC. Above deviation did not affect the study results, because validity criteria were met.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control:	vehicle water + control with surfactant (distilled water with 1% of Triton X-100) positive control: dimethoate

3. Test organism

Species:	bumbleebee (*Bombus* spp.)
Source:	commercial supplier: Koppert Polska sp. z o.o.
Age:	adult worker bumblebees
Acclimation period:	acclimatized to the test conditions for about 18.5 hours before starting the experiment
Diet:	50% sucrose solution
Test units:	plastic isolators

4. Environmental conditions:

Temperature:	22.7 – 25.7ºC
Relative humidity:	45.4 – 67.5%
Photoperiod:	darkness

STUDY DESIGN AND METHOD

The aims of the study were to determine the acute contact toxicity of BSK-FUN 500SL to bumblebees (*Bombus* spp.) with a laboratory method and to demonstrate, that the LD50 and NOED values are greater than the dose used in the study.
The contact toxicity study on BSK FUN 500 SC was conducted to determine the median lethal doses, i.e. the LD50 contact value of the test item. One concentration of the test item was used. It was performed as limit test. The bumblebees were exposed to the test item diluted in ultra-pure water with surfactant Triton X-100 and applied to the dorsal part of the thorax, using a microapplicator. The volume was 2 µL/bumblebee. The insects were selected for the exposure in terms of their sizes. After that, the insects were kept individually in isolators. The sensitivity of the test bumblebees was verified using a reference item, i.e. dimethoate at the dose of 10.0 µg/bumblebee. The insects were observed for mortality and other signs of toxicity 4, 24, and 48 hours after the start of the experiment. The acute contact toxicity experiment finished after 48-hour observation.

Test design:	the test item group was divided into 50 replicates (1 bumblebee/replicate), the control group (50 bumblebees)
Exposure time:	acute test, 48 h
Tested concentrations, definitive test:	400 µg/bumblebee (limit test)
Stability of the test compound:	the concentration of boscalid in the test item sample was chemically determined using the validated own chromatographic method, the aim was to make sure that the liquid was prepared properly, the recovery of boscalid in the sample collected at exposure initiation was 101.9% of the nominal concentration, the results confirmed correct preparation of the test item concentration
Dates:	start of the experimental part: 19.10.2023 end of the experimental part: 26.10.2023
Statistic:	due to the lack of mortality, statistical points have not been calculated
Validity of the test:	The following validity criteria were met: - Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%). - Mortality in the toxic reference item group (dimethoate) at the end of the test was 93.33% (criterion: ≥ 50%).

RESULTS

Mortality of the treated insects is presented below. Mortality of the control group was 0.0% after 48 hours of exposure. The percentage of mortality after 48 h hours of exposure to the test item at the dose

of 400.0 µg test item/bumblebee was 0.0%.

Table KCP 10.3.1.1.2-1: *Bombus* spp. mortality after 4 hours of exposure – main experiment

Dose [µg test item/bumblebee]	Number of tested bumblebee [no.]	Mortality	
		Number of dead bumblebee [no.]	[%]
Control	50	0	0.0
400.0	50	0	0.0
dimethoate			
10.0	30	18	60.0

Table KCP 10.3.1.1.2-2: *Bombus* spp. mortality after 24 hours of exposure – main experiment

Dose [µg test item/ bumblebee]	Number of tested bumblebee [no.]	Mortality		LD_{50} [µg test item/ bumblebee]
		Number of dead bumblebee [no.]	[%]	
Control	50	0	0.0	–
400.0	50	0	0.0	> 400.0
NOED [µg test item/bumblebee]		≥ 400.0		
dimethoate				
10.0	30	28	93.33	–

Table KCP 10.3.1.1.2-3: *Bombus* spp. mortality after 48 hours of exposure – main experiment

Dose [µg test item/ bumblebee]	Number of tested bumblebee [no.]	Mortality		LD_{50} [µg test item/ bumblebee]
		Number of dead bumblebee [no.]	[%]	
Control	50	0	0.0	–
400.0	50	0	0.0	> 400.0
NOED [µg test item/bumblebee]		≥ 400.0		
dimethoate				
10.0	30	28	93.33	–

During the experiment no sublethal effects (toxic symptoms) were observed in the test item group and the control group. Sublethal effects were observed in the reference item group. The percentage of mortality after 48 h hours of exposure to the reference item at the dose of 10.0 µg/bumblebee was 93.33%.

Table KCP 10.3.1.1.2-4: *Bombus* spp. sublethal effects – main experiment

Dose [µg test item/bumblebee]	Time of exposure [h]		
	4	24	48
	Number of bumblebee showing signs of toxicity * / number of living bumblebees		
Control	50u/50	50u/50	50u/50
400.0	50u/50	50u/50	50u/50
dimethoate			
10.0	8a, 4u/12	2a/2	2a/2

* bumblebees showing signs of toxicity were classified according to the following criteria:
a – affected
m – moribund
u - unaffected

The mean weights of the bumblebees in each group were:

- 0.253 g for the control group,
- 0.259 g for the group treated with the test item: 400.0 µg test item/bumblebee
- 0.251 g for the group treated with the reference item.

CONCLUSION

The median lethal doses for the test item (LD50/24 h, LD50/48 h) are higher than the dose used in the test, i.e. > 400.0 µg test item/bumblebee.

Table KCP 10.3.1.1.2-5: *Bombuss* spp. acute contact toxicity test - final results

Dose [µg test item/bumblebee]	Number of tested bumblebees [no.]	Number of dead bumblebees[no.]	LD_{50} [µg test item/bumblebee]	
			24 h	48 h
Control	50	0	-	
400.0	50	0	> 400.0	> 400.0
Active ingredient – Boscalid [µg/bumblebee]			> 171.52	> 171.52
NOED [µg test item/bumblebee]			≥ 400.0	
NOED Active ingredient – Boscalid [µg/bumblebee]			≥ 171.52	
Dimethoate [µg/bumblebee]	**Number of dead bumblebees [no.]**	**Number of tested bumblebees [no.]**	**Mortality [%] after 48 h**	
10.0	28	30	**93.33**	

A 2.3.1.2 KCP 10.3.1.2 Chronic toxicity to bees

Comments of zRMS: The study is acceptable. The validity criteria according to OECD 245 of the test were met.

Validity criteria:

Results

Validity criteria of the study

Mortality across replicates in the control group ≤ 15% at the end of the test	Average mortality across replicates for the control (50% w/v sucrose solution only) ≤ 15% at the end of the test (actual value was 6.67%), therefore, the validity criterion was met).
Mortality in the reference group ≥50% at the end of the test	Mortality rate at the end of the test period of 100% (actual value was 100.00%), therefore, the validity criterion was met).

Deviation of the study: none

Agreed toxicity endpoints:

Mortality of young adult bees after 10 days (dosages on µL f.p./bee – mL f.p./Kg)

Treatment number	Treatment	Application rate (f.p. nominal intake)	Concentration (mL f.p./kg feeding solution)	Concentration (µL f.p./bee/day)	Mortality (%)	p^a	Survivors' correction (%)[b]
T1	Control	Sucrose solution 50% w/v	---	---	6.67	-	-
T2	BSK-FUN 500 SC	0.028 µL f.p./bee	0.13 mL f.p./kg	0.0026 µL f.p./bee/day	6.67	n.s.	0.00
T3	BSK-FUN 500 SC	0.055 µL f.p./bee	0.27 mL f.p./kg	0.0053 µL f.p./bee/day	6.67	n.s.	0.00
T4	BSK-FUN 500 SC	0.11 µL f.p./bee	0.53 mL f.p./kg	0.011 µL f.p./bee/day	10.00	n.s.	3.57
T5	BSK-FUN 500 SC	0.22 µL f.p./bee	1.18 mL f.p./kg	0.023 µL f.p./bee/day	16.67	n.s.	10.71
T6	BSK-FUN 500 SC	0.40 µL f.p./bee	2.08 mL f.p./kg	0.041 µL f.p./bee/day	46.67	***	42.86
T7	ROGOR L 40 ST	1 mg dimethoate/kg feeding solution			100	***	100

Endpoints	mL test item/Kg feeding solution
LC_{10} [95% confidence intervals]	0.97 [0.55 – 1.25]
LC_{20} [95% confidence intervals]	1.34 [0.97 – 1.75]
LC_{50} [95% confidence intervals]	> 2.08 [95%-CLs n.d.]
NOEC	1.18
LOEC	2.08
Endpoints	**µL test item/bee/day**
LDD_{10} [95% confidence intervals]	0.019 [0.011 – 0.025]
LDD_{20} [95% confidence intervals]	0.027 [0.019 – 0.034]
LDD_{50} [95% confidence intervals]	> 0.041 [95% – CLs n.d.]
NOEDD	0.023
LOEDD	0.041

[a], Cochran-Armitage test and Chi^2 2x2 Table tests (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *
[b], mean survivors corrected by Abbott's formula
f.p., formulated product; a.i., active ingredient
n.s., not significantly different compared to the control

Mortality of young adult bees after 10 days (dosages on µg a.i./bee – mg a.i./Kg)

Treatment number	Treatment	Application rate (a.i. nominal intake)	Concentration (mg a.i./kg feeding solution)	Concentration (µg a.i./bee/day)	Mortality (%)	p^a	Survivors' correction (%)[b]
T1	Control	Sucrose solution 50% w/v	---	---	6.67	-	-
T2	BSK-FUN 500 SC	13.75 µg a.i./bee	63.75 mg a.i./kg	1.28 µg a.i./bee/day	6.67	n.s.	0.00
T3	BSK-FUN 500 SC	27.50 µg a.i./bee	133.20 mg a.i./kg	2.66 µg a.i./bee/day	6.67	n.s.	0.00
T4	BSK-FUN 500 SC	55 µg a.i./bee	263.35 mg a.i./kg	5.27 µg a.i./bee/day	10.00	n.s.	3.57
T5	BSK-FUN 500 SC	110 µg a.i./bee	578.00 mg a.i./kg	11.56 µg a.i./bee/day	16.67	n.s.	10.71
T6	BSK-FUN 500 SC	200 µg a.i./bee	1027.70 mg a.i./kg	20.55 µg a.i./bee/day	46.67	***	42.86
T7	ROGOR L 40 ST	1 mg dimethoate/kg feeding solution			100	***	100

Endpoints	mg a.i./Kg feeding solution
LC_{10} [95% confidence intervals]	477.38 [273.93 – 616.84]
LC_{20} [95% confidence intervals]	662.59 [481.79 – 864.12]
LC_{30} [95% confidence intervals]	> 1027.70 [95%-CLs n.d.]
NOEC	578.00
LOEC	1027.70
Endpoints	**µg a.i./bee/day**
LDD_{10} [95% confidence intervals]	9.55 [5.48 – 12.34]
LDD_{20} [95% confidence intervals]	13.25 [9.64 – 17.28]
LDD_{50} [95% confidence intervals]	> 20.55 [95%-CLs n.d.]
NOEDD	11.56
LOEDD	20.55

[a], Cochran-Armitage and Chi² 2x2 Table tests (reference item ROGOR L40 ST), α≤0.001 ***, 0.01 **, 0.05 *
[b], mean survivors corrected by Abbott's formula
f.p., formulated product
a.i., active ingredient
n.s., not significantly different compared to the control
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

Reference: KCP 10.3.1.2/01

Report: Effects of BSK-FUN 500 SC on Honeybees (Apis mellifera L.) in the laboratory – Chronic Oral Toxicity Test; 2024; Study Code: 1142.F.SAG23/r

Guideline(s): Yes, OECD 245

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): BSK-FUN 500 SC

Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control: vehicle: 50% sucrose solution
positive control: ROGOR L 40 ST (nominally dimethoate 400 g/L)

3. Test organism

Species:	honeybee *Apis mellifera* x Ligustica
Source:	Beekeeper Marco Messa, via della colla 1, Pocapaglia (CN), 12060, three commercial beehives, queen-right, healthy (disease free) and adequately fed, with normal population of young adult worker individuals (approx. 2 weeks old)
Maintenance:	no chemical substances had been applied to the hive for at least 1 month prior to the start of the study
Bees collection:	one day before test start, bees were collected from brood combs without the use of smoke and without anaesthetics, by means of a proper brush, the bees were collected in plastic containers with holes for oxygenation and immediately transported to SAGEA's laboratory
Age:	young adults (max 2 days old)
Acclimation period:	the test units were placed into an incubator and kept under darkness at the mean environmental conditions of 33±2 °C; 50-70% RH for at least 1 day, until the beginning of the test, bees were fed ad libitum with sucrose solution only
Diet:	sucrose solution in water with a final concentration of 500 g/L (50% w/v) was used as food ad libitum, the syrup was administered using a 2.5 mL syringe, the syringes were inserted into the cage via an open-ing in the top of the test unit, food was daily replaced by changing the feeders until the end of test. Food consumption was adjusted for the test solutions evaporation from the feeders
Test units:	ventilated stainless steel cages 8.5 cm x 6.5 cm x 4.5 cm (length x height x width) with removable glass panel and perforated with 50 ventilation holes; Ø 2 mm, lined with filter paper

4. Environmental conditions:

Temperature:	33.82± 0.71 °C (32.82 – 34.77 °C)
Relative humidity:	66.0± 1.8% (68.6 – 62.5%)
Photoperiod:	0 h light: 24 h dark

STUDY DESIGN AND METHOD

Aim of this study was to determine the potential effects of test item BSK-FUN 500 SC (boscalid 500 g/L) to young adult bees to treated food (sucrose solution) over a period of 10 days. Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, was also assessed. For this purpose, a not-GLP Range Finding test was initially performed followed by the Definitive Test. The Definitive Test rates were established taking into consideration the Range finding test results. The study consisted of 8 treatments (6 rates of the test item, 1 control group, 1 reference item) with 3 replicates, each containing 10 bees per cage. Dosages of the test and reference items were dispersed in a 50% sucrose solution in water and offered ad libitum. Feeding solutions were replaced daily by changing the feeders. Mortality was recorded daily for 10 days.

Test design:	tested dose and control in three replicates, 10 bees per replicate
Exposure time:	chronic test, 10 days
Tested concentrations, definitive test:	Control group with (50% sucrose solution only) – T1 0.028 µL test item/bee (13.75 µg a.i.*/bee) – T2 0.055 µL test item/bee (27.50 µg a.i.*/bee) – T3 0.11 µL test item/bee (55 µg a.i.*/bee) – T4 0.22 µL test item/bee (110 µg a.i.*/bee) – T5 0.40 µL test item/bee (200 µg a.i.*/bee) – T6
Dates:	start of the study: 08.09.2023 start of the experimental part: 03.10.2023 end of the experimental part: 13.10.2023 end of the study: 20.03.2024
Statistic:	Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using Cochran-Armitage and Chi2 2x2 Table tests (α≤0.05). Correction for control mortality was carried out using the Abbott's formula. At least the 10-d LD50 and LDD50 values were determined for the test item with 95% confidence interval, where possible. The No Observed Effect Dietary Dose (NOEDD), the No Observed Effect Concentration (NOEC), the Lowest Observed Effect Dietary Dose (LOEDD) and the Lowest Observed Effect Concentration (LOEC) values for mortality were calculated.
Validity of the test:	The following criteria should be satisfied in the control 10 days following start of exposure for a test result to be considered valid: - average mortality across replicates for the control (50% w/v sucrose solution only) ≤ 15% at the end of the test; - mortality in the reference group ≥ 50% at the end of the test period.

Stability of test compound:	The content of boscalid active ingredient was determined in the lowest concentration and in the highest concentration of the feeding solutions prepared in the biological phase of the study.

RESULTS

All study validity criteria were met. The results are summarized in the following table.

At the end of the exposure period the cumulative mortality in the control group (sucrose solution in water 50% w/v) was 6.67% and BSK-FUN 500 SC values ranged from 6.67% in treatments T2 (63.75 mg a.i./Kg feeding solution) and T3 (133.20 mg a.i./Kg feeding solution) to 46.67% in treatment T6 (1027.70 mg a.i./Kg feeding solution). Reference item ROGOR L40 ST showed a mortality value of 100%.

Table KCP 10.3.1.2-1: Average percentage of young adult bee's mortality at day 10 (dosages on µL f.p./bee – mL f.p./Kg)

Treatment number	Treatment	Application rate (f.p. nominal intake)	Concentration (mL f.p./kg feeding solution)	Concentration (µL f.p./bee/day)	Mortality (%)	p^a	Survivors' correction (%)[b]
T1	Control	Sucrose solution 50% w/v	---	---	6.67	-	-
T2	BSK-FUN 500 SC	0.028 µL f.p./bee	0.13 mL f.p./kg	0.0026 µL f.p./bee/day	6.67	n.s.	0.00
T3	BSK-FUN 500 SC	0.055 µL f.p./bee	0.27 mL f.p./kg	0.0053 µL f.p./bee/day	6.67	n.s.	0.00
T4	BSK-FUN 500 SC	0.11 µL f.p./bee	0.53 mL f.p./kg	0.011 µL f.p./bee/day	10.00	n.s.	3.57
T5	BSK-FUN 500 SC	0.22 µL f.p./bee	1.18 mL f.p./kg	0.023 µL f.p./bee/day	16.67	n.s.	10.71
T6	BSK-FUN 500 SC	0.40 µL f.p./bee	2.08 mL f.p./kg	0.041 µL f.p./bee/day	46.67	***	42.86
T7	ROGOR L 40 ST	1 mg dimethoate/kg feeding solution			100	***	100

Endpoints	mL test item/Kg feeding solution
LC_{10} [95% confidence intervals]	0.97 [0.55 – 1.25]
LC_{20} [95% confidence intervals]	1.34 [0.97 – 1.75]
LC_{50} [95% confidence intervals]	> 2.08 [95%-CLs n.d.]
NOEC	1.18
LOEC	2.08
Endpoints	**µL test item/bee/day**
LDD_{10} [95% confidence intervals]	0.019 [0.011 – 0.025]
LDD_{20} [95% confidence intervals]	0.027 [0.019 – 0.034]
LDD_{50} [95% confidence intervals]	> 0.041 [95% – CLs n.d.]
NOEDD	0.023
LOEDD	0.041

[a], Cochran-Armitage test and Chi^2 2x2 Table tests (reference item ROGOR L 40 ST), $\alpha \leq 0.001$ ***, 0.01 **, 0.05 *
[b], mean survivors corrected by Abbott's formula
f.p., formulated product; a.i., active ingredient
n.s., not significantly different compared to the control

Table KCP 10.3.1.2-2: Average percentage of young adult bee's mortality at day 10 (dosages on µg a.i./bee – mg a.i./Kg)

Treatment number	Treatment	Application rate (a.i. nominal intake)	Concentration (mg a.i./kg feeding solution)	Concentration (µg a.i./bee/day)	Mortality (%)	p^a	Survivors' correction (%)[b]
T1	Control	Sucrose solution 50% w/v	---	---	6.67	-	-
T2	BSK-FUN 500 SC	13.75 µg a.i./bee	63.75 mg a.i./kg	1.28 µg a.i./bee/day	6.67	n.s.	0.00
T3	BSK-FUN 500 SC	27.50 µg a.i./bee	133.20 mg a.i./kg	2.66 µg a.i./bee/day	6.67	n.s.	0.00
T4	BSK-FUN 500 SC	55 µg a.i./bee	263.35 mg a.i./kg	5.27 µg a.i./bee/day	10.00	n.s.	3.57
T5	BSK-FUN 500 SC	110 µg a.i./bee	578.00 mg a.i./kg	11.56 µg a.i./bee/day	16.67	n.s.	10.71
T6	BSK-FUN 500 SC	200 µg a.i./bee	1027.70 mg a.i./kg	20.55 µg a.i./bee/day	46.67	***	42.86
T7	ROGOR L 40 ST	1 mg dimethoate/kg feeding solution			100	***	100

Endpoints	mg a.i./Kg feeding solution
LC_{10} [95% confidence intervals]	477.38 [273.93 – 616.84]
LC_{20} [95% confidence intervals]	662.59 [481.79 – 864.12]
LC_{50} [95% confidence intervals]	> 1027.70 [95%-CLs n.d.]
NOEC	578.00
LOEC	1027.70
Endpoints	**µg a.i./bee/day**
LDD_{10} [95% confidence intervals]	9.55 [5.48 – 12.34]
LDD_{20} [95% confidence intervals]	13.25 [9.64 – 17.28]
LDD_{50} [95% confidence intervals]	> 20.55 [95%-CLs n.d.]
NOEDD	11.56
LOEDD	20.55

[a], Cochran-Armitage and Chi² 2x2 Table tests (reference item ROGOR L40 ST), α≤0.001 ***, 0.01 **, 0.05 *
[b], mean survivors corrected by Abbott's formula
f.p., formulated product
a.i., active ingredient
n.s., not significantly different compared to the control
95%-CLs n.d., Confidence Limits not determined due to mathematical reasons

At each assessment, before and after feeding the syringes were weighed to determine the total amount ingested for each cage. The mean uptake µg a.i./bee/day and the mean mg a.i./Kg feeding solution over the test period were calculated taking into account the number of alive bees, as well as the feeders' solution evaporation. After 10 days, bees exposed to test item BSK-FUN 500 SC showed a sum uptake of mg a.i./bee/day feeding solution (expressed as sum of the mean values) ranging from 63.75 mg (treatment T2, lowest test item' dosage) to 1027.70 mg a.i./bee/day feeding solution (treatment T6,

highest test item' dosage). Reference item ROGOR L40 ST (treatment T7) showed a value of 0.62 mg a.i./bee/day.
After 10 days of exposure period, the mean uptake µg of a.i./bee (expressed as sum of the mean values) ranged from 12.75 µg (treatment T2, lowest test item' dosage) to 205.54 µg a.i./bee/day (treatment T6, highest test item' dosage). Reference item ROGOR L40 ST (treatment T7) showed a value of 0.12 µg a.i./bee/day.

Test item BSK-FUN 500 SC mean values (expressed as mean of the mean values) ranged from 1.28 to 20.55 µg a.i./bee/day on treatments T2 (1.28 µg a.i./bee/day) and T6 (20.55 µg a.i./bee/day), respectively. Reference item ROGOR L40 ST showed a mean value of 0.030 µg a.i./bee/day.

CONCLUSION

The endpoints are summarized in the tables above.

A 2.3.1.3 KCP 10.3.1.3 Effects on honeybee development and other honey bee life stages

Not relevant. No studies submitted.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 239 of the test were met. **Validity criteria:** **Validity criteria of the study** Mortality in the control group: Cumulative larval mortality from day 3 (D3) to day 8 (D8) was 8.33%, therefore the validity criterion was met. Adult emergence at day 22 (D22) was 87.50%, therefore the validity criterion was met. Mortality in the reference group at day 8 (D8): Larval mortality was 100% at D8. **Deviation of the study:** none **Agreed toxicity endpoints:**

Adults' emergence at day-22

Treatment number	Treatment	Application rate (Nominal intake)	Test item concentration in the larval diet	Adults' emergence rate (%)	p^a	Er (%)[b]
T1	Control	---	---	87.50	-	-
T2	BSK-FUN 500 SC	0.024 µL f.p./larva (11.97 µg a.i./larva)	155.65 µL f.p./Kg of diet (77.82 mg a.i./Kg of diet)	81.25	n.s.	7.14
T3	BSK-FUN 500 SC	0.041 µL f.p./larva (20.35 µg a.i./larva)	264.60 µL f.p./Kg of diet (132.30 mg a.i./Kg of diet)	75.00	n.s.	14.29
T4	BSK-FUN 500 SC	0.069 µL f.p./larva (34.60 µg a.i./larva)	449.83 µL f.p./Kg of diet (224.91 mg a.i./Kg of diet)	70.83	**	19.05
T5	BSK-FUN 500 SC	0.12 µL f.p./larva (58.82 µg a.i./larva)	764.71 µL f.p./Kg of diet (382.35 mg a.i./Kg of diet)	58.33	***	33.33
T6	BSK-FUN 500 SC	0.20 µL f.p./larva (100 µg a.i./larva)	1300 µL f.p./Kg of diet (650 mg a.i./Kg of diet)	29.17	***	66.67
T7	ROGOR L 40 ST	0.018 µL f.p./larva (7.39 µg a.i./larva)	120µL f.p./Kg diet (48 mg a.i./Kg of diet)	0.00	***	100

[a], Cochran-Armitage and Chi^2 2x2 Table tests (reference item ROGOR L 40 ST), α≤0.001 ***, 0.01 **, 0.05 *
[b], Er = emergence % reduction in comparison to the control
-, not applicable
f.p.: formulated product
a.i.: active ingredient
n.s., not significantly different compared to the control

Endpoints for the adults' emergence at day-22

Endpoints	µg a.i./bee	µL test item/bee
ED_{10} [95% confidence intervals]	17.84 [11.22 – 23.61]	0.036 [0.022 – 0.047]
ED_{20} [95% confidence intervals]	29.47 [21.92 – 36.56]	0.059 [0.044 – 0.074]
ED_{50} [95% confidence intervals]	76.99 [61.00 – 109.26]	0.15 [0.12 – 0.22]
NOED	20.35	0.041
LOED	34.60	0.069
Endpoints	**mg a.i./Kg of diet**	**µL test item/Kg of diet**
ED_{10} [95% confidence intervals]	115.97 [72.94 – 153.47]	231.94 [145.88 – 306.94]
ED_{20} [95% confidence intervals]	191.56 [142.52 – 237.63]	383.14 [285.05 – 475.27]
EC_{50} [95% confidence intervals]	500.43 [396.50 – 710.14]	1000.85 [793.00 – 1420.27]
NOEC	132.30	264.60
LOEC	224.91	449.83

a.i.: active ingredient

Reference: KCP 10.3.1.4/01

Report: Effects of BSK-FUN 500 SC on Honeybees (*Apis mellifera* L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure; Mautino G.; 2024; Study Code: 1143.I.SAG23/r;

Guideline(s): Yes, OECD GD 239

Deviations: No

GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027
2. Vehicle and/or positive control:	vehicle: sucrose solution positive control: dimethoate

3. Test organism

Species:	Insecta, Hymenoptera (*Apis mellifera* L.)
Source:	Beekeeper Marco Messa, via della colla 1, Pocapaglia (CN), 12060. Three commercial beehives, queen-right, healthy (disease free) and adequately fed, with normal population of young adult worker individuals (approx. 2 weeks old)
Maintenance:	no chemical substances had been applied to the hive for at least 1 month prior to the start of the study
Bees collection:	at day-1, the combs containing first instar larvae were carried from the hive and immediately transported to SAGEA's laboratory in an insulated container in order to avoid temperature variation then, maintained at ambient temperature; newly hatched larvae were allocated randomly to the plates for each colony
Stage at test start:	first instar larvae
Acclimation period:	-

Diet:	The larval food was composed of the three following diets, adapted to the needs of the larvae at different stages of development: - Diet A (09 Oct 2023) for all the treatments: 50% weight of fresh royal jelly (5.500 g) + 50% weight of an aqueous solution containing 2% weight of yeast extract (0.110 g), 12% weight of glucose (0.660 g), 12% weight of fructose (0.660 g) and 4.070 g of deionized water. - Diet B (11 Oct 2023) for treatment T1 (control group): 50% weight of fresh royal jelly (1.100 g) + 50% weight of an aqueous solution containing 3% weight of yeast extract (0.033 g), 15% weight of glucose (0.165 g), 15% weight of fructose (0.165 g) and 0.737 g of deionized water. - Diet B (11 Oct Aug 2023) for treated group: 50% weight of fresh royal jelly (5.500 g) + 50% weight of an aqueous solution containing 3% weight of yeast extract (0.165 g), 15% weight of glucose (0.825 g), 15% weight of fructose (0.825 g) and 2.635 g of deionized water. - Diet C (12 Oct 2023) for treatment T1 (control group): 50% weight of fresh royal jelly (11.000 g) + 50% weight of an aqueous solution containing 4% weight of yeast extract (0.440 g), 18% weight of glucose (1.980 g), 18% weight of fructose (1.980 g) and 6.600 g of deionized water. - Diet C (12 Oct 2023) for treated group: 50% weight of fresh royal jelly (27.500 g) + 50% weight of an aqueous solution containing 4% weight of yeast extract (1.100 g), 18% weight of glucose (4.950 g), 18% weight of fructose (4.950 g) and 11.050 g of deionized water. After preparation, both containers of diet C has been preserved in fridge well covered with parafilm at 4 °C for two days (min: 3.7 °C; max: 4.3°C).

Test units:	Larvae were reared in crystal polystyrene grafting cells having an internal diameter of 9 mm and a depth of 8 mm. Each cell was placed into a well of a 48 multi-well plate. The top of the grafting cell was maintained at the level of the plate by placing a piece of dental roll. The plates have been sterilized before being used. The well-plates were placed into a hermetic Plexiglas desiccator and kept at a relative humidity of 95.5± 0.1% RH adequate for larvae from D1 to D8. The desiccator was placed into an incubator equipped with a forced air circulation system at 35.07± 0.263°C to equilibrate temperature around the desiccator for the duration of the test. On D8 (pre-pupae stage), the well-plates were transferred into a hermetic Plexiglas desiccator at a relative humidity of 81.1± 0.7% RH adequate for pupae. The container was then placed into an incubator equipped with a forced air circulation system at 34.53 ± 0.074°C. On D15 (pupae stage), each plate was transferred into an emergence box (290 x 230 x 130 mm) with a cover aerated. Emerging bees were fed with syrup/sucrose solution dispensed ad libitum, using feeder. The boxes were transferred into an incubator at 34.79± 0.331°C and at relative humidity of 66.3± 0.9% RH.
4. Environmental conditions:	
Temperature:	D1 – D8: 35.07± 0.263 °C (34.5 – 35.7 °C) D8 – D15: 34.53± 0.074 °C (34.44 – 34.67 °C) D15 – D22: 34.79± 0.331 °C (34.27 – 35.27 °C)
Relative humidity:	D1 – D8: 95.5± 0.1% RH (95.3 – 95.7%) D8 – D15: 81.1 ± 0.7% RH (80.4 – 82.0%) D15 – D22: 66.3± 0.9% RH (65.3 – 67.8%)
Photoperiod:	darkness (except during observation and food replacement)

STUDY DESIGN AND METHOD

Aim of this study was to determine the chronic oral toxicity of the BSK-FUN 500 SC (boscalid 500 g/L) on honeybee larvae (*Apis mellifera* L.) consequently to a repeated exposure under laboratory conditions, providing larvae with food added with the test item. Adults' emergence at day-22 was used as the toxic endpoint. A not-GLP Range finding test was initially performed followed by the Definitive Test. The Definitive Test rates were established taking into consideration the Range finding test results. The study was performed using 5 dosages of the test item in a geometric series, with a spacing factor of 1.7 and covering the range for ED/EC50 values. Larvae were collected from three different colonies, each one representing a replicate. No. 16 larvae per replicate were collected, overall no. 48 per treatment. Test item was compared with a control group and a reference item as recommended in the guideline for an ED/EC50 approach. Reference item was ROGOR L 40 ST (nominally dimethoate 400 g/L) to achieve a

mortality ≥ 50% on day-8 (D8) across all replicates. From day-3 to day-6, test and reference items were dispersed in deionized water and then mixed into the diet, following the OECD DG no. 239 scheme (see Section 9.5), at the suitable concentrations. Larval mortality was recorded at the time of feeding from day-4 to day-8, moreover on day-15 and on day-22 pupal mortality was evaluated and on day-22, the number of emerged adults was counted.

Test design:	16 larvae X 3 colonies = 48 larvae
Exposure time:	22 days
Tested concentrations, definitive test:	Control group as Untreated diet based on the day – T1 0.024 µL test item/larva (11.97 µg a.i.*/larva) – T2 0.041 µL test item/larva (20.35 µg a.i.*/larva) – T3 0.069 µL test item/larva (34.60 µg a.i.*/larva) – T4 0.12 µL test item/larva (58.82 µg a.i.*/larva) – T5 0.20 µL test item/larva (100 µg a.i.*/larva) – T6
Stability of the test compound:	The content of acetamiprid active ingredient was determined in the lowest concentration and in the highest concentration of the water stock solutions prepared in the biological phase of the study.
Dates:	start of the study 20.09.2023 start of the experimental part: 09.10.2023 end of the experimental part: 30.10.2023 end of the study: 20.03.2023
Statistic:	Software used for statistical analysis was “ToxRatPro” Solutions GmbH, version 3.3.0. Mortality data were processed using Cochran-Armitage and Chi2 2x2 Table tests (α≤0.05). At least the ED50/EC50 values were determined for the test item with 95% confidence interval, where possible. The No Observed Effect Dose (NOED) and Lowest Observed Effect Dose (LOED) values for adults’07 emergence rate were calculated, where possible.
Validity of the test:	The following criteria should be satisfied in the control and reference item for a test result to be considered valid: - in the control plate(s), cumulative larval mortality from day-3 to day-8 ≤ 15% across all replicates; - in the control plate(s), the adult emergence rate on day-22 ≥ 70% across all replicates; - Reference item: larval mortality ≥ 50% on day-8 across all replicates.

RESULTS

All study validity criteria were met. The results are summarized in the following table.

From day-3 to day-8, larvae were exposed to the control and treated groups. The diet volume and composition were adapted on a daily basis.

Table KCP 10.3.1.4-1: Number of bee's larvae alive from day-2 to day-8

Treatment no.	Treatment	Application rate (Nominal intake)	Test item concentration in the larval diet	Bee's larvae alive						
				D2	D3	D4	D5	D6	D7	D8
T1	Control	---	---	48	48	48	47	46	46	44
T2	BSK-FUN 500 SC	0.024 µL f.p./larva (11.97 µg a.i./larva)	155.65 µL f.p./Kg of diet (77.82 mg a.i./Kg of diet)	48	48	46	43	41	40	40
T3	BSK-FUN 500 SC	0.041 µL f.p./larva (20.35 µg a.i./larva)	264.60 µL f.p./Kg of diet (132.30 mg a.i./Kg of diet)	48	48	44	42	37	37	37
T4	BSK-FUN 500 SC	0.069 µL f.p./larva (34.60 µg a.i./larva)	449.83 µL f.p./Kg of diet (224.91 mg a.i./Kg of diet)	48	48	45	41	37	36	34
T5	BSK-FUN 500 SC	0.12 µL f.p./larva (58.82 µg a.i./larva)	764.71 µL f.p./Kg of diet (382.35 mg a.i./Kg of diet)	48	48	43	39	34	31	28
T6	BSK-FUN 500 SC	0.20 µL f.p./larva (100 µg a.i./larva)	1300 µL f.p./Kg of diet (650 mg a.i./Kg of diet)	48	48	40	37	29	24	15
T7	ROGOR L 40 ST	0.018 µL f.p./larva (7.39 µg a.i./larva)	120 µL f.p./Kg of diet (48 mg a.i./Kg of diet)	48	48	33	26	0	0	0

D = day
f.p.: formulated product
a.i.: active ingredient

Table KCP 10.3.1.4-2: Cumulative mortality of bee's larvae from day-3 to day-8

Treatment		Application rate (Nominal intake)	Test item concentration in the larval diet	Cumulative %mortality					p^a
				D4	D5	D6	D7	D8	
T1	Control	---	---	0.00	2.08	4.17	4.17	8.33	-
T2	BSK-FUN 500 SC	0.024 µL f.p./larva (11.97 µg a.i./larva)	155.65 µL f.p./Kg of diet (77.82 mg a.i./Kg of diet)	4.17	10.42	14.58	16.67	16.67	n.s.
T3	BSK-FUN 500 SC	0.041 µL f.p./larva (20.35 µg a.i./larva)	264.60 µL f.p./Kg of diet (132.30 mg a.i./Kg of diet)	8.33	12.50	22.92	22.92	22.92	**
T4	BSK-FUN 500 SC	0.069 µL f.p./larva (34.60 µg a.i./larva)	449.83 µL f.p./Kg of diet (224.91 mg a.i./Kg of diet)	6.25	14.58	22.92	25.00	29.17	**
T5	BSK-FUN 500 SC	0.12 µL f.p./larva (58.82 µg a.i./larva)	764.71 µL f.p./Kg of diet (382.35 mg a.i./Kg of diet)	10.42	18.75	29.17	35.42	41.67	***
T6	BSK-FUN 500 SC	0.20 µL f.p./larva (100 µg a.i./larva)	1300 µL f.p./Kg of diet (650 mg a.i./Kg of diet)	16.67	22.92	39.58	50.00	68.75	***
T7	ROGOR L 40 ST	0.018 µL f.p./larva (7.39 µg a.i./larva)	120 µL f.p./Kg of diet (48 mg a.i./Kg of diet)	31.25	45.83	100.00	100.00	100.00	***

D = day
[a], Cochran-Armitage and Chi^2 2x2 Table tests (reference item), α≤0.001 ***, 0.01 **, 0.05 *
-, not applicable
f.p.: formulated product
a.i.: active ingredient
n.s., not significantly different compared to the control

At day-8 (D8), the cumulative mortality ranged from 16.67% to 68.75% on treatments T2 and T6, respectively. Reference item ROGOR L 40 ST and the control group showed a cumulative mortality of 100% and 8.33%, respectively.

Larval mortality was evaluated from day-3 to day-8 after an exposure period of 3 days (from day-3 to day-6). Pupal mortality was calculated in percentage from D8 to D22.

Table KCP 10.3.1.4-3: Percent pupal mortality at day-15 and day-22 from day-8

Treatment		Application rate (Nominal intake)	Test item concentration in the larval diet	% pupae mortality at D15	Corrected mortality at D15	% pupal mortality at D22	p^a	Corrected mortality at D22[b]
T1	Control	---	---	4.44	-	0.00	-	-
T2	BSK-FUN 500 SC	0.024 µL f.p./larva (11.97 µg a.i./larva)	155.65 µL f.p./Kg of diet (77.82 mg a.i./Kg of diet)	2.38	-2.16	0.00	n.s.	0.00
T3	BSK-FUN 500 SC	0.041 µL f.p./larva (20.35 µg a.i./larva)	264.60 µL f.p./Kg of diet (132.30 mg a.i./Kg of diet)	2.56	-1.97	0.00	n.s.	0.00
T4	BSK-FUN 500 SC	0.069 µL f.p./larva (34.60 µg a.i./larva)	449.83 µL f.p./Kg of diet (224.91 mg a.i./Kg of diet)	0.00	-4.65	0.00	n.s.	0.00
T5	BSK-FUN 500 SC	0.12 µL f.p./larva (58.82 µg a.i./larva)	764.71 µL f.p./Kg of diet (382.35 mg a.i./Kg of diet)	0.00	-4.65	0.00	n.s.	0.00
T6	BSK-FUN 500 SC	0.20 µL f.p./larva (100 µg a.i./larva)	1300 µL f.p./Kg of diet (650 mg a.i./Kg of diet)	6.67	2.33	0.00	n.s.	0.00

D = day
[a], Cochran-Armitage and Chi² 2x2 Table tests (reference item), α≤0.001 ***, 0.01 **, 0.05 *
[b], mean mortality corrected by Schneider-Orelli's formula
-, not applicable
-, not applicable
f.p.: formulated product
a.i.: active ingredient
n.s., not significantly different compared to the control

At day-15 (D15), mortality ranged from 2.38% (corrected value: -2.16%) to 6.67 (corrected value: 2.33%) in treatments T2 and T6, respectively. Mortality in the control group corresponds to 4.44%. At day-22, pupal mortality ranged was 0.00% across all replicates.

Adults' emergence and percent reduction in the adults' emergence were evaluated at day-22.

Table KCP 10.3.1.4-4: Adults' emergence at day-22

Treatment		Application rate (Nominal intake)	Test item concentration in the larval diet	Emergence rate (%)	p^a	Er (%)[b]
T1	Control	---	---	87.50	-	-
T2	BSK-FUN 500 SC	0.024 µL f.p./larva (11.97 µg a.i./larva)	155.65 µL f.p./Kg of diet (77.82 mg a.i./Kg of diet)	81.25	n.s.	7.14
T3	BSK-FUN 500 SC	0.041 µL f.p./larva (20.35 µg a.i./larva)	264.60 µL f.p./Kg of diet (132.30 mg a.i./Kg of diet)	75.00	n.s.	14.29
T4	BSK-FUN 500 SC	0.069 µL f.p./larva (34.60 µg a.i./larva)	449.83 µL f.p./Kg of diet (224.91 mg a.i./Kg of diet)	70.83	**	19.05
T5	BSK-FUN 500 SC	0.12 µL f.p./larva (58.82 µg a.i./larva)	764.71 µL f.p./Kg of diet (382.35 mg a.i./Kg of diet)	58.33	***	33.33
T6	BSK-FUN 500 SC	0.20 µL f.p./larva (100 µg a.i./larva)	1300 µL f.p./Kg of diet (650 mg a.i./Kg of diet)	29.17	***	66.67

[a], Cochran-Armitage test, α≤0.001 ***, 0.01 **, 0.05 *
[b], Er = emergence % reduction
-, not applicable
f.p.: formulated product
a.i.: active ingredient
n.s., not significantly different compared to the control

Emergence rate ranged from 29.17% on treatment T6 to 81.25% with treatment T2. Control group showed a value of 87.50%. Percent reduction in emergence (Er%) ranged from 7.14% to 66.67% for treatments T2 and T6, respectively.

CONCLUSION

The effects of BSK-FUN 500 SC on mortality of honey bee larvae are summarized below:

Table KCP 10.3.1.4-5: Endpoints for the adults' emergence at day-22

Endpoints	µg a.i./bee	µL test item/bee
ED_{10} [95% confidence intervals]	17.84 [11.22 – 23.61]	0.036 [0.022 – 0.047]
ED_{20} [95% confidence intervals]	29.47 [21.92 – 36.56]	0.059 [0.044 – 0.074]
ED_{50} [95% confidence intervals]	76.99 [61.00 – 109.26]	0.15 [0.12 – 0.22]
NOED	20.35	0.041
LOED	34.60	0.069
Endpoints	**mg a.i./Kg of diet**	**µL test item/Kg of diet**
ED_{10} [95% confidence intervals]	115.97 [72.94 – 153.47]	231.94 [145.88 – 306.94]
ED_{20} [95% confidence intervals]	191.56 [142.52 – 237.63]	383.14 [285.05 – 475.27]
EC_{50} [95% confidence intervals]	500.43 [396.50 – 710.14]	1000.85 [793.00 – 1420.27]
NOEC	132.30	264.60
LOEC	224.91	449.83

a.i.: active ingredient

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

Not relevant. No studies submitted. The higher tier tests are not considered essential, because existing laboratory data for formulation are used and deemed to be sufficient for evaluation and risk assessment.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Not relevant. No studies submitted. The higher tier tests are not considered essential, because existing laboratory data for formulation are used and deemed to be sufficient for evaluation and risk assessment.

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

Comments of zRMS:	The study is acceptable. The validity criteria according to SETAC; ESCORT I, ESCORT II; IOBC/BART/EPPO of the test were met. **Validity criteria:**

VALIDITY OF THE STUDY

The following validity criteria were met during the experiment [1]:

- mortality of the control group was 2.5% after 48 hours of exposure (criterion: a maximum of 13.0%),
- after 24 hours, mortality of the group treated with the reference item at the rate of 0.12 g/ha was 80.0% (criterion: 75–100%),
- all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
- the mean number of offspring per female in the control group was 13.1 (criterion: a minimum of 5.0 offspring/female),
- all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Deviation of the study: In the GLP study, one temperature deviation occurred: Dimethoate should be stored in the temperature of 5 ± 4ºC according to the information included in the Certificate of Analysis. However on 30.08.2023, between1412–1420, the temperature was above this range, and the highest value was 9.3ºC.

Above deviation did not affect the study results, since validity criteria were met.

Agreed toxicity endpoints:

Test item rate [L/ha]	Mortality (after 48 h)		Test item rate [L/ha]	Fecundity	
	Total [%]	Corrected[a] [%]		Mean number of offspring/ female [no.]	Fecundity reduction [%]
0.0 (control)	2.5	–	0.0 (control)	13.1	–
Test item: BSK-FUN 500 SC					
0.25	2.5	0.000	0.25	11.7	10.204
0.5	5.0	2.564	0.5	12.5	4.592
1.0	5.0	2.564	1.0	11.1	15.306
LR_{50}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]		ER_{50}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]	
LR_{10}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]		ER_{10}	0.549[L/ha] 276.4 [g boscalid/ ha]	
$NOER_{mortality}$	≥ 1.0 [L/ha] ≥ 503.4 [g boscalid/ ha]		$NOER_{fecundity}$	≥ 1.0 [L/ha] ≥ 503.4 [g boscalid/ ha]	
Reference item: dimethoate					
Rate [g/ha]	Total mortality after 24 h [%]		Fecundity		
0.12	80.0		not assessed		

[a]: mortality corrected according to the Abbott formula

Report	A laboratory test for evaluating the effects of BSK FUN 500 SC on the parasitic wasp, *Aphidius rhopalosiphi;* Wiktorek-Smagur A; 2024; Study Code: ETOX-2023-25
Guideline(s):	Yes, SETAC; ESCORT I, ESCORT II; IOBC/BART/EPPO
Deviations:	In the study, one deviation w as occurred 1. Dimethoate should be stored at the temperature 5 ± 4ºC according to the information included in the Certificate of Analysis (Appendix No. 3). However on 30.08.2023, on 14 12 14 20 , the temperature was above this range, and the highest value was 9.3º Above deviation did not affect the study results, because validity criteria were met.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control: vehicle: distilled water
positive control: dimethoate

3. Test organism

Species:	the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez)
Source:	Katz Biotech AG, Baruth, Germany
Age:	imago, up to 48 hours after emergence
Acclimation period:	-
Diet:	1:3 (v/v) solution of honey in water

Test units:	Martality: two glass plates (10.5 x 10.5 cm) fitted with rubbers to a stainless steel frame, on the side walls, there were ten holes covered with fine-gauge mesh providing ventilation for the insects and two holes to introduce the wasps to the test units, later these holes were sealed with cotton bungs soaked with a 1:3(v/v) solution of honey in water used as a source of food, to prevent a build-up of pesticide vapours within the units, air was drawn through using a small pump Reproduction: pots contained approximately 20 seedlings of 7-day-old barley infested with the bird cherry-oat aphid, *Rhopalosiphum padi* (> 100 aphids per pot) were used, for 24-hours oviposition period, there were clear-walled, ventilated plastic cylinder placed above each pot, to provide good ventilation, the apex of each cylinder was covered with fine netting, hole in the cylinder to introduce the wasps to the test units
Plant material:	barley plants (*Hordeum vulgare.* L., Gramineae), 7 days old, the 2nd leaf growth stage, 10–40 plants
Host organism:	bird chery-oat aphid (*Rhopalosiphum padi*)

4. Environmental conditions:

Temperature:	18.7 – 21.4°C
Relative humidity:	61 – 89%
Photoperiod:	2486 lux (mortality) 4486 lux (reproduction) light : dark 16 h:8 h

STUDY DESIGN AND METHOD

The aim of the extended laboratory test was to assess the effects of the test item, BSK FUN 500 SC on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. On the basis of the preliminary test results, it was decided to use three rates of the test item in the main test. These were 0. 25, 0. 5 and 1 .0 L/ha. Adult wasps were exposed to the test item applied to glass plates. Mortality assessments were made 2, 24 and 48 hours after the introduction of the wasps to the test units. Then, all females which survived 48-hour exposure to BSK FUN 500 and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, fifteen female wasps from the groups treated with the test item and the control group were individually introduced into fecundity units containing barley plants infested with the aphid, *Rhopalosiphum padi*. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which wasp pupae were developing) was recorded. Mortality of the wasps after 48 hours of exposure and the percentage of fecundity reduction 12 days after the oviposition were the endpoints. To verify the sensitivity of the wasps and the precision of the test procedure, dimethoate was used as a reference item. The rate of the reference item was 0.12 g/ha. The control group was treated with ultrapure water.

Test design:	four replicates of each study group (10 wasps/replicate)

Exposure time:	mortality phase: 48 hours parasitisation period was 24 hours, all treatment groups were evaluated 12 days after parasitisation
Tested concentrations, definitive test:	0.25, 0.5 and 1.0 L/ha, volume of application was 200 L/ha
Dates:	start of the experimental part: 08.01.2024 end of the experimental part: 26.01.2024
Statistic:	Statistical analysis was performed using ToxRat Proffesional software, version 3.3.0. Significance of differences in mortality between control and groups exposed to the test item was checked using Chi2 2x2 Table Test with Bonferroni Correction, statistical differences at p(z) < Alpha 0.05 were considered significant. Significance of differences in mean number of offspring per female between the control and the groups exposed to the test item was checked using Dunnet's Multiple t-test Procedure, statistical differences at |t|>|t*| were considered significant.
Validity of the test:	The following validity criteria were met during the experiment: − mortality of the control group was 2.5% after 48 hours of exposure (criterion: a maximum of 13.0%), − after 24 hours, mortality of the group treated with the reference item at the rate of 0.12 g/ha was 80.0% (criterion: 75–100%), − all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity), − the mean number of offspring per female in the control group was 13.1 (criterion: a minimum of 5.0 offspring/female), − all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

RESULTS

In the main test, mortality of the control group after 48 hours of exposure was 2.5%. After 48 hours of exposure, the percentages of mortality, corrected according to the formula of Abbott, of the groups treated with test item at the rates of 0.25, 0.5 and 1.0 L/ha were 0.000, 2.564 and 2.564%, respectively. The mortality results, in the main test, during the 48-h exposure period are presented below.

Table KCP 10.3.2.1-1: The effects of BSK-FUN 500 SC on mortality of *Aphidius rhopalosiphi* after 2h

Study group [L/ha]	Number of tested wasps [no.]	Mortality					
		Dead wasps [no.]				Total	
		Replicates					
		I	II	III	IV	[no.]	[%]
Control	40	0	0	0	0	0	0.00
Test item							
0.25	40	0	0	0	0	0	0.00
0.5	40	0	0	0	0	0	0.00
1.0	40	0	0	0	0	0	0.00
Reference item: dimethoate							
0.12 [g/ha]	40	3	2	1	3	9	22.50

Table KCP 10.3.2.1-2: The effects of BSK-FUN 500 SC on mortality of *Aphidius rhopalosiphi* after 24h

Study group [L/ha]	Number of tested wasps [no.]	Mortality					
		Dead wasps [no.]				Total	
		Replicates					
		I	II	III	IV	[no.]	[%]
Control	40	0	0	0	0	0	0.00
Test item							
0.25	40	1	0	0	0	1	2.50
0.5	40	0	0	0	0	0	0.00
1.0	40	0	0	1	0	1	2.50
Reference item: dimethoate							
0.12 [g/ha]	40	6	9	7	10	32	80.00

Table KCP 10.3.2.1-3: The effects of BSK-FUN 500 SC on mortality of *Aphidius rhopalosiphi* after 48h

Study group [L/ha]	Number of tested wasps [no.]	Mortality						
		Dead wasps [no.]				Total		
		Replicates						
		I	II	III	IV	[no.]	[%]	Corrected[a] [%]
Control	40	0	0	1	0	1	2.5	–
Test item								
0.25	40	1	0	0	0	1	2.5	0.000
0.5	40	0	2	0	0	2	5.0	2.564
1.0	40	0	0	2	0	2	5.0	2.564
LR_{50}		> 1.0 [L/ha]				> 503.4 [g boscalid/ ha]		
LR_{10}		> 1.0 [L/ha]				> 503.4 [g boscalid/ ha]		
$NOER_{mortality}$		≥ 1.0 [L/ha]				≥ 503.4 [g boscalid/ ha]		

There were no statistically significant differences in mortality in the groups treated with the test item at all the tested rates, i.e. of 0.25, 0.5 and 1.0 L/ha in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > alpha 0.05).

After 24 hours of exposure to dimethoate at the rate of 0.12 g/ha, the percentage of mortality was 80.0%. Therefore, the validity criterion specified in the method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

In the groups treated with the test item, no repellent effect, as well as no marked difference in the general activity of the test insects (e.g. intense grooming), or their behaviour (e.g. inactivity in comparison to the control group were observed. The general condition of the wasps during the exposure period is presented below.

Table KCP 10.3.2.1-4: Observations of the general condition of *Aphidius rhopalosiphi* after 2h

No. of replicate	Condition of the wasps	Study group				
		Control	BSK-FUN 500 SC			Dimethoate 0.12 [g/ha]
			Application rate [L/ha]			
			0.25	0.5	1.0	
I	living	10	10	10	10	7
	affected	0	0	0	0	0
	moribund	0	0	0	0	0
	dead	0	0	0	0	3
II	living	10	10	10	10	8
	affected	0	0	0	0	0
	moribund	0	0	0	0	0
	dead	0	0	0	0	2
III	living	10	10	10	10	9
	affected	0	0	0	0	0
	moribund	0	0	0	0	0
	dead	0	0	0	0	1
IV	living	10	10	10	10	7
	affected	0	0	0	0	0
	moribund	0	0	0	0	1
	dead	0	0	0	0	2
Repellent effect			–	–	–	–
Difference in activity or behaviour			–	–	–	–

–: no visible change in comparison to the control group
Difference in general activity of wasps:
gr: intense grooming
i: inactivity

Table KCP 10.3.2.1-5: Observations of the general condition of *Aphidius rhopalosiphi* after 24h

No. of replicate	Condition of the wasps	Study group				
		Control	BSK-FUN 500 SC			Dimethoate 0.12 [g/ha]
			Application rate [L/ha]			
			0.25	0.5	1.0	
I	living	10	9	10	10	4
	affected	0	0	0	0	0
	moribund	0	0	0	0	0
	dead	0	1	0	0	6
II	living	10	10	10	10	1
	affected	0	0	0	0	0
	moribund	0	0	0	0	0
	dead	0	0	0	0	9
III	living	10	10	10	9	3
	affected	0	0	0	0	0
	moribund	0	0	0	0	0
	dead	0	0	0	1	7
IV	living	10	10	10	10	0
	affected	0	0	0	0	0
	moribund	0	0	0	0	1
	dead	0	0	0	0	9
Repellent effect			–	–	–	–
Difference in activity or behaviour			–	–	–	–

–: no visible change in comparison to the control group
Difference in general activity of wasps:
gr: intense grooming
i: inactivity

Table KCP 10.3.2.1-6: Observations of the general condition of *Aphidius rhopalosiphi* after 48h

No. of replicate	Condition of the wasps	Study group			
		Control	BSK-FUN 500 SC		
			Application rate [L/ha]		
			0.25	0.5	1.0
I	living	10	9	10	10
	affected	0	0	0	0
	moribund	0	0	0	0
	dead	0	1	0	0
II	living	10	10	8	10
	affected	0	0	0	0
	moribund	0	0	0	0
	dead	0	0	2	0
III	living	9	10	10	8
	affected	0	0	0	0
	moribund	0	0	0	0
	dead	1	0	0	2
IV	living	10	10	10	10
	affected	0	0	0	0
	moribund	0	0	0	0
	dead	0	0	0	0
Repellent effect			–	–	–
Difference in activity or behaviour			–	–	–

–: no visible change in comparison to the control group
Difference in general activity of wasps:
gr: intense grooming
i: inactivity

The fecundity results are presented below. Fecundity of the surviving wasps from the control group and all the groups treated with test item, i.e. at the rates of 0.25, 0.5 and 1.0 L/ha was assessed, since mortality of these groups was < 50.0%. The mean number of offspring (mummies) per female in the control group was 13.1.

Table KCP 10.3.2.1-7: Number of offspring and effects on fecundity of the test item on *Aphidius rhopalosiphi* – main test

Number of replicate	Number of offspring per female [no.]			
	Control	Application rate [L/ha]		
		0.25	0.5	1.0
1	12	12	14	13
2	17	7	10	9
3	16	12	22	18
4	7	10	12	6
5	8	14	13	9
6	15	8	9	10
7	9	5	19	12
8	21	12	15	14
9	18	13	10	19
10	15	22	9	7
11	13	6	15	12
12	6	12	12	14
13	14	10	11	8
14	13	14	7	10
15	12	19	9	5
Mean ± SD	13.1 ± 4.23	11.7 ± 4.56	12.5 ± 4.05	11.1 ± 4.08
Fecundity reduction [%]	–	10.204	4.592	15.306
ER_{50}		> 1.0 [L/ha]	> 503.4 [g boscalid/ ha]	
ER_{10}		0.549 [L/ha]	276.4 [g boscalid/ ha]	
$NOER_{fecundity}$		≥ 1.0 [L/ha]	≥ 503.4 [g boscalid/ ha]	

In the group treated with the test item at the rates of 0.25, 0.5 and 1.0 L/ha the mean number of offspring (i.e. ‘ mummies per female were 11.7, 12.5 and 11.1, respectively. There were no statistically significant differences in mean number of offspring per female between the groups treated with the test item at the rates of 0.25, 0.5 and 1.0 L/ha and the control group (Dunnett’s Multiple t-test Procedure, $|t|<|t^*|$). Fecundity reduction (Pr) in the groups treated with the test item at the rates of 0.25, 0.5 and 1.0 L/ha were 10.204, 4.592 and 15.306%, respectively.

CONCLUSION

On the basis of the obtained mortality results, the LR10 and LR50 values could not be determined. However, it can be concluded that the LR10 and LR50 values are higher than the maximum tested rate 1.0 L/ha, i.e. > 503.4 g boscalid/ha. NOERmortality is higher than or equal to 1.0 L/ha, i.e. ≥ 503.4 g boscalid/ha.

Based on the obtained fecundity results the ER50 value could not be determined. However, it can be assumed that the ER50 value is higher than the maximum tested rate 1.0 L/ha, i.e. > 503.4 g boscalid/ ha. The ER10 value is equal to 0.549 L/ha (i.e. 276.4 g boscalid/ ha). NOERfecundity is higher than or equal to 1.0 L/ha, i.e. ≥ 503.4 g boscalid/ha.

Table KCP 10.3.2.1-8: *Aphidius rhopalosiphi* - mortality and reproduction endpoints

Test item rate [L/ha]	Mortality (after 48 h)		Test item rate [L/ha]	Fecundity	
	Total [%]	Corrected[a] [%]		Mean number of offspring/ female [no.]	Fecundity reduction [%]
0.0 (control)	2.5	–	0.0 (control)	13.1	–
Test item: BSK-FUN 500 SC					
0.25	2.5	0.000	0.25	11.7	10.204
0.5	5.0	2.564	0.5	12.5	4.592
1.0	5.0	2.564	1.0	11.1	15.306
LR_{50}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]		ER_{50}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]	
LR_{10}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]		ER_{10}	0.549[L/ha] 276.4 [g boscalid/ ha]	
$NOER_{mortality}$	≥ 1.0 [L/ha] ≥ 503.4 [g boscalid/ ha]		$NOER_{fecundity}$	≥ 1.0 [L/ha] ≥ 503.4 [g boscalid/ ha]	
Reference item: dimethoate					
Rate [g/ha]	Total mortality after 24 h [%]		Fecundity		
0.12	80.0		not assessed		

Comments of zRMS:	The study is acceptable. The validity criteria according to IOBC, BART, EPPO of the test were met. **Validity criteria:** VALIDITY OF THE STUDY The following validity criteria were met during the experiment [1]: – mortality of the control group was 11.667% on day 7 of exposure (criterion: a maximum of 20%), – mortality of the mites exposed to the reference item at the rate of 4.0 g/ha, was 100.0% on day 7 of exposure (criterion: from 50 to 100%), – the cumulative mean number of eggs per female in the control group was 5.4 (required: ≥ 4 eggs per female). **Deviation of the study:** In the non GLP study, one temperature deviation

occurred:

1. Temperature should meet the requirements specified in the test Method and the Study Plan (25 ± 2ºC), however in the preliminary test, the temperature dropped below this range, and the lowest value was 22.0°Con 23.10.2023.
In the GLP study, one temperature deviation occurred:
1. Dimethoate should be stored in the temperature 5 ± 4ºC according to the information included in the Certificate of Analysis. However on 30.08.2023, on 1412–1420, the temperature was above this range, and the highest value was 9.3ºCand on 11.01.2024 at 1300the temperature ranged 9.1ºC.

Above deviation did not affect the study results, since validity criteria were met.

Agreed toxicity endpoints:

Test item rate [L/ha]	Mortality (dead + escaped mites) Total [%]	Mortality (dead + escaped mites) Corrected* [%]	Test item rate [L/ha]	Reproduction Mean reproduction rate (Rr) [no.]	Reproduction Reproduction reduction (Pr) [%]
control	11.667	–	control	5.4	–
0.25	16.667	5.660	0.25	5.3	1.443
0.5	20.000	9.434	0.5	5.1	4.925
1.0	23.333	13.208	1.0	4.6	15.004
LR_{50}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]		ER_{50}	> 1.0 [L/ha] > 503.4 [g boscalid/ ha]	
LR_{10}	0.59 [L/ha] 297.0 [g boscalid/ ha]		ER_{10}	0.76 [L/ha] 382.6 [g boscalid/ ha]	
$NOER_{mortality}$	≥ 1.0 [L/ha] ≥ 503.4 [g boscalid/ ha]		$NOER_{reproduction}$	≥ 1.0 [L/ha] ≥ 503.4 [g boscalid/ ha]	
Reference item: dimethoate					
Rate [g/ha]	Total [%]	Corrected* [%]	Reproduction		
4.0	100.000	100.000	not assessed		

*: mortality corrected according to the Abbott formula

Reference: KCP 10.3.2.1/02

Report: Laboratory residual contact test with the predatory mite *Typhlodromus pyri* for regulatory testing of BSK-FUN 500 SC
Kulec-Płoszczyca E; 2024; Study Code: ETOX-2023-24

Guideline(s): Yes, IOBC, BART, EPPO

Deviations: In this study, temperature deviation was occurred:
Temperature should meet the requirements specified in the test Method and the Study Plan (25 2ºC), however in the preliminary test the temperature dropped below this range, and the lowest value was 22. 0 °C on 23.10.2023
The study was performed in compliance with the principl es of Good Laboratory Practice
In the study, a deviation was occurred, concerning reference item storage temperature:

	1. Dimethoate should be stored in the temperature 5 ± 4ºC according to the information included in the Certificate of Analysis. However on 30.08.2023, between 14 12 14 20 the temperature was above this range, and the highest value was 9.3ºC and on 11.01.2024 at 13 00 the temperature ranged 9.1ºC Above deviations did not affect the study results, because validity criteria were met.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control:	vehicle: deionised water positive control: dimetholate

3. Test organism

Species:	the predatory mite, *Typhlodromus pyri Scheuten* (Acari: *Phytoseiidae*)
Source:	Katz Biotech AG, Baruth, Germany
Age:	24-hour-old protonymphs
Acclimation period:	-
Diet:	pine pollen (*Pinus* sp.)
Test units:	plastic discs (ø 45 mm) floating on the water surface in Petri dishes ('island dishes', ø 54 mm) with central holes at the bottom (ø 6 mm)

4. Environmental conditions:

Temperature:	23.0 – 26.4°C
Relative humidity:	60.0 – 83.6%
Photoperiod:	light intensity: 864.2 lux

STUDY DESIGN AND METHOD

The aim of the extended laboratory test was to assess the effects of the test item, BSK FUN 500 SC on mortality and reproduction of the predatory mite, *Typhlodromus pyri* On the basis of the preliminary test results, it was decided to use three rates of the test item in the main test. These were 0. 25, 0. 5 and 1 .0 L/ha. The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to plastic discs. The mites were fed with pine pollen (Pinus sp.). Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and groups treated with the test item at all the test rates, i.e. 0. 25, 0.5 and 1 .0 L/ha, were made after 9, 11, and 14 days of the treatment. Mortality of *T. pyri* after 7 days of the treatment, the mean reproduction rate (Rr) after 14 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints. To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, dimethoate was used as a reference item. The rate of the reference item was 4.0 g/ha. The control group was treated with ultrapure water.

Test design:	three replicates of each study group (20 mites/replicate)
Exposure time:	14 days (7 days of mortality phase + 7 days of fecundity test)
Tested concentrations, definitive test:	0. 25, 0.5 and 1 .0 L/ha, 200 L water/ha
Dates:	start of the experimental part: 15.01.2024 end of the experimental part: 31.01.2024
Statistic:	Statistical analysis was performed using ToxRat Proffesional software, version 3.3.0. Significance of differences in mortality assessment was checked using Chi2 2x2 Table Test with Bonferroni Correction, statistical differences at p(z) < Alpha 0.05 were considered significant. Significance of differences in reproduction assessment was checked using Williams Multiple Sequential t-test Procedure, statistical differences at |t|>|t*| were considered significant.

RESULTS

In the main test, mortality of the control group after 7 days of exposure was 11.667%. After 7 days of exposure to BSK-FUN 500 SC at rates of 0.2 5 , 5 and 1 .0 L/ha ha, the percentages of mortality corrected according to the Abbott’s formula, were 5.660, 9.434 and 13.208%, respectively.

Table KCP 10.3.2.1-9: BSK-FUN 500 SC - Mortality of *Typhlodromus pyri*

Test item rate [L/ha]	Mortality (dead + escaped mites)		Test item rate [L/ha]	Reproduction	
	Total [%]	Corrected[a] [%]		Mean reproduction rate (Rr) [no.]	Reproduction reduction (Pr) [%]
control	11.667	–	**control**	5.4	–
0.25	16.667	**5.660**	**0.25**	5.3	**1.443**
0.5	20.000	**9.434**	**0.5**	5.1	**4.925**
1.0	23.333	**13.208**	**1.0**	4.6	**15.004**
LR_{50}	**> 1.0 [L/ha]** > 503.4 [g boscalid/ ha]		**ER_{50}**	**> 1.0 [L/ha]** > 503.4 [g boscalid/ ha]	
LR_{10}	**0.59 [L/ha]** 297.0 [g boscalid/ ha]		**ER_{10}**	**0.76 [L/ha]** 382.6 [g boscalid/ ha]	
$NOER_{mortality}$	**≥ 1.0 [L/ha]** ≥ 503.4 [g boscalid/ ha]		**$NOER_{reproduction}$**	**≥ 1.0 [L/ha]** ≥ 503.4 [g boscalid/ ha]	
Reference item: dimethoate					
Rate [g/ha]	**Total [%]**	**Corrected[a] [%]**	**Reproduction**		
4.0	100.000	**100.000**	not assessed		

[a]: mortality corrected according to the Abbott formula

There were no statistically significant differences in mortality the group treated with the test item at the rates of 0.25, 0.5 and 1.0 L/ha in comparison to the control group (Chi2 2x2 Table Test with Bonferroni Correction, p(z) > alpha 0.05).

After 7 days of exposure to dimethoate at the rate of 4.0 g/ha, the percentage of Abbott's corrected mortality was 100.0%. Therefore, the validity criterion specified in the method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

In the main test, there were 6.667% escaped mites observed the control group. The percentages of escaped mites at the rates of 0.25, 0.5 and 1.0 L/ha were 8.333%. From the obtained results, the LR50 and NOER values for escape could not be determined. In regard to the mites that escaped during the study, no statistically significant difference was found in the tested rates.

Reproduction of the surviving mites from the control group and all the groups treated with test item, i.e. at the rates of 0.25, 0.5 and 1.0 L/ha was assessed, since mortality of these groups was < 50.0%. The mean reproduction rate (Rr), i.e. cumulative number of offspring per female in the control group was 5.4 offspring/female. The mean reproduction rates (Rr) after 14 days of exposure to test item at the rates of

0.25, 0.5, and 1.0 L/ha were 5.3, 5.1 and 4.6 offspring/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.25, 0.5, and 1.0 L/ha were 1.443, 4.925 and 15.004%, respectively.

Table KCP 10.3.2.1-10: BSK-FUN 500 SC - Reproduction of *Typhlodromus pyri*

Study group [L/ha]	Replicate	Number of	Observation period DAT 9	DAT 11	DAT 14	RrX	Rr	Pr [%]
Control 0.0	I	Eggs	6	18	19	5.3	5.4	–
		Larvae	0	2	3			
		Males	11	10	10			
		Females	9	9	9			
	II	Eggs	4	14	20	5.2		
		Larvae	0	0	0			
		Males	8	8	7			
		Females	8	7	7			
	III	Eggs	5	15	17	5.6		
		Larvae	0	0	0			
		Males	9	8	8			
		Females	8	6	6			
0.25	I	Eggs	4	8	13	4.8	5.3	1.443
		Larvae	0	0	0			
		Males	8	8	8			
		Females	7	5	4			
	II	Eggs	5	9	15	7.5		
		Larvae	0	0	1			
		Males	12	11	10			
		Females	4	4	4			
	III	Eggs	3	7	12	3.6		
		Larvae	0	0	0			
		Males	10	10	9			
		Females	6	6	6			
0.5	I	Eggs	3	9	11	4.4	5.1	4.925
		Larvae	0	0	0			
		Males	10	10	8			
		Females	7	5	4			
	II	Eggs	4	12	18	5.7		
		Larvae	0	1	1			
		Males	8	8	7			
		Female	7	6	6			
	III	Eggs	2	8	19	5.2		
		Larvae	0	0	1			
		Males	9	9	8			
		Females	6	6	5			

Study group [L/ha]	Replicate	Number of	Observation period DAT 9	DAT 11	DAT 14	RrX	Rr	Pr [%]
1.0	I	Eggs	1	6	9	3.4	4.6	15.004
		Larvae	0	0	2			
		Males	8	7	6			
		Females	6	5	5			
	II	Eggs	2	2	10	7.0		
		Larvae	0	0	0			
		Males	12	12	12			
		Females	2	2	2			
	III	Eggs	1	5	12	3.3		
		Larvae	0	0	0			
		Males	10	9	9			
		Females	7	6	4			
ER_{50}		**> 1.0 [L/ha]**				> 503.4 [g boscalid/ ha]		
ER_{10}		**0.76 [L/ha]**				382.6 [g boscalid/ ha]		
$NOER_{reproduction}$		**≥ 1.0 [L/ha]**				≥ 503.4 [g boscalid/ ha]		

DAT: days after treatment
RrX: the reproduction rate for each replicate (X) of a given study group after 14 days, calculated according to equation no. 2 (section. 5.2)
Rr: the mean reproduction rate after 14 days
Pr: the percentage of reproduction reduction calculated according to equation no. 3 (section. 5.2.)

There was no statistically significant difference in reproduction between the group treated with the test item at the rates of 0.25, 0.5, and 1.0 L/ha and the control group (Williams Multiple Sequential t-test Procedure, |t|<|t*|).

CONCLUSION

Based on the obtained mortality results, the LR50 value could not be determined. However, it can be assumed that the LR50 value is higher than the maximum tested rate, i.e. > 1.0 L/ha, i.e. > 503.4 g boscalid/ ha. LR10 value is equal to 0.59 L/ha, i.e. 297.0 g boscalid/ ha. NOER mortality is higher than or equal to 1.0 L/ha, i.e. ≥ 503.4 g boscalid/ha.

Based on the obtained reproduction results, the ER50 value could not be determined. However, it can be assumed that the ER50 value is higher than the maximum tested rate, i.e. > 1.0 L/ha, i.e. > 503.4 g boscalid/ ha. ER10 value is equal to 0.76 L/ha, i.e. 382.6 g boscalid/ ha. NOERreproduction is higher than or equal to 1.0 L/ha, i.e. ≥ 503.4 g boscalid/ha.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Not relevant. No studies submitted. The higher tier tests are not considered essential, because existing laboratory data for formulation are used and deemed to be sufficient for evaluation and risk assessment.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 222 of the test were met. **Validity criteria:** **VALIDITY OF THE STUDY** The following validity criteria were met during the experiment in the control group. – There was no mortality of adult worms over initial 28 days of the experiment (criterion: it have not to exceed 10%). – The lowest number of offspring produced in replicate was 38 (criterion: a minimum of 30 offspring are produced in each replicate containing 10 adults). – The coefficient of variation of reproduction was equal to 28.859% (criterion: it should not exceed 30%). Thus the study is considered valid. **Deviation of the study:** **DEVIATIONS IN THE STUDY** One deviation from OECD Guideline No. 222 occurred: – earthworms were humanely euthanized by freezing at about - 20°C, instead of -80°C, as it is stated in OECD 222 Guideline. No other deviations from OECD Guideline No. 222 (2016), Study Plan and the SOPs occurred. Above deviation did not affect the study results. Above deviation did not affect the study results, since validity criteria were met. **Agreed toxicity endpoints:**

Endpoints values based on the nominal test item concentrations

Endpoints based on the nominal test item concentration [mg test item/kg dry soil]					
Mortality of adult earthworms		Weight of adult earthworms at the end of experiment		Number of juveniles at the end of experiment	
LC_{10}	> 1000	EC_{10}	238.93 (103.57 – 375.60)	EC_{10}	60.55 (28.23 – 84.05)
LC_{20}	> 1000	EC_{20}	1094.63 (655.58 – 3720.82)	EC_{20}	81.97 (47.53 – 106.20)
LC_{50}	> 1000	EC_{50}	> 1000	EC_{50}	146.32 (114.95 – 186.20)
NOEC	≥ 1000	NOEC	59.60	NOEC	59.60
LOEC	> 1000	LOEC	95.37	LOEC	95.37

Table 10. Endpoints values based on the nominal active substance concentrations

Endpoints based on the nominal active substance concentration [mg boscalid/kg dry soil]					
Mortality of adult earthworms		Weight of adult earthworms at the end of experiment		Number of juveniles at the end of experiment	
LC_{10}	> 428.79	EC_{10}	102.45 (44.41 – 161.05)	EC_{10}	25.96 (12.10 – 36.04)
LC_{20}	> 428.79	EC_{20}	469.37 (281.11 – 1595.45)	EC_{20}	35.15 (20.38 – 45.54)
LC_{50}	> 428.79	EC_{50}	> 428.79	EC_{50}	62.74 (49.29 – 79.84)
NOEC	≥ 428.79	NOEC	25.56	NOEC	25.56
LOEC	> 428.79	LOEC	40.89	LOEC	40.89

Chemical analysis:

The recovery of boscalid in the sample collected at exposure initiation (Day 0) was between 88.3 – 104.0% of the nominal concentrations. The results confirmed correct preparation of the concentrations.
The recovery of boscalid in the sample collected on Day 28 was between 71.7 – 94.6% of the nominal concentrations.
The recovery of boscalid in the sample collected at the end of the exposure (Day 56) was between 63.2 – 85.6% of the nominal concentrations.

The study for formulation of **BSK-FUN 500 SC** for earthworms with risk assessment was accepted by zRMS only provisionally. The toxicity endpoints were based on nominal concentration. At the end on the studies concentration of substances active – boscalid fell under 80% of nominal. The TWA or geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. Please complete the calculation the toxicity endpoints based on geometric mean measured concentration.

It should be considered at MSs level.

Updated December 2024

	The Applicant provided the new calculation the toxicity endpoints for earthworms study based on geometric mean measured concentration. The calculation was accepted by zRMS. The risk assessment for earthworms was updated by Applicant. Risk assessment based new calculation was accepted by zRMS. The long-term TER values for active substance and **BOSKALID 500 SC** are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011. **No additional action required.** **It should be considered at MSs level.**

Reference:	KCP 10.4.1.1/01
Report	Earthworm Reproduction Test (Eisenia andrei); Wesołowska K; 2024; Study Code: ETOX-2023-26 STUDY REPORT AMENDMENT No. 1 Earthworm Reproduction Test (Eisenia andrei); Wesołowska K; 2024; Study Code: ETOX-2023-26
Guideline(s):	Yes, OECD 222
Deviations:	earthworms were humanely euthanized by freezing at about - 20°C, instead of -80°C, as it is stated in OECD 222 Guideline
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	SC (boscalid 500 g/L)
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control: vehicle: deionized water
positive control: carbendazim

3. Test organism

Species:	earthworm *Eisenia andrei*
Source:	Havelwurm Wurmkultur Brielower Landstrasse, 32b, 14772 Brandenburg
Age:	3 months and didn't differ in age by more than 4 weeks
Body weight:	-

Acclimation period:	44 hours pre-test acclimatisation in polypropylene vessel containing prepared artificial soil substrate adjusted to a moisture content similar to one used in the study was made. Pre-test acclimatisation was carried out in an environmental room temperature at 19.6 - 20.4°C with a 16 hours light/8 hours dark photoperiod. The earthworms were fed with oatmeal.
Diet:	oatmeal
Test units:	test vessels used in the study were made of polypropylene with a lid that was permeable to air and light, size of each test vessel was 12 cm x 16 cm x 10 cm and capacity equal to 1.9 L, cross-sectional area was equal to 192 cm2 and the filling of artificial soil was equal to 550 g dry weight of artificial soil per test vessels

4. Environmental conditions:

Temperature:	19.5 – 20.9°C
Soil:	artificial soil substate (OECD Guideline No. 222) with 10% sphagnum peat
pH:	5.90 – 6.02 (Day 0) 5.14 – 5.40 (Day 56)
Soil moisture content:	28.86 – 29.98 % (Day 0) 28.09 – 30.77 % (Day 56) 50.10 – 52.06 % WHCmax (Day 0) 48.77 – 53.41% WHCmax (Day 56)
Photoperiod:	light-dark cycle: 16h : 8h, 463.5 – 493.1 lux

STUDY DESIGN AND METHOD

The study aimed at evaluating the effect of BSK-FUN 500 SC on to the reproduction of the earthworms (*Eisenia andrei*) in an artificial soil substate for 56 days. Adult earthworms were exposed to the test item for the first 28 days of the experiment. On Day 28 worms were removed from the test vessels to be examined for signs of toxicity and mortality. The soil and cocoons were returned to test vessels for an additional 28 days to determine the number of juveniles produced in each replicate by the end of the experiment on Day 56. Each treatment was divided into four replicates and control was divided into eight replicates.
Observations of burrowing behaviour were conducted at the beginning of the experiment. Mortality, behavioural and morphological changes were assessed after 28 days of exposure. The number of juveniles were determined at the end of the experiment, on Day 56.

Test design:	control in 8 replicates with 10 earthworms for each replication; tested concentrations in 4 replicates with 10 earthworms for each replication
Exposure time:	56 days

Tested concentrations, definitive test:	37.25, 59.60, 95.37, 152.6, 244.1, 390.6, 625.0 and 1000 mg test item/kg dry soil
Dates:	start of the experimental part: 05.01.2024 end of the experimental part: 08.03.2024
Statistic:	Shapiro-Wilk's Test on Normal Distribution or Levene's Test (with Residuals), Step-down Jonckheere-Terpstra Test Procedure, Williams Multiple Sequential t-test Procedure
Validity of the test:	The following validity criteria were met during the experiment in the control group. − there was no mortality of adult worms over initial 28 days of the experiment (criterion: it have not to exceed 10%), − the lowest number of offspring produced in replicate was 38 (criterion: a minimum of 30 offspring are produced in each replicate containing 10 adults), − the coefficient of variation of reproduction was equal to 28.859% (criterion: it should not exceed 30%). Thus the study is considered valid.
Stability of test compound:	In order to verify the nominal test item concentration, the analytical measurements of the artificial soil treated with the test item at the concentrations 1000, 152.6 and 37.25 mg test item/kg dry soil and the control was provided. Analytical measurements were performed at the beginning (D0), after 28 days of the experiment (Day 28) and at the end of the test (Day 56).

RESULTS

After 28 days of exposure to test item, there was no mortality observed in both control and treatment groups. All alive adult earthworms in the control group and treatment groups were normal in appearance and behaviour on Day 28, during the examination. Earthworms in both, the control and treatment groups, exhibited no aversion to the soil at the beginning of the experiment.
After 28-day exposure period, the mean body weights changes of the survived adult worms in the control and treatment groups were between 1.87 and 17.81%.
The mean number of juveniles in the control and treatment groups were between 3.25 and 50.50. The mean numbers of juveniles in treatment groups: 95.37, 152.6, 244.1, 390.6, 625.0 and 1000 mg test item/kg dry soil, were significantly different when compared to the mean value of control group. The EC50, LC50 and NOEC values determined on the basis of number of juveniles at the end of experiment, mortality of adult earthworms and weight of adult earthworms at the end of experiment expressed as mg of test item/kg dry soil are given below.

Table KCP 10.4.1.1-1: Earthworm reproduction test – final results

Endpoints based on the nominal test item concentration [mg test item/kg dry soil]	
Number of juveniles at the end of experiment	
EC_{50}	146.32 (114.95 – 186.20)
NOEC	59.60
Mortality of adult earthworms	
LC_{50}	≥ 1000
NOEC	≥ 1000
Weight of adult earthworms at the end of experiment	
EC_{50}	≥ 1000
NOEC	59.60

Table KCP 10.4.1.1-2: Earthworm reproduction test – final results, active substance

Endpoints based on the geometric mean concentrations for boscalid [mg boscalid/kg dry soil]	
Number of juveniles at the end of experiment	
EC_{50}	63.83
NOEC	11.75
Mortality of adult earthworms	
LC_{50}	> 404.96
NOEC	≥ 404.96
Weight of adult earthworms at the end of experiment	
EC_{50}	> 404.96
NOEC	51.90

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant. No studies submitted. The higher tier tests are not considered essential, because existing laboratory data for formulation are used and deemed to be sufficient for evaluation and risk assessment.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Not relevant. No studies submitted. The toxicity studies with additional soil organisms are not considered essential, because existing laboratory data for earthworms and arthropods are used and deemed to be sufficient for evaluation and risk assessment.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Not relevant. No studies submitted. The higher tier tests are not considered essential, because existing laboratory data for formulation are used and deemed to be sufficient for evaluation and risk assessment.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:

The study is acceptable. The validity criteria according to OECD 216 of the test were met.

Validity criteria:

VALIDITY OF THE STUDY

The coefficients of variation (CV) of nitrate concentration in the control group were: 11.8; 1.1; 3.4 and 1.5%, after 0, 7, 14 and 28 days of incubation respectively (data obtained from statistical analysis performed in ToxRat – Appendix No. 5). The validity criterion was met, because the variation between replicate control samples was less than ± 15%.

Deviation of the study:

In the study, one deviation was occurred. According to the study plan, the study should be completed in December 2023, however, it was completed of January, 2024.

Above deviation did not affect the study results, since validity criteria were met.

Agreed toxicity endpoints:

Nitrate formation rate [mg nitrate/kg dry weight of soil/day] for selected time intervals.*

Interval of sampling days (X-Y)	Control				PEC 2.0 mg of the test item/kg dry weight of soil (0.86 mg of boscalid /kg dry weight of soil)				Upper PEC 10.0 mg of the test item/kg of soil (4.29 mg of boscalid /kg dry weight of soil)			
	Replicate 1	Replicate 2	Replicate 3	Mean ± SD	Replicate 1	Replicate 2	Replicate 3	Mean ± SD	Replicate 1	Replicate 2	Replicate 3	Mean ± SD
0-7[2,3]	5.284	5.498	5.215	**5.332 ± 0.148**	6.096	5.379	5.523	**5.666 ± 0.379**	5.240	6.739	6.666	**6.215 ± 0.845**
0-14[2]	3.179	3.499	3.000	**3.226 ± 0.253**	3.262	3.476	3.724	**3.488 ± 0.231**	3.083	3.084	2.976	**3.048 ± 0.062**
0-28[2]	1.625	1.518	1.588	**1.577 ± 0.054**	1.737	1.648	1.720	**1.702 ± 0.047**	1.328	1.595	1.541	**1.488 ± 0.141**
7-14[3]	1.026	1.666	0.667	**1.120 ± 0.506**	0.859	1.287	1.783	**1.310 ± 0.4624**	-0.049	-0.046	-0.263	**-0.120[+] ± 0.124**
14-28[3]	0.025	-0.190	-0.049	**-0.071 ± 0.109**	-0.013	-0.192	-0.047	**-0.084 ± 0.095**	-0.393	0.142	0.035	**-0.072 ± 0.283**

*Nitrate formation rates were calculated as follows: $\frac{\text{Concentration of nitrate on day Y} - \text{Average concentration of nitrate on day X}}{Y \text{ days}}$ [mg/kg dry weight of soil/day]

[+] statistically significant differences in nitrate concentrations between the control soil and the soil treated with the test item (STUDENT-t test for homogeneous variances. two-side

[2] Mean, SD based on the data obtained from ToxRat statistical analysis (Appendix No. 5)
[3] Mean, SD based on the data obtained from ToxRat statistical analysis (Appendix No. 6)

Deviations from the control based on nitrate formation rate for selected time intervals [%]

Day of incubation	PEC 2.0 mg of the test item/kg dry weight of soil (0.86 mg of boscalid /kg dry weight of soil))	Upper PEC 10.0 mg of the test item/kg of soil (4.29 mg of boscalid /kg dry weight of soil)
0-7d[2,3]	-6.3	-16.6
0-14d[2]	-8.1	5.5
0-28d[2]	-7.9	5.6
7-14d[3]	-17.0	110.7
14-28d[3]	-17.8	-0.9

"-" higher formation rate of nitrate as compared to control

[2] Mean, SD based on the data obtained from ToxRat statistical analysis (Appendix No. 5)
[3] Mean, SD based on the data obtained from ToxRat statistical analysis (Appendix No. 6)

Reference:	KCP 10.5/01
Report	Soil Microorganisms: Nitrogen Transformation Test; Szlauer S; 2024; Study Code: ETOX-2023-27
Guideline(s):	Yes, OECD 216
Deviations:	In the study, one deviations were occurred: 1. According to the study plan, the study should be completed in December 2023, however, it was completed of January, 2024. Above deviations did not affect the study results, because validity criteria were met.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027

2. Vehicle and/or positive control: vehicle: deionized water
positive control: not relevant

3. Test organism

Soil:	soil type 5M, batch number: 5M 4023
Source:	purchased from LUFA Speyer Obere Langgasse 40, 67346 Speyer, collected on 06.10.2023, sampling depth was ca. 20 cm, sampling site, owned by Sigrid Mossmann, Mechtersheim, was "In der Speyer Hohl", No. 977, in Germany/Rheinland Pflatz/Mechtersheim (Counry/ State/ Community), WGS 84: Lat 49.272035, Long 8.404384, the sampling site during the sampling and in former years (2019 – 2023) was a meadow, there was no organic fertilization and pesticides use at the sampling site in neither sampling year (2023) nor former years (2019 – 2022), the soil was manually cleared of large objects, e.g. stones, parts of plants, etc. and sieved through a 2 mm sieve, after delivery of the soil to the Test Facility, it was taken for preincubation
,Soil preparation:	soil was preincubated for 12 days at temperature: 19.43 – 20.4ºC in darkness, the soil moisture content during preincubation was 43.25% of the maximum water holding capacity, after preincubation, a laboratory soil sample weighing 5.4 kg was prepared
Stability of the compound:	-
Test units:	test containers was covered with perforated polyethylene foil

4. Environmental conditions:

Temperature:	19.43 – 20.40°C
pH	7.33
Organic carbon content:	0.97 ± 0.21%
Microbial biomass:	4.78%
Soil moisture:	42.63 to 45.93% of the maximum water holding capacity
Photoperiod:	dark

STUDY DESIGN AND METHOD

The study aimed at possible detecting long term adverse effects of the test item, BSK FUN 500 SC on the process of nitrogen transformation in aerobic surface soils. Agricultural soil, cleared of large objects (e.g. rocks) and sieved to particles of 2 mm was used. Two concentrations of the test item were used. They were defined as PEC 2.0 mg of the test item/kg dry weight of soil (0.86 mg of boscalid/kg dry weight of soil) and upper PEC (5xPEC) 10.0 mg of the test item/kg of soil (4.29 mg of boscalid/kg dry weight of soil). The soil was divided into three portions two treated portions and control soil; each of them was divided into three replicates. On day 0, 7, 14 and 28 of experiment soil samples from each test vessel were collected and soil extracts with 0.1M KCl were prepared. In particle free soil extracts quantities of nitrate were determined. The method was based on spectrophotometrical measurement. The nitrate formation rate in each treated group was compared to that in the control and the percent deviation of the

treated from the control was calculated.

Test design:	concentrations and control in 3 replicates
Exposure time:	28 days
Tested concentrations, definitive test:	1×PEC – 2 mg test item/kg soil (0.86 mg as/kg soil), 5×PEC – 10 mg test item/kg soil (4.29 mg as/kg soil)
Dates:	start of the experimental part: 30.10.2023 end of the experimental part: 06.12.2023
Statistic:	ToxRat Professional (version 3.3.0) computer software: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity STUDENT-t test for Homogeneous Variances
Validity of the test:	The coefficients of variation (CV) of nitrate concentration in the control group were: 11.8; 1.1; 3.4 and 1.5%, after 0, 7, 14 and 28 days of incubation respectively (data obtained from statistical analysis performed in ToxRat). The validity criterion was met, because the variation between replicate control samples was less than ± 15%.

RESULTS

The aim of this study was to detect long-term adverse effects of the test item BSK-FUN 500 SC on the process of nitrogen transformation in aerobic surface soils. The difference in the nitrate formation rate between control soil and treated soils did not exceed 25% on 28 day of analysis. The endpoints were calculated based on the time intervals 0 – 7, 0 – 14, 0 – 28 and 7 – 14, 14 – 28 days. On the basis of the results, it was found that BSK-FUN 500 SC at the concentrations defined as PEC – 2.0 mg of the test item/kg dry weight of soil (0.86 mg of boscalid/kg dry weight of soil) and upper PEC – 10.0 mg of the test item/kg of soil (4.29 mg of boscalid/kg dry weight of soil) can be evaluated as having no long-term influence on nitrogen transformation in soils. The table below summarizes the results of the study on the last day of the experiment, i.e. day 28, based on the results obtained from the ToxRat statistical analysis.

Table KCP 10.5.-1: Nitrogen transformation (deviation from the control) – final results

Interval of sampling days (X-Y)	Control				PEC 2.0 mg of the test item/kg dry weight of soil (0.86 mg of boscalid /kg dry weight of soil)				Upper PEC 10.0 mg of the test item/kg of soil (4.29 mg of boscalid /kg dry weight of soil)			
	Replicate 1	Replicate 2	Replicate 3	Mean ± SD	Replicate 1	Replicate 2	Replicate 3	Mean ± SD	Replicate 1	Replicate 2	Replicate 3	Mean ± SD
0-7[2,3]	5.284	5.498	5.215	**5.332 ± 0.148**	6.096	5.379	5.523	**5.666 ± 0.379**	5.240	6.739	6.666	**6.215 ± 0.845**
0-14[2]	3.179	3.499	3.000	**3.226 ± 0.253**	3.262	3.476	3.724	**3.488 ± 0.231**	3.083	3.084	2.976	**3.048 ± 0.062**
0-28[2]	1.625	1.518	1.588	**1.577 ± 0.054**	1.737	1.648	1.720	**1.702 ± 0.047**	1.328	1.595	1.541	**1.488 ± 0.141**
7-14[3]	1.026	1.666	0.667	**1.120 ± 0.506**	0.859	1.287	1.783	**1.310 ± 0.4624**	-0.049	-0.046	-0.263	**-0.120[+] ± 0.124**
14-28[3]	0.025	-0.190	-0.049	**-0.071 ± 0.109**	-0.013	-0.192	-0.047	**-0.084 ± 0.095**	-0.393	0.142	0.035	**-0.072 ± 0.283**

CONCLUSION

Based on the experiment results, it can be concluded that the test item, BSK-FUN 500 SC does not have a long-term influence on nitrogen transformation in soil microorganisms.

Table KCP 10.5.-2: Nitrogen transformation (deviation from the control) – final results

Day of incubation	PEC 2.0 mg of the test item/kg dry weight of soil (0.86 mg of boscalid /kg dry weight of soil))	Upper PEC 10.0 mg of the test item/kg of soil (4.29 mg of boscalid /kg dry weight of soil)
0-7d[2,3]	-6.3	-16.6
0-14d[2]	-8.1	5.5
0-28d[2]	-7.9	5.6
7-14d[3]	-17.0	110.7
14-28d[3]	-17.8	-0.9

"-" higher formation rate of nitrate as compared to control

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 208 of the test were met. **Validity criteria:** The following validity criteria were met: 1. The seedling emergence in control group (validity criterion: at least 70%) was as follows: 95.24% cabbage, 90.00% carrot, 100.00% sunflower, 90.00% soybean, 85.00% onion, 85.00% ryegrass. 2. The mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%). 3. The control seedlings did not exhibit any visible phytotoxic symptoms. 4. Environmental conditions for all plants belonging to the same species were identical. **Deviation of the study:** Two deviation from study plan occurred:

according to the study plan, the study experimental completion date should be December, 2023, however, it was completed in January, 2024, according to the study plan, the study should be completed in January2024, however, it was completed in February, 2024.

No other deviations from OECD Guideline No. 208 (2006), Study Plan and the SOPs occurred.

Above deviation did not affect the study results, since validity criteria were met.

Agreed toxicity endpoints:

ER_{10}, ER_{25}, ER_{50}, and NOER values (mL/ha)

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant emergence at the end of the experiment						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Plant number at the end of the experiment						
LR_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Shoot length (plants without roots)						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Plant dry weight (plants without roots)						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Phytotoxic effects						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00

ER_{10}, ER_{25}, ER_{50}, and NOER values (g of boscalid / ha)

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant emergence at the end of the experiment						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Plant number at the end of the experiment						
LR_{10}	>3524	>3524	>3524	>3524	>3524	>3524
LR_{25}	>3524	>3524	>3524	>3524	>3524	>3524
LR_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Shoot length (plants without roots)						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Plant dry weight (plants without roots)						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Phytotoxic effects						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524

Reference:	KCP 10.6.2/01
Report	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test; Wesołowska K.; 2024; Study Code: ETOX-2023-28
Guideline(s):	Yes, OECD 208
Deviations:	Two deviation from study plan occurred : − according to the study plan, the study experimental completion date should be December 2023, however, it was completed in January, 2024 −according to the study plan, the study should be completed in January 2024, it was completed in February 2024. No other deviations from OECD Guideline No. 208 (2006), Study Plan and the SOPs occurred. Above deviation did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name):	BSK-FUN 500 SC
Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027
2. Vehicle and/or positive control:	vehicle control: water positive control: not relevant
3. Test plants:	Class : Dicotyledonae − cabbage (*Brassica oleracea* var. capitata), − carrot (*Daucus carota*), −sunflower (*Helianthus annus*), −soybean (*Glycine* max. (G. Soja)). Class: Monocotyledonae −onion (*Allium cepa*), −perennial ryegrass (*Lolium perenne*)
Soil:	agricultural soil
Watering:	top (volume of water: 10-50 mL/pot) and bottom (volume of water: 300 mL/tray) watering were used during the exposure period
Organic carbon:	0.53%
pH:	6.22
Test containers:	plastic pots (pot's diameter – 15 cm, surface about: 177 cm^2)
4. Environmental conditions:	
Temperature:	16.7 – 21.6°C
Relative humidity:	46.8 – 73.5%
Photoperiod:	16 hours light and 8 hours dark, light intensity: 312.5 – 330.1 µE/m^2/s
CO_2 concentration:	570 – 635 ppm

STUDY DESIGN AND METHODS

The study aimed at evaluating the effect of BSK-FUN 500 SC on seedling emergence and early growth of six selected terrestrial plant species, was conducted on 4 dicotyledonous (cabbage, carrot, sunflower and soybean) and 2 monocotyledonous species (onion and perennial ryegrass). Five rates of the test item were used in the experiment for all tested species. Untreated control group was conducted simultaneously for each species. The test item was sprayed onto the soil surface. During the study, the plants were observed

for emergence (every day before the emergence of 50% of the control seedlings and then every 2 – 3 days) and visual phytotoxicity (7 and 14 day after the emergence of 50% of the control seedlings). Phytotoxic effects and plant damage were recorded. The experiment finished 14 days after the germination of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed. The results concerning the emergence, plant survival, phytotoxic effects, the shoot length, and the dry weight were statistically analyzed to determine the ER10, ER25, ER50, NOER, and LOER.

Test design:	Number of replicates/rate: − 4 (for carrot, ryegrass and onion), − 7 (for cabbage), − 10 (for sunflower and soybean). The total number of plants per application rate: 20 (for sunflower, carrot, soybean, onion, and ryegrass) or 21 (for cabbage)
Exposure time:	14 days after 50% emergence of the seedlings in the control group
Tested concentrations, definitive test:	7000, 2333, 777.8, 259.3, 86.42 mL test item/ha volume of ultrapure water used: 100 L/ha
Stability of test compound:	the concentrations of boscalid in ultrapure water were determined with a validated analytical method, the recovery of boscalid in the samples collected at application day was 94.8 – 99.1% of the nominal test item concentration, the results confirmed correct preparation of the test item suspensions
Dates:	start of the experimental part: 28.11.2023 end of the experimental part: 12.01.2024
Statistic:	Shapiro-Wilk's Test on Normal Distribution or Tarone's Test Procedure, Levene's Test (with Residuals), Step-down Cochran-Armitage Test
Validity of the test:	1. The seedling emergence in control group (validity criterion: at least 70%) was as follows: 95.24% cabbage, 90.00% carrot, 100.00% sunflower, 90.00% soybean, 85.00% onion, 85.00% ryegrass. 2. The mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%). 3. The control seedlings did not exhibit any visible phytotoxic symptoms. 4. Environmental conditions for all plants belonging to the same species were identical.

RESULTS

Cabbage (*Brassica oleracea var. capitata*)

After the application of the test item at all tested rates, seedling emergence of cabbage was not delayed when compared with the control. After the application of the test item at all tested rates, the plant

mortality was not observed. After the application of the test item at all tested rates, the cabbage shoot length was between 100.07 – 113.83% of the control shoot length. After the application of the test item at all tested rates, the cabbage shoot dry weight was between 97.03 – 107.43% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-1: Cabbage (*Brassica oleracea var. capitata*) – seedling emergence

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]									
		1-2	3	4	5*	7	9	12	14	16	19
0.0 (control)	1	0	0	0	2	2	3	3	3	3	3
	2	0	0	1	2	2	3	3	3	3	3
	3	0	0	1	2	2	3	3	3	3	3
	4	0	0	1	1	2	2	2	2	2	2
	5	0	0	2	2	3	3	3	3	3	3
	6	0	0	2	2	3	3	3	3	3	3
	7	0	0	0	1	2	2	3	3	3	3
86.42	1	0	0	1	3	3	3	3	3	3	3
	2	0	0	1	3	3	3	3	3	3	3
	3	0	0	1	3	3	3	3	3	3	3
	4	0	0	2	3	3	3	3	3	3	3
	5	0	0	1	2	2	3	3	3	3	3
	6	0	0	1	2	3	3	3	3	3	3
	7	0	0	0	3	3	3	3	3	3	3
259.3	1	0	0	1	2	2	3	3	3	3	3
	2	0	0	1	3	3	3	3	3	3	3
	3	0	0	1	2	3	3	3	3	3	3
	4	0	0	3	3	3	3	3	3	3	3
	5	0	0	1	3	3	3	3	3	3	3
	6	0	0	1	2	2	2	2	2	2	2
	7	0	1	2	3	3	3	3	3	3	3
777.8	1	0	0	1	3	3	3	3	3	3	3
	2	0	0	0	3	3	3	3	3	3	3
	3	0	0	2	3	3	3	3	3	3	3
	4	0	0	0	1	2	2	2	2	2	2
	5	0	0	1	2	2	2	3	3	3	3
	6	0	0	2	3	3	3	3	3	3	3
	7	0	0	1	3	3	3	3	3	3	3

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]									
		1-2	3	4	5*	7	9	12	14	16	19
2333	1	0	0	3	3	3	3	3	3	3	3
	2	0	0	0	3	3	3	3	3	3	3
	3	0	0	1	3	3	3	3	3	3	3
	4	0	0	1	2	2	2	2	2	2	2
	5	0	0	2	3	3	3	3	3	3	3
	6	0	0	0	0	2	2	2	2	2	2
	7	0	0	1	2	2	3	3	3	3	3
7000	1	0	0	0	3	3	3	3	3	3	3
	2	0	0	1	1	3	3	3	3	3	3
	3	0	0	1	2	3	3	3	3	3	3
	4	0	0	1	2	3	3	3	3	3	3
	5	0	0	0	3	3	3	3	3	3	3
	6	0	0	1	1	3	3	3	3	3	3
	7	0	0	1	3	3	3	3	3	3	3

Table KCP 10.6.2-2: Cabbage (*Brassica oleracea var. capitata*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates at the end of the experiment [No.]							Total number of plants at the end of the experiment [No.]	Seedling emergence * [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4	5	6	7			
0.0 (control)	21	3	3	3	2	3	3	3	**20**	95.24	**100.00**
86.42	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**
259.3	21	3	3	3	3	3	2	3	**20**	95.24	**100.00**
777.8	21	3	3	3	2	3	3	3	**20**	95.24	**100.00**
2333	21	3	3	3	2	3	2	3	**19**	90.48	**100.00**
7000	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**

* seedling emergence after 7 and 14 days (after the emergence of 50% of the control seedlings)

Table KCP 10.6.2-3: Cabbage (*Brassica oleracea var. capitata*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	67.60	12.27	-
86.42	72.38	11.45	**107.07**
259.3	74.35	8.51	**109.99**
777.8	67.65	8.19	**100.07**
2333	75.68	13.08	**111.96**
7000	76.95	9.28	**113.83**

Table KCP 10.6.2-4: Cabbage (*Brassica oleracea var. capitata*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]							Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7			
0.0 (control)	7.67	7.00	4.00	8.50	4.67	6.67	6.33	6.4	1.59	-
86.42	6.33	7.00	5.33	5.33	6.67	6.67	7.00	6.33	0.72	**98.88**
259.3	6.00	5.67	5.00	6.33	6.33	7.50	6.67	6.21	0.79	**97.03**
777.8	8.33	5.33	5.67	5.50	8.00	8.00	6.67	6.79	1.31	**105.95**
2333	6.33	7.00	6.33	7.00	6.33	8.50	6.67	6.88	0.77	**107.43**
7000	5.33	6.33	8.00	7.33	6.33	7.33	5.67	6.62	0.97	**103.35**

Table KCP 10.6.2-5: Cabbage (*Brassica oleracea var. capitata*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
86.42	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
259.3	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
777.8	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
2333	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
7000	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		

* no change

Carrot (*Daucus carota*)

After the application of the test item at all tested rates, seedling emergence of carrot was not delayed when compared with the control. After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the carrot shoot

length was between 97.91 – 105.53% of the control shoot length. After the application of the test item at all tested rates, the carrot shoot dry weight was between 90.64 – 110.12% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-6: Carrot *(Daucus carota)* – seedling emergence

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]									
		1-5	6	7	8*	10	12	15	17	20	22
0.0 (control)	1	0	0	1	3	5	5	5	5	5	5
	2	0	0	2	4	4	5	5	5	5	5
	3	0	0	2	2	3	3	3	3	3	3
	4	0	0	1	3	3	5	5	5	5	5
86.42	1	0	0	1	3	4	5	5	5	5	5
	2	0	0	0	2	2	2	2	2	2	2
	3	0	1	2	4	4	5	5	5	5	5
	4	0	0	1	2	3	5	5	5	5	5
259.3	1	0	0	2	3	4	5	5	5	5	5
	2	0	0	3	3	5	5	5	5	5	5
	3	0	1	1	5	5	5	5	5	5	5
	4	0	0	0	2	3	5	5	5	5	5
777.8	1	0	0	2	4	4	5	5	5	5	5
	2	0	0	1	3	5	5	5	5	5	5
	3	0	0	1	4	5	5	5	5	5	5
	4	0	0	0	3	3	4	4	4	4	4
2333	1	0	0	1	3	4	4	4	4	4	4
	2	0	0	2	2	3	5	5	5	5	5
	3	0	0	0	3	4	5	5	5	5	5
	4	0	1	1	4	4	5	5	5	5	5
7000	1	0	0	0	2	3	4	4	4	4	4
	2	0	0	2	2	4	5	5	5	5	5
	3	0	0	1	3	3	4	4	4	4	4
	4	0	0	1	3	4	4	4	4	4	4

* emergence of 50 % of the control plants

Table KCP 10.6.2-7: Carrot *(Daucus carota)* – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates at the end of the experiment [No.]				Total number of plants at the end of the experiment [No.]	Seedling emergence * [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4			
0.0 (control)	20	5	5	3	5	18	90.00	100.00
86.42	20	5	2	5	5	17	85.00	100.00
259.3	20	5	5	5	5	20	100.00	100.00
777.8	20	5	5	5	4	19	95.00	100.00
2333	20	4	5	5	5	19	95.00	100.00
7000	20	4	5	4	4	17	85.00	100.00

* seedling emergence after 7 and 14 days (after the emergence of 50% of the control seedlings)

Table KCP 10.6.2-8: Carrot *(Daucus carota)* – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	61.94	15.07	-
86.42	60.65	10.11	97.91
259.3	61.60	16.90	99.44
777.8	65.37	13.83	105.53
2333	63.84	9.85	103.06
7000	60.65	10.81	97.91

Table KCP 10.6.2-9: Carrot *(Daucus carota)* – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg] 1	2	3	4	Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
0.0 (control)	1.30	1.72	1.40	1.56	1.50	0.18	-
86.42	1.44	1.10	1.66	1.22	1.36	0.25	**90.64**
259.3	1.42	1.62	1.38	1.66	1.52	0.14	**101.67**
777.8	1.52	1.24	1.30	1.40	1.37	0.12	**91.30**
2333	1.73	1.30	1.60	1.96	1.65	0.27	**110.12**
7000	1.10	1.36	1.90	1.75	1.53	0.36	**102.17**

Table KCP 10.6.2-10: Carrot *(Daucus carota)* – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1 2 3 4	0 0 0 0	**0.00**	**nc***	0 0 0 0	**0.00**	**nc***
86.42	1 2 3 4	0 0 0 0	**0.00**	**nc***	0 0 0 0	**0.00**	**nc***
259.3	1 2 3 4	0 0 0 0	**0.00**	**nc***	0 0 0 0	**0.00**	**nc***
777.8	1 2 3 4	0 0 0 0	**0.00**	**nc***	0 0 0 0	**0.00**	**nc***
2333	1 2 3 4	0 0 0 0	**0.00**	**nc***	0 0 0 0	**0.00**	**nc***
7000	1 2 3 4	0 0 0 0	**0.00**	**nc***	0 0 0 0	**0.00**	**nc***

* no change

Sunflower (*Helianthus annus*)

After the application of the test item at all tested rates, seedling emergence of sunflower was not delayed when compared with the control. After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the sunflower shoot length was between 103.28 – 112.57% of the control shoot length. After the application of the test item at all tested rates, the sunflower shoot dry weight was between 91.16 – 100.38% of the control shoot weight.

After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-11: Sunflower (*Helianthus annus*) – seedling emergence

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]									
		1-2	3	4*	5	6	8	11	13	16	18
0.0 (control)	1	0	0	0	2	2	2	2	2	2	2
	2	0	0	1	2	2	2	2	2	2	2
	3	0	0	1	2	2	2	2	2	2	2
	4	0	0	2	2	2	2	2	2	2	2
	5	0	0	1	2	2	2	2	2	2	2
	6	0	0	2	2	2	2	2	2	2	2
	7	0	1	2	2	2	2	2	2	2	2
	8	0	0	2	2	2	2	2	2	2	2
	9	0	0	2	2	2	2	2	2	2	2
	10	0	0	2	2	2	2	2	2	2	2
86.42	1	0	0	2	2	2	2	2	2	2	2
	2	0	0	2	2	2	2	2	2	2	2
	3	0	0	2	2	2	2	2	2	2	2
	4	0	0	2	2	2	2	2	2	2	2
	5	0	0	1	2	2	2	2	2	2	2
	6	0	0	1	1	2	2	2	2	2	2
	7	0	0	0	1	1	1	1	1	1	1
	8	0	0	1	1	2	2	2	2	2	2
	9	0	0	1	2	2	2	2	2	2	2
	10	0	0	2	2	2	2	2	2	2	2
259.3	1	0	0	2	2	2	2	2	2	2	2
	2	0	2	2	2	2	2	2	2	2	2
	3	0	0	2	2	2	2	2	2	2	2
	4	0	0	2	2	2	2	2	2	2	2
	5	0	0	1	2	2	2	2	2	2	2
	6	0	0	1	2	2	2	2	2	2	2
	7	0	0	2	2	2	2	2	2	2	2
	8	0	0	2	2	2	2	2	2	2	2
	9	0	0	1	2	2	2	2	2	2	2
	10	0	0	1	1	1	1	1	1	1	1

777.8	1	0	0	1	2	2	2	2	2	2	2
	2	0	0	1	2	2	2	2	2	2	2
	3	0	0	2	2	2	2	2	2	2	2
	4	0	0	2	2	2	2	2	2	2	2
	5	0	0	0	0	0	0	0	0	0	0
	6	0	1	2	2	2	2	2	2	2	2
	7	0	1	2	2	2	2	2	2	2	2
	8	0	2	2	2	2	2	2	2	2	2
	9	0	1	2	2	2	2	2	2	2	2
	10	0	0	1	2	2	2	2	2	2	2
2333	1	0	0	2	2	2	2	2	2	2	2
	2	0	0	2	2	2	2	2	2	2	2
	3	0	0	1	1	1	1	1	1	1	1
	4	0	0	2	2	2	2	2	2	2	2
	5	0	0	2	2	2	2	2	2	2	2
	6	0	0	0	2	2	2	2	2	2	2
	7	0	1	2	2	2	2	2	2	2	2
	8	0	0	1	2	2	2	2	2	2	2
	9	0	0	1	2	2	2	2	2	2	2
	10	0	0	1	1	1	1	1	1	1	1
7000	1	0	0	1	2	2	2	2	2	2	2
	2	0	0	1	2	2	2	2	2	2	2
	3	0	0	0	2	2	2	2	2	2	2
	4	0	0	1	1	1	1	1	1	1	1
	5	0	0	2	2	2	2	2	2	2	2
	6	0	0	2	2	2	2	2	2	2	2
	7	0	1	2	2	2	2	2	2	2	2
	8	0	0	1	2	2	2	2	2	2	2
	9	0	1	2	2	2	2	2	2	2	2
	10	0	0	1	2	2	2	2	2	2	2

* emergence of 50 % of the control plants

Table KCP 10.6.2-12: Sunflower (*Helianthus annus*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates at the end of the experiment [No.]										Total number of plants at the end of the experiment [No.]	Seedling emergence * [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4	5	6	7	8	9	10			
0.0 (control)	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	**100.00**
86.42	20	2	2	2	2	2	2	1	2	2	2	**19**	95.00	**100.00**
259.3	20	2	2	2	2	2	2	2	2	2	1	**19**	95.00	**100.00**
777.8	20	2	2	2	2	0	2	2	2	2	2	**18**	90.00	**100.00**
2333	20	2	2	1	2	2	2	2	2	2	1	**18**	90.00	**100.00**
7000	20	2	2	2	1	2	2	2	2	2	2	**19**	95.00	**100.00**

* seedling emergence after 7 and 14 days (after the emergence of 50% of the control seedlings)

Table KCP 10.6.2-13: Sunflower (*Helianthus annus*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	174.95	24.55	-
86.42	196.95	26.68	**112.57**
259.3	192.11	35.03	**109.81**
777.8	186.28	25.71	**106.47**
2333	185.44	23.89	**106.00**
7000	180.68	26.23	**103.28**

Table KCP 10.6.2-14: Sunflower (*Helianthus annus*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]										Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7	8	9	10			
0.0 (control)	49.00	62.00	52.50	44.00	48.00	48.50	55.50	50.50	56.50	54.00	52.05	5.17	-
86.42	58.00	59.50	45.00	41.50	48.00	47.50	53.00	48.50	50.00	53.00	50.40	5.58	**96.83**
259.3	49.00	39.00	49.50	62.50	42.50	41.00	68.50	43.00	61.00	49.00	50.50	10.15	**97.02**
777.8	57.00	54.50	43.50	48.00	-	48.50	51.50	54.00	51.50	49.50	50.89	4.05	**97.77**
2333	53.50	63.00	52.00	47.50	50.50	52.00	59.50	45.50	53.00	46.00	52.25	5.58	**100.38**
7000	52.50	45.50	46.50	47.00	58.50	50.50	40.00	42.00	48.50	43.50	47.45	5.41	**91.16**

"-" plants not emerged

Table KCP 10.6.2-15: Sunflower (*Helianthus annus*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
86.42	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
259.3	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
777.8	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	-			-		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
2333	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		

7000	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		

* no change "-" plants not emerged

Soybean (*Glycine max (G. Soja)*)

After the application of the test item at all tested rates, seedling emergence of soybean was not delayed when compared with the control. After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the soybean shoot length was between 95.16 – 113.52% of the control shoot length. After the application of the test item at all tested rates, the soybean shoot dry weight was between 92.68 – 107.02% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-16: Soybean (*Glycine max (G. Soja)*) – seedling emergence

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]								
		1-3	4	5*	7	9	12	14	16	19
0.0 (control)	1	0	0	1	2	2	2	2	2	2
	2	0	0	1	1	2	2	2	2	2
	3	0	1	2	2	2	2	2	2	2
	4	0	0	1	2	2	2	2	2	2
	5	0	1	1	1	2	2	2	2	2
	6	0	0	1	1	1	2	2	2	2
	7	0	1	1	2	2	2	2	2	2
	8	0	0	0	1	1	1	1	1	1
	9	0	0	2	2	2	2	2	2	2
	10	0	0	0	1	1	1	1	1	1
86.42	1	0	0	1	2	2	2	2	2	2
	2	0	1	1	2	2	2	2	2	2
	3	0	0	0	1	1	2	2	2	2
	4	0	1	2	2	2	2	2	2	2
	5	0	0	1	2	2	2	2	2	2
	6	0	0	0	1	1	1	1	1	1
	7	0	0	1	1	1	1	1	1	1
	8	0	0	1	2	2	2	2	2	2
	9	0	0	2	2	2	2	2	2	2
	10	0	0	0	1	1	2	2	2	2
259.3	1	0	0	1	1	1	1	1	1	1
	2	0	0	1	1	1	1	1	1	1
	3	0	1	2	2	2	2	2	2	2
	4	0	1	1	1	1	1	1	1	1
	5	0	0	1	1	2	2	2	2	2
	6	0	0	1	1	1	1	1	1	1
	7	0	0	2	2	2	2	2	2	2
	8	0	1	2	2	2	2	2	2	2
	9	0	0	2	2	2	2	2	2	2
	10	0	0	1	1	1	1	1	1	1

777.8	1	0	1	2	2	2	2	2	2	2
	2	0	0	0	1	1	2	2	2	2
	3	0	1	1	1	1	1	1	1	1
	4	0	0	1	1	1	2	2	2	2
	5	0	0	1	1	2	2	2	2	2
	6	0	1	1	2	2	2	2	2	2
	7	0	0	1	2	2	2	2	2	2
	8	0	1	1	2	2	2	2	2	2
	9	0	0	0	0	0	1	1	1	1
	10	0	0	0	2	2	2	2	2	2
2333	1	0	1	2	2	2	2	2	2	2
	2	0	0	1	1	1	1	1	1	1
	3	0	0	2	2	2	2	2	2	2
	4	0	0	0	0	0	1	1	1	1
	5	0	1	2	2	2	2	2	2	2
	6	0	1	1	2	2	2	2	2	2
	7	0	1	1	2	2	2	2	2	2
	8	0	2	2	2	2	2	2	2	2
	9	0	1	2	2	2	2	2	2	2
	10	0	1	2	2	2	2	2	2	2
7000	1	0	1	1	2	2	2	2	2	2
	2	0	1	2	2	2	2	2	2	2
	3	0	0	1	1	1	2	2	2	2
	4	0	0	0	0	0	0	0	0	0
	5	0	2	2	2	2	2	2	2	2
	6	0	1	2	2	2	2	2	2	2
	7	0	0	0	2	2	2	2	2	2
	8	0	0	0	1	2	2	2	2	2
	9	0	0	1	1	1	1	1	1	1
	10	0	0	0	2	2	2	2	2	2

* emergence of 50 % of the control plants

Table KCP 10.6.2-17: Soybean (*Glycine max (G. Soja)*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates at the end of the experiment [No.]										Total number of plants at the end of the experiment [No.]	Seedling emergence * [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4	5	6	7	8	9	10			
0.0 (control)	20	2	2	2	2	2	2	2	1	2	1	**18**	90.00	**100.00**
86.42	20	2	2	2	2	2	1	1	2	2	2	**18**	90.00	**100.00**
259.3	20	1	1	2	1	2	1	2	2	2	1	**15**	75.00	**100.00**
777.8	20	2	2	1	2	2	2	2	2	1	2	**18**	90.00	**100.00**
2333	20	2	1	2	1	2	2	2	2	2	2	**18**	90.00	**100.00**
7000	20	2	2	2	0	2	2	2	2	1	2	**17**	85.00	**100.00**

* seedling emergence after 7 and 14 days (after the emergence of 50% of the control seedlings)

Table KCP 10.6.2-18: Soybean (*Glycine max (G. Soja)*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	239.83	45.72	-
86.42	267.67	23.90	**111.61**
259.3	272.27	17.24	**113.52**
777.8	228.22	46.40	**95.16**
2333	270.28	17.92	**112.69**
7000	254.94	20.97	**106.30**

Table KCP 10.6.2-19: Soybean (*Glycine max (G. Soja)*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]										Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7	8	9	10			
0.0 (control)	137.50	148.00	126.50	120.00	147.00	160.50	138.50	129.00	111.50	114.00	133.25	15.91	-
86.42	125.00	106.00	144.00	129.00	127.00	125.00	109.00	153.00	125.50	158.00	130.15	17.02	**97.67**
259.3	138.00	107.00	132.50	119.00	139.50	134.00	149.50	132.00	125.50	143.00	132.00	12.29	**99.06**
777.8	156.00	147.50	144.00	142.00	164.00	110.50	142.00	134.00	115.00	171.00	142.60	19.26	**107.02**
2333	151.50	142.00	132.50	127.00	134.50	119.50	117.00	160.50	163.50	137.00	138.50	15.99	**103.94**
7000	149.50	125.50	130.50	-	121.50	120.50	108.00	114.00	131.00	111.00	123.50	12.67	**92.68**

"-" plants not emerged

Table KCP 10.6.2-20: Soybean (*Glycine max (G. Soja)*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
86.42	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
259.3	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
777.8	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		
2333	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	0			0		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		

7000	1	0	0.00	nc*	0	0.00	nc*
	2	0			0		
	3	0			0		
	4	-			-		
	5	0			0		
	6	0			0		
	7	0			0		
	8	0			0		
	9	0			0		
	10	0			0		

* no change "-" plants not emerged

Onion (*Allium cepa*)

After the application of the test item at all tested rates, seedling emergence of onion was not delayed when compared with the control. After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the onion shoot length was between 94.77 – 106.88% of the control shoot length. After the application of the test item at all tested rates, the onion shoot dry weight was between 94.37 – 109.26% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-21: Onion (*Allium cepa*) – seedling emergence

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]									
		1-5	6	7	8*	10	12	15	17	20	22
0.0 (control)	1	0	0	2	3	4	4	4	4	4	4
	2	0	0	1	3	4	4	4	4	4	4
	3	0	1	2	2	4	5	5	5	5	5
	4	0	0	1	4	4	4	4	4	4	4
86.42	1	0	0	2	3	4	4	4	4	4	4
	2	0	0	1	4	4	4	4	4	4	4
	3	0	0	3	3	3	3	3	3	3	3
	4	0	0	2	2	3	4	4	4	4	4
259.3	1	0	0	2	3	3	4	4	4	4	4
	2	0	1	2	2	3	4	4	4	4	4
	3	0	2	2	3	3	3	3	3	3	3
	4	0	0	1	3	5	5	5	5	5	5
777.8	1	0	0	2	2	4	4	4	4	4	4
	2	0	0	0	2	3	4	4	4	4	4
	3	0	0	3	3	4	4	4	4	4	4
	4	0	1	1	4	5	5	5	5	5	5
2333	1	0	0	0	4	4	4	4	4	4	4
	2	0	0	2	2	3	5	5	5	5	5
	3	0	1	2	2	3	4	5	5	5	5
	4	0	0	1	3	3	3	3	3	3	3
7000	1	0	1	1	3	3	4	4	4	4	4
	2	0	0	2	2	3	3	4	4	4	4
	3	0	0	2	3	3	3	3	3	3	3
	4	0	0	2	2	2	4	4	4	4	4

* emergence of 50 % of the control plants

Table KCP 10.6.2-22: Onion (*Allium cepa*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates at the end of the experiment [No.]				Total number of plants at the end of the experiment [No.]	Seedling emergence * [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4			
0.0 (control)	20	4	4	5	4	17	85.00	100.00
86.42	20	4	4	3	4	15	75.00	100.00
259.3	20	4	4	3	5	16	80.00	100.00
777.8	20	4	4	4	5	17	85.00	100.00
2333	20	4	5	5	3	17	85.00	100.00
7000	20	4	4	3	4	15	75.00	100.00

* seedling emergence after 7 and 14 days (after the emergence of 50% of the control seedlings)

Table KCP 10.6.2-23: Onion (*Allium cepa*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	84.76	11.77	-
86.42	90.60	14.05	106.88
259.3	81.38	15.74	96.00
777.8	87.59	16.55	103.33
2333	87.06	18.10	102.71
7000	80.33	14.58	94.77

Table KCP 10.6.2-24: Onion (*Allium cepa*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
0.0 (control)	2.15	1.70	2.16	1.80	1.95	0.24	-
86.42	2.40	1.65	2.13	2.35	2.13	0.34	109.26
259.3	1.90	1.55	2.20	1.72	1.84	0.28	94.37
777.8	1.95	1.70	2.45	1.92	2.01	0.32	102.69
2333	1.80	1.60	1.92	2.13	1.86	0.22	95.43
7000	1.60	2.05	1.73	2.00	1.85	0.21	94.54

Table KCP 10.6.2-25: Onion (*Allium cepa*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
86.42	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
259.3	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
777.8	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
2333	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
7000	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*

* no change

Ryegrass (*Lolium perenne*)

After the application of the test item at all tested rates, seedling emergence of ryegrass was not delayed when compared with the control (Table 31). After the application of the test item at all tested rates, the plant mortality was not observed (Table 32).

After the application of the test item at all tested rates, the ryegrass shoot length was between 93.10 – 102.75% of the control shoot length (Table 33).

After the application of the test item at all tested rates, the ryegrass shoot dry weight was between 96.77 – 106.45% of the control shoot weight (Table 34).

Table KCP 10.6.2-26: Ryegrass (*Lolium perenne*) – seedling emergence

Application rate [mL/ha]	Replicate	Number of plants on individual days [no.]								
		1-3	4	5*	7	9	12	14	16	19
0.0 (control)	1	0	3	4	5	5	5	5	5	5
	2	0	1	3	3	3	3	3	3	3
	3	0	2	3	5	5	5	5	5	5
	4	0	0	1	3	4	4	4	4	4
86.42	1	0	1	4	5	5	5	5	5	5
	2	0	3	5	5	5	5	5	5	5
	3	0	1	3	4	4	5	5	5	5
	4	0	2	5	5	5	5	5	5	5
259.3	1	0	1	2	4	4	5	5	5	5
	2	0	1	4	4	4	4	4	4	4
	3	0	3	4	4	4	4	4	4	4
	4	0	0	3	4	4	4	4	4	4
777.8	1	0	1	2	4	4	4	4	4	4
	2	0	1	3	4	4	4	4	4	4
	3	0	2	3	3	4	5	5	5	5
	4	0	2	3	4	4	4	4	4	4
2333	1	0	3	4	5	5	5	5	5	5
	2	0	1	4	5	5	5	5	5	5
	3	0	1	4	4	4	4	4	4	4
	4	0	2	5	5	5	5	5	5	5
7000	1	0	1	3	5	5	5	5	5	5
	2	0	3	3	5	5	5	5	5	5
	3	0	2	4	4	5	5	5	5	5
	4	0	1	5	5	5	5	5	5	5

* emergence of 50 % of the control plants

Table KCP 10.6.2-27: Ryegrass (*Lolium perenne*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of seeds	Number of plants in particular replicates at the end of the experiment [No.]				Total number of plants at the end of the experiment [No.]	Seedling emergence * [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4			
0.0 (control)	20	5	3	5	4	**17**	85.00	**100.00**
86.42	20	5	5	5	5	**20**	100.00	**100.00**
259.3	20	5	4	4	4	**17**	85.00	**100.00**
777.8	20	4	4	5	4	**17**	85.00	**100.00**
2333	20	5	5	4	5	**19**	95.00	**100.00**
7000	20	5	5	5	5	**20**	100.00	**100.00**

* seedling emergence after 7 and 14 days (after the emergence of 50% of the control seedlings)

Table KCP 10.6.2-28: Ryegrass (*Lolium perenne*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	156.12	24.65	-
86.42	146.65	25.64	**93.94**
259.3	146.71	21.28	**93.97**
777.8	160.41	29.62	**102.75**
2333	159.21	23.15	**101.98**
7000	145.35	25.39	**93.10**

Table KCP 10.6.2-29: Ryegrass (*Lolium perenne*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
0.0 (control)	3.60	3.33	4.00	2.50	3.36	0.63	-
86.42	3.20	3.00	3.20	3.60	3.25	0.25	96.77
259.3	3.40	3.00	3.75	3.00	3.29	0.36	97.89
777.8	3.25	4.00	3.80	3.25	3.58	0.38	106.45
2333	3.40	3.40	2.75	3.60	3.29	0.37	97.89
7000	3.40	3.40	3.00	3.60	3.35	0.25	99.75

Table KCP 10.6.2-30: Ryegrass (*Lolium perenne*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS					
		Day 7			Day 14		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
86.42	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
259.3	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
777.8	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
2333	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*
7000	1 2 3 4	0 0 0 0	0.00	nc*	0 0 0 0	0.00	nc*

* no change

CONCLUSION

The effective rate (ER_{10}, ER_{25} and ER_{50}), NOEC and LOEC values of seedling emergence, seedling survival, shoot height, and dry shoot weight and phytotoxicity was calculated based on the nominal concentration of the test item are in table below.

Table KCP 10.6.2-31: Seedling emergence and seedling growth test endpoints

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant emergence at the end of the experiment						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Plant number at the end of the experiment						
LR_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Shoot length (plants without roots)						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Plant dry weight (plants without roots)						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Phytotoxic effects						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00

Plant emergence at the end of the experiment						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Plant number at the end of the experiment						
LR_{10}	>3524	>3524	>3524	>3524	>3524	>3524
LR_{25}	>3524	>3524	>3524	>3524	>3524	>3524
LR_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Shoot length (plants without roots)						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Plant dry weight (plants without roots)						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524
Phytotoxic effects						
ER_{10}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{25}	>3524	>3524	>3524	>3524	>3524	>3524
ER_{50}	>3524	>3524	>3524	>3524	>3524	>3524
NOER	≥3524	≥3524	≥3524	≥3524	≥3524	≥3524
LOER	>3524	>3524	>3524	>3524	>3524	>3524

Comments of zRMS:	The study is acceptable. The validity criteria according to OECD 227 of the test were met. **Validity criteria:**

	VALIDITY OF THE STUDY The following validity criteria were met (Table 33): 1. The seedling emergence (validity criterion: at least 70%) was as follows: - 97.62 – 100.00% cabbage, - 75.00 – 80.00% carrot, - 93.33 – 100.00% sunflower, - 90.00 – 100.00% soybean, - 75.00 – 82.50% onion, - 95.00 – 100.00% ryegrass. 2. The mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%). 3. The control seedlings did not exhibit any visible phytotoxic symptoms. 4. Environmental conditions for all plants belonging to the same species were identical.
	Deviation of the study: Two deviation from study plan occurred: – according to the study plan, the study experimental completion date should be December, 2023, however, it was completed in January, 2024, – according to the study plan, the study should be completed in January 2024, however, it was completed of February, 2024. – No other deviations from OECD Guideline No. 227 (2006), Study Plan and the SOPs occurred.
	Above deviation did not affect the study results, since validity criteria were met. **Agreed toxicity endpoints:**

ER10, ER25, ER50, and NOER values (mL/ha)

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant number at the end of the experiment						
LR_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Shoot length (plants without roots)						
ER_{10}	>7000.00	2061.18 (241.21 –34296.70*)	3355.69 (1667.14 – 11855.86*)	>7000.00	>7000.00	6583.70 (1530.59 – n.d.)
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Plant dry weight (plants without roots)						
ER_{10}	>7000.00	3810.08	503.78 (0.89* – 1500.48)	19510.52* (4289.54 – n.d.)	>7000.00	160.46
ER_{25}	>7000.00	>7000.00	19223.80* (5372.20 – n.d.)	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Phytotoxic effects						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00

n.d. : not determined due to mathematical reasons
* value is out of the tested rates

ER_{10}, ER_{25}, ER_{50}, and NOER values (g of boscalid / ha)

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant number at the end of the experiment						
LR_{10}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
LR_{25}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
LR_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
Shoot length (plants without roots)						
ER_{10}	>3523.80	1037.60 (121.43 – 17264.96*)	1689.25 (839.24 – 5968.24*)	>3523.80n.d.	>3523.80	3314.23 (770.50 – n.d.)
ER_{25}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
ER_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
Plant dry weight (plants without roots)						
ER_{10}	>3523.80	1917.99	253.60 (0.45* – 755.34)	9821.60* (2159.35 – n.d.)	>3523.80	80.78
ER_{25}	>3523.80	>3523.80	9677.26* (2704.37 – n.d.)	>3523.80	>3523.80	>3523.80
ER_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
Phytotoxic effects						
ER_{10}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
ER_{25}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
ER_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80

n.d. : not determined due to mathematical reasons
* value is out of the tested rates

Reference: KCP 10.6.2/02

Report: Terrestrial Plant Test: Vegetative Vigour Test; Wesołowska K.; 2024; Study Code: ETOX-2023-29

Guideline(s): Yes, OECD 227

Deviations: Two deviation from study plan occurred:
− according to the study plan, the study experimental completion date should be December, 2023, however, it was completed in January, 2024,
− according to the study plan, the study should be completed in January 202 4 , however, it was completed in February, 2024.
No other deviations from OECD Guideline No. 227 (2006), Study Plan and the SOPs occurred.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study): No

MATERIALS AND METHODS

1. Test material

Test item (chemical/other name): BSK-FUN 500 SC

Formulation:	nominal: 500 g boscalid/L, CoA: 503.4 g boscalid/L
Description (physical state):	-
Batch no.:	1/BSK/2023
Production date:	18.04.2023
Expiration date:	18.04.2027
2. Vehicle and/or positive control:	vehicle control: water positive control: not relevant
3. Test plants:	Class : Dicotyledonae − cabbage (*Brassica oleracea* var. capitata), − carrot (*Daucus carota*), −sunflower (*Helianthus annus*), −soybean (*Glycine* max. (G. Soja)). Class: Monocotyledonae −onion (*Allium cepa*), −perennial ryegrass (*Lolium perenne*)
Soil:	agricultural soil
Organic carbon:	0.53%
pH:	6.22
Test containers:	non-porous plastic pots (diameter: 15 cm, surface about: 177 cm2) with a tray under the pot large enough to allow normal growth and limit overlap of leaves among plants
4. Environmental conditions:	
Temperature:	16.7 – 21.6°C
Relative humidity:	46.8 – 73.5%
Photoperiod:	16h day : 8h night, light intensity: 310.7 – 329.2 µE/m^2/s
CO_2 concentration:	583 – 623 ppm

STUDY DESIGN AND METHODS

Application of test item did not result in mortality for all tested plant species up to the highest rate tested, 7000 mL/ha. None of the tested species showed phytotoxic symptoms up to a rate of 7000 mL/ha.

No statistically significant reduction of plant length was observed for all tested plant species following the application of test item up to 7000 mL/ha. No statistically significant adverse effects of test item on plant dry weight were observed for all tested plant species up to the highest tested rate of 7000 mL/ha. On the basis of the obtained test results, the ER50 and LR50 values determined for plants number at the end of the experiment, shoot length, shoot dry weight measurements, and the phytotoxic effects for each tested species, could not be determined. However, it can be assumed that the mentioned above ER50 and LR50 values are higher than the maximum tested rate, i.e. 7000.00 mL/ha.

Test design:	Number of replicates/rate: − 4 (for carrot, ryegrass and onion), − 7 (for cabbage), − 10 (for sunflower and soybean). The total number of plants per application rate: 20 (for sunflower, carrot, soybean, onion, and ryegrass) or 21 (for cabbage)
Exposure time:	21 days after the spraying
Tested concentrations, definitive test:	7000, 2333, 777.8, 259.3, 86.42 mL test item/ha volume of ultrapure water used: 100 L/ha
Stability of test compound:	the concentrations of boscalid in ultrapure water were determined with a validated own analytical method, the recovery of boscalid in the samples collected at application day was 94.8 – 99.0% of the nominal test item concentration. The results confirmed correct preparation of the test item suspensions
Dates:	start of the experimental part: 28.11.2023 end of the experimental part: 12.01.2024
Statistic:	Shapiro-Wilk's Test on Normal Distribution or Tarone's Test Procedure, Levene's Test (with Residuals), Step-down Cochran-Armitage Test, Dunnett`s Multiple t-test, Step-down Jonckheere-Terpstra Test, Multiple Sequentially-rejective t-test After Bonferroni-Holm, Williams Multiple Sequential t-test
Validity of the test:	1. The seedling emergence (validity criterion: at least 70%) was as follows: 97.62 – 100.00% cabbage, 75.00 – 80.00% carrot, 93.33 – 100.00% sunflower, 90.00 – 100.00% soybean, 75.00 – 82.50% onion, 95.00 – 100.00% ryegrass. 2. The mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%). 3. The control seedlings did not exhibit any visible phytotoxic symptoms. 4. Environmental conditions for all plants belonging to the same species were identical.

RESULTS

Cabbage (*Brassica oleracea var. capitata*)

After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the cabbage shoot length was between 94.23 – 109.63% of the control shoot length. After the application of the test item at all tested rates, the cabbage shoot dry weight was between 94.53 – 108.95% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-32: Cabbage (*Brassica oleracea var. capitata*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants	Number of plants in particular replicates [No.]							Total number of plants at the end of the experiment [No.]	Total number of plants [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4	5	6	7			
0.0 (control)	21	3	3	3	3	3	3	3	**21**	100.00	-
86.42	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**
259.3	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**
777.8	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**
2333	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**
7000	21	3	3	3	3	3	3	3	**21**	100.00	**100.00**

Table KCP 10.6.2-33: Cabbage (*Brassica oleracea var. capitata*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	159.19	24.77	-
86.42	150.00	14.92	**94.23**
259.3	164.05	18.65	**103.05**
777.8	165.38	19.41	**103.89**
2333	174.52	19.56	**109.63**
7000	161.48	20.57	**101.44**

Table KCP 10.6.2-34: Cabbage (*Brassica oleracea var. capitata*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]							Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7			
0.0 (control)	511.67	470.33	396.67	366.33	494.67	335.00	450.00	432.10	67.13	-
86.42	412.33	500.67	386.00	488.00	509.33	523.33	475.67	470.76	51.75	**108.95**
259.3	372.33	490.33	330.00	364.67	555.33	386.00	405.00	414.81	79.47	**96.00**
777.8	392.33	431.67	440.00	442.67	383.67	410.67	394.00	413.57	24.53	**95.71**
2333	450.67	423.33	442.00	338.33	325.33	458.67	421.00	408.48	54.21	**94.53**
7000	526.00	431.67	429.00	398.67	479.00	359.33	456.00	439.95	54.13	**101.82**

Table KCP 10.6.2-35: Cabbage (*Brassica oleracea var. capitata*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
86.42	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
259.3	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
777.8	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
2333	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
7000	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		

* no change

Carrot (*Daucus carota*)

After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the carrot shoot length was between 87.61 – 112.32% of the control shoot length. After the application of the test item at all tested rates, the carrot shoot dry weight was between 84.88 – 113.42% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-36: Carrot (*Daucus carota*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants	Number of plants in particular replicates [No.]				Total number of plants at the end of the experiment [No.]	Total number of plants [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4			
0.0 (control)	20	5	5	5	5	**20**	100.00	-
86.42	20	5	5	5	5	**20**	100.00	**100.00**
259.3	20	5	5	5	5	**20**	100.00	**100.00**
777.8	20	5	5	5	5	**20**	100.00	**100.00**
2333	20	5	5	5	5	**20**	100.00	**100.00**
7000	20	5	5	5	5	**20**	100.00	**100.00**

Table KCP 10.6.2-37: Carrot (*Daucus carota*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	152.95	28.26	-
86.42	169.05	32.07	**110.53**
259.3	171.80	33.19	**112.32**
777.8	152.05	31.59	**99.41**
2333	134.00	30.89	**87.61**
7000	156.20	40.56	**102.12**

Table KCP 10.6.2-38: Carrot (*Daucus carota*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
0.0 (control)	64.20	45.60	66.20	59.40	58.85	9.28	-
86.42	66.00	70.00	52.80	78.20	66.75	10.60	**113.42**
259.3	71.40	59.20	73.20	53.80	64.40	9.41	**109.43**
777.8	54.80	50.00	61.80	65.80	58.10	7.06	**98.73**
2333	53.00	59.40	55.80	31.60	49.95	12.51	**84.88**
7000	52.60	64.00	71.40	45.00	58.25	11.74	**98.98**

Table KCP 10.6.2-39: Carrot (*Daucus carota*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
86.42	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
259.3	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
777.8	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
2333	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
7000	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*

* no change

Sunflower (*Helianthus annus*)

After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the sunflower shoot length was between 91.90 – 111.12% of the control shoot length. After the application of the test item at all tested rates, the sunflower shoot

dry weight was between 83.07 – 109.21% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-40: Sunflower (*Helianthus annus*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants	Number of plants in particular replicates [No.]										Total number of plants at the end of the experiment [No.]	Total number of plants [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4	5	6	7	8	9	10			
0.0 (control)	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	-
86.42	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	**100.00**
259.3	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	**100.00**
777.8	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	**100.00**
2333	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	**100.00**
7000	20	2	2	2	2	2	2	2	2	2	2	**20**	100.00	**100.00**

Table KCP 10.6.2-41: Sunflower (*Helianthus annus*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	401.95	62.95	-
86.42	446.65	65.91	**111.12**
259.3	428.35	35.40	**106.57**
777.8	388.25	53.20	**96.59**
2333	396.05	43.11	**98.53**
7000	369.40	26.19	**91.90**

Table KCP 10.6.2-42: Sunflower (*Helianthus annus*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]										Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7	8	9	10			
0.0 (control)	1002.50	949.50	914.50	528.50	692.50	870.50	575.50	784.00	932.00	1140.00	838.95	192.99	-
86.42	807.50	1195.50	780.50	827.50	806.00	1022.00	947.50	966.50	1040.00	769.00	916.20	141.40	**109.21**
259.3	918.00	614.00	816.00	924.00	661.00	884.00	642.00	1006.50	839.00	739.00	804.35	134.66	**95.88**
777.8	788.50	829.50	678.50	788.50	690.00	478.00	803.00	534.00	672.50	739.00	700.15	116.77	**83.46**
2333	699.50	614.00	926.00	857.50	937.50	642.00	824.00	755.00	722.00	521.50	749.90	136.99	**89.39**
7000	803.50	513.00	609.00	611.50	508.00	694.50	929.50	620.00	759.00	921.50	696.95	152.83	**83.07**

Table KCP 10.6.2-43: Sunflower (*Helianthus annus*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
86.42	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
259.3	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
777.8	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
2333	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
7000	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		

* no change

Soybean (*Glycine max (G. Soja)*)

After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the soybean shoot length was between 99.07 – 110.26% of the control shoot length. After the application of the test item at all tested rates, the soybean shoot dry weight was between 94.70 – 110.38% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-44: Soybean *(Glycine max (G. Soja))* – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants	Number of plants in particular replicates [No.]										Total number of plants at the end of the experiment [No.]	Total number of plants [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4	5	6	7	8	9	10			
0.0 (control)	20	2	2	2	2	2	2	2	2	2	2	20	100.00	-
86.42	20	2	2	2	2	2	2	2	2	2	2	20	100.00	100.00
259.3	20	2	2	2	2	2	2	2	2	2	2	20	100.00	100.00
777.8	20	2	2	2	2	2	2	2	2	2	2	20	100.00	100.00
2333	20	2	2	2	2	2	2	2	2	2	2	20	100.00	100.00
7000	20	2	2	2	2	2	2	2	2	2	2	20	100.00	100.00

Table KCP 10.6.2-45: Soybean *(Glycine max (G. Soja))* – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	796.00	104.34	-
86.42	788.60	114.26	99.07
259.3	862.60	75.08	108.37
777.8	835.35	121.74	104.94
2333	877.65	84.60	110.26
7000	818.65	55.81	102.85

Table KCP 10.6.2-46: Soybean *(Glycine max (G. Soja))* – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]										Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4	5	6	7	8	9	10			
0.0 (control)	1102.50	983.50	841.00	767.50	839.00	990.50	837.50	993.00	999.00	976.00	932.95	104.46	-
86.42	878.00	943.00	992.00	846.50	867.00	824.50	825.00	975.00	1133.50	1005.00	928.95	99.37	**99.57**
259.3	1020.00	1169.50	921.00	1125.00	1232.00	1088.00	946.00	937.00	953.00	906.00	1029.75	116.26	**110.38**
777.8	1031.00	1063.50	1127.50	984.50	1008.50	1021.00	856.50	996.50	806.00	728.00	962.30	124.73	**103.15**
2333	802.50	1068.00	1031.00	897.00	1178.50	1045.50	861.00	838.00	901.50	854.00	947.70	123.99	**101.58**
7000	780.50	817.50	1133.00	1026.00	1018.00	781.50	746.00	783.00	905.50	844.00	883.50	132.11	**94.70**

Table KCP 10.6.2-47: Soybean *(Glycine max (G. Soja))* – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
86.42	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
259.3	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
777.8	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
2333	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		
7000	1	0	0	nc*	0	0	nc*	0	0	nc*
	2	0			0			0		
	3	0			0			0		
	4	0			0			0		
	5	0			0			0		
	6	0			0			0		
	7	0			0			0		
	8	0			0			0		
	9	0			0			0		
	10	0			0			0		

* no change

Onion (*Allium cepa*)

After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the onion shoot length was between 99.87 – 109.69% of the control shoot length. After the application of the test item at all tested rates, the onion shoot dry weight was between 91.36 – 113.17% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-48: Onion (*Allium cepa*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants	Number of plants in particular replicates [No.]				Total number of plants at the end of the experiment [No.]	Total number of plants [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4			
0.0 (control)	20	5	5	5	5	20	100.00	-
86.42	20	5	5	5	5	20	100.00	100.00
259.3	20	5	5	5	5	20	100.00	100.00
777.8	20	5	5	5	5	20	100.00	100.00
2333	20	5	5	5	5	20	100.00	100.00
7000	20	5	5	5	5	20	100.00	100.00

Table KCP 10.6.2-49: Onion (*Allium cepa*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	150.20	28.19	-
86.42	164.75	25.92	109.69
259.3	150.00	28.50	99.87
777.8	158.70	25.33	105.66
2333	159.60	27.87	106.26
7000	151.70	24.62	101.00

Table KCP 10.6.2-50: Onion (*Allium cepa*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
0.0 (control)	10.60	13.60	15.00	9.40	12.15	2.59	-
86.42	16.00	14.60	11.40	10.60	13.15	2.57	**108.23**
259.3	10.60	14.20	10.60	9.00	11.10	2.20	**91.36**
777.8	17.60	14.80	10.60	12.00	13.75	3.10	**113.17**
2333	11.20	12.20	14.60	13.60	12.90	1.50	**106.17**
7000	9.40	16.40	12.60	11.80	12.55	2.90	**103.29**

Table KCP 10.6.2-51: Onion (*Allium cepa*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
86.42	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
259.3	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
777.8	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
2333	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
7000	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*

* no change

Ryegrass (*Lolium perenne*)

After the application of the test item at all tested rates, the plant mortality was not observed. After the application of the test item at all tested rates, the ryegrass shoot length was between 91.93 – 98.77% of the control shoot length. After the application of the test item at all tested rates, the ryegrass shoot dry

weight was between 83.37 – 102.25% of the control shoot weight. After the application of the test item at all testes rates, the plants damages were not observed.

Table KCP 10.6.2-52: Ryegrass (*Lolium perenne*) – plant number at the end of the experiment

Application rate [mL/ha]	Total number of plants	Number of plants in particular replicates [No.]				Total number of plants at the end of the experiment [No.]	Total number of plants [%]	Plant survival in comparison to the control at the end of the experiment [%]
		1	2	3	4			
0.0 (control)	20	5	5	5	5	20	100.00	-
86.42	20	5	5	5	5	20	100.00	100.00
259.3	20	5	5	5	5	20	100.00	100.00
777.8	20	5	5	5	5	20	100.00	100.00
2333	20	5	5	5	5	20	100.00	100.00
7000	20	5	5	5	5	20	100.00	100.00

Table KCP 10.6.2-53: Ryegrass (*Lolium perenne*) – shoot length

Application rate [mL/ha]	Mean shoot length [mm]	SD	Shoot length in comparison to the control [%]
0.0 (control)	509.95	76.61	-
86.42	503.70	56.57	98.77
259.3	493.75	62.87	96.82
777.8	477.30	55.68	93.60
2333	484.40	54.36	94.99
7000	468.80	71.81	91.93

Table KCP 10.6.2-54: Ryegrass (*Lolium perenne*) – plant weight

Application rate [mL/ha]	Mean shoot weight in particular replicates [mg]				Mean shoot weight [mg]	SD	Shoot weight in comparison to the control [%]
	1	2	3	4			
0.0 (control)	213.40	260.60	253.00	250.60	244.40	21.10	-
86.42	231.40	211.20	211.40	175.60	207.40	23.22	**84.86**
259.3	299.20	233.00	239.00	228.40	249.90	33.15	**102.25**
777.8	206.00	264.60	187.20	240.40	224.55	34.61	**91.88**
2333	181.60	179.40	225.80	228.20	203.75	26.88	**83.37**
7000	219.60	213.00	199.40	205.00	209.25	8.87	**85.62**

Table KCP 10.6.2-55: Ryegrass (*Lolium perenne*) – plant damage

Application rate [mL/ha]	Replicate	PHYTOTOXIC EFFECTS								
		Day 7			Day 14			Day 21		
		Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*	Mean effects/ replicate [%]	Mean effects/ application rate [%]	Symptoms*
0.0 (control)	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
86.42	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
259.3	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
777.8	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
2333	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*
7000	1 2 3 4	0 0 0 0	0	nc*	0 0 0 0	0	nc*	0 0 0 0	0	nc*

* no change

CONCLUSION

The effective rate (ER_{10}, ER_{25} and ER_{50}), NOER and LOER values of plant mortality, shoot height, and dry shoot weight and phytotoxicity was calculated based on the nominal concentration of the test item and are provided below.

Table KCP 10.6.2-56: Vegetative vigour test results endpoints

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant number at the end of the experiment						
LR_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
LR_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Shoot length (plants without roots)						
ER_{10}	>7000.00	2061.18 (241.21 –34296.70*)	3355.69 (1667.14 – 11855.86*)	>7000.00	>7000.00	6583.70 (1530.59 – n.d.)
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Plant dry weight (plants without roots)						
ER_{10}	>7000.00	3810.08	503.78 (0.89* – 1500.48)	19510.52* (4289.54 – n.d.)	>7000.00	160.46
ER_{25}	>7000.00	>7000.00	19223.80* (5372.20 – n.d.)	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
Phytotoxic effects						
ER_{10}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{25}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
ER_{50}	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00
NOER	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00	≥7000.00
LOER	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00	>7000.00

	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Sunflower *Helianthus annus*	Soybean *Glycine max. (G. Soja)*	Onion *Allium cepa*	Ryegrass *Lolium perenne*
Plant number at the end of the experiment						
LR_{10}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
LR_{25}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
LR_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
Shoot length (plants without roots)						
ER_{10}	>3523.80	1037.60 (121.43 – 17264.96*)	1689.25 (839.24 – 5968.24*)	>3523.80n.d.	>3523.80	3314.23 (770.50 – n.d.)
ER_{25}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
ER_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
Plant dry weight (plants without roots)						
ER_{10}	>3523.80	1917.99	253.60 (0.45* – 755.34)	9821.60* (2159.35 – n.d.)	>3523.80	80.78
ER_{25}	>3523.80	>3523.80	9677.26* (2704.37 – n.d.)	>3523.80	>3523.80	>3523.80
ER_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
Phytotoxic effects						
ER_{10}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
ER_{25}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
ER_{50}	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80
NOER	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80	≥3523.80
LOER	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80	>3523.80

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant. No studies submitted. The higher tier tests are not considered essential, because existing laboratory data for formulation are used and deemed to be sufficient for evaluation and risk assessment.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant. No studies submitted.

A 2.8 KCP 10.8 Monitoring data

Not relevant. No studies submitted.