

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**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**

**NATIONAL ASSESSMENT Poland**

**(authorization)**

**Applicant: ProAgri Intrenational Sp. z o.o.**

**Submission date: April 2024, update August 2024**

**MS Finalisation date: December 2024; June 2025;  
November 2025**

## Version history

When	What
August 2024	Additional data provided by the Applicant
September 2024	Assessment by ZRMS.
December 2024	ZRMs evaluated dRR submitted by Applicant.
June 2025	Corrections made after the commenting period.
November 2025	Corrected after comments of Ministry

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

This document describes the acceptable used conditions required for the registration of BSK-FUN 500 SC, containing active substance boscalid, 500 g/L in Poland. This evaluation is required since the product is a new formulation and has not yet been authorised in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in the Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to BSK-FUN 500 SC where that data has not been considered in the EU review. Otherwise, assessments for the safe use of BSK-FUN 500 SC have been made using endpoints agreed in the EU review of boscalid.

This document describes the specific conditions of use and labelling required for Poland for the registration of BSK-FUN 500 SC.

#### **1.1 Application background**

This application was submitted by ProAgri International Spółka z o.o.

This is the application for registration plant protection product under working name of BSK-FUN 500 SC according to Article 33 of Regulation 1107/2009. BSK-FUN 500 SC is a suspension concentrate (SC), containing 500 g/L of boscalid to be used as a fungicide to protect winter and spring cereals as well as winter oilseed rape against fungal diseases.

#### **1.2 Letters of Access**

Letter of Access is submitted. See Appendix 3.

#### **1.3 Justification for submission of tests and studies**

Please refer to the justification as provided for in the list of references in Appendix 4.

#### **1.4 Data protection claims**

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

### **2 Details of the authorization decision**

## 2.1 Product identity

Product code	BSK-FUN 500 SC
Product name in MS	Boskalid 500 SC
Authorization number	Not applicable.
Function	Fungicide.
Applicant	ProAgri International Sp. z o. o.
Active substance(s) (incl. content)	BSK-FUN 500 g/L
Formulation type	Suspension Concentrate [SC]
Packaging	250mL, 0.5L, 1L, 2L, 5L, 10L, 20L bottles, cannisters HDPE, HDPE/PA (COEX), fHDPE and 220L, 1000L drums and containers HDPE professional
Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identity	Not applicable.
Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

## 2.2 Conclusion

**The evaluation of the application for product Boskalid 500 SC resulted in the decision to grant the authorization.**

### Physical and chemical properties:

Data gap – shelf life study. Provisional authorization for 2 years is possible and proposed.

### Efficacy:

ZRMs accepted conditionally use against SEPTTR on winter wheat, PYRNTE on winter barley, RHYNSE on winter rye and LEPTMA on winter oilseed rape (spring application). Within 24 months after registration, Applicant should submit at least 1-2 efficacy trials carried out on winter wheat against SEPTTR, winter barley against PYRNTE, winter rye against RHYNSE and winter oilseed rape against LEPTMA carried out in N-E EPPO zone. Use against SEPTTR on spring barley, winter triticale and spring triticale and against PYRNTE on spring barley and SCLESC on winter oilseed rape (spring application) were accepted. Use against PUCCRE and PSDCHA on winter wheat was excluded due to not enough number of trials for autumn and combine application (spring/autumn) against SCLESC and LEPTMA in winter oilseed rape due to lack of trials. Recommended water volume for cereals is 200-300 L/ha and for winter oilseed rape is 300-400 L/ha.

### Mammalian toxicology:

BSK-FUN 500 SC is unclassified. **Contains 1,2-benzisothiazol-3(2H)-one and methylisothiazolone**  
**May produce an allergic reaction. [EUH208]**

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

during field operations. Also for bystanders and residents (children and adults) no health risk was found at a buffer zone of 2-3 m.

#### Metabolism and residues:

Uses are accepted.

#### Fate and behaviour:

No risk to groundwater is expected. The PECs and PECsw/sed can be used for further assessment in ecotoxicology.

**Ecotoxicology section:** All Uses are accepted. No minigation measure for aquatic is required.

~~The applications for product Boskalid 500 SC in GAP have been provisionally approved by RMS. The study of the acute toxicity effect of the plant protection product Boskalid 500 SC for fish should be performed by the Applicant or the study on the acute toxicity of fish for a similar formulation to Boskalid 500 SC should be submitted. The product should be comparable to Boskalid 500 SC in terms of toxicity to different groups of organisms and physicochemical properties. The results of the fish study to formulation Boskalid 500 SC probably will bring no change to the risk assessment and conclusions previously reached. It should be considered at MSs level.~~

Evaluators verified whether the co-formulants contained in plant protection product BSK-FUN 500 SC are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product BSK-FUN 500 SC does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product BSK-FUN 500 SC meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

**Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in the dRR Part C and in the Annex to Part C (confidential)..**

## 2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

## 2.4 Classification and labelling


### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Acute 1, H400 Aquatic Chronic 2, H411
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The following labelling information is derived from the classification and to be mentioned in the safety

data sheet. The information which is determined for the label is formatted bold:

Hazard pictograms:	 <b>GHS09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H410 - Very toxic to aquatic life with long lasting effects.</b> <del>H411 - Toxic to aquatic life</del>
Precautionary statement(s):	<b>P273 - Avoid release to the environment.</b> <b>P280 - Wear protective gloves/protective clothing/eye protection/face protection</b> <b>P391 - Collect spillage.</b>
Additional labelling phrases:	<b>To avoid risks to man and the environment, comply with the instructions for use. [EUH401]</b>
	<b>Contains 1,2-benzisothiazol-3(2H)-one and methylisothiazolone May produce an allergic reaction. [EUH208]</b>

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	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).
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## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Workwear and gloves during mixing/loading and during application.
Worker protection:	



-	Workwear.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

## 2.6 Intended uses (only NATIONAL GAP)

GAP rev.1, date: 2024-03-01

PPP (product name/code): BSK-FUN 500 SC  
Active substance 1: boscalid  
Safener: n.a.  
Synergist: n.a.  
Applicant: ProAgri International Sp. z o. o.  
Zone(s): Central Zone <sup>(d)</sup>  
Verified by MS: no

Formulation type: SC <sup>(a, b)</sup>  
Conc. of as 1: 500 <sup>(c)</sup>  
Conc. of safener: n.a. <sup>(c)</sup>  
Conc. of synergist: n.a. <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

Field of use: Fungicide

1	2	3	4	5	6	7	8	10	11	12	13	14	
Use- No.	Member state(s)	Crop and/ or situation  (crop desti- nation / purpose of crop)	F G 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. safen- er/synergist per ha  e.g. recommend- ed or mandatory tank mixtures	
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between appli- cations) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Poland	Winter wheat	F	Septoria leaf blotch ( <i>Zymoseptoria tritici</i> ) SEPTTR  Eyespot of cereals ( <i>Oculimacula acutiformis</i> ) PSDCHA  Brown rust of cereals ( <i>Puccinia recondita</i> ) PUCCRE	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	100 200-300 L/ha	56 days	<b>Efficacy section:</b> only use against SEPTTR accepted conditionally. Recommended water volume: 200-300 L/ha  <b>Ecotoxicology section:</b> The application ac- cepted provision- ally.	

2	Poland	Spring wheat	F	Septoria leaf blotch ( <i>Zymoseptoria tritici</i> ) 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	100 200-300 L/ha	56 days	<b>Efficacy section:</b> recommended water volume: 200-300 L/ha. <b>Ecotoxicology section:</b> The application ac- cepted provision- ally.
3	Poland	Winter triticale	F	Septoria leaf blotch ( <i>Zymoseptoria tritici</i> ) 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	100 200-300 L/ha	56 days	<b>Efficacy section:</b> recommended water volume: 200-300 L/ha. <b>Ecotoxicology section:</b> The application ac- cepted provision- ally.
4	Poland	Spring tritica- le	F	Septoria leaf blotch ( <i>Zymoseptoria tritici</i> ) 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	100 200-300 L/ha	56 days	<b>Efficacy section:</b> recommended water volume: 200-300 L/ha. <b>Ecotoxicology section:</b> The application ac- cepted provision- ally.
5	Poland	Winter barley	F	Net blotch of barley ( <i>Pyrenophora teres</i> ) 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	100 200-300 L/ha	56 days	<b>Efficacy section:</b> PYRNTE accept- ed conditionally. Recommended water volume: 200-300 L/ha. <b>Ecotoxicology section:</b> The application ac- cepted provision- ally.
6	Poland	Spring barley	F	Net blotch of barley ( <i>Pyrenophora teres</i> ) 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	100 200-300 L/ha	56 days	<b>Efficacy section:</b> recommended water volume: 200-300 L/ha. <b>Ecotoxicology section:</b> The

												application accepted provisionally.
7	Poland	Winter oilseed rape	F	Black leg of crucifers ( <i>Leptosphaeria maculans</i> ) 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 <b>Efficacy section:</b> not accepted <b>Ecotoxicology section:</b> The application accepted provisionally.
8	Poland	Winter oilseed rape	F	Black leg of crucifers ( <i>Leptosphaeria maculans</i> ) 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 <b>Efficacy section:</b> not accepted <b>Ecotoxicology section:</b> The application accepted provisionally.
9	Poland	Winter oilseed rape	F	Black leg of crucifers ( <i>Leptosphaeria maculans</i> ) LEPTMA Cottony rot <i>Sclerotinia sclerotiorum</i> SCLESC	broadcast spraying	BBCH 57-71	2 a) 1 b) 2 (14 days)	0.2-0.4-0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-200-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-300-400 L/ha	N/A	<b>Efficacy section:</b> LEPTMA accepted conditionally, Recommended dose: 0.4-0.5 L/ha, Recommended water volume: 300-400 L/ha. <b>Ecotoxicology section:</b> The application accepted provisionally.
10	Poland	Winter rye	F	Leaf blotch of cereals ( <i>Rhynchosporium secalis</i> ) 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 boscalid a) 350 g boscalid b) 350 g boscalid	100-200-300 L/ha	56 days	<b>Efficacy section:</b> RHYNSE accepted conditionally, Recommended water volume:

												200-300 L/ha. <b>Ecotoxicology</b> <b>section:</b> The application ac- cepted provision- ally.
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**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when 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 a.s. 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

### 3 Background of authorization decision and risk management

#### 3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that white liquid suspension of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 570 °C. In aqueous solution, it has a pH value around 7.3 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicating a shelf life at ambient temperature is ongoing. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.1 to 0.35%.

Not recommended for tank-mixes usage.

#### 3.2 Efficacy (Part B, Section 3)

##### 3.3 Efficacy data

This document summarizes the information related to the efficacy of the plant protection product – BSK-FUN 500 SC (product code). BSK-FUN 500 SC is a suspension concentrate (SC) containing 500 g/L of boscalid.

Boscalid is a fungicide that is particularly effective against a range of fungal diseases affecting crops such as winter and spring cereals and winter oilseed rape. It belongs to the carboxamide chemical class, and its mode of action primarily involves inhibiting fungal respiration. Boscalid has many benefits. It offers control over a variety of fungal pathogens, including powdery mildew, rusts and septoria leaf blotch in cereals and diseases like sclerotinia stem rot in oilseed rape. It works well as part of an integrated pest management strategy, offering a different mode of action compared to other fungicides, thus helping to delay the development of resistance. Generally considered safe for humans when used as directed. Proper protective equipment should be worn during application to minimize exposure. While it is effective, there are considerations regarding its environmental impact. It is relatively persistent in soil and can affect non-target organisms, so care is required to avoid runoff to water bodies. Boscalid is a versatile and effective fungicide for managing a range of fungal diseases in winter and spring cereals and winter oilseed rape. When used according to guidelines, it provides significant benefits in disease control, contributing to healthy crop yields.

For now, this mentioned active substance (boscalid) is on the list of approved active substances. All necessary information's about tested plant protection product, active substance, studied fungal diseases, reference products, etc. were correctly presented in this dossier by Applicant. In Poland, 44 plant protection products containing boscalid as an active compound are already registered (on the basis of Ministry Registry, dated 18.09.2024).

This product (BSK-FUN 500 SC) containing boscalid (500g/L) by ProAgri International Sp. z o.o. will be sold as trade name Boscalid 500 SC.

**Preliminary studies:** Boscalid has been used as a fungicide since its introduction in the early 2000s. It was first registered by BASF in 2002 and has since become widely adopted in agriculture for its effectiveness in controlling a broad spectrum of fungal diseases in various crops. Boscalid works by inhibiting fungal respiration, thus protecting crops like fruits, vegetables and cereals from damaging pathogens. So, it has been in use for roughly two decades. In Poland, Boscalid was first registered in 2005.

Large scale efficacy trials are available to evaluate the effectiveness of products containing boscalid. So, preliminary tests were not necessary in this case in our opinion. Also, some formulations of boscalid 500 g/L which are currently authorised on cereals and winter oilseed rape (OSR) against the same target diseases requested for BSK-FUN 500 SC. For example, in Poland over 40 plant protection products with boscalid are registered.

**Minimum effective dose:** The minimum effective dose of boscalid can vary depending on factors such as the specific crop, fungal pathogen and local agricultural guidelines. Typical application rates range for cereals from 125 to 250 grams of boscalid per hectare. For winter oilseed rape recommended rates are also range around 150 to 250 grams per hectare. It is crucial to follow the specific product label instructions and regulations. The Applicant has proposed doses of BSK-FUN 500 SC that reflect those of currently authorised boscalid products across the EU. To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line to EPPO 1/225(2).

Applicant did not present any separate MED trials. Minimum effective dose was studied during efficacy trials (37 in total). All trials were carried out in Poland (N-E EPPO zone) on winter wheat (8 trials), spring wheat (2 trials), winter triticale (2 trials), spring triticale (2 trials), winter barley (7 trials), spring barley (1 trial), winter rye (8 trials) and winter oilseed rape (7 trials). Those trials were carried out in one growing season (2023).

Following fungal diseases were studied during trials:

- ✓ *winter wheat*: PSDCHA (2 trials), PUCCSI (1 trial), PUCCRE (2 trials), PYRNTR (1 trial), SEPTTR (5 trials)
- ✓ *spring wheat*: SEPTTR (2 trials)
- ✓ *winter triticale*: ERYSYGR (2 trials), SEPTTR (1 trial)
- ✓ *spring triticale*: ERYSYGR (1 trial), SEPTTR (1 trial)
- ✓ *winter barley*: ERYSYGR (1 trial), PUCCHD (1 trial), PUCCRE (1 trial), PYRNTE (5 trials)
- ✓ *spring barley*: PYRNTE (1 trial)
- ✓ *winter rye*: ERYSYGR (2 trials), PUCCRE (2 trials), PUCCSI (1 trial), RHYNSE (5 trials), SEPTTR (2 trials)
- ✓ *winter oilseed rape*: ALTEBA (1 trial), LEPTMA (5 trials) and SCLESC (7 trials).

During trials carried out on cereals following doses were studied: 0.42 L/ha (0.6N); 0.50 L/ha (0.71N); 0.6 L/ha (0.85N) and 0.70 L/ha (N recommended).

During trials carried out on winter oilseed rape following doses were studied: 0.2 L/ha (0.4N); 0.3 L/ha (0.6N); 0.4 L/ha (0.8N) and 0.5 L/ha (N dose recommended).

On the basis on submitted results it can be concluded that for the most of studied fungal diseases in cereals the most effective dose was 0.7 L/ha and for winter oilseed rape – dose 0.4-0.5 L/ha. Dose 0.2-0.3 L/ha in winter oilseed rape and dose 0.72-0.60 L/ha in cereals were characterized by worse efficacy and should not be recommended for use.

Based on results achieved on fungal diseases in the submitted trials, it can be concluded that BSK-FUN 500 SC applied at 0.7 L/ha in cereals and applied at dose 0.4-0.5 L/ha in winter oilseed rape achieved good to excellent control on several target diseases. Dose 0.4 L/ha in winter oilseed rape should be used only in case of low level of occurrence the diseases like LEPTMA and SCLESC. The higher recommended dose should be applied in the case of high pressure of LEPTMA and SCLESC or worse weather conditions. Does 0.2 L/ha and 0.3 L/ha should be excluded from GAP and label project due to worse efficacy than was noted for doses 0.4 and 0.5 L/ha. Inferior efficacy at the level of intermediate eradication or reduction of diseases incidence still significantly increases the risk of resistance to boscalid by these pathogens and should therefore not be recommended for use in the opinion of ZRMs. Autumn use and combination use (1 in spring and 1 in autumn) in winter oilseed rape should be excluded due to lack of trials.

The proposed rates (0.7 L/ha for cereals and 0.4-0.5 L/ha for winter oilseed rape for spring application) should be considered the minimum effective dose to deliver broad spectrum control of the target diseases on cereals and winter oilseed rape under a wide range of environmental conditions in the context of trials

and existing knowledge on the active substance and other relevant formulations with boscalid on the market.

### **Efficacy:**

On the basis on literature data, boscalid is effective against several key fungal disease affecting cereals, like: septoria leaf blotch, net blotch, rhynchosporium, brown rust, powdery mildew and sclerotinia stem rot, phoma stem canker and alternaria leaf spot and pod spot in winter oilseed rape. It is recommended to use it as a part of an integrated disease management program, including rotating fungicides with different modes of action and applying fungicides based on diseases risk.

Trials were conducted according to the EPPO guidelines. The GEP certificates of the official testing organizations were provided. EPPO Standard PP 1/226 provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years. Applicant submitted in total 37 efficacy trials carried out in N-E EPPO zone (Poland) in one growing season (2023). Conducting trials only in one growing season is not in line to EPPO standard 1/181. However, at the start of this dossier, Applicant submitted explanations about conducting only one season. These clarifications were accepted by ZRMs. Boscalid is a fungicide commonly used on both cereals (such as wheat, barley, etc.) and winter oilseed rape. It is particularly valued for its broad-spectrum activity against key fungal diseases in these crops, though it is often applied in mixtures with other fungicides to enhance its efficacy and prevent resistance development.

The Applicant was notified that according to PP 1/226 at least 6 trials in case of major crop are required. In the opinion of ZRMs, number of trials for winter wheat (8 trials), winter barley (7 trials), winter rye (8 trials) and winter oilseed rape (7 trials) is acceptable. Spring wheat (2 trials), winter triticale (2 trials), spring triticale (2 trials) and spring barley (1 trial) can be also accepted on the basis on the extrapolating results from cereals represented by sufficient number of trials in line to harmonization agreements.

**Cereals:** Number of trials for studied diseases is also important. Major diseases should be represented by at least 6 valid trials. However, SEPTTR in winter wheat, PYRNTE in winter barley and RHYNSE in winter rye were represented by only 5 trials carried out in one growing season. All those trials were characterized by acceptable level of infestation. In special cases where the results of the tests are consistent, a reduction to 5 tests, carried out in 2 seasons, is possible. All noted results were consistent, but considering the fact that testing will only be carried out in one season and that there are only a limited number of plant protection products with boscalid in a similar formulation to the product under consideration, registration will only be possible conditionally. Within 24 months after registration, Applicant should submitted 1-2 additional efficacy trials carried out on winter wheat against SEPTTR, winter barley against PYRNTE and winter rye against RHYNSE in N-E EPPO zone. PUCCRE (2 trials) and PSDCHA (2 trials) on winter wheat should be excluded from GAP and label project due to not enough number of trials (at least 6 are required). SEPTTR on spring wheat (2 trials), winter triticale (1 trial) and spring triticale (1 trial) can be accepted on the basis on extrapolating results from winter wheat. PYRNTE on spring barley (1 trial) can be accepted on the basis on extrapolating results from winter barley.

Following application window was studied during 30 cereals trials: BBCH 30-51. ZRMs accepted proposed by Applicant application window (BBCH 30-49) as compatible with submitted trials. Following water volume: 200-300 L/ha was studied during trials. In the opinion of ZRMs, accepted water volume for cereals should be 200-300 L/ha, not 100-300 L/ha.

### **✓ *Winter wheat:***

**SEPTTR** (5 trials) – accepted conditionally. It is a major diseases in winter wheat. It can be concluded that BSK-FUN 500 SC at recommended dose (0.7 L/ha) effectively control SEPTTR on winter wheat (95.4% eff.). Results were compared to st. ref. product (94.6% eff.). Level of infestation of the untreated control was accepted in all trials (average 6.5%, range 5.1-8.7%).

**PUCCRE** (2 trials) – not accepted due to limited number of trials (at least 6 should be presented). Major disease in winter wheat. It is a major disease in winter wheat. On the submitted documentation, registra-



tion of this disease is not possible.

**PSDCHA** (2 trials) – not accepted due to limited number of trials (at least 6 should be presented). Major disease in winter wheat. It is a major disease in winter wheat. On the submitted documentation, registration of this disease is not possible.

✓ *Spring wheat:*

**SEPTTR** (2 trials) – accepted on the basis of extrapolating results from winter wheat. Major disease in spring wheat. On the submitted results it can be stated that BSK-FUN 500 SC effectively control (92.5% eff.) SEPTTR on spring wheat at recommended dose (0.7 L/ha). Results were compared to st. ref. product (91.0% eff.). Level of infestation of the untreated control was accepted in all trials (average 7.0%, range 6.3-7.7%).

✓ *Winter triticale:*

**SEPTTR** (1 trial) – accepted on the basis of extrapolating results from winter wheat. It is not included as a major disease in integrated production methodologies. However, triticale, being a hybrid cereal that combines the characteristics of wheat and rye, is susceptible to many diseases that affect wheat, including septoria leaf blotch. The symptoms of the disease in triticale are similar to those found in wheat – small, dark spots appear on the leaves, which can gradually cause leaf necrosis, limiting photosynthesis and reducing yield. Septoria leaf blotch can particularly threaten triticale yields in conditions favorable to the disease's development, such as high humidity and moderate temperatures. Therefore, it is important to monitor triticale crops for symptoms of this disease and apply appropriate plant protection measures, including fungicides, if the first signs of infection appear. On the submitted results it can be stated that BSK-FUN 500 SC effectively control SEPTTR on winter triticale (92.0% eff.). Results were comparable to st. ref. product (91.0% eff.). Level of infestation of the untreated control was accepted in all trials (7.9%).

✓ *Spring triticale:*

**SEPTTR** (1 trial) – accepted on the basis of extrapolating results from winter wheat. It is not included as a major disease in integrated production methodologies. On the submitted results it can be stated that BSK-FUN 500 SC effectively control SEPTTR on spring triticale (86.0% eff.). Results were comparable to st. ref. product (86.0% eff.). Level of infestation of the untreated control was accepted in all trials (9.3%).

✓ *Winter barley:*

**PYRNTE** (5 trials) – accepted conditionally. It is a major disease in winter barley. On the submitted results it can be stated that BSK-FUN 500 SC effectively control (92.8% eff.) PYRNTE on winter barley at recommended dose (0.7 L/ha). Results were compared to st. ref. product (93.0% eff.). Level of infestation of the untreated control was accepted in all trials (average 5.7%).

✓ *Spring barley:*

**PYRNTE** (1 trial) – accepted on the basis of extrapolating results from winter barley. It is a major disease in spring barley. On the submitted results it can be stated that BSK-FUN 500 SC effectively control PYRNTE on spring barley (99.0% eff.). Results were comparable to st. ref. product (99% eff.). Level of infestation of the untreated control was accepted in all trials (13.4%).

✓ *Winter rye:*

**RHYNSE** (5 trials) – accepted conditionally. It is a major disease in winter rye. On the submitted results it can be stated that BSK-FUN 500 SC effectively control (89.8% eff.) RHYNSE on winter rye at recommended dose (0.7 L/ha). Results were compared to st. ref. product (88.2% eff.). Level of infestation of the untreated control was accepted in all trials (average 7.96%).

**Winter oilseed rape:** All trials (7) were studied spring application. Lack of efficacy trials for autumn application and combine application (1 in spring and 1 in autumn). Due to lack of autumn efficacy trials, this use should be excluded from GAP table and label project. Only registration of spring application is possible. Following application window was studied during 7 trials: BBCH 57-69. ZRMs accepted pro-

posed by Applicant application window (BBCH 57-71) as compatible with submitted trials for spring application. BSK-FUN 500 SC was applied two times in spring (May) with 14 days interval. Following water volume: 300-400 L/ha was studied during trials. In the opinion of ZRMs, accepted water volume for winter oilseed rape should be 300-400 L/ha, not 100-400 L/ha.

ZRMs did not agree for registration use number 7 (autumn BBCH 13-18 and spring BBCH 31-57 against LEPTMA) and use number 8 (spring BBCH 31-57 against LEPTMA). Those uses were not represented by submitted documentation for BSK-FUN 500 SC. Only registration of use number 9 (spring BBCH 57-71 against LEPTMA and SCLESC) is possible in line to documentation. Below, ZRMs presented results supporting registration use number 9 in winter oilseed rape:

Major diseases should be represented by at least 6 valid trials. However, LEPTMA in winter oilseed rape were represented by only 5 trials carried out in one growing season. All those trials were characterized by acceptable level of infestation. In special cases where the results of the tests are consistent, a reduction to 5 tests, carried out in 2 seasons, is possible. All noted results were consistent, but considering the fact that testing will only be carried out in one season and that there are only a limited number of plant protection products with boscalid in a similar formulation to the product under consideration, registration will only be possible conditionally. Within 24 months after registration, Applicant should submitted 1-2 additional efficacy trials carried out on winter oilseed rape against LEPTMA in N-E EPPO zone. SCLESC (7 trials) were characterized by acceptable number of trials.

**LEPTMA** (5 trials) – accepted conditionally. It is a major disease. On the submitted results it can be stated that BSK-FUN 500 SC effectively control (82.26% eff. and 87.54) LEPTMA on winter oilseed rape at recommended dose (0.4 L/ha and 0.5 L/ha). Results were compared to st. ref. product (96.78% eff.). Level of infestation of the untreated control was accepted in all trials (average 14.6%).

**SCLESC** (7 trials) – accepted. It is a major disease. On the submitted results it can be stated that BSK-FUN 500 SC moderately effectively (79.6% control SCLESC on winter oilseed rape at recommended dose 0.4 L/ha and effectively control (85.83% eff.) SCLESC on winter oilseed rape at recommended dose 0.5 L/ha. Results were compared to st. ref. product (84.95% eff.). Level of infestation of the untreated control was accepted in all trials (average 38.2%). Given the high level of infestation and the fact that the product at 0.4 L/ha had an efficacy of almost 80% and at 0.5 L/ha an efficacy of more than 80%, the ZRMS is of the opinion that this disease should be classified as susceptible to BSK-FUN 500 SC.

### 3.3.1 Information on the occurrence or possible occurrence of the development of resistance

According to FRAC active substance boscalid belongs to the pyridine-carboxamides group (also known as carboxins or oxathiins, group FRAC C2). The mode of action of boscalid is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain. Like other complexes of the respiratory chain, this enzyme is a component of the inner mitochondrial membrane. FRAC describes risk of resistance occurrence for this group as medium.

Strategies and General Guidelines for management of SDHI fungicide resistance in all crops:

- Strategies for the management of SDHI fungicide resistance, in all crops, are based on the statements listed below. These statements serve as a fundamental guide for the development of local resistance management programs.
- Resistance management strategies have been designed in order to be proactive and to prevent or delay the development of resistance to SDHI fungicides.
- A fundamental principle that must be adhered to when applying resistance management strategies for SDHI fungicides is that:
- The SDHI fungicides (benodanil, benzovindiflupyr, bixafen, boscalid, carboxin, cyclobutrifluram, fenfuram, fluindapyr, fluopyram, flutolanil, fluxapyroxad, furametpyr, inpyrfluxam, isofetamid,

isoflucypram, isopyrazam, mepronil, oxycarboxin, penflufen, penthiopyrad, pydiflumetofen, sedaxane, thifluzamide) are in the same cross-resistance group.

- Fungicide programs must deliver effective disease management. Apply SDHI fungicide-based products at effective rates and intervals according to manufacturers' recommendations.
- Effective disease management is a critical component to delay the build-up of resistant pathogen populations.
- The number of applications of SDHI fungicide-based products within a total disease management program must be limited.
- When mixtures are used for SDHI fungicide resistance management, applied as tank mix or as a co-formulated mixture, the mixture partner:
  - should provide satisfactory disease control when used alone on the target disease.
  - must have a different mode of action.
- Mixtures of two or more SDHI fungicides can be applied to provide good biological efficacy; however, they do not provide an anti-resistance strategy and must be treated as a solo SDHI for resistance management. Each application of such a mixture when used in a spray program counts as one SDHI application.
- SDHI fungicides should be used preventively or at the early stages of disease development.
- Please refer to the "mixture document" for more information on fungicide mixtures for resistance management.
- Species can carry different mutations which affect SDHIs. A few mutations can lead to different sensitivities depending on the chemical structure of the active ingredient.
- As SDHIs are cross-resistant, resistance management must be the same for all SDHIs.
- All monitoring and guideline related statements refer to the entire group of SDHIs.

Strategies and General Guidelines for management of SDHI fungicide resistance in cereals:

- Apply SDHI fungicides always in mixtures
- The mixture partner should provide satisfactory disease control when used alone on the target disease and must have a different mode of action.
- Apply a maximum of 2 SDHI fungicide containing sprays per cereal crop.
- Apply the SDHI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of SDHI fungicides.
- Strongly reduced rate programs including multiple applications must not be used. Refer to manufacturers' recommendations for rates.

Strategies and General Guidelines for management of SDHI fungicide resistance in oilseed rape:

Extensive monitoring programs have been carried out. Reduced sensitivity has been detected in *S. sclerotiorum*. Further monitoring programs will continue and clarify the necessity for a specific crop guideline. The general guidelines for the use of SDHIs are currently considered to be sufficient because current data shows sporadic detection, no consistent increase and spread of resistant mutations. In addition, the life cycle of the pathogen, its distribution and rotation with non-host crops confirm that Sclerotinia in oilseed rape justify the classification as a low risk pathogen

### 3.3.2 Adverse effects on treated crops

Boscalid is generally effective and safe when used according to guidelines. However, when applied at higher than recommended doses, Boscalid can cause phytotoxicity, which may manifest as stunted growth, chlorosis or necrosis. Repeated and excessive use of Boscalid can lead to the development of

resistance in fungal populations, reducing its effectiveness over time. This can necessitate the use of higher doses or additional fungicides, potentially increasing the risk of adverse effects. Using boscalid responsibly and adhering to integrated pest management practices can help minimize adverse effects while maintaining its benefits in controlling fungal diseases in cereals and winter oilseed rape

The applicant carried out 37 efficacy trials in which selectivity of the BSK-FUN 500 SC was assessed according to EPPO general and crop specific guidelines:

- 8 trials in winter wheat were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 2 trials in spring wheat were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 2 trials in winter triticale were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 2 trials in spring triticale were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 7 trials in winter barley were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 1 trial in spring barley were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 8 trials in winter rye were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.  
No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 1x0.7 L/ha of BSK-FUN 500 SC was used.
- 7 trials in winter oilseed rape were carried out in Poland, in year 2023 on a wide range of commercially grown varieties.

No phytotoxicity symptoms were recorded in all of the trials performed on winter wheat, when proposed label rate of 2x0.5 L/ha of BSK-FUN 500 SC was used

EPPO PP 1/226(3) standard states - it is not required to conduct phytotoxicity trials for fungicides. However, phytotoxicity was evaluated in each type of the performed efficacy trials, also yield and its quality traits was evaluated according to EPPO guidelines.

Summary: No adverse effects on cereals (winter: wheat, triticale, barley, rye and spring: wheat, triticale, barley) and winter oilseed rape regarding phytotoxicity were observed in any of submitted efficacy trials (37) treated with BSK-FUN 500 SC in N-E EPPO zone. No negative impact of the product BSK-FUN 500 SC is to be expected when at the intended rate and used according to the label recommendations.

**Impact on the yield:** Boscalid effectively controls diseases such as *Sclerotinia sclerotinum* in oilseed rape and septoria, rusts and powdery mildew in cereals. Improved disease control generally leads to healthier plants and increased yields. Weather conditions influence disease pressure and fungicide performance. In wet, humid conditions where fungal diseases are more prevalent, the yield benefits from

Boscalid treatments can be more pronounced. In conclusion, the use of boscalid fungicide has the potential to positively impact the yield of winter oilseed rape and cereals through effective disease management, provided it's used judiciously and in combination with other agronomic practices. However, the specific yield responses can vary depending on disease pressure, environmental conditions and how well the fungicide application is managed.

In conclusion, no negative impact of the product BSK-FUN 500 SC on the yield is to be expected when at the intended rate and used according to label recommendations. Detailed results were presented in point 3.2.3 Efficacy tests in tables: Table 3.2.31 to Table 3.2.46 from B3 part. Yield was assessed in 37 trials carried out on winter wheat (8 trials), spring wheat (2 trials), winter triticale (2 trials), spring triticale (2 trials), winter barley (7 trials), spring barley (1 trial), winter rye (7 trials) and winter oilseed rape (7 trials). Those results show that BSK-FUN 500 SC will have no adverse effect on yield and in the presence of disease are likely to result in a significant increase. Results were comparable to st. ref. product.

**Effect on the quality of yield:** Effective diseases control generally leads to improved plant health, which can translate into higher yields. Healthier plant produce better quality seeds, which in turn can improve the quality of oil extracted from winter oilseed rape. The oil might have better fatty acid profiles and reduced levels of undesirable compounds. Healthier cereal plants often produce grain with better protein content. This is particularly important for cereals like wheat where protein content can affect baking quality. In summary, the judicious use of boscalid fungicide can significantly enhance the quality and yield of winter oilseed rape and cereals by controlling diseases.

Quality of yield was assessed during 37 efficacy trials carried out in winter wheat (8 trials), spring wheat (2 trials), winter triticale (2 trials), spring triticale (2 trials), spring barley (1 trial), winter barley (7 trials), winter rye (8 trials) and winter oilseed rape (7 trials). Following quality parameters of quality were studied: moisture (cereals, winter oilseed rape), weight of 1000 grains (cereals, winter oilseed rape), test weight (cereals) and oil content (winter oilseed rape). Those results show that BSK-FUN 500 SC will have no adverse effect on the quality of yield and in the presence of disease are likely to result in a significant increase. Results were comparable to st. ref. product.

### 3.3.3 Observations on other undesirable or unintended side-effects

**Effect on transformation processes:** Boscalid is a fungicide, effective in reducing fungal diseases. Baking might degrade some boscalid residues, although not necessarily to non-detectable levels. It is important to monitor and potential residue levels post-baking to ensure safety. Boscalid residue interactions would depend on the microorganisms used and fermentation conditions. Some pesticide might be metabolized by microbes, potentially reducing residue levels. The seeds are often cold-pressed or solvent-extracted to obtain oil. Boscalid might partition differently between the oil and the remaining seed cake.

In summary, each processing method can potentially alter the residue profile of boscalid. Mitigating any risk involves strict residue monitoring and understanding processing specific impacts on residue levels to ensure consumer safety. Since, the market introduction no effects on transformation processes have been recorded for any of these products have any label restrictions concerning their use on crops destined for processing. In the opinion of ZRMs, no undesirable effects are expected on transformation processes. On the basis of data from DAR for nicobifen (boscalid) from 2022 it can be concluded that boscalid is stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation, and no additional metabolites are formed in processed commodities as compared to raw agricultural commodities.

**Impact on the propagating purposes:** Pesticide residues on seed could potentially impact their viability. While boscalid is typically designed to minimize phytotoxicity, excessive residue levels may still interfere with seed germination. Seeds exposed to high levels of fungicide can sometimes show reduced germination rates. Ensuring that boscalid residue levels are within safe limits is crucial for maintaining healthy germination. In summary, while boscalid is valuable for diseases management in winter oilseed rape and cereals, its use for propagating purposes requires careful consideration. Paying attention to residue levels,



compliance with regulations and potential impacts on soil ecosystems will help ensure successful and safe of these treated seeds for future crops.

No phytotoxicity symptoms occurring during the field trials suggested that product application in accordance to label recommendation has no negative impact on parts of plant used for propagating purposes. Also, the fungicides containing boscalid have been allowed to use for many years. Through the application of the fungicide with boscalid, in the mean no negative effects on the process and on treated plants or plant products used for propagation were detected. Based on this knowledge, it can be concluded that no adverse effects on treated plants such as phytotoxicity symptoms, negative impact on yield quality, quantity and transformation processes were observed in efficacy trials of BSK-FUN 500 SC. According to the above statement additional research are not required in this range, in the opinion of ZRMs.

**Impact on the succeeding crops:** Boscalid has a relatively long-life in soil, meaning it can persist for several months after application. The residual presence of boscalid in the soil can potentially affect subsequent crops, particularly those sensitive to fungicides. Different crops exhibit varying levels of sensitivity to residual boscalid. While boscalid is an effective tool against various fungal diseases, its prolonged soil persistence necessitates careful planning for subsequent crops. By testing soil, choosing appropriate rotations and managing field conditions to accelerate fungicide degradation, farmers can mitigate adverse impacts on succeeding crops and maintain soil health.

Impact on the succeeding crops should be assessed in line to EPPO 1/207. However, Applicant did not provide any data about impact of tested PPP on the succeeding crops. What is important, BSK-FUN 500 SC is a fungicide without any herbicidal action and therefore not expected to be harmful for any succeeding crop. In conclusion, BSK-FUN 500 SC is considered to be safe for succeeding crops when applied according to label recommendations. Only, in case of the need to sift the treated plantation (as a result of crop damage by frost, disease or pest), every crop can be grown after performing 25 cm ploughing.

**Impact on adjacent crops:** Spray drift during application can lead to inadvertent contamination of adjacent crops. This can occur due to wind, incorrect sprayer settings or application methods. Some crops may be sensitive to even small amounts of boscalid, showing symptoms like leaf discoloration, stunted growth or necrosis.

Boscalid can move through the soil or via runoff, potentially reaching the root zones or nearby unsprayed crops. Adjacent crops may absorb boscalid residues through their roots, which could inhibit nutrient uptake and overall growth. Runoff can introduce boscalid to nearby water sources used for irrigation. Under certain conditions, boscalid can volatilize and later deposit onto nearby crops.

While boscalid is an effective fungicide, careful attention to application methods and environmental conditions is vital to minimize its impact on adjacent crops. Implementing buffer zones, precise application, and regular monitoring can substantially reduce the risk of contamination and ensure healthy crop production. It is not expected that appropriate applications of BSK-FUN 500 SC will lead to adverse effects on adjacent crops. No negative effects of applications of boscalid containing products on adjacent crops are known, neither from field trials nor from long term agricultural use when the products were applied according to the use instructions. According to the above statement additional research are not required in this range, in the opinion of ZRMs.

**Impact on the beneficial and non-target organisms:** In summary, boscalid's impact on non-target organisms can vary. While it is relatively safe for bees and many soil microorganisms when used correctly, its potential to cause disruptions in aquatic environments and soil ecosystems highlights the importance of prudent application and integrated pest management practices.

### 3.4 Methods of analysis (Part B, Section 5)

#### 3.4.1 Analytical method for the formulation

Analytical methods for determination of boscalid in BSK-FUN 500 SC was not evaluated as part of the EU review of boscalid. Therefore, all relevant data are provided and are considered adequate.

The method for determination of boscalid in BSK-FUN 500 SC formulation is based on HPLC using an internal standard and UV detector. In order to confirm method specificity, chromatograms of acetonitrile, placebo, standard and analysed sample were superimposed and compared.

There were no peaks interfering with the boscalid peak. The correlation coefficient was  $R^2 > 0.99$ . The relative standard deviation of instrument precision for the determined active substance was  $RSD = 0.15\%$  (criterion of acceptability is  $H_r \leq 1$ ). Acceptable relative standard deviation of repeatability for the determined active substance is  $\leq 1.52$ . The obtained results of 0.1% is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The recovery value for the main component should be 97% ÷ 103%. The obtained result 101.7% is acceptable.

The method for determination of boscalid in BSK-FUN 500 SC fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

#### 3.4.2 Analytical methods for residues

Commodity/crop	Supported/ Not supported
Cereals	Supported
Winter oilseed rape	Supported

##### Data gaps:

- According to MRL Reg. (EU) 2022/1324, the MRL for muscle has been set at 0.01 mg/kg. LOQ of the EU agreed analytical methods for muscle is 0.025 mg/kg.

New methods for muscle (primary and ILV) with LOQ at 0.01 mg/kg are required (data gap). This gap can be filled after registration (within two years).

- The LOQ of the method of Class, 2000 for eggs, is not sufficient for currently stated MRL.

The method of Kampke Thiel, 2001 is not validated for eggs and meat.

Data gap: ILV method for eggs. This gap can be filled after registration (within two years).

### 3.5 Mammalian toxicology (Part B, Section 6)

#### 3.5.1 Acute toxicity

No acute toxicity studies were performed for product BSK-FUN 500 SC. The classification of product is based on the composition of the product and was performed according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16<sup>th</sup>, 2008, *on classification, labelling and packaging of substances and mixtures*. Details on composition and classification of formulants are provided in dRR Part C.

Regarding acute toxicity and other toxicological data for product BSK-FUN 500 SC no classification is required with **EUH208: Contains 1,2-benzisothiazol-3(2H)-one, and methylisothiazolone May produce an allergic reaction**

### **3.5.2 Operator exposure**

The operator exposure was assessed against the AOEL agreed in the EU review of boscalid. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption) and SAN-TE/2018/10591 rev.1 of 24 October 2018 were used for the calculations.

Operator exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

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

### **3.5.3 Worker exposure**

The worker exposure was assessed against the AOEL agreed in the EU review of boscalid. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption) and SAN-TE/2018/10591 rev.1 of 24 October 2018 were used for the calculations.

Worker exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

The results of the performed exposure calculations show that the use of BSK-FUN 500 SC according to the list of intended uses presented in GAP Table, causes no health risk for the worker equipped with workwear (arms, body and legs covered) during field activities.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

### **3.5.4 Bystander and resident exposure**

The bystander and resident exposure was assessed against the AOEL agreed in the EU review of boscalid. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption) and SANTE/2018/10591 rev.1 of 24 October 2018 were used for the calculations.

The bystander and resident exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

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

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



### **3.6 Residues and consumer exposure (Part B, Section 7)**

#### **3.6.1 Residues**

##### **Storage stability**

In the framework of the peer review, storage stability of boscalid was demonstrated for a period of 16 months in commodities with high acid content (grape) and 24 months in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw.

Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen.

Additionally, the applicant provided new storage stability study for wheat and oilseed rape matrices. The boscalid is stable for a period of 5 months storage at  $\leq -18^{\circ}\text{C}$  in the dark in wheat (whole plant, straw and grain) and oilseed rape (whole plant, pods and seeds)

##### **Metabolism in plants and animals**

Plant residue definition for monitoring Boscalid (Regulation n°2022/1324)

Plant residue definition for risk assessment Boscalid (EFSA 2014)

##### **Magnitude of residues in plants**

Winter wheat, triticale, barley, rye;  
spring wheat, triticale, barley

Proposed GAP:

1 application, BBCH 30-49, 350 g as/ha, PHI: 56 days

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP (wheat): 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor

Residues: 0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731 mg/kg (2 x <0.01, 0.04, 2 x 0.05, 2 x 0.06, 0.07 mg/kg)

Sufficient trials are available to support the proposed use on wheat.

According to SANTE/2019/12752 Rev.01 extrapolation from wheat to triticale, barley and rye is possible before forming the edible part.

The data submitted show that no exceedance of the EU MRLs for wheat, triticale, barley and rye will occur.

Winter oilseed rape

Proposed GAP:

2 applications; BBCH Autumn - BBCH 13-18 Spring - BBCH 31-57; 100 - 250 g as/ha, PHI: n/a  
one in autumn, one in spring (30 days interval) or 2 in spring (14 days interval)

2 applications; BBCH 57-71 (spring, 14 days interval); 100 - 250 g as/ha, PHI: n/a

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 2 x 0.25 kg as/ha, BBCH 57-71, PHI NA, outdoor

2x< 0.002, 0.0071, 0.0144, 0.0182, 0.0253, 0.0532, 0.1070 mg/kg (3 x<0.01, 0.01, 0.02, 0.03, 0.05, 0.11 mg/kg)

Sufficient trials are available to support the proposed use on oilseed rape.

The data submitted show that no exceedance of the EU MRLs for oilseed rape will occur.

### **Magnitude of residues in livestock**

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

STMR and HR from the new residue trials are less than used in dietary burden calculation for art.12 review (EFSA Journal 2014;12(7):3799). Additional data are not required.

### **Processing studies**

Studies investigating the magnitude of residues in processed commodities of different crops were reported in the framework of the peer review (DAR, 2002). Data are considered acceptable to derive robust processing factors for different crops. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment

### **Magnitude of residues in representative succeeding crops**

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*Occurrence of Boscalid residues in rotational crops was already investigated during the peer review. It is concluded that metabolic patterns in primary and succeeding crops are similar and that a potential for accumulation of Boscalid residues in crops grown in rotation is expected. EFSA is aware that instead of defining risk mitigating measures, risk managers may have the interest to establish MRLs accommodating for the uptake of residues from previously treated soils, EFSA therefore recalculated the MRL proposals to take into account such residues.*

Waiting periods before planting following succeeding crops: not required.

Additional data are not required.

### **Other / special studies**

Four new semi-field/tunnel studies in N-EU zone (Poland and N-France) and S-EU zone (S-France and Italy) in 2023-2024 have been performed on *Phacelia tanacetifolia* to investigate the magnitude of boscalid residues in honey. These trials consider a “worst case” situation (the most critical scenario was used on Phacelia plants representing a worst case in terms of residues in honey). All results are  $\leq$  LOQ, which is below MRL. The results are acceptable. No risk for consumers is expected.

## **3.6.2 Consumer exposure**

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological refer-

ence values (i.e., the ADI and the ARfD).

As ARfD was not deemed necessary for boscalid, acute risk assessment is not relevant.

The chronic risk assessment based on current MRLs (Reg. (EU) Reg. (EU) 2022/1324), represents the worst-case scenario, significantly exceeds ADI. Therefore, the refinement based on median residue (EFSA, 2014) was carried out as a realistic scenario. According to calculations the highest chronic exposure was calculated for NL toddler diet, representing 70% of the ADI. Since IEDI value is below 100%, further refinement is not required.

TMDI (% ADI) according to EFSA PRIMo	400 % (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo	70 % (based on NL toddler diet)
IESTI (% ARfD) according to EFSA PRIMo*	Not relevant.

The proposed uses of boscalid in the formulation BSK-FUN 500 SC do not represent unacceptable chronic risks for the consumer.

STMR from the new trials of wheat and oilseed rape are less than used in EFSA calculation. Therefore, no recalculation using these values is required. ADI will not be exceeded..

### 3.7 Environmental fate and behaviour (Part B, Section 8)

#### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

PEC<sub>soil</sub> modelling for boscalid was performed with ESCAPE v. 2. PEC<sub>soil</sub> for formulation was obtained from PEC<sub>soil</sub> for active substance taking into account content of active substance and density of the formulation. The obtained PEC<sub>soil</sub> values were used in further soil organisms risk assessment.

#### 3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

Based on FOCUS PEARL and PELMO simulations values of PEC<sub>gw</sub> for boscalid are far below the threshold concentration of 0.1 µg/L for all scenarios and crops. There is no unacceptable risk of groundwater contamination.

**The replacement crop for spring cereals for scenario R1 is winter cereals.**

#### 3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

PEC<sub>sw</sub> for boscalid were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3. PEC<sub>sw</sub> values were used in aquatic risk assessment.

#### 3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The vapour pressure at 20 °C of the active substance boscalid is < 10<sup>-5</sup> Pa. Hence, the active substance boscalid is regarded as non-volatile. Additionally, it is rapidly degraded in air. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance boscalid due to volatilization with subsequent deposition does not have to be considered.

### 3.8 Ecotoxicology (Part B, Section 9)

#### 3.8.1 Effects on terrestrial vertebrates

##### 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.**

#### 3.8.2 Effects on aquatic species

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 PEC<sub>sw</sub> 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, 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  
**Formulation: H410**

The applications for product BSK-FUN 500 SC in GAP have been provisionally approved by RMS. The study of the acute toxicity effect of the plant protection product BSK-FUN 500 SC for fish should be performed by the Applicant. **It should be considered at MSs level.**

### 3.8.3 Effects on bees

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 (SAN-CO/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.**

### 3.8.4 Effects on other arthropod species other than 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 (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

The required study on oral and contact toxicity of the formulated product BSK-FUN 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 BSK-FUN 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 BSK-FUN 500 SC according to the proposed use pattern.

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

### 3.8.5 Effects on soil organisms

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.**

### 3.8.6 Effects on non-target terrestrial plants

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.**

### 3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

### **3.9 Relevance of metabolites (Part B, Section 10)**

Not relevant.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

BSK-FUN 500 SC contains boscalid which is non approved as a candidate for substitution. As a conclusion providing of the comparative assessment of a plant protection product BSK-FUN 500 SC is not required.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

### **Analytical methods for residues**

Data gaps:

- New methods for muscle (primary and ILV) with LOQ at 0.01 mg/kg are required. This gap can be filled after registration (within two years).
- ILV method for eggs. This gap can be filled after registration (within two years).

**Ecotoxicology section:** The applications for product BSK-FUN 500 SC in GAP have been provisionally approved by RMS. The study of the acute toxicity effect of the plant protection product BSK-FUN 500 SC for fish should be performed by the Applicant. ~~It should be considered at MSs level.~~

## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.



## Appendix 2 Copy of the product label

**Los i zachowanie w środowisku, pozostałości i fiz-chemu:** brak uwag

**Ekotoksykologia:** Zastosowania zostały zaakceptowane. Wprowadzono poprawną klasyfikację środka na H410 ~~tylczasowo~~.

**Sekcja skuteczności:** Do etykiety do środków ostrożności dodano następujący zapis: „W przypadku konieczności likwidacji uprawianej rośliny (w wyniku uszkodzenia uprawy przez mróz, choroby lub szkodniki), na tym samym polu można uprawiać każdą uprawę po wykonaniu 25 cm orki”. Wykreślono zastosowanie przeciwko PSDCHA i PUCCRE w pszenicy ozimej oraz zastosowanie je-sienne i kombinowane (1 zabieg wiosną i 1 zabieg jesienią) dla rzepaku ozimego. Zmieniono rekomendowaną ilość wody: w zbożach (200-300 L/ha) i w rzepaku ozimym (300-400 L/ha). W rzepaku zaakceptowano tylko zastosowaniem wiosenne przeciwko LEPTMA i SCLESC max 2 razy na sezon w odstępie 14 dni w okienku aplikacyjnym BBCH 57-71. Rekomendowana dawka dla rzepaku to: 0,4-0,5 L/ha aplikowana wiosną. Wyższa z rekomendowanych dawek powinna być stosowana w przypadku dużej presji choroby. Pozostałych zapisów – nie zmieniano.

**Posiadacz zezwolenia:**

Pestila Sp. z o. o., Studzianki 24A, 97-320 Wolbórz, tel./fax: +48 44 616 43 75,  
e-mail: [info@pestila.pl](mailto:info@pestila.pl).

### BOSCALID 500 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

boskalid (substancja z grupy karbosyamidów) – 500 g/l (42,74%)

Zezwolenie MRiRW nr R- /2025 z dnia .2025 r.



**Uwaga**

<del>H411</del> H410	Działa <b>bardzo</b> toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
EUH208	Zawiera 1,2-benzoizotiazol-3-(2H)-on. Może powodować wystąpienie reakcji alergicznej.
P273	Unikać uwolnienia do środowiska.

P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę
P391	twarzy Zebrać wyciek.

## OPIS DZIAŁANIA

FUNGICYD w formie koncentratu w postaci stężonej zawiesiny do rozcieńczania wodą, o działaniu układowym do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami powodowanymi przez grzyby.

Środek zawiera substancję czynną boskalid - wg FRAC Grupa 7.

## STOSOWANIE ŚRODKA

Środek do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

### Pszenica ozima

~~Łamliwość źdźbła zbóż i traw (PSDCHA)~~ septorioza paskowana liści pszenicy (SEPTTR), ~~rdza brunatna pszenicy (PUGCRE)~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 l/ha

Termin stosowania: środek zastosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49). W przypadku zwalczania łamliwości źdźbła zabieg wykonać do fazy 2 kolanka (BBCH 32).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: ~~400~~ 200-300 l/ha

Zalecane opryskiwanie: drobnokropliste

### Pszenica jara

septorioza paskowana liści pszenicy (SEPTTR)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 l/ha

Termin stosowania: środek zastosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: ~~400~~ 200-300 l/ha

Zalecane opryskiwanie: drobnokropliste

### Jęczmień ozimy, jęczmień jary

plamistość siatkowa jęczmienia (PYRNTE)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 l/ha

Termin stosowania: środek zastosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: ~~400~~ 200-300 l/ha

Zalecane opryskiwanie: drobnokropliste

### Pszenżyto ozime, pszenżyto jare

septorioza paskowana liści (SEPTTR)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 l/ha

Termin stosowania: środek zastosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 400 200-300 l/ha

Zalecane opryskiwanie: drobnokropliste

## **Żyto**

*rynchosporioza zbóż (RHYNSE)*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 l/ha

Termin stosowania: środek zastosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby, od początku fazy strzelania w źdźbło do fazy, gdy widoczne są pierwsze ości (BBCH 30-49)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 400 200-300 l/ha

Zalecane opryskiwanie: drobnokropliste

## **Rzepak ozimy**

*sucha zgnilizna kapustnych (LEPTMA), zgnilizna twardzikowa (SCLESC)*

Środek stosować zapobiegawczo lub po wystąpieniu pierwszych objawów chorób w następujących terminach:

~~Termin stosowania: jesienią, w fazie 3-8 liści rzepaku (BBCH 13-18)~~

~~*sucha zgnilizna kapustnych (LEPTMA)*~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0,5 kg/ha~~

~~Zalecana dawka dla jednorazowego zastosowania: 0,2 0,5 kg/ha~~

~~Liczba zabiegów: 1~~

~~Termin stosowania: wiosną, w fazie wzrostu pędu głównego do fazy, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe (kwiatostany boczne (BBCH 31-57).~~

~~*sucha zgnilizna kapustnych (LEPTMA)*~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0,5 kg/ha~~

~~Zalecana dawka dla jednorazowego zastosowania: 0,2 0,5 kg/ha~~

~~Liczba zabiegów: 1~~

Termin stosowania: **wiosną**, od fazy gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe (kwiatostany boczne) do fazy wykształcania się pierwszych łuszczyń (BBCH 57-71).

*sucha zgnilizna kapustnych (LEPTMA), zgnilizna twardzikowa (SCLESC)*

Maksymalna dawka dla jednorazowego zastosowania: 0,5 kg/ha

Zalecana dawka dla jednorazowego zastosowania: 0,2 0,4– 0,5 kg/ha

Wyższą z dawek stosować w przypadku dużego nasilenia choroby

Liczba zabiegów: 1 2

Odstęp między zabiegami: 14 dni

Zalecana ilość wody: 300-400 L/ha

Zalecane opryskiwanie: drobnokropliste

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2 (łącznie zabieg jesienią i/lub wiosną)~~

~~Odstęp między zabiegami: co najmniej 14 dni~~

~~Zalecana ilość wody: 100-400 l/ha~~

~~Zalecane opryskiwanie: drobnokropliste~~

## **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Pszenica, jęczmień, pszenżyto, żyto — 56 dni

Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych.

Środek w dawkach zalecanych poniżej 0,5 kg/ha można zastosować tylko w przypadku, gdy nasilenie występowania chorób (w tym prognozowane) jest na niższym poziomie.

Środek zawiera jako substancję czynną boskalid, związek z grupy karboksamidów (fungicydy inhibitory dehydrogenazy bursztynianowej – SDHI, wg FRAC grupa 7).

W ramach strategii przeciwdziałania odporności sprawców chorób środki grzybobójcze zawierające substancje czynne z grupy FRAC 7 należy stosować maksymalnie w dwóch zabiegach w sezonie na danej plantacji. Ponadto zaleca się:

- stosowanie środka przede wszystkim do zabiegów zapobiegawczych,
- stosowanie środka wyłącznie w zalecanych dawkach i terminach,
- w przypadku łącznego stosowania drugi środek powinien zawierać substancję czynną z innej grupy, o innym mechanizmie działania i wykazywać wysoką skuteczność w zwalczaniu chorób, które mają być celem zabiegu,
- w przypadku konieczności wykonania kolejnych zabiegów użycie środków grzybobójczych, zawierających substancje czynne o innych mechanizmach działania (stosowanie przemienne).
- w przypadku konieczności likwidacji uprawianej rośliny (w wyniku uszkodzenia uprawy przez mróz, choroby lub szkodniki), na tym samym polu można uprawiać każdą uprawę po wykonaniu 25 cm orki.

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed użyciem wstrząsnąć zawartością opakowania.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaściu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą to mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć oraz przepłukać co najmniej dwukrotnie wodą.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

### **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

### **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody.

W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W przypadku połknięcia: niezwłocznie zasięgnij porady lekarza – pokaż opakowanie lub etykietę.

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....



### **Appendix 3 Letter of Access**

Letter of Access is provided in a separate appendix.

## Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>Section B1-B2 and B4: Identity, Physical and Chemical Properties, Further information</b>							
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Garofani S.	2023	BSK-FUN 500 SC: Determination of the Physico-chemical Properties Report No CH-0855-2023 ChemService S.r.l. Controlli e Ricerche GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 2.2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Garofani S.	2023	BSK-FUN 500 SC: Determination of the Physico-chemical Properties Report No CH-0854-2023 ChemService S.r.l. Controlli e Ricerche GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 2.7.1 KCP 2.7.3	Garofani S.	2023	BSK-FUN 500 SC: Determination of the Physico-chemical Properties Report No CH-0857-2023 ChemService S.r.l. Controlli e Ricerche	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP: Yes Published: No				
KCP 2.7.4	Garofani S.	2023	BSK-FUN 500 SC: Determination of the Low Temperature Stability Report No CH-0856-2023 ChemService S.r.l. Controlli e Ricerche GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
<b>Section B3: Efficacy Data and Information</b>							
KCP 3.2/01	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202301 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/02	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202302 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/03	Figurski R.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202303 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/04	Figurski R.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202304 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/05	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against stem diseases on cereals (winter wheat). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland;	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No.: S23-103648-01 GEP: Yes Published: No			with GEP.	
KCP 3.2/06	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against stem diseases on cereals (winter wheat). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-02 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/07	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter wheat). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-03 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/08	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter wheat). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-04 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/09	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202305 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/10	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (spring wheat). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-05 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/11	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202306 GEP: Yes	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published: No				
KCP 3.2/12	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter triticales). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-06 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/13	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202307 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/14	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (spring triticales). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-07 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/15	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202308 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/16	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202309 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/17	Figurski R.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202310 GEP: Yes	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published: No				
KCP 3.2/18	Figurski R.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023 Green & Property Poland; Report No.: 018GPSE202311 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/19	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter rye). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-08 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/20	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter rye). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-09 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/21	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter rye). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-10 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/22	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter rye). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-11 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/23	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (spring barley). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-12 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/24	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in	N	Y	New data for formulation, not pre-	Pestila*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			cereals in Poland 2023. Green & Property Poland; Report No.: 018GPSE202312 GEP: Yes Published: No			viously submitted or evaluated. Study conducted in compliance with GEP.	ProAgri**
KCP 3.2/25	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023. Green & Property Poland; Report No.: 018GPSE202313 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/26	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases in cereals in Poland 2023. Green & Property Poland; Report No.: 018GPSE202314 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/27	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter barley). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-13 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/28	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter barley). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-14 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/29	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter barley). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland; Report No.: S23-103648-15 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/30	Głowacki G.	2023	Determination of the efficacy of BSK-FUN 500 SC (boscalid 500 g/l) against foliar diseases on cereals (winter barley). Poland 2023. Eurofins Agroscience Services Sp. z o.o., Poland;	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No.: S23-103648-16 GEP: Yes Published: No			with GEP.	
KCP 3.2/31	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202301 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/32	Springer M.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202302 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/33	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202303 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/34	Huszcza-Podgórska A.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202304 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/35	Ptaszek R.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202305 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 3.2/36	Ptaszek R.	2023	Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202306 GEP: Yes	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2/37	Springer M.	2023	Published: No Efficacy evaluation of BSK-FUN 500 SC against diseases oilseed rape in Poland 2023. Green & Property Poland; Report No.: 019GPSE202307 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
<b>Section B5: Analytical Methods</b>							
KCP 5.1.1	Garofani S.	2023	BSK-FUN 500 SC: Validation of the Analytical Method for the Determination of the Active Ingredient Content Report No: CH-0853-2023 ChemService S.r.l. Controlli e Ricerche GLP Studies Department GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/01 (filled as KCP 10.2.1.2/01)	Kolek L.	2024	<i>Daphnia</i> sp., Acute Immobilisation Test report no. ETOX-2023-20 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
			Amendment No. 1 <i>Daphnia</i> sp., Acute Immobilisation Test report no. ETOX-2023-20 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/02 (filled as KCP 10.2.1.3/01)	Kolek L.	2024	Freshwater Alga and Cyanobacteria, Growth Inhibition Test report no. ETOX-2023-21 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
			Amendment No. 1 Freshwater Alga and Cyanobacteria, Growth Inhibition Test report no. ETOX-2023-21 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/03	Szlauer S.	2023	Bumblebees ( <i>Bombus spp.</i> ), Acute Contact Toxicity Test	N	Y	New data for formulation, not pre-	Pestila*



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(filled as KCP 10.3.1.1.2/02)			report no. ETOX-2023-23 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No			viously submitted or evaluated. Study conducted in compliance with GLP.	ProAgri**
KCP 5.1.2/04 (filled as KCP 10.3.1.1.1/02)	Szlauer S.	2023	Bumblebees ( <i>Bombus spp.</i> ), Acute Oral Toxicity Test report no. ETOX-2023-22 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/05 (filled as KCP 10.6.2/01)	Wesołowska K.	2024	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test report no. ETOX-2023-28 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/06 (filled as KCP 10.6.2/02)	Wesołowska K.	2024	Terrestrial Plant Test: Vegetative Vigour Test report no. ETOX-2023-29 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/07 (filled as KCP 10.3.1.2/01)	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Chronic Oral Toxicity Test report no. 1142.1F.SAG23 SAGEA Centro di Saggio s.r.l. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/08 (filled as KCP 10.3.1.4/01)	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure report no. 1143.1F.SAG23 SAGEA Centro di Saggio s.r.l. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/09	Sala A.	2023	Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			report no. LBN-0118-2023 LabAnalysis s.r.l. GLP: Yes Published: No				
	Sala A.	2024	Final Report Amendment 1 Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0118-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/10	Sala A.	2023	Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after two application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0119-2023 LabAnalysis s.r.l. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
	Sala A.	2024	Final Report Amendment 1 Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after two application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0119-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
KCP 5.1.2/11 (filled as KCP 10.4.1.1/01)	Wesołowska K.	2024	Earthworm Reproduction Test ( <i>Eisenia andrei</i> ) Report no.: ETOX-2023-26 Source: EcoTox Alliance Sp. z o. o., Poland GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/12 and KCP 5.2/01	Schlewitz P.	2024	Validation of the Analytical Method for the Analysis of Boscalid in Honey Report no.: R C3128 ANADIAG SAS, France GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila* ProAgri**
<b>Section B7: Metabolism and Residues</b>							
KCA 6.3/01	Ptaszek R.	2024	Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity - RAC) grown in open field conditions after one application of a formulated product BSK-FUN 500 SC- four harvest and four decline curve trials in Northern Europe GBA Polska Sp. z o.o. AGRO Services Study number: GBA-DPL-2023-14 GEP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCA 6.3/02	Ptaszek R.	2024	Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity - RAC) grown in open field conditions after one application of a formulated product BSK-FUN 500 SC - four harvest and four decline curve trials in Northern Europe GBA Polska Sp. z o.o. AGRO Services Study number: GBA-DPL-2023-15 GEP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCA 6.3/03	Sala A.	2023	Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0118-2023 LabAnalysis s.r.l. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
	Sala A.	2024	Final Report Amendment 1 Magnitude of the residue of Boscalid (188425-85-6) in wheat	N	Y	New data for formulation, not previously submitted or evaluated.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			(Raw Agricultural Commodity – RAC) grown in open field conditions after one application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0118-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No			Study conducted in compliance with GEP.	
KCA 6.3/04	Sala A.	2023	Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after two application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0119-2023 LabAnalysis s.r.l. GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
	Sala A.	2024	Final Report Amendment 1 Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after two application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0119-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCA 6.1/01	Sala A.	2024	Freezer storage stability of Boscalid in Wheat and Oilseed rape samples Report No. LBN-0126-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCA6.10, 6.10.1/01	Schneider E.	2024	Determination of Boscalid Residues in Honey Following Application on Phacelia with BSK-FUN 500 SC under semi field Conditions in Northern and Southern Europe in 2023-2024 Report No. R C3127 ANADIAG	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP: Yes Published: No				
<b>Section B8: Environmental Fate</b>							
KCP 9.2.4/01	Tabor E.	2024	BSK-FUN 500 SC Calculation of predicted environmental concentrations of boscalid in groundwater after application to maize using the FOCUS groundwater scenarios (PEARL v5.5.5, FOCUS PELMO v6.6.4) Company Report No: EST/7/2024 ESTICON Sp. z o.o. GLP: No Published: No	N	N	-	Pestila* ProAgri**
KCP 9.2.5/01	Tabor E.	2024	BSK-FUN 500 SC Calculation of Predicted Environmental Concentrations of boscalid in surface water after application to maize using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/8/2024 ESTICON Sp. z o.o. GLP: No Published: No	N	N	-	Pestila* ProAgri**
<b>Section B9: Ecotoxicology</b>							
KCP 10.2.1.2/01	Kolek L.	2024	<i>Daphnia</i> sp., Acute Immobilisation Test Study Code: ETOX-2023-20 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
			Amendment No. 1 <i>Daphnia</i> sp., Acute Immobilisation Test report no. ETOX-2023-20 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No				
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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Amendment No. 1 Freshwater Alga and Cyanobacteria, Growth Inhibition Test report no. ETOX-2023-21 EcoTox Alliance Sp. z o. o. GLP: Yes Published: No				
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 ( <i>Apis mellifera</i> 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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 10.3.1.1.1/02	Szlauer S.	2023	Bumblebees ( <i>Bombus</i> spp.), Acute Oral Toxicity Test Study code: ETOX-2023-22 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 10.3.1.1.2/02	Szlauer S.	2023	Bumblebees ( <i>Bombus</i> spp.), Acute Contact Toxicity Test Study Code: ETOX-2023-23 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 10.3.1.2/01	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees ( <i>Apis mellifera</i> 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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 10.3.1.4/01	Mautino G.	2024	Effects of BSK-FUN 500 SC on Honeybees ( <i>Apis mellifera</i> L.) in the laboratory – Larval Toxicity Test Following Repeated Exposure Study Code: 1043.I.SAG23/r; Source: SAGEA Centro di Saggio s.r.l., Italy GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
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, <i>Aphidius rhopalosiphi</i> Study Code: ETOX-2023-25	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila* ProAgri**

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished			with GEP.	
KCP 10.3.2.1/02	Kulec-Płoszczyca E.	2024	Laboratory residual contact test with the predatory mite <i>Typhlodromus pyri</i> for regulatory testing of BSK-FUN 500 SC Study Code: ETOX-2023-24 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
KCP 10.4.1.1/01	Wesołowska K.	2024	Earthworm Reproduction Test ( <i>Eisenia andrei</i> ); Study Code: ETOX-2023-26 Source: EcoTox Alliance Sp. z o. o., Poland GLP Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
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 Unpublished	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**
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	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila* ProAgri**

\*Pestila Spółka z ograniczoną odpowiedzialnością (short name Pestila Sp. z o. o.)

\*\* ProAgri International Spółka z ograniczoną odpowiedzialnością or ProAgri Spółka z ograniczoną odpowiedzialnością (short name: ProAgri International Sp. z o. o. or ProAgri 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	Data protection claimed Y/N	Justification if data protection is claimed	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

List of data relied on and 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner