

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: BSK-FUN 500 SC

Product name(s): -

Chemical active substance:

boscalid, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

### CORE ASSESSMENT

(authorization)

Applicant:

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

Submission date: April 2024

MS Finalisation date: December 2024; February 2025,

June 2025,

## Version history

When	What
December 2024	ZRMs evaluated dRR submitted by Applicant.
February 2025	The final Registration Report.
June 2025	Corrections made after the commenting period.

## Table of Contents

<b>0</b>	<b>Product background, regulatory context and GAP information .....</b>	<b>4</b>
0.1	Introduction.....	4
0.1.1	Reason for application .....	4
0.1.2	Details of zRMS(s) and concerned MS .....	4
0.1.3	Regulatory history of the active(s).....	4
0.1.3.1	Boscalid.....	4
0.2	zRMS conclusion .....	6
<b>Appendix 1</b>	<b>ALL intended uses .....</b>	<b>8</b>

## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. This application is according to the Article 33 of Regulation 1107/2009.

In case of active substances data out of protection are used. In addition to the submission of studies as listed in particular sections, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland	Not relevant.

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Boscalid

**Table 0.1-2: Summary of regulatory history of CAS No: 188425-85-6**

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, <i>Paecilomyces lilacinus</i> and prothioconazole as active substances  COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances  COMMISSION IMPLEMENTING REGULATION (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet,

<b>Status</b>	
	diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, Helicoverpa armigera nucleopolyhedrovirus, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum strain T34 and Trichoderma atroviride strain I-1237
RMS	SK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/08/2008
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2009
Date of final Commission (re-registration) deadline (Step 2)	31.01.2010
Current expiration of approval	15/04/2026
Low risk substance or Candidate for Substitution?	Not applicable

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the operator safety;
- the long-term risk to birds and soil organisms;
- the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation.

The SANCO report for Boscalid (SANCO/3919/2007 – rev. 5) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

**Table 0.1-3: Information on minimum purity of boscalid**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
960 g/kg	<del>minimum purity of active substance – confidential information referred in Part C of dRR</del> 975 g/kg Equivalence report available: Y RMS: <del>please refer to the Letter of Access</del> NL

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\* If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Not relevant.	Not relevant.	Not relevant.

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

## 0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: all  
Residues section: all  
Environmental fate and behavior section: all  
Ecotoxicology section: The applications for product **Boskalix 500 SC** in GAP have been provisionally approved by RMS. The study of the acute toxicity effect of the plant protection product **Boscalix 500 SC** for fish should be performed by the Applicant. It should be considered at MSs level.

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none  
Residues section: none  
Environmental fate and behavior section: none  
Ecotoxicology section: The applications for product **Boskalix 500 SC** in GAP have been provisionally approved by RMS. The study of the acute toxicity effect of the plant protection product **Boscalix 500 SC** for fish should be performed by the Applicant. It should be considered at MSs level.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Residues section: none

Residues section:  
All uses/ GAPs are covered by established MRLs.

### The conclusions

#### 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..

#### **Environmental fate and behavior:**

No unacceptable risk for groundwater was identified.

#### **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.

**Justification:** In the case of formulation the BSK-FUN 500 SC product, the substance content is approximately 50%, so it can be assumed that the active substance will be the main component that will affect the toxicity of the product, and therefore extrapolate from the substance data can be considered. Furthermore, based on the acute toxicity data for the active substance, it can be concluded that fish are not the most sensitive aquatic organism to boscalid, so duplicating studies on vertebrate fish may not be necessary in the RMS assessment. On the other hand, unprotected data on the representative product BAS 510 01 F from the RAR indicates even lower sensitivity of fish compared to other organism groups. However, SC formulations are often more toxic in the short term to aquatic organisms, including fish. Due to many doubts the other MSs should be considered if the packed data in this case is sufficient. The results of the fish study to formulation BSK-FUN 500 SC probably will bring no change to the risk assessment and conclusions previously reached. It should be considered by MSs level.

#### **Considering the December 2024 update:**

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

#### **Risk assessment for *Folsomia candida* and *Hypoaspis aculeifer***

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

Appendix 1 ALL intended uses

PPP (product name/code):

BSK-FUN 500 SC

Active substance 1:

boscalid

Active substance 2:

-

Active substance....:

-

Safener:

n.a.

Synergist:

n.a.

Applicant:

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

Zone(s):

Central Zone <sup>(d)</sup>

Verified by MS:

no

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

Formulation type:

SC <sup>(a, b)</sup>

Conc. of as 1:

500 <sup>(c)</sup>

Conc. of as 2:

-

Conc. of as ....:

-

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 acuformis</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	<u>Efficacy section:</u> only use against SEPTTR accepted conditionally. Recommended water volume: 200-300 L/ha.  <u>Ecotoxicology section:</u> The applica- tion accepted provisionally.	



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	<del>100</del> 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.
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	<del>100</del> 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.
4	Poland	Spring 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	<del>100</del> 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.
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	<del>100</del> 200 -300 L/ha	56 days	<b>Efficacy section:</b> PYRNTE accepted conditionally. Recommended water volume: 200-300 L/ha. <b>Ecotoxicology section:</b> The application accepted provisionally.
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	<del>100</del> 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 <b>Ecotoxicology section:</b> The application accepted provisionally.

**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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	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.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions