

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: GLOB1811F

Product name(s): RASPUT

Chemical active substance:

Boscalid, 500 g/kg

Poland – Art. 33

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: June 2021

MS Finalisation date: 18/03/2022

Version history

When	What
December 2021	First zRMS PL evaluation
March 2022	RR finalized by zRMS after commenting period

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is for a product containing 500 g/kg of Boscalid and formulated as a water dispersible granule (WG). This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

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	PL Product code: GLOB1811F Product name: RASPUT	Not applicable

0.1.3 Regulatory history of the active

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 91/414/EEC (2008/44/EC)/2011 Extension of Approval Reg. (EU) 2021/745
RMS	DE
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	31/07/2022
Low risk substance or Candidate for Substitution?	N/A

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 of 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.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for Boscalid (SANCO/3919/2007-rev.5 – 21/01/2008) 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	≥ 986 g/kg Equivalence report available: Y RMS: DE

* 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.

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-4: Summary of regulatory history of the product GLOB1811F

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
GLOB1811F	RASPUT	UK	2190491	15.03.2020	-
GLOB1811F	RASPUT	FR	00A518-00	31.07.2020	-
GLOB1811F	RASPUT	DE	19252	31.07.2020	-

0.2 zRMS conclusion

The formulated product Rasput containing 500 g/kg boscalid should not be classified for human health reason but required classification for the environment as Toxic to aquatic life with long lasting effects, H411 (Regulation EC No 1272/2008). According to the model calculations, it can be concluded that the risk for the operator, worker and bystander is acceptable. The proposed use of boscalid does not represent unacceptable chronic risks for the consumers. No unacceptable risk to birds, mammals, non-target aquatic organisms, bees, non-target arthropods, non-target plants is expected following the application of Rasput according to proposed use. The efficacy of Rasput was sufficiently demonstrated for use in winter oilseed rape.

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

Insert relevant use number from GAP table in Appendix 1.

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

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with identified risk.

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:

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with assessment to be confirmed.

The following text is to be shortened or to be amended as necessary.

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP rev. 1.0, date: 2021-04-30

PPP (product name/code): RASPUT / GLOB1811F
Active substance 1: Boscalid
Safener: /
Synergist: /
Applicant: Globachem NV
Zone(s): Central
Verified by MS: no

Formulation type: WG
Conc. of as 1: 500 g/kg
Conc. of safener: /
Conc. of synergist: /
Professional use: ☒
Non professional use: ☐

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	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	CEU	Oilseed rape (Winter & Spring)	F	<i>Sclerotina sclerotiorum</i>	Foliar Spray	BBCH 55-69	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.250 b) 0.500	100- 400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases
2	CEU	Oilseed rape (Winter & Spring)	F	<i>Alternaria brassicae</i>	Foliar Spray	BBCH 55-69	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.250 b) 0.500	100- 400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases
3	CEU	Oilseed rape (Winter & Spring)	F	<i>Leptosphaeria maculans</i>	Foliar Spray	BBCH 20-59	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.250 b) 0.500	100- 400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases

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