

REGISTRATION REPORT

Part A

Risk Management

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: 01/06/2022

Version history

When	What
December 2021	First zRMS PL evaluation
March 2022	RR finalized by zRMS after commenting period
June 2022	Correction to the national label

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorization decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	7
2.6	Intended uses (only NATIONAL GAP)	8
3	Background of authorization decision and risk management	10
3.1	Physical and chemical properties (Part B, Section 2)	10
3.2	Efficacy (Part B, Section 3)	10
3.3	Methods of analysis (Part B, Section 5)	12
3.3.1	Analytical method for the formulation	12
3.3.2	Analytical methods for residues	13
3.4	Mammalian toxicology (Part B, Section 6)	14
3.4.1	Acute toxicity	14
3.4.2	Operator exposure	15
3.4.3	Worker exposure	15
3.4.4	Bystander and resident exposure	15
3.5	Residues and consumer exposure (Part B, Section 7)	16
3.5.1	Residues	16
3.5.2	Consumer exposure	17
3.6	Environmental fate and behaviour (Part B, Section 8)	17
3.6.1	Predicted environmental concentrations in soil (PEC _{soil})	17
3.6.2	Predicted environmental concentrations in groundwater (PEC _{gw})	17
3.6.3	Predicted environmental concentrations in surface water (PEC _{sw})	18
3.6.4	Predicted environmental concentrations in air (PEC _{air})	18
3.7	Ecotoxicology (Part B, Section 9)	18
3.7.1	Effects on terrestrial vertebrates	18
3.7.2	Effects on aquatic species	19
3.7.3	Effects on bees	19
3.7.4	Effects on other arthropod species other than bees	19
3.7.5	Effects on soil organisms	19

3.7.6	Effects on non-target terrestrial plants	19
3.7.7	Effects on other terrestrial organisms (Flora and Fauna).....	19
3.8	Relevance of metabolites (Part B, Section 10)	20
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	20
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization	20
Appendix 1	Copy of the product authorization	21
Appendix 2	Copy of the product label	22
Appendix 3	Letter of Access	25
Appendix 4	Lists of data considered for national authorization.....	26

PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Globachem NV in June 2021.

The application is for approval of GLOB1811F / RASPUT, a water dispersible granule (WG) containing 500 g/kg boscalid for use as a fungicide in oilseed rape in Poland.

1.2 Letters of Access

The Annex III dossier does not contain letters of access.

1.3 Justification for submission of tests and studies

This application was made in accordance with the article 33 of the Regulation 1107/2009. It 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.

1.4 Data protection claims

Data protection is claimed for all documents and data included in this dossier. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Globachem NV.

2 Details of the authorization decision

2.1 Product identity

Product code	GLOB1811F
Product name in MS	RASPUT
Authorization number	xxxx – xx
Function	Fungicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Boscalid, 500 g/kg
Formulation type	Water dispersible granule [WG]
Packaging	0.5, 1, 2, 3, 5, 10, 20 L HDPE or 0.02, 0.05-0.1, 0.5, 1, 2.5, 5, 10, 15, 20 kg silver foil bags, professional user

Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for RASPUT resulted in the decision to grant the authorization for winter oilseed rape consistently with the GAP reported in the present part A paragraph 2.6

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 Chronic 2
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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:	GHS09
Signal word:	-
Hazard statement(s):	H411
Precautionary statement(s):	P101, P102, P273, P391
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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:	
-	Work wear (arms, body and legs covered) is recommended during M/L and A
Worker protection:	
-	Work wear (arms, body and legs covered) is recommended during M/L and A
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SP1	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).
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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.
SPe3	-	3

2.6 Intended uses (only NATIONAL GAP)

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

WG

PPP (product name/code): RASPUT / GLOB1811F

Formulation type:

Active substance 1: Boscalid

Conc. of as 1:

500 g/kg

Safener: /

Conc. of safener:

/

Synergist: /

Conc. of synergist:

/

Applicant: Globachem NV

Professional use:

☒

Zone(s): Central

Non professional use:

☐

Verified by MS: yes/no

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. ^(e)	Mem- ber state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. g safen- er/synergist per ha (f)	zRMS conclu- sion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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 (Win- ter)	F	<i>Sclerotina sclero- tiorum</i>	Foliar Spray	BBCH 55-69	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.250 b) 0.500	200-300	-	Maximum 2 applications of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A
2	CEU	Oilseed rape (Win- ter)	F	<i>Alternaria brassi- cae</i>	Foliar Spray	BBCH 55-69	a) 2 b) 2	14	a) 0.5 b) 1.0	a) 0.250 b) 0.500	200-300	-	Maximum 2 applications of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	R
3	CEU	Oilseed rape (Win- ter)	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	200-300	-	Maximum 2 applications of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	R

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional

and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3 Background of authorization decision and risk management

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

The product GLOB1811F is a water dispersible granule formulation.

The phys.-chem. properties of RASPUT (product name: GLOB1811F) have been determined under GLP and according to test methods internationally recognized such as CIPAC methods, the 'EC methods' (Regulation (EC) No. 440/2008) and OECD methods.

After 14 days storage at 54°C, neither the active ingredient content nor the technical properties were changed.

After two years storage at ambient temperature, neither the active ingredient content nor the technical properties were changed.

Appearance (physical state, colour) and odour remained unchanged over the storage period – 2 years at ambient temperature.

The user properties of the formulation are acceptable for a water dispersible granule (WG) both initially and after storage for two years at ambient temperature.

HDPE packs remain in good condition over the 2 years storage period at ambient temperature, with no corrosion and no other influence of the product on the original container.

After storage for 2 years at ambient temperature, the formulation showed good chemical and physical properties.

A minimum shelf life of 2 years (at ambient temperature) is expected for this product according to FAO specifications when stored in HDPE or silver foil bags.

3.2 Efficacy (Part B, Section 3)

The aim of this document is the support of an application for authorization of the fungicide GLOB1811F containing 500g/kg of boscalid, formulated as a wettable granule (WG) developed by Globachem NV for the control of *Sclerotinia sclerotiorum*, *Alternaria brassicae*, and *Plenodomus lingam* (*Leptosphaeria maculans*) in oilseed rape.

Preliminary tests:

No preliminary range-finding tests are available. Based on the knowledge about this active substance and the experiences with products, preliminary tests in field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose:

To fulfil the requirements of justifying the minimum effective dosage according to EPPO guideline PP1/225 (1) GLOB1811F in winter rape was tested rates of 0.2 – 0,5 kg/ha. All trials were conducted as part of the efficacy tests. The results of dosage range tests clearly show that in case of higher pest pressure, the efficacy of GLOB1811F against SCLESC, LEPTMA and ALTEBA increase with higher dose rates of up to 0.5 kg/ha. However, these results also demonstrate that acceptable levels of control can be reached at the lowest tested dose rate of 0.2 kg/ha, in cases with relatively low pest pressure. It would therefore be justified that rates below 0.5 kg/ha may be applied only when pest pressure or forecast pest pressure is at a lower level.

EFFICACY TESTS:

Collected results show that efficacy of GLOB1811F was consistently similar or even higher than that of the standard product Cantus with the same spectrum of activity against winter oilseed rape pathogens. In case of higher pest pressure, the efficacy of GLOB1811F against SCLESC, LEPTMA and ALTEBA increase with higher dose rates of up to 0.5 kg/ha. It would therefore be reasonable that rates below 0.5 kg/ha may be applied only when pest pressure or forecast pest pressure is at a lower level. Moreover, according to the standard EPPO PP 1/226(2), an insufficient number of trials for LEPTMA and ALTEBA were presented. As adverse weather conditions had a significant influence on the results of the efficacy trials and GLOB1811F has achieved under these conditions similar or higher efficacy than CANTUS is reasonable to conditionally register GLOB1811F in the requested uses. The applicant will need to submit the missing LEPTMA and ALTEBA trials at a later date.

No efficacy data is available to support use on spring oilseed rape. This use may be claimed as "minor uses" under Article 51 of Regulation 1107/2009 as an extension of the registration.

Information on possible occurrence of the development of resistance:

Boscalid is a fungicide active ingredient belonging to the pyridine-carboxamides group (also known as carboxins or oxathiins, group FRAC 7). 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 (Kulka and von Schmeling 1995).

According to the findings of the SDHI Working Group of the Fungicide Resistance Action Committee FRAC (Virtual Meeting on January 20 - 21, 2021), currently there is no evidence of field strains of *Leptosphaeria maculans*, *Sclerotinia sclerotiorum* or *Alternaria brassicae* that are resistant to SDHI fungicides in oilseed rape in Poland. Based on the information above, the zRMS considers that the risk of resistance developing to boscalid from the proposed use of GLOB1811F is low to moderate. Anyhow, to further ensure a high level of efficacy of the test product on the target diseases, measures for a resistance management are recommended:

Strategies and General Guidelines for the 2020/21 season:

- 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” (link) 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 SDHI.

Yield and parameters:

In all trials, the effects of GLOB1811F were similar to those of the reference product tested at the same rates. No unacceptable yield effects caused by GLOB1811F at the higher dose rate of 0.5 kg/ha were recorded in any of the trials. Therefore, it can be supposed that GLOB1811F applied at 0.2 up to 0.5 kg/ha has no negative effect on yield.

Phytotoxicity to host crop:

GLOB1811F was completely selective in oilseed rape. Therefore, it is maintained that this fungicide will be safe when used as proposed.

Adverse effects on adjacent crops:

During many years of commercial use, no negative impact of boscalid on other plants including adjacent crops was observed under practical agricultural conditions. Boscalid is registered and used for many years on a wide range of crops. Therefore, even if drift to adjacent monocotyledonous or dicotyledonous crops should occur, no crop injury is expected due to the large safety margin of GLOB1811F on all potential adjacent crops.

Adverse effects on succeeding crops

During many years of commercial use, no negative impact of boscalid on following crops was observed under practical agricultural conditions. The absence of any negative impact on following crops can be explained by the good selectivity of this active substance. Boscalid is currently registered for use on different crops and no negative impact was reported until now.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for boscalid in plant, animal, water, air, soil and in the formulation Boscalid 50% WG are available.

3.3.1 Analytical method for the formulation

Analytical methods for determination of Boscalid in GLOB1811H were not evaluated as part of the EU review of the active substance. Therefore, all relevant data are provided and are considered adequate. An

HPLC-PDAD method was submitted to analyse the active ingredient content in the formulation. This method was successfully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3029/99 rev. 4, 11/07/2000.

3.3.2 Analytical methods for residues

Component of residue definition: Boscalid				
High water content	Primary	0.01 mg/kg 0.02 0.05 mg/kg	GC-MS HPLC-MS/MS	DAR 2002 (Weeren and Pelz, 1999) DAR 2002; FAO, 2006 (Funk and Mackenroth, 2000)
	ILV	0.01 mg/kg	GC-MS	DAR 2002 (Reichert, 2001)
High acid content	Primary	0.01 mg/kg 0.05 mg/kg	GC-MS HPLC-MS/MS	DAR 2002 (Weeren and Pelz, 1999) DAR 2002; FAO, 2006 (Funk and Mackenroth, 2000)
	ILV	0.01 mg/kg	GC-MS	DAR 2002 (Reichert, 2001)
High oil content	Primary	0.02 mg/kg 0.05 mg/kg	GC-MS HPLC-MS/MS	DAR 2002 (Weeren and Pelz, 1999) DAR 2002; FAO, 2006 (Funk and Mackenroth, 2000)
	ILV	0.02 mg/kg	GC-MS	DAR 2002 (Reichert, 2001)
High protein/high starch content (dry)	Primary	0.01 mg/kg	GC-MS	DAR 2002 (Weeren and Pelz, 1999)
	ILV	0.01 mg/kg	GC-MS	DAR 2002 (Reichert, 2001)
Difficult (if required, depends on intended use)	Primary	0.05 mg/kg	GC-MS *	DAR 2002 (Reichert, 2001)
Component of residue definition: Sum of Boscalid and its hydroxy metabolite 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (free and conjugated) expressed as Boscalid				
Milk	Primary	0.01 mg/kg	GC-ECD HPLC-MS/MS	DAR 2002 (Class, 2000) DAR 2002 (Grosshans, 2000)
	ILV	0.01 mg/kg	GC-ECD	DAR 2002 (Kampke-Thiel, 2001)
	Confirmatory (if required)	0.01 mg/kg	GC-MS	DAR 2002 (Class, 2000)
Eggs	Primary	0.025 mg/kg 0.01 mg/kg	GC-ECD HPLC-MS/MS	DAR 2002 (Class, 2000) DAR 2002 (Grosshans, 2000)

	ILV	0.01 mg/kg 0.025 mg/kg	GC-ECD	DAR 2002 (Kampke-Thiel, 2001)
	Confirmatory (if required)	0.025 mg/kg	GC-MS	DAR 2002 (Class, 2000)
Muscle	Primary	0.025 mg/kg	GC-ECD HPLC-MS/MS	DAR 2002 (Class, 2000) DAR 2002 (Grosshans, 2000)
	ILV	0.025 mg/kg	GC-ECD	DAR 2002 (Kampke-Thiel, 2001)
	Confirmatory (if required)	0.025 mg/kg	GC-MS	DAR 2002 (Class, 2000)
Fat	Primary	0.025 mg/kg	GC-ECD HPLC-MS/MS	DAR 2002 (Class, 2000) DAR 2002 (Grosshans, 2000)
	ILV	0.025 mg/kg	GC-ECD	DAR 2002 (Kampke-Thiel, 2001)
	Confirmatory (if required)	0.025 mg/kg	GC-MS	DAR 2002 (Class, 2000)
Kidney, liver	Primary	0.025 mg/kg	GC-ECD HPLC-MS/MS	DAR 2002 (Class, 2000) DAR 2002 (Grosshans, 2000)
	ILV	0.025 mg/kg	GC-ECD	DAR 2002 (Kampke-Thiel, 2001)
	Confirmatory (if required)	0.025 mg/kg	GC-MS	DAR 2002 (Class, 2000)
Component of residue definition: Boscalid				
Soil	Primary	0.01 mg/kg	GC-MS	DAR 2002 (Keller, 1998a)
Component of residue definition: Boscalid				
Drinking water	Primary	0.05 mg/kg	GC-MS	DAR 2002 (Keller, 1998b)
Surface water	Primary	0.5 mg/kg	GC-MS	DAR 2002 (Grote, 2001)
Component of residue definition: Boscalid				
Air	Primary	1.5 µg/m ³	GC-MS	DAR 2002 (Zangmeister, 2000)

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

No studies were performed for this submission. Acute toxicity was based on theoretical calculations. See Part C.

3.4.2 Operator exposure

Operator exposure to GLOB1811F was not evaluated as part of the EU review of Boscalid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Operator exposure for Boscalid was assessed against the AOEL agreed in the EU review (0.1 mg a.i./kg bw/d). The default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) were used for the concentrate as well as for the spray dilution.

Operator exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using GLOB1811F on oilseeds is acceptable (risk is 33.2%) wearing adequate work clothing (but no PPE).

3.4.3 Worker exposure

Worker exposure to GLOB1811F was not evaluated as part of the EU review of Boscalid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Worker exposure for Boscalid was assessed against the AOEL agreed in the EU review (0.1 mg a.i./kg bw/d). The default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) were used for the concentrate as well as for the spray dilution.

Worker exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the worker using GLOB1811F on oilseeds is acceptable (risk is 30.2%) wearing adequate work clothing (but no PPE) when re-entering crops treated with GLOB1811F.

3.4.4 Bystander and resident exposure

Resident exposure to GLOB1811F was not evaluated as part of the EU review of Boscalid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Resident exposure for Boscalid was assessed against the AOEL agreed in the EU review (0.1 mg a.i./kg bw/d). The default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) were used for the concentrate as well as for the spray dilution.

Resident exposure was modelled using the AOEM model.

According to the model calculations, It is concluded that there is no undue risk to any resident after long-term exposure to Boscalid (risk is 50.1% for children and 21.2% for adults). This has no labelling implications.

No AAOEL value exists for Boscalid and thus the calculation of the bystander exposure cannot be done. Nevertheless, the risk assessment for bystander is covered by the resident risk assessment and as this one is acceptable, it is also acceptable for the bystander.

3.5 Residues and consumer exposure (Part B, Section 7)

3.5.1 Residues

All presented data are out of data protection and can be used for this application for authorization. They are sufficient to support the intended uses. No new data were submitted in the framework of this application.

Storage stability

In the framework of the peer review, storage stability of boscalid was demonstrated for a period of 24 months at -18 °C in high oil content commodities (rape seed). No additional studies are required.

Metabolism in plants and animals

Metabolism of boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-¹⁴C-diphenyl and 3-¹⁴C-pyridine labelled boscalid

Plant residue definition for monitoring and risk assessment: boscalid

Magnitude of residues in plants

Proposed GAP:

Oilseed rape, BBCH 55-69, 1 application, 0.25 a.s./ha, PHI – not required.

Proposed GAP is less critical than EU GAP (max. 2 application in the accepted EU GAP).

Sufficient EU trials on oil seed rape are available to support the proposed uses. The residue data are valid with regard to storage stability. Residues are below 0.05 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for oil seed rape (1.0 mg/kg, Commission Regulation (EU) 2016/156).

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded. Additional studies are no required.

Processing studies

As quantifiable residues of boscalid exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Specific plant-back restrictions related to the use of Rasput are not required, provided that the product is used according to GAP.

Conclusion:

According to the available data, the intended uses on oil seed rape are considered acceptable.

Proposed PHI: not required

3.5.2 Consumer exposure

Consumer exposure regarding Boscalid

TMDI (% ADI) according to EFSA PRIMo	47 % (based on NL toddler population)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo	Not relevant

The proposed use of Boscalid in the formulation GLOB1811F does not represent unacceptable chronic risks for the consumers.

3.6 Environmental fate and behaviour (Part B, Section 8)

Concentrations of Boscalid in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.

Intended use pattern of GLOB1811F

Crop	Application rate (kg ai/ha)	Application method	Max. number of applications	Minimum application interval (days)	Application timing
Oilseed rape	Boscalid: 0.250	Foliar spray	2	14	BBCH 55-69
Oilseed rape	Boscalid: 0.250	Foliar spray	2	14	BBCH 20-59

3.6.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with boscalid using the EU agreed endpoints (SANCO/3919 /2007-rev. 5).

As a result of the calculations for boscalid it was obtained:

Initial PEC_{soil} value: **0.133 mg/kg**

Maximum PEC_{soil accumulation} value: **0.191 mg/kg**, following the application rate of 0.500 kg boscalid/ha*.

* As a worst case situation, 1 application with a double dose was considered instead of 2 with a minimum interval of 14 days.

The following PEC_{soil} values were obtained for the formulation

GLOB1811F/Rasput:

Initial PEC_{soil}: **1.33 mg/kg**

PEC_{soil,plateau}: **0.58 mg/kg**

PEC_{accumulation}: **1.913 mg/kg**

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} has been determined for Boscalid, using the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and EU agreed endpoints (SANCO/3919 /2007-rev. 5).

PEC_{gw} values for boscalid were below the trigger value 0.1 µg/L in all modelled scenarios. No unacceptable risk for groundwater is identified.

3.6.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{sw/SED} of Boscalid has been assessed with the models FOCUS STEP 1, 2, 3 and 4 using EU agreed endpoints (SANCO/3919 /2007-rev. 5). Please refer to Part B, Section 9, Point 8.9 for more details about the results obtained.

In the Step 3 all scenarios were assessed. The maximum PEC_{sw} at Step 3 was obtained:

- in D2 ditch scenario for winter oilseed rape: 24.08 µg/L (Early application (BBCH 20))
- in D2 ditch scenario for spring oilseed rape: 8.624 µg/L (Early application (BBCH 20)).

The maximum PEC_{sw} for formulation is 2.8063 µg/L for ditch scenario.

3.6.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of Boscalid is $< 10^{-5}$ Pa. Hence Boscalid is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the Boscalid due to volatilization with subsequent deposition should not be considered.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds

According to the screening and first-tier assessments for oilseed rape, all the TERA and TER_{lt} values for active substance Boscalid are greater than the trigger set by Commission regulation (EU) 546/2011 for accept-ability of effects, indicating that GLOB1811F presents no unacceptable acute and long-term risk to birds according to the intended uses on oilseed rape. The risk of secondary poisoning is assumed to be low because the log KOW of Boscalid is < 3 .

An acceptable acute and long-term risk for birds is expected, as well as risk from drinking water, after the application of GLOB1811F according to the proposed GAP.

Mammals

According to the screening and first-tier assessments for oilseed rape, all the TERA and TER_{lt} values for active substance Boscalid are greater than the trigger set by Commission regulation (EU) 546/2011 for accept-ability of effects, indicating that GLOB1811F presents no unacceptable acute and long-term risk to mammals according to the intended uses on oilseed rape. The risk of secondary poisoning is assumed to be low because the log KOW of Boscalid is < 3 .

An acceptable acute and long-term risk for mammals is expected, as well as risk from drinking water, after the application of GLOB1811F according to the proposed GAP.

3.7.2 Effects on aquatic species

Based on FOCUS Steps 1,2 and 3 (scenarios relevant for Poland: D3, D4 and R1), calculated PEC/RAC ratios for the active substance, Boscalid; and for the formulation GLOB1811F, did not indicate an unacceptable risk for aquatic organisms for all intended uses.

3.7.3 Effects on 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 hazard quotients after oral and contact exposures are below the trigger value of 50. Therefore an acceptable acute risk to bees is expected from the application of GLOB1811F according to the intended GAP.

The chronic TERs for honey bee adults and larvae are higher than the trigger of 1, indicating that the proposed uses according to the intended GAP of GLOB1811F poses an acceptable chronic risk to honey bee adults and larvae.

3.7.4 Effects on other arthropod species other than bees

The HQ values for recommended species *Typhlodromus pyri* and *Aphidius rhopalosiphii* are below the trigger value of 1, indicating acceptable in-field and off-field risk to non-target arthropods with no need for risk mitigation measures.

3.7.5 Effects on soil organisms

As the PEC_{soil}, accumulation of Boscalid and the formulation are all lower than the concentration at which no significant effects are detected, it can be concluded that the risk of GLOB1811F to soil micro-organisms is acceptable in accordance with the intended use.

3.7.6 Effects on non-target terrestrial plants

Rasput (GLOB1811F) is a fungicide and is therefore not expected to have any significant herbicidal activity. The risk assessment was performed based on the EU agreed endpoint for representative formulation BAS 510 01 F (Boscalid 500 g/kg) because GLOB1811F is similar formulation, containing 500 g boscalid/kg. The TER value is above the trigger value of 5 indicating acceptable risk to non-target terrestrial plants in accordance with the intended use.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant. Boscalid doesn't have metabolites in soil.

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

Boscalid is not a candidate for substitution.

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

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.
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Appendix 2 Copy of the product label

Załącznik do decyzji MRiRW nr R - z dnia r.

Posiadacz zezwolenia:

Globachem N.V., Brustem Industriepark, Lichtenberglaan 2019, B-3800 Sint-Truiden, Królestwo Belgii,
tel.: +32-11 785717, e-mail: globachem@globachem.com

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:

.....

RASPUT

Środek przeznaczony do stosowania przez użytkowników profesjonalnych.

Zawartość substancji czynnych:

boskalid (związek z grupy anilidów) - 500 g/kg (50%)

Zezwolenie MRiRW nr R -



H411 Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH 401 W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

OPIS DZIAŁANIA

FUNGICYD w formie granul do sporządzania zawiesiny wodnej(WG) o działaniu układowym do stosowania zapobiegawczego i interwencyjnego w zwalczaniu chorób rzepaku.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Rzepak ozimy

czern krzyżowych, zgnilizna twardzikowa

Maksymalna dawka dla jednorazowego zastosowania: 0,5 kg/ha
zalecana dawka dla jednorazowego zastosowania: 0,2 – 0,5 kg/ha.

Termin stosowania: środek stosować od fazy pojawiania się pąków do końca kwitnienia (BBCH 55-69).
Pierwszy zabieg wykonać zapobiegawczo zgodnie z sygnalizacją lub z chwilą pojawienia się pierwszych objawów choroby.

Sucha zgnilizna kapustnych

Termin stosowania: środek stosować po ruszeniu wegetacji wiosna do fazy żółtego pąka (BBCH 30-59).
Pierwszy zabieg wykonać zapobiegawczo zgodnie z sygnalizacją lub z chwilą pojawienia się pierwszych objawów choroby

Maksymalna dawka dla jednorazowego zastosowania: 0,5 kg/ha
zalecana dawka dla jednorazowego zastosowania: 0,2 – 0,5 kg/ha

Zalecana ilość wody: 100-400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: 14 dni.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Środek stosować przemiennie z fungicydami o odmiennym mechanizmie działania.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

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 wlewniu 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 do 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.

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 w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

P272 Zanieczyszczonej odzieży ochronnej nie wnosić poza miejsce pracy.

P280 Stosować rękawice ochronne, odzież ochronną, ochronę oczu, ochronę twarzy.

P333 + P313 W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady, zgłosić się pod opiekę lekarza.

P363 Wyprać zanieczyszczoną odzież przed ponownym użyciem

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.

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.

P273 Unikać uwolnienia do środowiska

P391 Zebrać wyciek

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, w temperaturze 0°C - 30°C,
- chronić przed dostępem wilgoci.

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 pojemnik lub etykietę

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letter of access submitted.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

This list refers to new studies, submitted and summarised in the dRR for support of the authorisation of GLOB1811F.

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 2.2.2 2.3.2 2.3.3 2.4.1 2.4.2 2.6.2 2.7.1 2.7.2 2.7.3 2.8.1 2.8.2 2.8.3.1 2.8.3.2 2.8.5.1.1 2.8.5.1.2 2.8.5.2.1 2.8.5.3 2.8.7.1	XXX, T.	2018	Determination of storage stability and shelf life specification data for a water dispersible granule formulation containing Boscalid stored at 54±2°C for two weeks, in compliance with good laboratory practice. DNA4728 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.2.1 (Filled in in Part C)	XXX, T.	2019	Theoretical certificate of explosive properties for a formulation containing Boscalid. DNA5297 David Norris Analytical Laboratories Ltd. Not GLP Unpublished	N	Globachem NV
KCP 2.7.5	XXX, T.	2020	Determination of storage stability and shelf life specification data for a water dispersible granule formulation containing Boscalid stored at ambient temperature for two years, in compliance with good laboratory practice. DNA4729 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Globachem NV

Section 3: Efficacy data and information

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2-01	XXX, T.	2019	Efficacy of boscalid in OSR. Trial ID: FE-19-A-BSCL-CZ01	N	Globachem NV
KCP 6.2-02	XXX, J.	2019	FE-19-A-BSCL-CZ02 -Efficacy of boscalid in OSR.	N	Globachem NV
KCP 6.2-03	XXX, J.	2019	Efficacy of Boscalid 50 WG in OSR	N	Globachem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			FE-19-A-BSCL-CZ03		NV
KCP 6.2-04	XXX, J.	2019	FE-19-A-BSCL-CZ04 - Efficacy of boscalid in OSR.	N	Globachem NV
KCP 6.2-05	XXX, B.	2019	Efficacy of boscalid in OSR FE-19-A-BSCL-SE07	N	Globachem NV
KCP 6.2-06	XXX, T.	2019	Efficacy of Prothioconazole and Boscalid in OSR.	N	Globachem NV
KCP 6.2-07	XXX, P.	2020	Efficacy and Selectivity of Prothioconazole and Boscalid in OSR. FE-20-A-PTZxBSCL-PL03	N	Globachem NV
KCP 6.2-08	XXX, J.	2020	Efficacy of Prothioconazole and Boscalid in OSR. FE-20-A-PTZxBSCL-PL04	N	Globachem NV
KCP 6.2-09	XXX, M.	2020	Biologiczna ekspertyza skuteczności działania fungicydów protiokonazol i boskalid w zwalczaniu suchej zgnilizny kapustnych i zgnilizny twardzikowej w rzapaku ozimym. FE-20-A-PTZxBSCL-PL05	N	Globachem NV
KCP 6.2-10	XXX, D.	2020	Efficacy of Prothioconazole and Boscalid in OSR FE-20-A-PTZxBSCL-FR02	N	Globachem NV

Section 5: Analytical methods

No studies submitted.

Section 6: Mammalian toxicology

No studies submitted.

Section 7: Metabolism and residues

No studies submitted.

Section 8: Environmental fate

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4.1	XXX, J-P.	2021a	Boscalid 50 WG - Estimations of the predicted environmental concentration in groundwater (PEC _{gw}) of Boscalid following the application of GLOB1811F on oilseed rape. Globachem NV, Report GLOB1811F – GW – Central EU Not GLP Unpublished	N	Globachem NV
KCP 9.2.5	XXX, J-P.	2021b	Difenoconazole 500 SC – Estimation of the Predicted Environmental concentrations in surface water (PEC _{SW}) and sediments (PEC _{SED}) for Boscalid following the application of GLOB1811F on oilseed rape. Globachem NV, Report GLOB1811F – SW/SED – Central EU Not GLP Unpublished	N	Globachem NV

Section 9: Ecotoxicology

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-01	XXX, D.	2021a	Effects of GLOB1811F to <i>Daphnia magna</i> in a 48-hour static test 20 48 ADL 0023 BioChem agrar Labor für biologische und chemische Analytik GmbH	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.2.1-02	XXX, D.	2021b	Effects of GLOB1811F on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions 20 48 ALE 0020 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.2.1-03	XXX, D.	2021c	Effects of GLOB1811F on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 20 48 AAL 0027 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.3.1.1	XXX, M.	2020	Acute toxicity of GLOB1811F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions 20 48 BAA 0156 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.3.1.2	XXX, K.	2021	Chronic toxicity of GLOB1811F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions 20 48 BAC 0096 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.3.1.3	XXX, M.	2021	GLOB1811F - Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions 20 48 BLC 0079 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.3.2-01	XXX, J.	2020a	GLOB1811F: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			155681063 Ibacon GmbH GLP Unpublished		
KCP 10.3.2-02	XXX, J.	2020b	GLOB1811F: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates 155681001 Ibacon GmbH GLP Unpublished	N	Globachem NV
KCP 10.4.1	XXX, S.	2020a	Effects of GLOB1811F on the reproduction of the earthworm <i>Eisenia fetida</i> in artificial soil 20 48 TEC 0061 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.4.2-01	XXX, S.	2020b	Effects of GLOB1811F on the reproduction of the collembolan <i>Folsomia candida</i> 20 48 TCC 0070 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.4.2-02	XXX L.	2020a	Effects of GLOB1811F on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> 20 48 THC 0055 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV
KCP 10.5	XXX L.	2020b	Effects of GLOB1811F on the activity of soil microflora (Nitrogen transformation test) 20 48 SMN 0061 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Globachem NV

Section 10: Assessment of the relevance of metabolites in groundwater

No studies submitted.