

# REGISTRATION REPORT

## **Part B**

### **Section 9**

#### **Ecotoxicology**

Detailed summary of the risk assessment

Product code: GLOB1811F

Product name(s): GLOB1811F

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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## 9 Ecotoxicology (KCP 10)

### **Review Comments:**

This application was submitted by Globachem NV for approval of Rasput (GLOB1811F) a water dispersible granule (WG) containing 500 g/kg boscalid for use as a fungicide in oilseed rape in Poland.

Boscalid was included on Annex I of Directive 91/414/EEC on 1 of August 2008 under Inclusion Directive 2008/44/EC.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

## 9.1 Critical GAP and overall conclusions

**Table 9.1-1: Table of critical GAPs**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	kg prod- uct/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	Oilseed rape (Winter & Spring)	F	<i>Sclerotina scleroti- orum</i>	Foliar Spray	BBCH 55- 69	a) 2 b) 2	14	a) 0.5 b) 1	a) 0.25 b) 0.5	100-400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A	A	A	A	A	A	A
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	a) 0.25 b) 0.5	100-400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A	A	A	A	A	A	A
3	CEU	Oilseed rape (Winter & Spring)	F	<i>Leptosphaeria macu- lans</i>	Foliar Spray	BBCH 20- 59	a) 2 b) 2	14	a) 0.5 b) 1	a) 0.25 b) 0.5	100-400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A	A	A	A	A	A	A

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

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

and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

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

**Remarks table:**

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
- (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8) The maximum number of application possible under practical conditions of use must be provided
- (9) Minimum interval (in days) between applications of the same product.
- (10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> 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

### **9.1.1 Overall conclusions**

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

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

#### **9.1.1.2 Effects on aquatic organisms (KCP 10.2)**

Based on FOCUS Steps 1,2 and 3, calculated PEC/RAC ratios for the active substance, Boscalid and for the formulation 1811F, did indicate an acceptable risk for aquatic organisms for all intended uses.

#### **9.1.1.3 Effects on bees (KCP 10.3.1)**

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 no unacceptable chronic risk to honey bee adults and larvae.

#### **9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)**

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.

The HQ values for recommended species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value of 2, indicating acceptable in-field and off-field risk to non-target arthropods with no need for risk mitigation measures.



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

All TER values exceed the relevant triggers indicating that GLOB1811F (Rasput) does not pose an unacceptable risk to earthworms and other non-target soil organisms following applications according to recommended use pattern.

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.

#### **9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)**

First tier risk assessment indicates that there is no unacceptable risk for non-target plants from the application of GLOB1811F according to the intended GAP.

#### **9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

Tests on other non-target species are not required.

### **9.1.2 Grouping of intended uses for risk assessment**

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

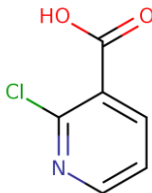
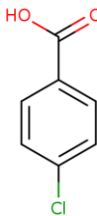
**Table 9.1-2: Critical use pattern of GLOB1811F grouped according to criterion**

Grouping according to criterion			
Group	Intended uses	relevant use parameters for grouping	relevant parameter or value for sorting
3	1, 2, 3	2 applications, <del>500</del> 250 g a.s./ha	BBCH 20-59

### **9.1.3 Consideration of metabolites**

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of GLOB1811F is indicated in the table.

**Table 9.1-3 Metabolites of Boscalid**

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
M510F47		157.6	Soil: anaerobic conditions. 2.6 % after 3 d, 6 % after 62 d, 5.9 % after 90 d, 6.7 % after 120 d	No
M510F64		156.56	Sediment: under outdoor conditions 7.3 % after 7 d 9 % after 14 d 9.4 % after 30 d 1.9 % after 120 d	No

## 9.2 Effects on birds (KCP 10.1.1)

### 9.2.1 Toxicity data

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

Effects on birds of GLOB1811F were not evaluated as part of the EU assessment of Boscalid.

However, the provision of further data on the GLOB1811F is not considered essential, because active substance data on toxicity to birds can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i>	Boscalid	Oral Acute	<b>LD<sub>50</sub> &gt; 2000 mg/kg bw</b>	SANCO/3919 /2007-rev. 5
<i>Anas platyrhynchos L.</i> <i>Colinus virginianus</i>	Boscalid	Dietary Short-term	LC <sub>50</sub> > 5000 mg/kg feed	SANCO/3919 /2007-rev. 5

Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i>	Boscalid	Dietary Reproductive toxicity	NOEL = 24.1 mg/kg bw/d	SANCO/3919 /2007-rev. 5

### 9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.2.2 Risk assessment for spray applications

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

To achieve a concise risk assessment, the risk envelope approach is applied (see 9.1.2).

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

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

**Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of GLOB1811F in oilseed rape**

Intended use		Oilseed rape				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 250				
Acute toxicity (mg/kg bw)		> 2000				
TER criterion						
Crop scenario	Indicator/generic focal species	SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>	
Growth stage						
Oilseed rape	Small omnivorous bird	158.8	1.2	47.64	41.98	
Reprod. toxicity (mg/kg bw/d)		24.1				
TER criterion						
Crop scenario	Indicator/generic focal species	SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>	
Growth stage						
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock"	2.7	1.4 × 0.53	2.0	48.12	
Oilseed rape BBCH 10-29	Small omnivorous bird “lark”	10.9	1.4 × 0.53	8.09	11.92	
Oilseed rape	Small omnivorous bird “lark”	3.3	1.4 × 0.53	2.45	39.37	

BBCH 30-39					
Oilseed rape BBCH $\geq 40$	Small omnivorous bird "lark"	2.7	$1.4 \times 0.53$	2.0	48.12
Oilseed rape BBCH 20-29	Medium herbivorous/granivorous bird "pigeon"	3.5	$1.4 \times 0.53$	2.60	37.12
Oilseed rape BBCH 30-39	Medium herbivorous/granivorous bird "pigeon"	1.1	$1.4 \times 0.53$	0.82	118.11
Oilseed rape BBCH $\geq 40$	Medium herbivorous/granivorous bird "pigeon"	0.9	$1.4 \times 0.53$	0.67	144.36
Oilseed rape 20-29	Small insectivorous bird "wagtail"	2.8	$1.4 \times 0.53$	2.08	46.40

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

According to the screening and first-tier assessments for oilseed rape, all the  $TER_a$  and  $TER_{lt}$  values for active substance Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that GLOB1811F presents no unacceptable acute and long-term risk to birds according to the intended uses on oilseed rape.

### 9.2.2.2 Higher-tier risk assessment

Not required.

### 9.2.2.3 Drinking water exposure

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

#### Leaf scenario

Since GLOB1811F is ~~not a product for spray applications~~ / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

With a  $K(f)_{oc}$  of 771.2, Boscalid belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied (see 9.1.2).

Effective application rate (g/ha) =	85.05		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.04
Reprod. toxicity (mg/kg bw/d) =	24.1	quotient =	3.53

When multiple spray applications are considered, a MAF based on the DT<sub>50</sub> in soil (single first order kinetics, geometric mean as used for PEC<sub>gw</sub> and PEC<sub>sw</sub>) is applied to achieve the effective application rate AR<sub>eff</sub>. Worst case DT<sub>50</sub>soil 208 (SANCO/3919 /2007-rev. 5)

$$AR_{eff} = AR \times MAF_m = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

Where

k = ln(2)/DT<sub>50</sub> (rate constant)  
n = number of applications  
i = application interval (days)

**Table 9.2-3 Effective application rate of GLOB1811F**

Crop	DT <sub>50</sub>	Max application rate (AR) (g as/ha)	No. of applications	MAF <sub>mean</sub>	AR <sub>eff</sub>
Rapeseed	208	250	2	1.954	488.5

With a K(f)oc of 507-1110 (SANCO/3919 /2007-rev. 5), Boscalid belongs to the group of more sorptive substances (trigger of 3000).

Effective application rate (g/ha) =	488.5		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.244
Reprod. toxicity (mg/kg bw/d) =	24.1	quotient =	20.27

#### 9.2.2.4 Effects of secondary poisoning

The log P<sub>ow</sub> of Boscalid amounts to 2.96 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

##### Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

##### Risk assessment for fish-eating birds via secondary poisoning

Not required.

#### 9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

### 9.2.4 Overall conclusions

According to the screening and first-tier assessments for oilseed rape, all the  $TER_a$  and  $TER_{lt}$  values for active substance Boscalid ~~are greater than the Annex VI~~ are above the trigger set by Commission regulation (EU) 546/2011 of 10 and 5, respectively, indicating that GLOB1811F presents no unacceptable acute and long-term risk to birds according to the intended uses on oilseed rape.

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

#### Review comments:

The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios ( $TER_A$  and  $TER_{LT}$ ) were calculated taking into account the EU agreed endpoints for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for accept-ability of effects. Revealed that there is no potential of risk for birds resulting from acute and long-term exposure to active substance following use of GLOB1811F in compliance with proposed GAP.

A quantitative drinking water risk assessment is not triggered for the proposed use pattern of GLOB1811F according to EFSA/2009/1438 criteria and therefore the risk to birds via drinking water is acceptable.

The risk of secondary poisoning is assumed to be low because the  $\log K_{OW}$  of Boscalid is  $< 3$ . It is therefore not necessary to consider the risk from secondary poisoning further. Therefore, based on the low  $\log K_{OW}$  values the risk from bioaccumulation to fish-eating and worm-eating birds is negligible.

No risk mitigation measures are required.

#### Conclusion

According to the performed risk assessment there is no potential of risk to birds resulting from exposure to active substance following use of Rasput (GLOB1811F) in compliance with proposed GAP.

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

#### 9.3.1 Toxicity data

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

Effects on mammals of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Rat	Boscalid	Oral 1 d Acute	<b>LD<sub>50</sub> &gt; 5000 mg/kg bw</b>	SANCO/3919 /2007-rev. 5
Rat	Boscalid	Dietary Reproductive toxicity Two-generation study	<b>NOAED = 67 mg/kg bw/d</b>	SANCO/3919 /2007-rev. 5

##### 9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

#### 9.3.2 Risk assessment for spray applications

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

To achieve a concise risk assessment, the risk envelope approach is applied (see 9.1.2).

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

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

**Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB1811F in oilseed rape**

Intended use	Oilseed rape
Active substance/product	Boscalid
Application rate (g/ha)	2 * 250
Acute toxicity (mg/kg bw)	> 5000

TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species		SV <sub>90</sub>	MAF <sub>90</sub>	DDD <sub>90</sub> (mg/kg bw/d)	TER <sub>a</sub>
Oilseed rape	Small herbivorous mammal		118.4	1.2	35.52	140.77
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species		SV <sub>m</sub>	MAF <sub>m</sub> × TWA	DDD <sub>m</sub> (mg/kg bw/d)	TER <sub>lt</sub>
Oilseed rape	Small herbivorous mammal		48.3	1.4 * 0.53	8.96	7.48

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

According to the screening and first-tier assessments for oilseed rape, all the TER<sub>a</sub> and TER<sub>lt</sub> values for active substance Boscalid are greater than the Annex VI trigger trigger set by Commission regulation (EU) 546/2011 of 10 and 5, respectively, indicating that GLOB1811F presents no unacceptable acute and long-term risk to mammals according to the intended uses on oilseed rape.

### 9.3.2.2 Higher-tier risk assessment

Not required.

### 9.3.2.3 Drinking water exposure

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

#### Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ( $K_{oc} < 500$  L/kg) or 3000 in the case of more sorptive substances ( $K_{oc} \geq 500$  L/kg).

With a  $K(f)_{oc}$  of 771.5, Boscalid belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied (see 9.1.2).

Effective application rate (g/ha)=	85.05	
Acute toxicity (mg/kg bw)=	5000	quotient = 0.01701
Reprod. toxicity (mg/kg bw/d)=	67	quotient = 1.27

When multiple spray applications are considered, a MAF based on the DT<sub>50</sub> in soil (single first order kinetics, geometric mean as used for PEC<sub>gw</sub> and PEC<sub>sw</sub>) is applied to achieve the effective application rate AR<sub>eff</sub>. Worst case DT<sub>50</sub>soil of 208 was used for calculation (SANCO/3919 /2007-rev. 5)



$$AR_{\text{eff}} = AR \times MAF_m = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

Where

k =  $\ln(2)/DT_{50}$  (rate constant)  
n = number of applications  
i = application interval (days)

**Table 9.3-3 Effective application rate of Boscalid**

Crop	DT <sub>50</sub>	Max application rate (AR) (g as/ha)	No. of applications	MAF <sub>mean</sub>	AR <sub>eff</sub>
Oilseed rape	208	250	2	1.954	488.5

With a K(f)oc of 507-1110 (SANCO/3919 /2007-rev. 5), Boscalid belongs to the group of more sorptive substances (trigger of 3000).

Rapeseed				
Effective application rate (g/ha) =		488.5		
Acute toxicity (mg/kg bw) =		5000	quotient =	0.0977
Reprod. toxicity (mg/kg bw/d) =		67	quotient =	7.29

#### 9.3.2.4 Effects of secondary poisoning

The log P<sub>ow</sub> of Boscalid amounts to 2.96 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

##### Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

##### Risk assessment for fish-eating mammals via secondary poisoning

Not required.

#### 9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

#### 9.3.4 Overall conclusions

According to the screening and first-tier assessments for oilseed rape, all the  $TER_a$  and  $TER_{lt}$  values for active substance Boscalid ~~are greater than the Annex VI~~ are above the trigger set by Commission regulation (EU) 546/2011 trigger of 10 and 5, respectively, indicating that GLOB1811F presents no unacceptable acute and long-term risk to mammals according to the intended uses on oilseed rape.

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.

##### **Review comments:**

The risk assessment to mammals was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).

The results of the 'screening phase' acute dietary risk assessment and long term dietary risk assessment - Toxicity Exposure Ratios ( $TER_A$  and  $TER_{LT}$ ) were calculated taking into account the EU agreed end-points for most sensitive species for the active substance and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for accept-ability of effects. Revealed that there is no potential of risk for wild mammals resulting from acute and long-term exposure to active substance following use of GLOB1811F in compliance with proposed GAP.

A quantitative drinking water risk assessment is not triggered for the proposed use pattern of Rasput (GLOB1811F) according to EFSA/2009/1438 criteria and therefore the risk to mammals via drinking water is acceptable.

The risk of secondary poisoning is assumed to be low because the  $\log K_{OW}$  of Boscalid is  $< 3$ . It is therefore not necessary to consider the risk from secondary poisoning further. Therefore, based on the low  $\log K_{OW}$  values the risk from bioaccumulation to fish-eating and worm-eating mammals is negligible.

No risk mitigation measures are required.

##### **Conclusion**

According to the performed risk assessment there is no potential of risk to mammals resulting from exposure to active substance following use of Rasput (GLOB1811F) in compliance with proposed GAP.

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

No data available.

## 9.5 Effects on aquatic organisms (KCP 10.2)

### 9.5.1 Toxicity data

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

Effects on aquatic organisms of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Boscalid	96 h, s	EC <sub>50</sub> = 2.7 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Oncorhynchus mykiss</i>	Boscalid	97 d, f	NOEC = 0.125 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Daphnia magna</i>	Boscalid	48 h, s	EC <sub>50</sub> = 5.33 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Daphnia magna</i>	Boscalid	21 d, ss	NOEC = 1.31 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Chironomus riparius</i>	Boscalid	28 d, s	NOEC = 1 mg a.s./L (spiked water)	SANCO/3919 /2007-rev. 5
<i>Chironomus riparius</i>	Boscalid	28 d, s	NOEC = 23.26 mg/kg dry sediment (spiked sediment)	Addendum 2 to DAR 2006
<i>Pseudokirchneriella subcapitata</i>	Boscalid	96 h, s	EC <sub>50</sub> = 1.34 mg a.s./L	SANCO/3919 /2007-rev. 5
<b>Higher-tier studies (micro- or mesocosm studies)</b>				
-				

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

**Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – GLOB1811F**

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	GLOB1811F	48 h	EC <sub>50</sub> > 100.0 mg/L NOEC > 100.0 mg/L LOEC > 100.0 mg/L	XXX, D. 2021a 20 48 ADL 0023
<i>Lemna gibba</i>	GLOB1811F	7d	NOEC = 0.894 mg/L LOEC > 2.86 mg/L	XXX, D. 2021b 20 48 ALE 0020

Species	Substance	Exposure System	Results	Reference
			<p>Fronnd number*</p> <p><math>E_rC_{50} = 9.93 \text{ mg/L}_{\text{nom}}</math> (equivalent to 4.9 mg a.s./L nom)</p> <p><math>E_yC_{50} = 2.46 \text{ mg/L}_{\text{nom}}</math> (equivalent to 1.2 mg a.s./L nom)</p> <p>Biomass*</p> <p><math>E_rC_{50} = 58.4 \text{ mg/L}_{\text{nom}}</math> (equivalent to 29.0 mg a.s./L nom)</p> <p><math>E_yC_{50} = 2.95 \text{ mg/L}_{\text{nom}}</math> (equivalent to 1.5 mg a.s./L nom)</p>	
<i>Pseudokirchneriella subcapitata</i>	GLOB1811F	72 h	<p><math>E_rC_{50} = 5.17 \text{ mg/L}_{\text{nom}}</math></p> <p><math>E_yC_{50} = 3.16 \text{ mg/L}_{\text{nom}}</math></p>	XXX, D. 2021c 20 48 AAL 0027
<b>Higher-tier studies (micro- or mesocosm studies)</b>				
-				

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

**Evaluator comments:** \*According to the *Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters* in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015, if the test with *Lemna gibba* was carried out, growth rate (calculated as  $E_rC_{50}$ ) is the preferred endpoint to be used in risk assessment.

### 9.5.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.5.2 Risk assessment

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

The relevant global maximum FOCUS Step 1, 2 and 3  $PEC_{\text{sw}}$  for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for aquatic organisms from all other intended uses in groups Oilseed rape (see 9.1.2).

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC<sub>SW</sub>, PEC<sub>SED</sub>) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

### Multiple applications

**Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations after 2 applications of GLOB1811F in Winter Oilseed rape**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 2700	NOEC 125	EC <sub>50</sub> 5330	NOEC 1310	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.3	131	134	100		2326
FOCUS Scenario	PEC <sub>SW-max</sub> (µg/L)							PEC <sub>SED ACCU</sub> (µg/kg)	
<b>Step 1</b>									
	86.754	<b>3.213</b>	<b>6.940</b>	<b>1.628</b>	0.662	0.647	0.868	2911.755	<b>1.252</b>
<b>Step 2</b>									
N-Europe March – May	18.248	0.676	<b>1.460</b>	0.342	0.139	0.136	0.182	615.398	0.265
N-Europe June – Sept	18.248	0.676	<b>1.460</b>	0.342	0.139	0.136	0.182	615.398	0.265
N-Europe Oct – Feb	42.030	<b>1.557</b>	<b>3.362</b>	0.789	0.321	0.314	0.420	1435.655	0.617
S-Europe March – May	34.103	<b>1.263</b>	<b>2.728</b>	0.640	0.260	0.254	0.341	1162.236	0.500

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro- longed	Algae	Sed. dwell. prolonged		Sed. dwell. pro- longed
S-Europe June – Sept	26.175	0.969	<b>2.094</b>	0.491	0.200	0.195	0.262	888.817	0.382
S-Europe Oct – Feb	34.103	<b>1.263</b>	<b>2.728</b>	0.640	0.260	0.254	0.341	1162.236	0.500
<b>Step 3: Early application – BBCH 20</b>									
D2/ditch	24.080	0.892	<b>1.926</b>	0.452	0.184	0.180	0.241	1129.591	0.486
D2/stream	15.020	0.556	<b>1.202</b>	0.282	0.115	0.112	0.150	653.472	0.281
D3/ditch	1.392	0.052	0.111	0.026	0.011	0.010	0.014	13.771	0.006
D4/pond	2.255	0.084	0.180	0.042	0.017	0.017	0.023	192.317	0.083
D4/stream	3.627	0.134	0.290	0.068	0.028	0.027	0.036	69.457	0.030
D5/pond	1.123	0.042	0.090	0.021	0.009	0.008	0.011	106.418	0.046
D5/stream	1.876	0.069	0.150	0.035	0.014	0.014	0.019	21.990	0.009
R1/pond	0.352	0.013	0.028	0.007	0.003	0.003	0.004	25.455	0.011
R1/stream	3.427	0.127	0.274	0.064	0.026	0.026	0.034	14.849	0.006
R3/stream	4.423	0.164	0.354	0.083	0.034	0.033	0.044	45.267	0.019
<b>Step 3: Late application – BBCH 55</b>									
D2/ditch	7.311	0.271	0.585	0.137	0.056	0.055	0.073	530.190	0.228
D2/stream	4.556	0.169	0.364	0.085	0.035	0.034	0.046	305.747	0.131
D3/ditch	1.387	0.051	0.111	0.026	0.011	0.010	0.014	10.771	0.005
D4/pond	0.733	0.027	0.059	0.014	0.006	0.005	0.007	70.963	0.031
D4/stream	1.183	0.044	0.095	0.022	0.009	0.009	0.012	23.720	0.010
D5/pond	0.765	0.028	0.061	0.014	0.006	0.006	0.008	69.942	0.030
D5/stream	1.277	0.047	0.102	0.024	0.010	0.010	0.013	14.350	0.006
R1/pond	0.599	0.022	0.048	0.011	0.005	0.004	0.006	44.607	0.019

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
R1/stream	3.518	0.130	0.281	0.066	0.027	0.026	0.035	45.554	0.020
R3/stream	4.029	0.149	0.322	0.076	0.031	0.030	0.040	23.435	0.010

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations after 2 applications of GLOB1811F in Spring Oilseed rape**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 2700	NOEC 125	EC <sub>50</sub> 5330	NOEC 1310	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.3	131	134	100		2326
FOCUS Scenario	PEC <sub>sw</sub> -max (µg/L)							PEC <sub>SED ACCU</sub> (µg/kg)	
<b>Step 1</b>									
	86.754	<b>3.213</b>	<b>6.940</b>	<b>1.628</b>	0.662	0.647	0.868	2911.755	<b>1.252</b>
<b>Step 2</b>									
N-Europe March – May	<del>9.470</del> <b>18.2476</b>	<del>0.351</del> <b>0.676</b>	<del>0.758</del> <b>1.460</b>	<del>0.178</del> <b>0.342</b>	<del>0.072</del> <b>0.139</b>	<del>0.071</del> <b>0.136</b>	<del>0.095</del> <b>0.182</b>	615.398	0.265
N-Europe June – Sept	<del>9.470</del> <b>18.2476</b>	<del>0.351</del> <b>0.676</b>	<del>0.758</del> <b>1.460</b>	<del>0.178</del> <b>0.342</b>	<del>0.072</del> <b>0.139</b>	<del>0.071</del> <b>0.136</b>	<del>0.095</del> <b>0.182</b>	615.398	0.265
N-Europe Oct – Feb	21.633	0.801	<b>1.731</b>	0.406	0.165	0.161	0.216	1435.655	0.617

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro- longed	Algae	Sed. dwell. prolonged		Sed. dwell. pro- longed
S-Europe March – May	<del>17.579</del> 34.1025	<del>0.651</del> 1.263	<del>1.406</del> 2.723	<del>0.330</del> 0.640	<del>0.134</del> 0.260	<del>0.131</del> 0.254	<del>0.176</del> 0.341	1162.236	0.500
S-Europe June – Sept	<del>13.524</del> 26.1750	<del>0.501</del> 0.969	<del>1.082</del> 2.094	<del>0.254</del> 0.491	<del>0.103</del> 0.200	<del>0.101</del> 0.195	<del>0.135</del> 0.2618	888.817	0.382
S-Europe Oct – Feb	17.579	0.651	1.406	0.330	0.134	0.131	0.176	1162.236	0.500
<b>Step 3: Early application – BBCH 20</b>									
D2/ditch	8.624	0.319	0.690	0.162	0.066	0.064	0.086	872.572	0.375
D2/stream	5.766	0.214	0.461	0.108	0.044	0.043	0.058	481.119	0.207
D3/ditch	1.386	0.051	0.111	0.026	0.011	0.010	0.014	9.876	0.004
D4/pond	1.292	0.048	0.103	0.024	0.010	0.010	0.013	118.549	0.051
D4/stream	1.872	0.069	0.150	0.035	0.014	0.014	0.019	40.676	0.017
D5/pond	1.087	0.040	0.087	0.020	0.008	0.008	0.011	92.695	0.040
D5/stream	1.461	0.054	0.117	0.027	0.011	0.011	0.015	19.590	0.008
R1/pond	0.501	0.019	0.040	0.009	0.004	0.004	0.005	41.807	0.018
R1/stream	4.232	0.157	0.339	0.079	0.032	0.032	0.042	24.707	0.011
R3/stream	8.624	0.319	0.690	0.162	0.066	0.064	0.086	872.572	0.375
<b>Step 3: Late application – BBCH 55</b>									
D2/ditch	6.108	0.226	0.489	0.115	0.047	0.046	0.061	622.910	0.268
D2/stream	3.983	0.148	0.319	0.075	0.030	0.030	0.040	344.868	0.148
D3/ditch	1.391	0.052	0.111	0.026	0.011	0.010	0.014	13.119	0.006
D4/pond	0.988	0.037	0.079	0.019	0.008	0.007	0.010	92.720	0.040
D4/stream	1.799	0.067	0.144	0.034	0.014	0.013	0.018	29.674	0.013
D5/pond	1.157	0.043	0.093	0.022	0.009	0.009	0.012	91.892	0.040



Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
D5/stream	1.456	0.054	0.116	0.027	0.011	0.011	0.015	20.618	0.009
R1/pond	0.592	0.022	0.047	0.011	0.005	0.004	0.006	58.830	0.025
R1/stream	3.427	0.127	0.274	0.064	0.026	0.026	0.034	37.965	0.016
R3/stream	6.108	0.226	0.489	0.115	0.047	0.046	0.061	622.910	0.268

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Evaluator comments:** For Spring Oilseed rape, for calculation of PEC/RAC ratio, PEC<sub>sw</sub> values at Step 2 after 1 application were used. It was corrected and recalculated.

### Single applications

**Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations after 1 application of GLOB1811F in Winter Oilseed rape**

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 2700	NOEC 125	EC <sub>50</sub> 5330	NOEC 1310	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.3	131	134	100		2326
FOCUS Scenario	PEC <sub>sw</sub> -max (µg/L)							PEC <sub>SED ACCU</sub> (µg/kg)	
<b>Step 1</b>									
	44.161	<b>1.636</b>	<b>3.533</b>	0.829	0.337	0.330	0.442	1428.061	0.614

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro- longed	Algae	Sed. dwell. prolonged		Sed. dwell. pro- longed
<b>Step 2</b>									
N-Europe March – May	9.470	0.351	0.758	0.178	0.072	0.071	0.095	318.657	0.137
N-Europe June – Sept	9.470	0.351	0.758	0.178	0.072	0.071	0.095	318.657	0.137
N-Europe Oct – Feb	21.633	0.801	<b>1.731</b>	0.406	0.165	0.161	0.216	738.171	0.317
S-Europe March – May	17.579	0.651	<b>1.406</b>	0.330	0.134	0.131	0.176	598.333	0.257
S-Europe June – Sept	13.524	0.501	<b>1.082</b>	0.254	0.103	0.101	0.135	458.495	0.197
S-Europe Oct – Feb	17.579	0.651	<b>1.406</b>	0.330	0.134	0.131	0.176	598.333	0.257
<b>Step 3: Early application – BBCH 20</b>									
D2/ditch	11.880	0.440	0.950	0.223	0.091	0.089	0.119	588.685	0.253
D2/stream	7.410	0.274	0.593	0.139	0.057	0.055	0.074	339.566	0.146
D3/ditch	1.589	0.059	0.127	0.030	0.012	0.012	0.016	11.336	0.005
D4/pond	0.899	0.033	0.072	0.017	0.007	0.007	0.009	83.608	0.036
D4/stream	1.697	0.063	0.136	0.032	0.013	0.013	0.017	28.250	0.012
D5/pond	0.497	0.018	0.040	0.009	0.004	0.004	0.005	52.206	0.022
D5/stream	1.476	0.055	0.118	0.028	0.011	0.011	0.015	10.192	0.004
R1/pond	0.155	0.006	0.012	0.003	0.001	0.001	0.002	12.345	0.005
R1/stream	1.356	0.050	0.108	0.025	0.010	0.010	0.014	6.411	0.003
R3/stream	2.466	0.091	0.197	0.046	0.019	0.018	0.025	16.238	0.007
<b>Step 3: Late application – BBCH 55</b>									
D2/ditch	3.898	0.144	0.312	0.073	0.030	0.029	0.039	290.410	3.898

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC <sub>50</sub> 2700	NOEC 125	EC <sub>50</sub> 5330	NOEC 1310	E <sub>r</sub> C <sub>50</sub> /E <sub>y</sub> C <sub>50</sub> 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.3	131	134	100		2326
FOCUS Scenario	PEC <sup>sw</sup> <sub>-max</sub> (µg/L)							PEC <sup>sed</sup> <sub>accu</sub> (µg/kg)	
Step 1									

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro- longed	Algae	Sed. dwell. prolonged		Sed. dwell. pro- longed
	44.161	<b>1.636</b>	<b>3.533</b>	0.829	0.337	0.330	0.442	1428.061	0.614
<b>Step 2</b>									
N-Europe March – May	9.470	0.351	0.758	0.178	0.072	0.071	0.095	318.657	0.137
N-Europe June – Sept	9.470	0.351	0.758	0.178	0.072	0.071	0.095	318.657	0.137
N-Europe Oct – Feb	21.633	0.801	<b>1.731</b>	0.406	0.165	0.161	0.216	738.171	0.317
S-Europe March – May	17.579	0.651	<b>1.406</b>	0.330	0.134	0.131	0.176	598.333	0.257
S-Europe June – Sept	13.524	0.501	<b>1.082</b>	0.254	0.103	0.101	0.135	458.495	0.197
S-Europe Oct – Feb	17.579	0.651	<b>1.406</b>	0.330	0.134	0.131	0.176	598.333	0.257
<b>Step 3: Early application – BBCH 20</b>									
D2/ditch	5.318	0.197	0.425	0.100	0.041	0.040	0.053	550.432	0.237
D2/stream	3.503	0.130	0.280	0.066	0.027	0.026	0.035	309.250	0.133
D3/ditch	1.584	0.059	0.127	0.030	0.012	0.012	0.016	8.562	0.004
D4/pond	0.649	0.024	0.052	0.012	0.005	0.005	0.006	62.869	0.027
D4/stream	1.297	0.048	0.104	0.024	0.010	0.010	0.013	20.645	0.009
D5/pond	0.550	0.020	0.044	0.010	0.004	0.004	0.005	46.981	0.020
D5/stream	1.263	0.047	0.101	0.024	0.010	0.009	0.013	10.128	0.004
R1/pond	0.229	0.008	0.018	0.004	0.002	0.002	0.002	21.160	0.009
R1/stream	1.828	0.068	0.146	0.034	0.014	0.014	0.018	11.093	0.005
R3/stream	5.318	0.197	0.425	0.100	0.041	0.040	0.053	550.432	0.237

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. pro- longed	Algae	Sed. dwell. prolonged		Sed. dwell. pro- longed
<b>Step 3: Late application – BBCH 55</b>									
D2/ditch	0.341	0.013	0.027	0.006	0.003	0.003	0.003	34.692	0.015
D2/stream	1.368	0.051	0.109	0.026	0.010	0.010	0.014	10.785	0.005
D3/ditch	0.411	0.015	0.033	0.008	0.003	0.003	0.004	33.884	0.015
D4/pond	1.476	0.055	0.118	0.028	0.011	0.011	0.015	7.635	0.003
D4/stream	0.290	0.011	0.023	0.005	0.002	0.002	0.003	31.401	0.014
D5/pond	2.313	0.086	0.185	0.043	0.018	0.017	0.023	30.749	0.013
D5/stream	3.137	0.116	0.251	0.059	0.024	0.023	0.031	332.430	0.143
R1/pond	1.982	0.073	0.159	0.037	0.015	0.015	0.020	185.663	0.080
R1/stream	1.588	0.059	0.127	0.030	0.012	0.012	0.016	10.511	0.005
R3/stream	0.341	0.013	0.027	0.006	0.003	0.003	0.003	34.692	0.015

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses on Oilseed rape, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC of 125 µg/L for *Onchorhynchus mykiss* in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further PEC/RAC ratios were calculated.

**Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for GLOB1811F for each organism group based on FOCUS Drift calculations for the use of GLOB1811F EC in Oilseed rape winter and Oilseed rape spring (2 x 500 g/ha)**

Group		Inverteb. acute	Plants	Algae
Test species		<i>D. magna</i>	<i>L. Gibba</i>	<i>Pseudokirchneriella subcapitata</i>
Endpoint		EC <sub>50</sub>	NOEC E <sub>r</sub> C <sub>50</sub>	E <sub>r</sub> C <sub>50</sub>
(µg/L)		100000	<del>894</del> 9930	5170
AF		100	<del>100</del> 10	10
RAC (µg/L)		1000	<del>8.94</del> 993	517
FOCUS Scenario	PEC <sub>el</sub> <sup>sw-max</sup> (µg/L)			
Ditch	<del>2.8063</del> 3.2123	<del>0.0028</del> 0.0032	<del>0.3139</del> 0.0032	<del>0.0054</del> 0.0062
Pond	<del>0.0896</del> 0.1095	<del>0.0001</del> 0.0001	<del>0.0100</del> 0.0001	<del>0.0002</del> 0.0002
Stream	<del>2.0616</del> 2.3839	<del>0.0021</del> 0.0024	<del>0.2306</del> 0.0024	<del>0.0040</del> 0.0046
Stream*	<del>2.4739</del> 2.8610	<del>0.0025</del> 0.0029	<del>0.2767</del> 0.0029	<del>0.0048</del> 0.0056

\*taking into account the 20% contribution from the upstream catchment

**Evaluator comments:** As maximum PEC<sub>sw</sub> values for GLOB1811F were re-calculated by Evaluator in Section 8 and the E<sub>r</sub>C<sub>50</sub> value from test with *L. Gibba* with AF of 10 should be used in risk assessment, therefore new PEC/RAC calculations were performed in table above.

### 9.5.3 Overall conclusions

Based on FOCUS Steps 1,2 and 3, calculated PEC/RAC ratios for the active substance, Boscalid and for the formulation 1811F, did indicate an acceptable risk for aquatic organisms for all intended uses.

#### Review Comments:

The endpoints for active substance as provided by the notifier are considered valid and are used in the risk assessment. For assessment of risk for Boscalid, FOCUS Step 1, Step 2 and Step 3 (scenarios **D3, D4 and R1**) PEC<sub>sw</sub> values were accepted in Section 8. The PEC<sub>sw</sub> values for Rasput (GLOB1811F) were corrected in Section 8, therefore the PEC/RAC ratio were recalculated accordingly.

For GLOB1811F, tests on invertebrates *Daphnia magna*, algae *Pseudokirchneriella subcapitata* and

additionally on aquatic plants *Lemna gibba* were provided by Applicant, but no tests are reported for fish.

According to the Commission Regulation (EU) No 546/2011, point 10.2.1 Acute toxicity:

“ Test shall be carried out on one species from each of the three/four groups of aquatic organisms, that is to say fish, aquatic invertebrates, algae...”

and

“Testing shall be performed where:

(a) the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance;..”

#### Acute toxicity data for active substance and formulation

Species	Boscalid	GLOB1811F
	Endpoint	Endpoint
<i>Oncorhynchus mykiss</i>	2.7 mg a.s./L	-
<i>Daphnia magna</i>	5.33 mg a.s./L	> 100 mg product/L corresponding to 49.7 mg a.s./L
<i>Pseudokirchneriella subcapitata</i>	1.34 mg a.s./L	5.17 mg product/L corre- sponding to 2.5 mg a.s./L
<i>Lemna gibba</i>	-	9.93 mg product/L corre- sponding to 4.9 mg a.s./L

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

Given that:

- the formulation contains only one active substance and
- results of studies performed with the formulation on daphnia and algae (the most sensitive species) did not show higher or unexpected toxicity than predicted based on the results of the active substance,

it can be assumed that acute toxicity to fish for formulation can be predicted on the basis of the data for the active substance and the risk assessment for fish for active substance is applicable to the assessment of the formulated product. Additionally, taking into consideration Article 62 of Regulation 1107/2009 and because of animal welfare regarding to studies on vertebrates, no acute fish study with the formulation is considered necessary.

For active substance and for GLOB1811F, tier 1-RAC<sub>sw,a</sub> are greater than Step 3 PEC<sub>sw</sub> values for all scenarios ~~D3, D4 and R1~~) and Tier 1-RAC<sub>sw,ch</sub> are greater than Step 3 PEC<sub>sw</sub> values (for all scenarios ~~D3, D4 and R1~~) with the exception of D2 scenarios after 2 applications in Winter Oilseed rape. However, it should be emphasized that D2 scenarios are not relevant to EU Central Zone.

In conclusion, according to the performed risk assessment there is no potential of risk for aquatic organisms resulting from acute and long-term exposure to active substance following use of **Rasput**

(GLOB1811F) in compliance with proposed GAP with no need for risk mitigation measures. The appropriate FOCUS Step 3 scenarios should be considered at national level. If it is necessary, Member states will need to further consider the risk to aquatic organisms based on national requirements.

## 9.6 Effects on bees (KCP 10.3.1)

### 9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Boscalid. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Boscalid	Oral	LD <sub>50</sub> = 166 µg a.s./bee	SANCO/3919 /2007-rev. 5
<i>Apis mellifera</i>	Boscalid	Contact	LD <sub>50</sub> = 200 µg a.s./bee	SANCO/3919 /2007-rev. 5
<i>Apis mellifera</i>	GLOB1811F	Oral	LD <sub>50</sub> > 1000 µg FP/bee (LD <sub>50</sub> > 497 µg a.s./bee)	XXX M., 2020 20 48 BAA 0156
<i>Apis mellifera</i>	GLOB1811F	Contact	LD <sub>50</sub> > 1000 µg FP/bee (LD <sub>50</sub> > 497 µg a.s./bee)	XXX M., 2020 20 48 BAA 0156
<i>Apis mellifera</i>	GLOB1811F	Chronic Adult 10d	LDD <sub>50</sub> > 202 µg FP/bee/day (101 µg a.s./bee/day) LDD <sub>20</sub> > 142 µg FP/bee/day (70.8 µg a.s./bee/day) LDD <sub>10</sub> > 77.5 µg FP/bee/day (38.7 µg a.s./bee/day) NOEDD <sub>20</sub> > 62.0 µg FP/bee/day (31.0 µg a.s./bee/day)	XXX K., 2021 20 48 BAC 0096
<i>Apis mellifera</i>	GLOB1811F	Chronic Larvae 22d	ED <sub>50</sub> = 34.972 µg FP/larva ED <sub>20</sub> = 4.821 µg FP/larva ED <sub>10</sub> = 1.711 µg FP/larva NOED = 3.0 µg FP/larva	XXX, M., 2021 20 48 BLC 0072

#### 9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.



## 9.6.2 Risk assessment

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).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for bee from all other intended uses in groups 1 and 2 (see 9.1.2).

### 9.6.2.1 Hazard quotients for bees

**Table 9.6-2: First-tier assessment of the risk for bees due to the use of GLOB1811F in oilseed rape**

Intended use	OSR		
Active substance	Boscalid		
Application rate (g/ha)	2 × 250		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	166	250	1.51
Contact toxicity	200		1.25
Product	GLOB1811F		
Application rate (g/ha)	2 × 500		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	> 1000	500	< 0.5
Contact toxicity	> 1000		< 0.5

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure. Q<sub>H</sub> values shown in bold breach the relevant trigger.

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

Not relevant.

### 9.6.2.3 Chronic risk assessment

The chronic risk to bees has been assessed following the **EPPO 2010 scheme**<sup>1</sup>, as proposed in the list of guidance documents relevant to the implementation of Regulation 1107/2009, published in the official EU Journal 2013/C 95/01 and 95/02.

#### Larval assessment according to EPPO 2010

Following the EPPO scheme for assessing potential risks to larvae (point 4 on the scheme), the scheme suggests that effects on growth or development can be excluded when considering GLOB1811F, since it is not IGR, and shows no effects on juvenile stages in other organisms as demonstrated by the risk as-

<sup>1</sup> EPPO/OEPP (2010). Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(3)). Bulletin OEPP/EPPO Bulletin 40: 323-331.

assessments for non-target arthropods, and soil organisms (*Collembola* and *Hypoaspis*). Thus, GLOB1811F can be categorized as posing a low risk to bees.

However, as a chronic larval study is available, this potential low risk can be further demonstrated by carrying out a worst-case risk assessment through the calculation of a TER value as set out in the EPPO 2010 scheme (point 5, on the scheme).

A worst-case of potential exposure via residues in pollen and nectar can be estimated based on the default worst-case residue of 1 mg a.s./kg proposed in the EPPO 2010 scheme (see Note 6), based on a database of measured values from aerial plant parts, as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst case data from *Rortais et al., 2005*<sup>2</sup>, as proposed in the EPPO scheme, have been used to estimate the consumption by bee larvae:

Worst case: drone larvae consuming 98.2 mg sugar in 6.5 days (= 15.1 mg sugar /day).

Thus, considering residues of 1 mg a.s./kg sugar x consumption of 15.1 mg sugar/bee/day

$$\text{Total exposure ETE} = 0.0151 \text{ } \mu\text{g a.s./bee/day}$$

This can be compared to the GLOB1811F larval NOED of 1.5  $\mu\text{g a.s./larva}$ , which is 0.068  $\mu\text{g a.s./larva/day}$  (based on 22 day study duration) which is equivalent to a NOEDD 0.3  $\mu\text{g a.s./larva/day}$  (based on 5 day development period).

$$\text{TER} = \text{NOEDD} (\mu\text{g a.s./larva/day}) / \text{ETE} (\mu\text{g a.s./bee/day}) = 0.068 / 0.0151 = 4.52$$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees. It is clear that with a TER value of 4.52, there is a safety margin, indicating that the proposed uses of GLOB1811F pose an acceptable risk to bee larval development.

#### Adult assessment according to EPPO 2010

The EPPO 2010 scheme does not recommend a chronic assessment for adults for foliar spray applications. However, as an approach is proposed as an assessment refinement for seed coatings/soil treatments (point 7, on the scheme), this approach can be adapted to provide a worst-case assessment for foliar sprays.

A worst-case of potential exposure via residues in pollen and nectar can be estimated, as before, based on the default worst-case value of 1 mg a.s./kg proposed in the EPPO 2010 scheme (see Note 6), based on a database of measured values from aerial plant parts as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst case data from *Rortais et al., 2005*, as proposed in the EPPO 2010 scheme, have been used to estimate the consumption by bee foragers:

Worst case: forager consuming 128 mg nectar/day.

Thus considering residues of 1 mg a.s./kg sugar x consumption of 128 mg nectar/bee/day

<sup>2</sup> Agnès RORTAIS, Gérard ARNOLD, Marie-Pierre HALM, Frédérique TOUFFET-BRIENS (2005). Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. *Apidologie* 36 (2005) 71–83

$$\text{Total exposure ETE} = 0.128 \mu\text{g a.s./bee/day}$$

This can be compared to the GLOB1811F adult NOED of 31.0  $\mu\text{g a.s./bee/day}$ .

$$\text{TER} = \text{NOED} (\mu\text{g a.s./bee/day}) / \text{ETE} (\mu\text{g a.s./bee/day}) = 31.0 / 0.128 = 242.19$$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees. It is clear that with a TER value of 242.19, there is a wide safety margin, indicating that the proposed uses of GLOB1811F pose an acceptable chronic risk to adult bees.

EPPO 2010 does not contain a chronic adult risk assessment scheme for sprayed products, only seed treatment products. For the chronic adult risk assessment for foliar spray products, the EPPO 2010 scheme as modified by ECPA (2017) is proposed.

This risk assessment approach is suggested by ECPA in "Proposal for a protective and workable regulatory European bee risk assessment scheme based on the EFSA bee guidance and other new data and available approaches" (2017).

$$\text{TER} = \text{NOEDD}/\text{daily dose}$$

Where daily dose (DD) is based on the worst case a sugar need of 128 mg/bee/day (Rortais et al 2005) of a bee feeding exclusively from nectar containing 30% sugar using the following equation:

$$\text{Daily dose} (\mu\text{g a.i./bee}) = \text{A.R.} \times [0.128 \text{ g}/(1000 \times 0.3) \times \text{RUD}]$$

A.R. = application rate in kg a.i./ha

RUD = residue per unit dose from the EFSA bee guidance. Mean RUD<sub>nectar</sub> = 2.9 mg a.s./kg (foliar sprays).

$$\text{Daily dose} (\mu\text{g a.i./bee}) = 0.25 \text{ kg a.s./ha} \times [0.128 \text{ g}/(1000 \times 0.3) \times 2.9 \text{ mg a.s./kg} \times 1000] = 0.309 \mu\text{g a.s./bee/day}$$

This can be compared to the GLOB1811F adult NOED of 31.0  $\mu\text{g a.s./bee/day}$ .

$$\text{TER} = \text{NOED} (\mu\text{g a.s./bee/day}) / \text{Daily dose} (\mu\text{g a.s./bee/day}) = 31.0 / 0.309 = 100.22$$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees. It is clear that with a TER value of 100.22, there is a wide safety margin, indicating that the proposed uses of Rasput poses an acceptable chronic risk to adult bees.

#### 9.6.2.4 Effects on bumble bees

No data available.

#### 9.6.2.5 Effects on solitary bees

No data available.

#### 9.6.2.6 Overall conclusions

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.

##### **Review comments:**

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

The required study on oral and contact toxicity of the formulated product GLOB1811F 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 specific requirements of the Regulation (EU) 546/2011 regarding effects on bee brood development and possible chronic effects on adults were included by the Applicant.

Evaluator corrected the NOEDD value used in the Tier 1 chronic risk assessment for bee larvae according to the KCP 10.3.1.3/02 and resulting calculation.

Because EPPO 2010 does not contain a chronic adult risk assessment scheme for sprayed products therefore evaluator added calculation according to the EPPO 2010 scheme as modified by ECPA (2017).

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees. All TER values for chronic risk assessment for adult bees and bee larvae were above a trigger of 1, indicating that the proposed uses of Rasput poses an acceptable chronic risk to adult bees.

#### 9.7 Effects on arthropods other than bees (KCP 10.3.2)

##### 9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Boscalid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. Therefore studies on non-target arthropods were performed with GLOB1811F and used for the risk assessment.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	BAS 510 01 F (Boscalid 50%)	Laboratory test Glass plates (2D) 14 d	LR <sub>50</sub> > 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Aphidius rhopalosiphi</i>	BAS 510 01 F (Boscalid 50%)	Laboratory test Glass plates (2D) 48 h	LR <sub>50</sub> > 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Typhlodromus pyri</i>	BAS 510 01 F (Boscalid 50%)	Extended laboratory test Glass plates (2D) 14 d	Mortality (after 1 week): 0% at 1800 g a.s./ha Fertility (after 4 weeks): 3% at 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Aphidius rhopalosiphi</i>	BAS 510 01 F (Boscalid 50%)	Extended laboratory test Glass plates (2D) 48 h	Mortality (after 1 week): 11% at 1800 g a.s./ha Fertility (after 4 weeks): 34% at 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Typhlodromus pyri</i>	GLOB1811F	Extended laboratory test Glass plates (2D) 7 d	LR <sub>50</sub> > 900 g FP/ha NOER ≥ 900 g FP/ha LOER > 900 g FP/ha	XXX, J. 2020a 155681063
<i>Aphidius rhopalosiphi</i>	GLOB1811F	Extended laboratory test Glass plates (2D) 14 d	LR <sub>50</sub> > 900 g FP/ha NOER ≥ 900 g FP/ha LOER > 900 g FP/ha	XXX, J. 2020b 155681001
<b>Field tests</b>				

#### 9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

#### 9.7.2 Risk assessment

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

##### 9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for non-target arthropods from all other intended uses in groups (see 9.1.2).

**Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of GLOB1811F in OSR (group 1)**

<b>Intended use</b>	OSR		
<b>Active substance/product</b>	Boscalid / GLOB1811F		
<b>Application rate (g/ha)</b>	2 × 500		
<b>MAF</b>	1.7 for 2 applications every 21 days (default value) for leaf-dwelling arthropods <b>1.9 (soil)</b>		
<b>Test species Tier I</b>	<b>LR<sub>50</sub> (lab.) (g/ha)</b>	<b>PER<sub>in-field</sub> (g/ha)</b>	<b>HQ<sub>in-field</sub> criterion: HQ ≤ 2</b>
<i>Typhlodromus pyri</i>	> 900	850 (foliar) <b>950 (soil)</b>	< 0.944 (foliar) <b>&lt; 1.06 (soil)</b>
<i>Aphidius rhopalosiphi</i>	> 900	850 (foliar) <b>950 (soil)</b>	< 0.944 (foliar) <b>&lt; 1.06 (soil)</b>

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

### 9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for non-target arthropods from all other intended uses in groups (see 9.1.2).

**Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of GLOB1811F in oil/seed rape (group 1)**

Intended use		OSR			
Active substance/product		Boscalid / GLOB1811F			
Application rate (g/ha)		2 × 500			
MAF		1.7 for 2 applications every 21 days (default value) for leaf-dwelling arthropods			
vdf		10 for 2D / 1 for 3D			
Test species Tier I	LR <sub>50</sub> (lab.) (g/ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	CF	HQ <sub>off-field</sub> criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	> 900	2.38	<del>2.023</del>	10	<del>&lt; 0.225</del> < 0.0225
<i>Aphidius rhopalosiphi</i>	> 900		2.023		<del>&lt; 0.225</del> < 0.0225

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR<sub>50</sub> or ER<sub>50</sub> from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

### 9.7.2.3 Additional higher-tier risk assessment

Not relevant.

#### 9.7.2.4 Risk mitigation measures

No risk mitigation needed.

#### 9.7.3 Overall conclusions

The in-field and off-field HQ values calculated for the product GLOB1811F for the representative species *Typhlodromus pyri* and *A. rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated in-field and off-field areas following application according to the proposed use patterns.

##### Review comments:

The endpoints as proposed by the notifier are considered acceptable and are used in the risk assessment.

Risk for other arthropods species was assessed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev. 2 (final), October 17, 2002) and ESCORT 2.

The HQ values for recommended species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value of 2, indicating acceptable in-field and off-field risk to non-target arthropods with no need for risk mitigation measures.

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

##### 9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Boscalid. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Boscalid	14 d, acute	LC <sub>50</sub> > 1000 mg a.s./kg dw LC <sub>50,corr</sub> > 500 mg a.s./kg dw*	SANCO/3919 /2007- rev. 5
<i>Eisenia fetida</i>	BAS 510 01 F	14 d, acute	LC <sub>50</sub> > 1000 mg	SANCO/3919 /2007-

Species	Substance	Exposure System	Results	Reference
	(Boscalid 500 g/kg)		prod./kg dw LC <sub>50, corr</sub> > 500 mg prod./kg dw*	rev. 5
<i>Eisenia fetida</i>	BAS 510 01 F (Boscalid 500 g/kg)	56 d, chronic	NOEC = 3.6 kg prod./ha NOEC <sub>corr</sub> = 1.8 kg prod./ha* <b>NOEC<sub>corr</sub> = 1.197 mg a.s./kg dw*</b>	SANCO/3919 /2007- rev. 5
<i>Folsomia candida</i>	BAS 510 01 F (Boscalid 500 g/kg)	28 d, chronic	NOEC (reproduction) >1000 mg BAS 510 01 F /kg soil (>500 mg a.s./kg soil) <b>NOEC<sub>corr</sub> &gt;500 mg BAS 510 01 F /kg soil* (&gt;250 mg a.s./kg soil*)</b>	Monograph Boscalid, 2002
<i>Eisenia fetida</i>	GLOB1811F	Mixed into substrate 56 d, chronic 10 % peat content	NOEC <sub>mortality</sub> = 250 NOEC <sub>biomass change</sub> = 139 NOEC <sub>reproduction</sub> = 42.9 mg/kg dw EC <sub>10</sub> = 45.4 EC <sub>20</sub> = 71.9 EC <sub>50</sub> =158 mg test item/kg soil dw	XXX, S. 2020a 20 48 TEC 0061
<i>Folsomia candida</i>	GLOB1811F	Mixed into substrate / Overspray 28 d, chronic 5 % peat content	LC <sub>50</sub> > 500 mg/kg dw NOEC = 500 mg/kg dw  EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> > 500 mg test item/kg soil dw	XXX S. 2020b 20 48 TCC 0070
<i>Hypoaspis aculeifer</i>	GLOB1811F	Mixed into substrate 14 d, chronic 5 % peat content	LC <sub>50</sub> > 1000 mg/kg dw NOEC ≥ 1000 mg/kg dw  EC <sub>10</sub> , EC <sub>20</sub> , EC <sub>50</sub> > 1000 mg test item/kg soil dw	XXX L. 2020a 20 48 THC 0055
<b>Field studies</b>				
None				
<b>Litter bag test</b>				
None				

\* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

### 9.8.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.8.2 Risk assessment

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



2002).

### 9.8.2.1 First-tier risk assessment

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Boscalid.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups 1 and 2 (see 9.1.2).

**Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of GLOB1811F in OSR (group 1)**

Intended use	Oilseed rape (winter and spring), 2 x 250 g as/ha, crop interception 80/80		
Acute effects on earthworms			
Product/active substance	LC <sub>50</sub> (mg/kg dw)	PEC <sub>soil accumulation</sub> (mg/kg dw)	TER <sub>a</sub> (criterion TER ≥ 10)
Boscalid	> 500	<del>0.1895</del> 0.191	<del>2638.52</del> 2617.8
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Boscalid	1.197	<del>0.1895</del> 0.191	<del>6.32</del> 6.27
GLOB1811F	42.9 21.45*	<del>1.8948</del> 1.913	<del>11.32</del> 11.21
Chronic effects on other soil macro- and mesofauna: <i>Folsomia candida</i>			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
Boscalid	> 250	<del>0.1895</del> 0.191	<del>1319.26</del> 1308.90
GLOB1811F	500 250*	<del>1.8948</del> 1.913	<del>131.94</del> 130.68
Chronic effects on other soil macro- and mesofauna: <i>Hypoaspis aculeifer</i>			
Product/active substance	NOEC (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	TER <sub>lt</sub> (criterion TER ≥ 5)
GLOB1811F	≥1000 ≥500*	<del>1.8948</del> 1.913	<del>≥263.88</del> ≥261.37

TER values shown in bold fall below the relevant trigger.

\*The endpoint was divided by 2 since log Kow>2

### 9.8.2.2 Higher-tier risk assessment

Not relevant.

### 9.8.3 Overall conclusions

The long-term TER values for *Folsomia candida* and *Hypoaspis aculeifer* exceed the Commission regulation (EU) 546/2011 Annex VI long-term trigger values of 5, indicating that GLOB1811F poses a low long-term risk to other non-target soil organisms when applied according to the intended GAP.

The acute-term TER values for earthworms exceed the Commission regulation (EU) 546/2011 Annex VI acute-term trigger values of 10, indicating that GLOB1811F poses a low acute risk to earthworms when applied according to the intended GAP.

Based on a higher-tier field study with earthworms, it can be concluded that the chronic risk of GLOB1811F to earthworms is acceptable in accordance with the intended GAP.

#### Review Comments:

As the maximum  $PEC_{soil}$  values for the active substance and GLOB1811F were corrected in Section 8, the TER calculations were revised accordingly by Evaluator in Table 9.8 2.

The acute risk assessment is no longer required, however the  $TER_A$  values for active substance is above the trigger value of 10 set by Commission Regulation (EU) No. 546/2011.

The long-term TER values for active substance and GLOB1811F are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011.

In conclusion, no unacceptable risk to non-target soil meso- and macrofauna is expected following the application of Rasput (GLOB1811F) according to the proposed use pattern.

## 9.9 Effects on soil microbial activity (KCP 10.5)

### 9.9.1 Toxicity data

Studies on effects of soil microorganisms have been carried out with Boscalid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

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

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy sand	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	SANCO/3919 /2007- rev. 5
C-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy silt	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg	SANCO/3919 /2007- rev. 5

Endpoint	Substance	Exposure System	Results	Reference
			a.s./kg soil	
N-mineralisation	GLOB1811F	28 d, aerobic loamy sand (DIN 4220)/loam (USDA)	No adverse effects (< 25%) at 1.5 mg f.p./kg dw soil and at 15 mg f.p./kg dw soil at the end of the 28-day incubation period	XXX L. 2020b 20 48 SMN 0061

### 9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

### 9.9.2 Risk assessment

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

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for the soil microorganisms from all other intended uses in groups 1 and 2 (see 9.1.2).

**Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB1811F in OSR (group 3)**

Intended use	Oilseed rape (winter and spring), 2 x 250 g as/ha, crop interception 80/80		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> accumulation (mg/kg dw)	Risk acceptable?
Boscalid (BAS 510 01F)	8 (at 28 d)	<del>0.1895</del> 0.191	yes
GLOB1811F	15 (at 28 d)	<del>1.8948</del> 1.913	yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> accumulation (mg/kg dw)	Risk acceptable?
Boscalid (BAS 510 01F)	8 (at 28 d)	<del>0.1895</del> 0.191	yes

### 9.9.3 Overall conclusions

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.

#### Review Comments:

As the PECs values for the active substance and GLOB1811F were recalculated in Section 8, these values were revised accordingly by Evaluator in Table 9.9-2.

C-mineralisation is no longer required.

The risk assessment was performed by comparison of PECs values with concentrations of the test items at which effects were below 25%. Rasput (GLOB1811F) had no significant effect on soil micro-organisms at 15 mg product/kg soil. This value is approximately 8 times higher than the worst-case  $PEC_{soil}$  at 1.913 mg product/kg soil.

In conclusion, no unacceptable risk to soil microbial activity is expected following the application of Rasput (GLOB1811F) according to the proposed use pattern.

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

### 9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Boscalid. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target terrestrial plants of GLOB1811F were not evaluated as part of the EU assessment of Boscalid. No new data submitted with this application. Since GLOB1811F is similar to the formulation used in the EU-review, the endpoints of these studies were used for risk assessment.

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

Species	Sub-stance	Exposure System	Results				Reference
			1.2 kg as BAS 510 01 F/ha Mean phytotoxicity (% control)	3.6 kg as BAS 510 01 F/ha Mean phytotoxicity (% control)	1.2 kg as BAS 510 01 F/ha Mean fresh weight (% control)	3.6 kg as BAS 510 01 F/ha Mean fresh weight (% control)	
<i>Daucus carota</i> <sup>1)</sup> <i>Brassica oleracea</i> <sup>2)</sup> <i>Pisum sativum</i> <sup>3)</sup> <i>Zea mays</i> <sup>4)</sup>	BAS 510 01 F (Boscalid 500)	14 d Vegetative vigour	<sup>1)</sup> 2.5 <sup>2)</sup> 0 <sup>3)</sup> 0 <sup>4)</sup> 0 <sup>5)</sup> 0	<sup>1)</sup> 5 <sup>2)</sup> 0 <sup>3)</sup> 0 <sup>4)</sup> 0 <sup>5)</sup> 0	<sup>1)</sup> 109.4 <sup>2)</sup> 100.2 <sup>3)</sup> 91.2 <sup>4)</sup> 101.9 <sup>5)</sup> 105.7	<sup>1)</sup> 110.6 <sup>2)</sup> 98.9 <sup>3)</sup> 97.5 <sup>4)</sup> 103.5 <sup>5)</sup> 99.5	Monograph Boscalid, 2002  No significant effects on weight.  There were no

Species	Sub- stance	Exposure System	Results				Reference
			1.2 kg as BAS 510 01 F/ha Mean phytotoxicity (% control)	3.6 kg as BAS 510 01 F/ha Mean phyto- toxicity (% control)	1.2 kg as BAS 510 01 F/ha Mean fresh weight (% control)	3.6 kg as BAS 510 01 F/ha Mean fresh weight (% control)	
<i>Avena sativa</i> m <sup>5)</sup> <i>Allium cepa</i> m <sup>6)</sup>	g/kg)		<sup>6)</sup> 0	<sup>6)</sup> 0	<sup>6)</sup> 108.2	<sup>6)</sup> 113.6	effects on phytotoxicity of more than 5 %.

m: monocotyledonous; d: dicotyledonous

#### 9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

#### 9.10.2 Risk assessment

##### 9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 3 also covers the risk for non-target terrestrial plants from all other intended uses in groups 1 and 2 (see 9.1.2).

**Table 9.10-2: Assessment of the risk for non-target plants due to the use of GLOB1811F in OSR (group 3)**

Intended use		Oilseed rape		
Active substance/product		Boscalid		
Application rate (g/ha)		2 x 250-500 g product/ha		
MAF		1.7		
Test species	ER <sub>50</sub> (g/ha)	Drift rate	PER <sub>off-field</sub> (g/ha)	TER criterion: TER ≥ 5

<i>Daucus carota</i>	>3600	0.0277	<del>11.77</del>	<del>&gt;305.80</del>
<i>Brassica oleracea</i>			23.543	>152.912
<i>Pisum sativum</i>				
<i>Zea mays</i>				
<i>Avena sativa</i>				
<i>Allium cepa</i>				

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

### 9.10.2.3 Higher-tier risk assessment

Not relevant.

### 9.10.2.4 Risk mitigation measures

No risk mitigation needed.

### 9.10.3 Overall conclusions

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for GLOB1811F shows that the Annex VI criterion value of 5 is exceeded, indicating that GLOB1811F poses a low risk to non-target terrestrial plants when applied according to the proposed GAP.

#### Review Comments:

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 set by Commission Regulation (EU) No. 546/2011.

In conclusion, no unacceptable risk to non-target terrestrial plants is expected following the application of Rasput according to the proposed use pattern.

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

No additional data available.

### 9.12 Monitoring data (KCP 10.8)

Not relevant.

### 9.13 Classification and Labelling

The ecotoxicological classification of GLOB1811F was based on theoretical calculations according to Regulation 1272/2008 or based on own available data on the formulation. Reference is made to part C of this dossier. As GLOB1811F contains boscalid in a concentration above the threshold, it **should be classified as Aquatic Chronic 2, H411**.

The following classification is than proposed from an ecotoxicological point of view.

**Pictogram:** GHS09  
**Signal word:** -

**H-statements**  
**H411** Toxic to aquatic life with long lasting effects.

**P-statements**  
**P273** Avoid release to the environment  
**P391** Collect spillage.  
~~**P501** Dispose of contents/container to ... in accordance with local/regional/national/international regulations (to be specified).~~

**Other safety/precautionary phrases:**

**SP1:** Do not contaminate water with the product or its container.  
**EUH401** To avoid risks to human health and the environment, comply with the instructions for use.

Review Comments:

The product is intended for professional use only and therefore a phrase P501 is not required.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1-01	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 GLP Unpublished	N	Globachem NV
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	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
			Unpublished		
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 155681063 Ibacon GmbH GLP Unpublished	N	Globachem NV
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	XXX L.	2020a	Effects of GLOB1811F on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i>	N	Globachem

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
10.4.2-02			20 48 THC 0055 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished		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

## Appendix 2 Detailed evaluation of the new studies

### A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

#### A 2.1.1 KCP 10.1.1 Effects on birds

##### A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

##### A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

#### A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

##### A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

##### A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

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

### A 2.2 KCP 10.2 Effects on aquatic organisms

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

Comments of zRMS:	<p>The study was performed according to OECD TG 202 and principles of GLP. The validity criteria are met. The immobility in the control group is below 10% (observed 0% ) The oxygen concentration over the whole test are between 8.16 – 8.78 mg/L (required &gt; 3 mg/L).</p> <p>The study is considered acceptable and suitable for the risk assessment. All results refer to nominal concentrations.</p>
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#### Reference:

KCP 10.2.1-01

#### Report

Acute toxicity of GLOB1811F to *Daphnia magna* in a 48-hour static test, XXX, D., 2021a, 20 48 ADL 0023, BioChem agrar Labor für biologische und chemische Analytik GmbH

#### Guideline(s):

Yes (OECD 202 (2004))

#### Deviations:

No

GLP: Yes

Acceptability: Yes

### Materials and methods

Test item: GLOB1811F  
Batch no.: 180511  
Content of active substance (analysed):  
Boscalid: 497.2 g/kg equivalent to 99.44% of the average declared amount

Test species: *Daphnia magna* STRAUS

Test system: Exposure of *Daphnia* to the test item applied in test medium (dilution water)

### Test conditions

Temperature 20.6 – 20.7 °C

Photoperiod: photoperiod: 16/8 hours light/darkness phases  
approximately 20  $\mu\text{E m}^{-2}\text{s}^{-1}$  (1000 lx)

Treatments: Control (untreated test medium)  
test item (GLOB1811F)

Number of test vessels/concentration: 4

Number of *Daphnia*/concentration: 20

Test concentration (nominal): 6.25, 12.5, 25.0, 50.0, 100.0 mg/L test item  
equivalent to:  
3109.5, 6219.0, 12438.0, 24875.9, 49699.1  $\mu\text{g/L a.s.}$

Exposure time: 48 hours (static test procedure)

Biological observations: Number of immobilised *Daphnia*:  
after 3, 24 and 48 hours

### Dates of work:

Biological phase: experimental start date: 09.03.2021  
experimental completion date: 11.03.2021

Analytical phase: experimental start: 10.05.2021  
experimental completion: 11.05.2021

### Results and discussions

The measured concentrations of Boscalid were within ranges of 93.8 – 100.6% of nominal concentrations in the freshly prepared test solutions at the start of the test and within a range of 86.1 – 107.4% in the spent solutions at the test end (48 hours) based on nominal values.

Therefore, the calculated endpoints are based on the nominal concentrations for the test item and on the active substances, since the measured concentrations were within 80 to 120% of nominal.

Table 1: Effects of the test item on immobility of *Daphnia magna*

Effect concentration	GLOB1811F					
	24 h			48 h		
	after application					
NOEC						
mg/L Test item, nominal	> 100.0			> 100.0		
µg/L Boscalid, nominal	> 49699.1			> 49699.1		
LOEC						
mg/L Test item, nominal	> 100.0			> 100.0		
µg/L Boscalid, nominal	> 49699.1			> 49699.1		
EC and 95% CI (lower – upper)	EC <sub>10</sub>	EC <sub>20</sub>	EC <sub>50</sub>	EC <sub>10</sub>	EC <sub>20</sub>	EC <sub>50</sub>
mg/L Test item, nominal	> 100.0	> 100.0	> 100.0	> 100.0	> 100.0	> 100.0
µg/L Boscalid, nominal	> 49699.1	> 49699.1	> 49699.1	> 49699.1	> 49699.1	> 49699.1

Calculations were conducted using unrounded values

Table 2: Observations

Time after application	Test concentration mg/L test item nominal					
	Control	6.25	12.5	25.0	50.0	100.0
	Test concentration µg/L Boscalid, nominal					
	Control	3109.5	6219.0	12438.0	24875.9	49699.1
	Immobility (%)					
3 h	0.0	0.0	0.0	0.0	0.0	0.0
24 h	0.0	0.0	0.0	0.0	0.0	0.0
48 h	0.0	0.0	0.0	0.0	0.0	0.0

### Conclusion

An acute immobilisation test was performed to assess the effects of the test item GLOB1811F on *Daphnia magna* during 48 hours of static exposure.

No immobility was observed at the nominal test concentrations  $\leq 100.0$  mg/L test item at 24 and 48 hours.

As a result, a LOEC higher than 100.0 mg/L test item was determined. The corresponding NOEC was higher than 100.0 mg/L test item. The EC<sub>50</sub> for immobility was higher than 100.0 mg/L test item at 24 and 48 hours.

Comments of zRMS:	<p>The study was performed according to OECD TG 221 and principles of GLP. The validity criteria are met. The doubling time of frond numbers in the control was less than 2.5 days (actually 2.27 days), as required by OECD 221 Guideline.</p> <p>The study is considered acceptable and suitable for the risk assessment. The results for formulation refer to nominal concentrations and the results for active substance refer to mean measured concentration.</p>
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Reference:	KCP 10.2.1-02
Report	Effects of GLOB1811F on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions, XXX, D., 2021b, 20 48 ALE 0020, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (OECD 221 (2006))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

## Materials and methods

Test item:	GLOB1811F Batch no.: 180511 Content of active substance (analysed): <u>Boscalid</u> : 497.2 g/kg equivalent to 99.44% of the average declared amount
Test species:	Duckweed – <i>Lemna gibba</i> L.
Test system:	Exposure of <i>Lemna gibba</i> to the test item applied in test medium (semi-static conditions)

## Test conditions

Temperature:	22.7 – 23.8°C (recorded in the water bath)
Lighting:	continuous illumination (on average $123 \mu\text{E} \times \text{m}^{-2} \times \text{s}^{-1}$ )
Treatments:	control, untreated test medium, test item (GLOB1811F)
Test concentration (nominal)*:	0.282, 0.894, 2.86, 9.16, 29.3, 93.8, 300.0 mg/L test item equivalent to 140.2, 444.5, 1423.0, 4552.4, 14567.0, 46612.5, 149160.0 $\mu\text{g/L}$ a.s.
Test concentrations (geometrical mean measured a.s.):	130.2, 411.5, 1358.8, 3377.7, 9449.0, 27867.3, 89607.0 $\mu\text{g/L}$ a.s.
Exposure time:	7 days (semi-static test procedure)
Biological observations:	Fronid number: day 0, 3, 5 and 7 Changes in plant development: day 0, 3, 5 and 7 Dry weight: day 0 and 7
Statistics:	LOEC/NOEC: Williams t-test, ( $\alpha = 0.05$ , one-sided smaller) $\text{EC}_{\text{x}}$ : Probit analysis using linear max. likelihood regression ToxRat Professional Version 3.3 (20.10.2018)
Dates of work:	
Biological phase:	experimental start date: 12.03.2021 experimental completion date (determination dry weight) : 22.03.2021
Analytical phase:	experimental start: 18.05.2021 experimental completion date: 19.05.2021

\* nominal test concentrations based on the weighed amount of test item (mean values of day 0, day 3 and day 5)  
a.s. – active substance

## Results and discussions

The measured concentrations of Boscalid remained within a range of 73.6 – 103.4% of nominal concentrations in the freshly prepared test solutions at test start and at each renewal in the freshly prepared test solutions. The Boscalid concentrations in the spent test solutions were determined at 30.5 – 98.9% of nominal at each renewal and at the end of the test (day 7).

Therefore, the calculated endpoints are based on the nominal concentrations for the test item and on the mean measured concentrations of the active ingredient Boscalid, since the measured concentrations were not within 80 to 120% of nominal.

Table 1: LOEC, NOEC and effect concentrations EC<sub>x</sub> of GLOB1811F for growth rate and yield based on frond number and biomass for *Lemna gibba* at day 7

Effect concentration	GLOB1811F			
	average specific growth rate inhibition		yield inhibition	
	Frond number	Biomass	Frond number	Biomass
<b>NOEC</b>				
mg/L test item, nominal	<b>0.894</b>	<b>0.894</b>	<b>0.894</b>	<b>0.894</b>
µg/L Boscalid, nominal	<b>444.5</b>	<b>444.5</b>	<b>444.5</b>	<b>444.5</b>
µg/L Boscalid, mean measured	<b>411.5</b>	<b>411.5</b>	<b>411.5</b>	<b>411.5</b>
<b>LOEC</b>				
mg/L test item, nominal	<b>2.86</b>	<b>2.86</b>	<b>2.86</b>	<b>2.86</b>
µg/L Boscalid, nominal	<b>1423.0</b>	<b>1423.0</b>	<b>1423.0</b>	<b>1423.0</b>
µg/L Boscalid, mean measured	<b>1358.8</b>	<b>1358.8</b>	<b>1358.8</b>	<b>1358.8</b>
<b>EC<sub>10</sub></b> (CI, lower - upper)	<b>E<sub>r</sub>C<sub>10</sub></b>	<b>E<sub>r</sub>C<sub>10</sub></b>	<b>E<sub>y</sub>C<sub>10</sub></b>	<b>E<sub>y</sub>C<sub>10</sub></b>
mg/L test item, nominal	<b>0.366</b> (0.137 – 0.982)	<b>0.210</b> (0.033 – 1.32)	<b>0.864</b> (0.534 – 1.40)	<b>0.520</b> (0.209 – 1.29)
µg/L Boscalid, nominal	<b>182.0</b> (68.1 – 488.3)	<b>104.4</b> (16.4 – 657.8)	<b>429.6</b> (265.5 – 694.6)	<b>258.5</b> (103.9 – 642.9)
µg/L Boscalid, mean measured	<b>190.6</b> (77.5 – 468.6)	<b>107.2</b> (8.0 – 383.4)	<b>403.2</b> (261.3 – 622.0)	<b>274.7</b> (121.7 – 620.0)

CI - confidence interval

Calculations performed using unrounded values

Table 1: LOEC, NOEC and effect concentrations EC<sub>x</sub> of GLOB1811F for growth rate and yield based on frond number and biomass for *Lemna gibba* at day 7 d (continued)

Effect concentration	GLOB1811F			
	average specific growth rate inhibition		yield inhibition	
	Frond number	Biomass	Frond number	Biomass
<b>EC<sub>20</sub></b> (CI, lower - upper)	<b>E<sub>r</sub>C<sub>20</sub></b>	<b>E<sub>r</sub>C<sub>20</sub></b>	<b>E<sub>y</sub>C<sub>20</sub></b>	<b>E<sub>y</sub>C<sub>20</sub></b>
mg/L test item, nominal	<b>1.14</b> (0.548 – 2.36)	<b>1.45</b> (0.426 – 4.93)	<b>1.24</b> (0.864 – 1.77)	<b>0.943</b> (0.475 – 1.87)
µg/L Boscalid, nominal	<b>565.3</b> (272.5 – 1173.4)	<b>719.9</b> (211.8 – 2449.7)	<b>615.0</b> (429.6 – 880.0)	<b>468.9</b> (236.2 – 929.3)
µg/L Boscalid, mean measured	<b>526.4</b>	<b>631.0</b>	<b>581.0</b>	<b>466.8</b>



	(271.0 – 1022.3)	(121.0 – 1528.0)	(418.0 - 807.6)	(252.6 - 862.5)
<b>EC<sub>50</sub></b> (CI, lower - upper)	<b>E<sub>r</sub>C<sub>50</sub></b>	<b>E<sub>r</sub>C<sub>50</sub></b>	<b>E<sub>y</sub>C<sub>50</sub></b>	<b>E<sub>y</sub>C<sub>50</sub></b>
mg/L test item, nominal	<b>9.93</b> (6.34 – 15.6)	<b>58.4</b> (25.5 – 134.0)	<b>2.46</b> (1.97 – 3.06)	<b>2.95</b> (1.90 – 4.57)
µg/L Boscalid, nominal	<b>4937.2</b> (3149.8 – 7739.4)	<b>29037.5</b> (12653.7 – 66634.2)	<b>1221.6</b> (981.0 – 1521.4)	<b>1465.2</b> (944.2 – 2273.7)
µg/L Boscalid, mean measured	<b>3674.9</b> (2459.1 – 5491.6)	<b>18758.7</b> (9486.3 – 50114.9)	<b>1168.6</b> (960.1 – 1422.4)	<b>1286.9</b> (884.9 – 1871.6)

CI - confidence interval

Calculations performed using unrounded values

Table 2: Effects of GLOB1811F on growth rate and yield for *Lemna gibba*

Treatment group  mg/L test item nominal	Final frond number  replicate mean day 7	Biomass (dry weight) replicate mean day 7 (mg)	% Inhibition			
			Average specific growth rate (% I <sub>r</sub> )		yield (% I <sub>y</sub> )	
			frond number	biomass	frond number	biomass
Control	76.7	11.9	n.r.	n.r.	n.r.	n.r.
0.282	75.0	12.1	1.0	-0.7*	2.5	-2.1*
0.894	76.0	11.8	0.3	0.4	1.0	1.2
2.86	32.7	4.4	39.8 +	36.0 +	65.0 +	66.9 +
9.16	21.3	3.4	59.7 +	45.1 +	81.8 +	76.1 +
29.3	16.7	2.9	71.2 +	51.7 +	88.7 +	80.9 +
93.8	15.0	2.7	76.1 +	53.0 +	91.1 +	82.1 +
300.0	76.7	11.9	75.1 +	53.0 +	90.6 +	82.1 +

n.r. - not relevant

\* negative values mean a higher growth compared to the control

+ significantly different to the control (Williams t-test; alpha = 0.05, one-sided)

### Validity criteria

The test was valid because the doubling time of frond numbers in the control was less than 2.5 days (actually 2.27 days), as required by OECD 221 Guideline (2006).

The validity criterion was accomplished as follows:

According to the guideline, the doubling time of the frond number in the control must be less than 2.5 d (60 h), corresponding to approximately a 7-fold increase in biomass in 7 days and an average specific growth rate of 0.275 d<sup>-1</sup>. The measured doubling time of the frond numbers in the control was on average 2.27 days (1.74 days for dry weight), corresponding to a 8.5-fold increase in frond number over the 7-day study period (mean of 9 to 76.7 fronds in the control vessels) and a 16.2-fold increase in dry weight (0.733 mg to 11.9 mg dry weight). The average specific growth rate in the control was 0.306 d<sup>-1</sup> for frond number and 0.398 d<sup>-1</sup> for dry weight.

The ErC50 (growth rate based on frond number) value for the reference item (toxic standard) 3,5-dichlorophenol was 3.27 mg/L. This value is included in the range 2.2 - 3.8 mg/L 3,5-dichlorophenol as stated in Guideline ISO 20079, demonstrating that the test system was sensitive.

## Conclusion

A *Lemna* growth inhibition test was performed to assess the effects of the test item GLOB1811F (active substances: Boscalid) to *Lemna gibba* (duckweed) during 7 days of exposure in a semi-static test design.

No statistically significant effect on yield and growth rate of *Lemna* based on frond number and biomass was observed at the nominal concentrations  $\leq 0.894$  mg/L test item, whereas statistically significant effects ( $\alpha = 0.05$ ) were calculated for nominal concentrations  $\geq 2.86$  mg/L test item. As a result, the NOEC for yield and growth rate based on frond number and biomass was determined to be 0.894 mg/L test item and the LOEC was determined to be 2.86 mg/L test item, based on nominal concentrations.

The lowest EC<sub>50</sub>-value (0-7 d) was 2.46 mg/L test item (nominal) for yield based on frond number.

Comments of zRMS:	<p>The study was performed according to OECD TG 201 and principles of GLP. The validity criteria are met. The biomass in the control cultures increased exponentially by a factor of 70.6 within the 72 hours test period (factor 16 after 72 hours is required according to guideline OECD Guideline 201 (2011)). The mean coefficient of variation for section-by-section specific growth rates in the control cultures was 20.6% (not exceeding 35%). The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was 1.4% and did not exceed 7%.</p> <p>The study is considered acceptable and suitable for the risk assessment. The results for test item refer to nominal concentrations and the results for active substance refer to the geometrical mean measured concentrations since the measured concentrations were not within 80 to 120% of nominal.</p>
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Reference:	KCP 10.2.1-03
Report	Effects of GLOB1811F on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test, XXX, D., 2021c, 20 48 AAL 0027, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (OECD 201 (2011))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

## Materials and methods

Test item:	GLOB1811F Batch no.: 180511 Content of active substance (analysed):
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	<u>Boscalid</u> : 497.2 g/kg equivalent to 99.44% of the average declared amount
Test species:	Freshwater green alga – <i>Pseudokirchneriella subcapitata</i> KORSHIKOV
Test system:	Exposure of <i>Pseudokirchneriella subcapitata</i> to the test item applied once in test medium (static conditions)
Test conditions:	Temperature: 22.8 – 23.6°C Continuous light: (on average 76 µE m <sup>-2</sup> s <sup>-1</sup> )
Treatments:	Control (untreated test medium) GLOB1811F
Test concentration (nominal):	2.09, 2.92, 4.08, 5.71, 8.00 mg/L test item equivalent to 1.04, 1.45, 2.03, 2.84, 3.98 mg/L Boscalid
Test concentration (geometrical mean measured concentrations over 0-72 hours):	970.8, 1379.9, 1916.9, 2529.2, 3158.9 µg/L Boscalid
Exposure time:	72 hours (static test procedure)
Biological observations:	Number of cells: after 24, 48 and 72 hours
Statistics:	EC <sub>x</sub> -values: linear regression: probit analysis LOEC/NOEC: Welch-t-test; Williams t-test, alpha = 0.05, one-sided smaller Statistical program: ToxRat Professional Version 3.3 (20.10.2018)
Dates of work:	Biological phase: experimental start date: 02.03.2021 experimental completion date: 05.03.2021  Analytical phase: experimental start: 17.05.2021 experimental completion: 18.05.2021

a.s. – active substance

## Results and discussions

Measured concentrations of Boscalid in test solutions were within a range of 93.2 to 96.1% of nominal values at the test start and after 72 hours the concentrations ranged from 67.0 to 96.6% of nominal in spent test solutions.

Therefore, the calculated endpoints are based on the nominal concentrations for the test item and on the geometrical mean measured concentrations for the active ingredient Boscalid, since the measured concentrations were not within 80 to 120% of nominal.

Table 1: Effects on growth rate and yield of *Pseudokirchneriella subcapitata*

Effect concentration	GLOB1811F	
	Average specific growth rate inhibition	Yield inhibition
	0 – 72 h after application	
<b>NOEC</b>		
mg/L test item, nominal	<b>2.09</b>	<b>2.09</b>
µg/L Boscalid, nominal	<b>1038.2</b>	<b>1038.2</b>
µg/L Boscalid, mean measured	<b>970.8</b>	<b>970.8</b>
<b>LOEC</b>		
mg/L test item, nominal	<b>2.92</b>	<b>2.92</b>
µg/L Boscalid, nominal	<b>1449.4</b>	<b>1449.4</b>
µg/L Boscalid, mean measured	<b>1379.9</b>	<b>1379.9</b>
<b>EC<sub>10</sub></b> and 95% confidence intervals (lower – upper)	<b>E<sub>r</sub>C<sub>10</sub></b>	<b>E<sub>y</sub>C<sub>10</sub></b>
mg/L test item, nominal	<b>2.52</b> (2.13 – 2.84)	<b>2.32</b> (2.14 – 2.46)
µg/L Boscalid, nominal	<b>1252.9</b> (1059.0 – 1412.0)	<b>1153.5</b> (1064.0 – 1223.1)
µg/L Boscalid, mean measured	<b>1248.3</b> (1099.5 - 1370.8)	<b>1087.1</b> 1007.4 - 1149.3

Table 1: Effects on growth rate and yield of *Pseudokirchneriella subcapitata* (continued)

Effect concentration	GLOB1811F	
	Average specific growth rate inhibition	Yield inhibition
	0 – 72 h after application	
<b>EC<sub>20</sub></b> and 95% confidence intervals (lower – upper)	<b>ErC<sub>20</sub></b>	<b>EyC<sub>20</sub></b>
mg/L test item, nominal	<b>3.22</b> (2.86 – 3.52)	<b>2.58</b> (2.43 – 2.70)
µg/L Boscalid, nominal	<b>1601.0</b> (1422.0 – 1750.1)	<b>1282.8</b> (1208.2 – 1342.4)
µg/L Boscalid, mean measured	<b>1534.4</b> (1401.8 - 1643.7)	<b>1212.4</b> (1146.3 - 1265.2)
<b>EC<sub>50</sub></b> and 95% confidence intervals (lower – upper)	<b>ErC<sub>50</sub></b>	<b>EyC<sub>50</sub></b>
mg/L test item, nominal	<b>5.17</b> (5.53 – 4.85)	<b>3.16</b> (3.06 – 3.27)
µg/L Boscalid, nominal	<b>2570.5</b> (2411.4 – 2749.5)	<b>1571.2</b> (1521.4 – 1625.8)
µg/L Boscalid, mean measured	<b>2277.2</b> (2175.6 – 2385.6)	<b>1493.9</b> (1448.0 - 1540.9)

Calculations were done using unrounded values

Table 2: Observations

Treatment group mg/L test item, nominal	% Inhibition	
	Average specific growth rate	Yield
	0 - 72 h after application	
Control	n.r.	n.r.
2.09	-0.7 <sup>1</sup>	-3.0 <sup>1</sup>
2.92	11.3 +	38.7 +
4.08	43.0 +	85.1 +
5.71	53.2 +	90.9 +
8.00	77.0 +	97.6 +

+ significantly different from control (Williams t-test; Welch-t-test, alpha = 0.05, one-sided smaller),

n.r. – not relevant

<sup>1</sup> negative values in % inhibition indicate a higher growth relative to that of the control

### Validity criteria

The biomass in the control cultures increased exponentially by a factor of 70.6 within the 72 hours test period (factor 16 after 72 hours is required according to guideline OECD Guideline 201 (2011)). The mean coefficient of variation for section-by-section specific growth rates in the control cultures was 20.6% (not exceeding 35%). The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was 1.4% and did not exceed 7%.

### Conclusion

A growth inhibition test was performed to assess the effects of the test item GLOB1811F to a freshwater green alga (*Pseudokirchneriella subcapitata*) during 72 hours of exposure.

The analysis of the test solutions demonstrates that the organisms were exposed to the appropriate concentration of test material at study initiation. The calculated endpoints are based on the nominal concentrations for the test item and on the geometrical mean measured concentrations for the active ingredient Boscalid since the measured concentrations were not within 80 to 120% of nominal.

In a 72-hour static test in which *Pseudokirchneriella subcapitata* were exposed to GLOB1811F, based on nominal concentrations the 72 h ErC50 (growth rate) was 5.17 mg/L test item and the 72 h EyC50 (yield) was 3.16 mg/L test item.

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

**A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms**

**A 2.3 KCP 10.3 Effects on arthropods**

### A 2.3.1 KCP 10.3.1 Effects on bees

#### A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

Comments of zRMS:	The study was conducted to OECD guidelines 213 and 214 and according to the principles of GLP. No deviations to the guideline were noted. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3.1.1
Report	Acute toxicity of GLOB1811F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions, XXX M., 2020a, 20 48 BAA 0156, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (OECD 213 (1998), OECD 214 (1998))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Materials and methods

Test item:	GLOB1811F (Water dispersible formulation containing 500 g/kg Boscalid); Batch No.: 180511		
	Content of active substance (a.s.):	<u>nominal</u>	<u>analysed</u>
	Boscalid:	500 g/L	497.2 g/L
Reference item:	Dimethoate 400 EC was tested parallel to test item (analysed content of 411.20 ± 3.47 g/L)		
Test species:	Honeybee – <i>Apis mellifera</i> L. subspecies Buckfast (Hymenoptera, Apoidea): worker bees of a healthy and queen-right colony; female, adult worker bees (forager bees) were collected in the morning before use; apiary: BioChem agrar GmbH, Kup- ferstr. 6, 04827 Machern OT Gerichshain, Germany		
Test design:	<u>Contact test:</u>	48-h; 2 control groups of deionised water, 1 % v/v tween solution; 5 dose rates of test item; 4 dose rates of the reference item; comprising 3 replicates per dose rate each of 10 bees, application volume: 4 µL/bee	
	<u>Oral test:</u>	48-h; 1 control group of 50 % w/v sucrose solution; 5 dose rates of test item; 4 dose rates of the reference item; comprising 3 replicates per dose rate each of 10 bees; application volume: 200 µL/cage by group feeding of 10 bees (corresponding to 20 µL/bee)	
	The mortality and the behaviour were assessed 4, 24, 48 hours after application for the contact and oral test		
Endpoints:	Mortality, behavioural impairments		
Dose rates	<u>Test item:</u>		
[product/bee]	Contact test:	1000, 500, 250, 125, 62.5 µg product/bee	
	Oral test (offered):	1000, 500, 250, 125, 62.5 µg product/bee	

Oral test (consumed): 1000, 500, 250, 125, 62.5 µg product/bee\*

**Dose rates**

[a.s./bee]

based on analysed  
content of a.s.

**Test item**

Contact test: 497, 249, 124, 62.2, 31.1 µg a.s./bee

Oral test (offered): 497, 249, 124, 62.2, 31.1 µg a.s./bee

Oral test (consumed): 497, 249, 124, 62.2, 31.1 µg a.s./bee\*

\* based on the actual food uptake

Test conditions: Temperature: 23.9 – 25.1 °C (contact and oral)  
Relative humidity: 50 - 65 % (contact and oral)  
Illumination: constant darkness throughout the test (diffuse artificial light only during handling and assessments)  
Food: 50 % (w/v) sucrose solution (after application *ad libitum*)

Statistics: Statistical program used: ToxRat Professional 3.3.0 (2018)

**Calculation of LD<sub>50</sub> values:**

Test item: Contact: no LD<sub>50</sub>-calculation (due to no mortality)

Oral: no LD<sub>50</sub>-calculation (due to no mortality)

Reference item: Contact: Probit analysis (linear maximum likelihood regression)

Oral: Probit analysis (linear maximum likelihood regression)

**Statistical significance of mortality values:**

Test item: Fisher's Exact Binomial Test with Bonferroni Correction ( $\alpha = 0.05$ )

Reference item: Fisher's Exact Binominal Test with Bonferroni Correction ( $\alpha = 0.05$ )

Validity criteria Control mortality (48 h):  $\leq 10$  %

LD<sub>50</sub> – value of the reference (24 h): 0.10 – 0.30 µg a.s./bee (contact)  
0.10 – 0.35 µg a.s./bee (oral)

Experimental  
phase:

15 - 17 September 2020

## Results

### Contact test

After 48 hours, the control groups either treated with deionised water or 1 % tween solution demonstrated no mortality. In the test item treatment group, no mortality was observed after thoracic application of up to 1000 µg GLOB1811F/bee, after 48 hours.

### Oral test

After 48 hours, the control group fed 50 % sucrose solution demonstrated no mortality. In the test item treatment group, no mortality was observed after oral consumption of up to 1000 µg GLOB1811F/bee, after 48 hours.



### LD<sub>50</sub>-values of the contact and oral toxicity test

LD <sub>50</sub> values	Contact toxicity test		Oral toxicity test <sup>1</sup>	
	24 h	48 h	24 h	48 h
LD <sub>50</sub> [µg product/bee]	> 1000	> 1000	> 1000	> 1000
LD <sub>50</sub> [µg a.s./bee]*	> 497	> 497	> 497	> 497

<sup>1</sup> Oral dose rates based on actual consumed doses; \* based on analysed content of a.s.

The contact and oral LD<sub>50</sub> (24 h) of the reference item was calculated to be 0.142 µg a.s./bee and 0.101 µg a.s./bee, respectively. All validity criteria have been met.

### Conclusion

The acute contact and oral toxicity of GLOB1811F was tested on honeybees under laboratory conditions over 48 hours.

The contact LD<sub>50</sub> (48 h) was > 1000 µg GLOB1811F/bee that is corresponding to >497 µg a.s./bee. The oral LD<sub>50</sub> (48 h) was > 1000 µg GLOB1811F/bee that is corresponding to >497 µg a.s./bee.

### A 2.3.1.2 KCP 10.3.1.2 Chronic toxicity to bees

Comments of zRMS:	The study was conducted to OECD guidelines 245 and according to the principles of GLP. No deviations to the guideline were noted. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3.1.2
Report	Chronic toxicity of GLOB1811F to the honey bee <i>Apis mellifera</i> L. under laboratory conditions, XXX K., 2021, 20 48 BAC 0096, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (OECD TG 245 (2017))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### I. MATERIALS AND METHODS

Test item:	GLOB1811F, Batch: 180511 Content of a.i.: Boscalid: 500 g/kg (nominal); 497.2 g/kg (analysed)
Reference item:	Danadim® Progress Content of a.i.: Dimethoate: 400 g/L (nominal); 411.20 g/L (analysed)

	Density: 1.069 g/mL
Test species:	<i>Apis mellifera</i> L. subspecies Buckfast (honey bee), max. two days old bees; derived from healthy and queen-right colonies; source: BioChem agrar GmbH, XXX, Germany
Guideline:	OECD TG 245 (2017) Deviations: none
Test design:	In a 10-day chronic toxicity feeding test, young adults of <i>Apis mellifera</i> L. (max. two days old) were continuously exposed to GLOB1811F diluted in the bee food (50% (w/v) aqueous sucrose solution + 0.1% (w/v) xanthan). The following treatment groups were set up: five doses of the test item, one untreated control group AC fed with 50% (w/v) aqueous sucrose solution, one untreated control group BC fed with 50% (w/v) aqueous sucrose solution + 0.1% (w/v) xanthan and one dose of the reference item. For each treatment group, three replicates per dose and 10 bees per replicate were used. All feeding solutions were freshly prepared every day and provided <i>ad libitum</i> . Assessments of bee mortality, food consumption and behavioural abnormalities were conducted daily. In the analytical phase of the study, the concentration of the active ingredient boscalid in the highest and lowest test item feeding solution applied on each day of application was determined.
Endpoints:	Mortality, behavioural abnormalities
Test concentrations:	Control group AC: untreated food (50% (w/v) aqueous sucrose solution) Control group BC: untreated food (50% (w/v) aqueous sucrose solution + 0.1% (w/v) xanthan)  Test item group: treated food at nominal doses of 400, 200, 100, 50.0 and 25.0 µg product/bee/day (equivalent to 200, 100, 50.0, 25.0 and 12.5 µg a.i./bee/day*) corresponding to concentrations of 10.185, 5.092, 2.546, 1.273 and 0.637 g product/kg food (equivalent to 5.092, 2.546, 1.273, 0.637 and 0.318 g a.i./kg food*) Effectively consumed doses: 202, 106, 62.0, 32.3 and 18.1 µg product/bee/day (equivalent to 101, 53.2, 31.0, 16.1 and 9.03 µg a.i./bee/day*) * based on the nominal content of active ingredient  Reference item group: treated food at a nominal dose of 27.3 ng dimethoate/bee/day (corresponding to a concentration of 0.694 mg dimethoate/kg food)
Test conditions:	Temperature: 32.5 – 32.9 °C Relative humidity: 55.8 – 65.5% Photoperiod: darkness (diffuse artificial light only during feeding and assessments) Food: 50% (w/v) aqueous sucrose solution
Statistics:	Statistical software used: ToxRat Professional 3.3.0 (2018). Step-down Cochran-Armitage Test Procedure for mortality data and determination of NOEDD/NOEC (one-sided greater, $\alpha = 0.05$ ). Since the obtained mortalities did not reach 50%, the LDD <sub>50</sub> and LC <sub>50</sub> values were estimated from the generated raw data. For the calculation of the LDD <sub>20/10</sub> and LC <sub>20/10</sub> values along with their 95% confidence limits, Probit analysis using linear maximum likelihood

regression was used.

Dates of work:	Experimental starting date (biological phase):	22 Sep 2020
	Experimental completion date (biological phase):	02 Oct 2020
	Experimental starting date (analytical phase):	02 Oct 2020
	Experimental completion date (analytical phase):	05 Oct 2020

## II. RESULTS AND DISCUSSION

All validity criteria for the study were met. After 10 days of continuous exposure, a mortality of 13.3% was observed in both blank control group AC and viscosifier control group BC. In the reference item group, a mortality of 96.7% was recorded.

Taking into account the actual food uptake and evaporated amount of feeding solution, the bees effectively consumed doses of 202, 106, 62.0, 32.3 and 18.1 µg product/bee/day (equivalent to 101, 53.2, 31.0, 16.1 and 9.03 µg a.i./bee/day) which resulted in mortalities of 36.7, 26.7, 20.0, 16.7 and 0.0% after 10 days, respectively (corrected for mortality of viscosifier control group BC: 26.9, 15.4, 7.7, 3.8 and 0.0%). Mortalities in the two highest test item doses (202 and 106 µg consumed product/bee/day) were statistically significantly increased compared to the viscosifier control group BC (Step-down Cochran-Armitage Test Procedure,  $\alpha = 0.05$ , one-sided greater).

During the course of the test, no behavioural abnormalities were observed in any test item treatment group on any assessment day.

Results are summarised in Table I.

**Table I Mean mortality, behaviour of bees and toxicity of GLOB1811F after 10 days**

Treat- ment group	Treat - ment grou p ID	Daily dose		Daily dose		Concentration		After 10 days		Number of bees show- ing behav- ioural ab- normalities <sup>2</sup>
		no- mi- nal [µg product/ bee/day]	con- sume d <sup>1</sup>	no- mi- nal [µg a.i./ bee/day]	con- sume d <sup>1</sup>	[g product/ kg food]	[g a.i./ kg foo d]	Mean mor- tality ab- so- lute [%]	cor- rec- ted [%]	
Blank control  Viscosi- fier con- trol	AC	--	--	--	--	--	--	13.3	--	0 out of 26
	BC	--	--	--	--	--	--	13.3	--	0 out of 26
Test item	AT	400	202	200	101	10.185	5.092	36.7 *	26.9	0 out of 19
	BT	200	106	100	53.2	5.092	2.546	26.7 *	15.4	0 out of 22
	CT	100	62.0	50.0	31.0	2.546	1.273	20.0	7.7	0 out of 24
	DT	50.0	32.3	25.0	16.1	1.273	0.637	16.7	3.8	0 out of 25
	ET	25.0	18.1	12.5	9.03	0.637	0.318	0.0	0.0	0 out of 30
		[ng product/ bee/day]		[ng a.i./ bee/day]		[mg produ ct/ ct/	[mg a.i ./			

						kg food]	kg foo d]			
Refer- ence item	AR	70.9	24.8	27.3	9.55	1.805	0.694	96.7	96.2	0 out of 1
		Endpoints					After 10 days			
Test item doses		LDD <sub>50</sub> [µg consumed product/bee/day <sup>1</sup> ] <sup>3</sup>					> 202			
		LDD <sub>20</sub> [µg consumed product/bee/day <sup>1</sup> ] <sup>4</sup>					142 (94.6 – 297)			
		LDD <sub>10</sub> [µg consumed product/bee/day <sup>1</sup> ] <sup>4</sup>					77.5 (40.2 – 117)			
		LDD <sub>50</sub> [µg consumed a.i./bee/day <sup>1</sup> ] <sup>3</sup>					> 101			
		LDD <sub>20</sub> [µg consumed a.i./bee/day <sup>1</sup> ] <sup>4</sup>					70.8 (47.3 – 149)			
		LDD <sub>10</sub> [µg consumed a.i./bee/day <sup>1</sup> ] <sup>4</sup>					38.7 (20.1 – 58.5)			
		NOEDD [µg consumed prod- uct/bee/day <sup>1</sup> ] <sup>5</sup>					62.0			
		NOEDD [µg consumed a.i./bee/day <sup>1</sup> ] <sup>5</sup>					31.0			
Test item concentrations		LC <sub>50</sub> [g product/kg food] <sup>3</sup>					> 10.185			
		LC <sub>20</sub> [g product/kg food] <sup>4</sup>					6.384 (4.302 – 15.966)			
		LC <sub>10</sub> [g product/kg food] <sup>4</sup>					3.420 (1.608 – 5.487)			
		LC <sub>50</sub> [g a.i./kg food] <sup>3</sup>					> 5.092			
		LC <sub>20</sub> [g a.i./kg food] <sup>4</sup>					3.417 (2.151 – 7.983)			
		LC <sub>10</sub> [g a.i./kg food] <sup>4</sup>					1.710 (0.804 – 2.744)			
		NOEC [g product/kg food] <sup>5</sup>					2.546			
		NOEC [g a.i./kg food] <sup>5</sup>					1.273			

Results are averages based on 3 replicates, containing 10 bees each; Calculations are performed with non-rounded values. corrected: corrected mortality (according to SCHNEIDER-ORELLI 1947); Mortality of the test item treatment group was corrected for mortality of untreated viscosifier control group BC, whereas mortality of the reference item treatment group was corrected for mortality of untreated blank control group AC. Negative values are treated as “0”.

\* Statistically significant difference in pairwise comparison between treatment and untreated viscosifier control group BC (Step-down Cochran-Armitage Test Procedure;  $\alpha = 0.05$ ; one-sided greater)

<sup>1</sup> Taking into account the actual food uptake and evaporation

<sup>2</sup> Number of bees showing behavioural abnormalities referring to the number of remaining bees

<sup>3</sup> Median lethal dietary dose/concentration (95%-cl lower – upper) were estimated from the generated raw data

<sup>4</sup> Lethal dietary doses/concentrations (95%-cl lower – upper) were calculated using Probit analysis (linear max. likelihood regression)

<sup>5</sup> No observed effect dietary doses/concentrations were determined using Step-down Cochran-Armitage Test Procedure ( $\alpha = 0.05$ ; one-sided greater)

In the test item group, the overall mean daily food consumption ranged between 19.9 and 28.4 mg feeding solution/bee/day which is 50.6% to 72.2% of the expected daily amount. In control group AC, the bees consumed on average 30.4 mg feeding solution/bee/day (=77.5% of the expected daily amount). In viscosifier control group BC, the bees consumed on average 28.8 mg feeding solution/bee/day (=73.3% of the expected daily amount).

The daily mean evaporation of 50% (w/v) sucrose solution ranged between 47.7 and 56.3 mg per cage. The daily mean evaporation of 50% (w/v) sucrose solution + 0.1% (w/v) xanthan ranged between 45.0 and 49.3 mg per cage. The food consumption per cage was corrected by subtracting the respective mean evaporation figure of the respective day of application.

The recovery rates of the active ingredient boscalid in samples of the test item feeding solutions were between  $\pm 20\%$  of the nominal concentrations. Therefore, the concentrations of active ingredient in the applied test item feeding solutions were verified and endpoints have been based on nominal concentrations. No residues of the active ingredient boscalid were found in the control samples.

### III. CONCLUSION

The chronic oral toxicity of GLOB1811F to young adult honey bees (*Apis mellifera* L.) was investigated in a 10-day chronic, dose-response feeding study under laboratory conditions.

Since the obtained mortalities did not reach 50%, the 10-day LDD<sub>50</sub> was estimated to be greater than 202 µg consumed product/bee/day (equivalent to 101 µg consumed a.i./bee/day) and the LC<sub>50</sub> was estimated to be greater than 10.185 g product/kg food (equivalent to 5.092 g a.i./kg food).

The 10-day LDD<sub>20</sub> was calculated to be 142 µg consumed product/bee/day (equivalent to 70.8 µg consumed a.i./bee/day) and the 10-day LC<sub>20</sub> was calculated to be 6.834 g product/kg food (equivalent to 3.417 g a.i./kg food).

The 10-day LDD<sub>10</sub> was calculated to be 77.5 µg consumed product/bee/day (equivalent to 38.7 µg consumed a.i./bee/day) and the 10-day LC<sub>10</sub> was calculated to be 3.420 g product/kg food (equivalent to 1.710 g a.i./kg food).

The NOEDD was determined to be 62.0 µg consumed product/bee/day (equivalent to 31.0 µg consumed a.i./bee/day), corresponding to a NOEC of 2.546 g product/kg food (equivalent to 1.273 g a.i./kg food).

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

Comments of zRMS:	The study was conducted to OECD guidelines 239 and according to the principles of GLP. No deviations to the guideline were noted. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3.1.3
Report	GLOB1811F - Repeated exposure of honey bee ( <i>Apis mellifera</i> L.) larvae under laboratory conditions, XXX M., 2021, 20 48 BLC 0079, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (239, OECD (2016))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

In a test under laboratory conditions, honey bee larvae (*Apis mellifera* L.) were repeatedly exposed to GLOB1811F. The toxicity of the test item was determined at cumulative doses of 79.8, 26.6, 8.9, 3.0 and 1.0 µg product/larva. The concentrations of test item in the diets were 504.3, 167.9, 56.0, 18.7 and 6.2 mg product/kg food. Additionally, honey bee larvae were treated with Dimethoate tech. as reference item at a total dose of 7.6 µg dimethoate/larva or with an untreated diet as control.

## II. MATERIAL AND METHODS

Test item:	GLOB1811F, Batch No.: 180511		
Reference item:	Dimethoate tech. (analysed purity: 98.8% ± 0.5%)		
Test species:	<i>Honey bee – Apis mellifera iberiensis</i> Engel (Hymenoptera, Apoidea): first instar larvae; derived from three healthy and queen-right colonies; source: BioChem AGROLOGÍA S.L.U., Utrera (Seville), Spain		
Test design:	<p>One day old honey bee larvae (D1) of <i>Apis mellifera</i> L. were transferred from brood combs to polystyrene grafting cells in 48-well cell culture plates 2 days before start of the treatment. On 4 successive days (D3 to D6) the larvae were repeatedly exposed to GLOB1811F diluted in the larval food (aqueous sugar solution mixed with royal jelly). After the applications, no additional feedings of the larvae took place. In total, 7 treatment groups were set up: 5 doses of the test item, one untreated control group and 1 dose of the reference item with 3 replicates per dose and 12 larvae per replicate, each. Assessments of larval mortality were performed on D4, D5, D6, D7 and D8. Additionally, other observations such as small body size or large quantities of remaining food on D8 were noted. Pupal mortality was assessed on D15 and emergence of adults was evaluated on D22.</p> <p>In an analytical phase of the study the concentration of the active ingredient in the test item stock solutions and in the control was determined.</p>		
Endpoints:	Successful adult emergence, mortality, qualitative observations: e.g. body size, remaining food		
Test concentrations:	Controls:	A	untreated diet B/C (aqueous sugar solution + royal jelly)
		C	
	Test item:	A	treated diet B/C at a concentration of 504.3 mg product/kg food
		T	
		BT	treated diet B/C at a concentration of 167.9 mg product/kg food
		CT	treated diet B/C at a concentration of 56.0 mg product/kg food
		D	treated diet B/C at a concentration of 18.7 mg product/kg food
		T	
		ET	treated diet B/C at a concentration of 6.2 mg product/kg food
	Reference:	A	treated diet B/C at a concentration of 48 mg a.i./kg food
		R	
Test conditions:	Temperature:	34.0 °C – 34.5 °C	
	Relative humidity:	D1 - D8: 92.4 – 100.0%; D8-D15: 80.3 – 84.9%; D15-D22: 55.1 – 69.5%	
	Photoperiod:	Darkness (except during assessments)	
	Food:	aqueous sugar solution with royal jelly	
Statistics:	Descriptive statistics, Step-down Cochran-Armitage Test (one-sided greater, alpha = 0.05) for determination of NOED/NOEC, ED/EC <sub>10/20/50</sub> values were determined by Probit analysis using linear weighted regression.		

## III. RESULTS AND DISCUSSION

The results are summarised below.

### Toxicity of GLOB1811F to larvae of *Apis mellifera* L. after repeated exposure

Treat-	Treat-	Dose	Concen-	On D8	On D15	On D22
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ment group	ment ID	tration		Larval mortality D3 to D8		Mean OO	Pupal mortality D8-D15		Total mortality D3-D22		Adult emer- gence rate
		[µg pro- duct/ larva]	[mg product/ kg food]	[%]			[%]		[%]		
				abs.	corr.		abs.	corr.	abs.	corr.	
Con- trol	AC	-	-	0.0	-	0.0	13.9	-	22.2	-	77.8
Test item	AT	79.8	504.3	11.1	11.1	0.0	40.6	31.0	72.2	64.3	27.8*
	BT	26.6	167.9	11.1	11.1	0.0	21.8	9.2	61.1	50.0	38.9*
	CT	8.9	56.0	5.6	5.6	0.0	23.2	10.9	52.8	39.3	47.2*
	DT	3.0	18.7	5.6	5.6	0.0	17.7	4.4	30.6	10.7	69.4
	ET	1.0	6.2	2.8	2.8	0.0	17.2	3.8	22.2	0.0	77.8
Refe- rence item	AR	[µg a.i./ larva]	[mg a.i./ kg food]								
		7.6	48	75.0	75.0	0.0	66.7	61.3	94.4	92.9	5.6

Treatment	Endpoint: Successful adult emergence	Up to D22
Test item doses	ED <sub>50</sub> [µg product/larva] <sup>2</sup>	34.972 (18.604 – 65.741)
	ED <sub>20</sub> [µg product/larva] <sup>2</sup>	4.821 (2.946 – 7.888)
	ED <sub>10</sub> [µg product/larva] <sup>2</sup>	1.711 (0.880 – 3.326)
	NOED [µg product/larva] <sup>1</sup>	3.0
Test item concentrations	EC <sub>50</sub> [mg product/kg food] <sup>2</sup>	220.683 (117.066 – 416.014)
	EC <sub>20</sub> [mg product/kg food] <sup>2</sup>	30.148 (18.384 – 49.440)
	EC <sub>10</sub> [mg product/kg food] <sup>2</sup>	10.650 (5.463 – 20.763)
	NOEC [mg product/kg food] <sup>1</sup>	18.7

Results are averages based on 3 replicates, containing 12 larvae each; see Appendix 4 for details

corr.: corrected mortality (according to SCHNEIDER-ORELLI 1947); test and reference item treated groups were corrected by AC; negative values were set to "0"; calculations were performed with non-rounded values; CL: confidence limit; abs.: absolute mortality as counted from the results; OO: Other observations (e.g. remaining food);

\* Statistically significantly different to the control (Step-down Cochran-Armitage Test; alpha=0.05; one sided greater)

Average% of pupal mortality: Sum of dead larvae between D8 and D15 / Sum of living larvae on D8 x 100% (replicate wise)

<sup>1</sup> Step-down Cochran-Armitage Test; alpha=0.05; one sided greater

<sup>2</sup> Probit analysis using linear weighted regression



On D8, a larval mortality of 0.0% was observed in the control (AC). Pupal mortality (between D8 and D15) was 13.9% in the control. The control group showed a total mortality of 22.2% on D22. In the test item treated groups, larval mortalities ranged between 2.8 and 11.1% on D8. Pupal mortalities (D8-D15) ranged between 17.2 and 40.6% in the test item treatment groups. Total mortalities ranged between 22.2 and 72.2% on D22. Mortality in the reference item treated group (AR) was above 50% across all replicates on D8, being 75.0%.

On D8, none of the remaining larvae treated with test item, were observed to have food left and/or a smaller body size.

In the final assessment on D22, an adult emergence rate of 77.8% was determined for the honey bees in the control group (AC). In the test item treated groups, the adult honey bees emerged at rates ranging between 27.8% and 77.8% following an application of 79.8, 26.6, 8.9, 3.0 and 1.0 µg product/larva, respectively, during the larval stages. On D22, larvae treated with 79.8, 26.6 and 8.9 µg product/larva showed emergence rates, which were statistically significantly decreased if compared to the control.

The recoveries of active ingredient in the test item final diets AT to ET ranged between xx% and xx%. No test item was detected in the control specimen.

Because control mortality was  $\leq 15\%$  on D8, cumulative mortality in the reference item treatment group was  $\geq 50\%$  on D8 and adult emergence in the control was  $\geq 70\%$  on D22, the study can be regarded as valid.

### III. CONCLUSION

In a repeated exposure larval toxicity study with GLOB1811F, the ED<sub>50</sub> (adult emergence up to D22) was determined to be 34.972 µg product/larva, which is equivalent to an EC<sub>50</sub> of 220.683 mg product/kg food. The ED<sub>20</sub> (adult emergence up to D22) was determined to be 4.821 µg product/larva, which is equivalent to an EC<sub>20</sub> of 30.148 mg product/kg food. The ED<sub>10</sub> (adult emergence up to D22) was determined to be 1.711 µg product/larva, which is equivalent to an EC<sub>10</sub> of 10.650 mg product/kg food. The NOED was 3.0 µg product/larva and the corresponding NOEC was 18.7 mg product/kg food.

**A 2.3.1.4      KCP 10.3.1.4      Sub-lethal effects**

**A 2.3.1.5      KCP 10.3.1.5      Cage and tunnel tests**

**A 2.3.1.6      KCP 10.3.1.6      Field tests with honeybees**

**A 2.3.2      KCP 10.3.2      Effects on arthropods other than bees**

Comments of zRMS:	The study was conducted to Blümel <i>et al.</i> 2000 guideline and according to the principles of GLP.
	Deviations:
	- study comprised 7 treatment groups (5 application rates of the test item, control, reference item) with only 3 replicates each containing 20 mites, according to method five replicates should be used. However in line with



	method minimum three replicates should be analysed, therefore such deviations is acceptable. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.3.2-01
Report	GLOB1811F: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates, XXX J., 2020a, 155681063, ibacon GmbH
Guideline(s):	Yes (Blümel <i>et al.</i> , 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

## Materials and methods

Test Item:	GLOB1811F; batch no.: 180511; analysed content of a.s.: 497.2 g/kg boscalid equivalent to 99.44% of the average declared amount.
Test Species:	Predatory Mite ( <i>Typhlodromus pyri</i> ), protonymphs not older than 24 hours; source: Katz Biotech AG, Baruth, Germany.
Test Design:	This study comprised 7 treatment groups (5 application rates of the test item, control, reference item) with 3 replicates each containing 20 mites. The mites were exposed to dried residues on treated glass plates. Survival of the mites was assessed after 3 and 7 days. For the reproduction assessment surviving mites from the control and from all test item groups where the corrected mortality was < 50 % were sexed and the number of eggs per female was recorded at 3 assessment days within one week.
Endpoints:	Mortality after 7 days of exposure; additionally, reproduction capacity for survived mites.
Validity Criteria:	<ul style="list-style-type: none"> <li>- Control mortality should not exceed 20 % on day 7 after exposure.</li> <li>- Reference item mortality should result in at least 50 % corrected mortality on day 7 after exposure.</li> <li>- Control reproductions (number of eggs per female) should be <math>\geq 4</math> eggs for the second week.</li> </ul>
Reference Item:	DANADIM PROGRESS (nominal: 400 g dimethoate/L).
Test Rates:	Control, 11.1, 33.3, 100, 300 and 900 g product/ha and reference item. The reference item was applied at an application rate of 9.0 mL DANADIM PROGRESS/ha. All treatments were applied in 200 L spray volume/ha. The spraying dilutions were sprayed onto glass plates via laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 24 - 26 °C; relative humidity: 63 - 72 %; photoperiod: 16 h light : 8 h dark; light intensity: 290 - 360 lux.
Statistics:	<p>Mortality: Chi<sup>2</sup> 2x2 Table Test with Bonferroni Correction, Fisher Exact Binomial Test (both one-sided greater, <math>\alpha = 0.05</math>)</p> <p>Reproduction: Dunnett's t-Test (one-sided smaller, <math>\alpha = 0.05</math>)</p>

## Results and discussions

The mortality of *Typhlodromus pyri* was not statistically significantly increased compared to the control up to and including the highest application rate of 900 g product/ha (Chi<sup>2</sup> 2x2 Table Test with Bonferroni Correction, one-sided greater,  $\alpha = 0.05$ , see Table 1).

Reproduction of *T. pyri* was assessed in the control and at all test item application rates. Reproduction was not statistically significantly reduced compared to the control up to and including the highest application rate of 900 g product/ha (Dunnett's t-Test, one-sided smaller,  $\alpha = 0.05$ ).

The reference item applied at a rate of 9.0 mL DANADIM PROGRESS/ha produced a statistically significant mortality of 100.0 % (corrected mortality 100.0 %) after 7 days.

**Table 1.** Mortality and reproduction of *Typhlodromus pyri*

	Rate <sup>1)</sup> [g product/ha]	Mortality <sup>2)</sup> [%]	Mortality corr. <sup>3)</sup> [%]	Reproduction <sup>4)</sup> [eggs/female]	Effect on re- production <sup>5)</sup> [%]
Control	0	10.0	--	4.2	--
GLOB1811F	11.1	21.7 n.s.	13.0	4.9 n.s.	-17.6
GLOB1811F	33.3	18.3 n.s.	9.3	6.2 n.s.	-47.5
GLOB1811F	100	10.0 n.s.	0.0	4.4 n.s.	-5.8
GLOB1811F	300	11.7 n.s.	1.9	5.1 n.s.	-21.3
GLOB1811F	900	13.3 n.s.	3.7	4.4 n.s.	-5.7
Endpoints <sup>6)</sup>					
LR <sub>50</sub> > 900 g product/ha					
ER <sub>50</sub> > 900 g product/ha					

1) Application rate in 200 L spray volume/ha

2) Mortality: after 7 days of exposure to spray residues on glass plates

(Chi<sup>2</sup> 2x2 Table Test with Bonferroni Correction; one-sided greater;  $\alpha = 0.05$ ; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli

4) Reproduction: mean number of eggs/female,

(Dunnett's t-Test; one-sided smaller;  $\alpha = 0.05$ ; n.s. = not significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

6) The LR<sub>50</sub> and ER<sub>50</sub> were not calculated as no mortality or effect on reproduction above 50% was noted.

## Conclusion

Under worst case laboratory conditions the LR<sub>50</sub> of GLOB1811F is greater than 900 g product/ha in 200 L water/ha. The NOER (no observed effect rate) for mortality is equal or greater than 900 g product/ha and the LOER (lowest observed effect rate) is greater than 900 g product/ha in 200 L water/ha.

Reproduction of *Typhlodromus pyri* was assessed in the control and at all test item application rates. Reproduction was not affected up to and including the highest application rate of 900 g product/ha. The ER<sub>50</sub> of GLOB1811F is estimated to be greater than 900 g product/ha in 200 L water/ha. The NOER is equal or greater than 900 g product/ha and the LOER is greater than 900 g product/ha in 200 L water/ha.

Comments of zRMS:	The study was conducted to Mead-Briggs <i>et al.</i> 2000 and Mead-Briggs <i>et al.</i> 2010 guidelines and according to the principles of GLP. No deviations to the guideline were noted. The study is considered to be reliable and suitable for the risk assessment.
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Reference: KCP 10.3.2-02

Report GLOB1811F: Effects on the Parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates,

	XXX J., 2020b, 155681001, ibacon GmbH
Guideline(s):	Yes (Mead-Briggs <i>et al.</i> 2000 and Mead-Briggs <i>et al.</i> 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

## Materials and methods

Test Item:	GLOB1811F; batch no.: 180511; analysed content of a.s.: 497.2 g/kg boscalid equivalent to 99.44% of the average declared amount.
Test Species:	Parasitoid ( <i>Aphidius rhopalosiphi</i> ), adults not older than 48 hours; source: Katz Biotech AG, Baruth, Germany.
Test Design:	This study encompassed 7 treatment groups (5 dose rates of the test item, control, reference item) with 4 replicates each containing 10 adult parasitoids. The parasitoids were exposed to dried residues on treated glass plates. Survival of the parasitoids was assessed after 2, 24 and 48 hours. At 48 hours, for treatment groups where the corrected mortality was $\leq 50\%$ the reproductive capacity was assessed by confining females individually over untreated barley plants infested with the host cereal aphids, <i>Rhopalosiphum padi</i> . The females were removed after 24 hours and the aphid-infested plants left for a further 11 - 12 days before the numbers of aphid mummies that had developed were assessed.
Endpoints:	Mortality of exposed parasitoids; additionally, reproductive capacity for female survivors.
Validity Criteria:	<ul style="list-style-type: none"><li>- Control mortality should be <math>\leq 13\%</math>.</li><li>- Reference item mortality <math>\geq 50\%</math> corrected mortality.</li><li>- Mean reproduction rate of control treatment <math>\geq 5</math> mummies per female.</li><li>- No more than 2 female parasitoids producing zero values.</li></ul>
Reference Item:	DANADIM PROGRESS (nominal: 400 g dimethoate/L).
Test Rates:	Control, 11.1, 33.3, 100, 300 and 900 g product/ha and reference item. The reference item was applied at an application rate of 0.3 mL DANADIM PROGRESS/ha. All treatments were applied in 200 L spray volume/ha. The spraying solutions were sprayed onto glass plates <i>via</i> laboratory spraying equipment, which were then air dried.
Test Conditions:	Temperature: 19 - 22 °C; relative humidity: 68 - 75 % (acclimatisation and exposure period), 77 - 79 % (post-exposure period, within the test units); photoperiod: 16 h light : 8 h dark; light intensity: 810 - 2030 lux (acclimatisation, exposure and parasitisation period), 8930 - 17540 lux (post-parasitisation period).
Statistics:	Mortality: Bonferroni-Holm Fisher's Exact Binomial Test, Fisher's Exact Binomial Test (both one-sided greater, $\alpha = 0.05$ ). Reproduction: Williams t-Test (one-sided smaller, $\alpha = 0.05$ ).

## Results

The mortality of *Aphidius rhopalosiphi* was not statistically significantly increased compared to the control up to and including the highest application rate of 900 g product/ha (Bonferroni-Holm Fisher's Exact Binomial Test, one-sided greater,  $\alpha = 0.05$ , see Table 1).

No behavioural abnormalities (affected and/or moribund parasitoids) were observed at any test item application rate after 2, 24 or 48 hours.

Reproduction of *A. rhopalosiphi* was assessed in the control and at all test item application rates. Reproduction was not statistically significantly reduced compared to the control up to and including the highest application rate of 900 g product/ha (Williams t-test, one-sided smaller,  $\alpha = 0.05$ ).

The reference item applied at a rate of 0.3 mL DANADIM PROGRESS/ha produced a statistically significant corrected mortality of 100.0 % after 48 hours.

**Table 1.** Mortality and parasitisation efficiency of the parasitoid wasp *Aphidius rhopalosiphi*

	Rate <sup>1)</sup> [g product/ha]	Mortality <sup>2)</sup> [%]	Mortality corr. <sup>3)</sup> [%]	Reproduction <sup>4)</sup> [mummies/female]	Effect on re- production <sup>5)</sup> [%]
Control	0	0.0	--	45.5	--
GLOB1811F	11.1	0.0 n.s.	0.0	56.5 n.s.	-24.2
GLOB1811F	33.3	5.0 n.s.	5.0	45.1 n.s.	0.8
GLOB1811F	100	0.0 n.s.	0.0	49.4 n.s.	-8.7
GLOB1811F	300	2.5 n.s.	2.5	41.7 n.s.	8.4
GLOB1811F	900	0.0 n.s.	0.0	43.4 n.s.	4.7
Endpoints <sup>6)</sup>					
LR <sub>50</sub> > 900 g product/ha					
ER <sub>50</sub> > 900 g product/ha					

1) Application rate in 200 L spray volume/ha

2) Mortality: after 48 hours of exposure to spray residues on glass plates,  
(Bonferroni-Holm Fisher's Exact Binomial Test; one-sided greater,  $\alpha = 0.05$ ; n.s. = not significant)

3) Corrected mortality according to Abbott and improvements by Schneider-Orelli

4) Reproduction: mean number of parasitised aphids/female,  
(Williams t-test, one-sided smaller,  $\alpha = 0.05$ ; n.s. = not significant)

5) Calculated on the exact raw data; negative values indicate better performance compared to the control

6) The LR<sub>50</sub> and ER<sub>50</sub> were not calculated as no mortality or effect on reproduction above 50% was noted.

## Conclusion

Under worst case laboratory conditions the LR<sub>50</sub> of GLOB1811F is greater than 900 g product/ha in 200 L water/ha. The NOER (no observed effect rate) for mortality is equal or greater than 900 g product/ha and the LOER (lowest observed effect rate) is greater than 900 g product/ha in 200 L water/ha.

Reproduction of *Aphidius rhopalosiphi* was assessed in the control and at all test item application rates. Reproduction was not affected up to and including the highest application rate of 900 g product/ha. The ER<sub>50</sub> of GLOB1811F is estimated to be greater than 900 g product/ha in 200 L water/ha. The NOER is equal or greater than 900 g product/ha and the LOER is greater than 900 g product/ha in 200 L water/ha.

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

### A 2.4.1 KCP 10.4.1 Earthworms

Comments of zRMS:	<p>The study was performed according to OECD TG 222 and principles of GLP. The validity criteria are met. For the control group:</p> <ul style="list-style-type: none"> <li>- number of juveniles per replicate: <math>\geq 30</math></li> <li>- the coefficient of variation of reproduction: <math>\leq 30\%</math></li> <li>- adult mortality after 4 weeks <math>\leq 10\%</math></li> </ul> <p>The study is considered acceptable and suitable for the risk assessment.</p>
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Reference: KCP 10.4.1

Report Effects of GLOB1811F on the reproduction of the earthworm *Eisenia fetida* in artificial soil, XXX S., 2020a, 20 48 TEC 0061, BioChem agrar Labor für biologische und chemische Analytik GmbH

Guideline(s): Yes (OECD 222 (2016))

Deviations: No

GLP: Yes

Acceptability: Yes

### Materials and methods

Name of the test item: GLOB1811F

Batch No.: 180511

Active ingredient/  
content: boscalid 500 g/kg (nominal), 497.2 g/kg (analysed)

Test species: earthworm *Eisenia fetida* (Savigny, 1826)

Test design: Effects on earthworms: 56 days;  
8 test item treatment groups and an untreated control group,  
8 replicates in the control group and 4 replicates in the test item treatment,  
10 worms per replicate; assessment of adult worm mortality, behavioural ef-  
fects and biomass development after 28 days, reproduction rate after  
an additional 28 days (assessed 56 days after application)

Test system: Exposure of worms to different concentrations of the test item mixed into arti-  
ficial soil substrate (with 10 % peat)

Reference item: Maypon Flow (Carbendazim, SC 500)  
The effects of the reference item were investigated in a separate study.

Test conditions: Temperature: 19.0 - 21.6 °C  
Light intensity: 640 lux  
Photoperiod: light : dark = 16 h : 8 h

Treatments: Control (untreated), test item (GLOB1811F)

Test concentrations: 4.1, 7.4, 13.2, 23.8, 42.9, 77.2, 139, 250 mg test item/kg soil dry weight  
(spacing factor: 1.8)

Dates of work: Experimental start date: 16 September 2020  
Experimental completion date: 11 November 2020

Statistics: Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm for  
mortality,  
( $\alpha = 0.05$ , one-sided greater), Williams t test for biomass change and repro-  
duction ( $\alpha = 0.05$ , one-sided smaller),  
Logit analysis for calculation of for calculation of EC<sub>x</sub>;  
Statistical program: ToxRat Professional 3.3.0 (2018)

## Results

The test item caused no statistically significant effect (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm,  $\alpha = 0.05$ , one-sided greater) on mortality. At a concentrations of 250 mg test item/kg soil d.w. the biomass increases of 19.3 % was significantly lower (Williams t test,  $\alpha = 0.05$ , one-sided smaller) compared to the control. Statistically significant effects (Williams t test,  $\alpha = 0.05$ , one-sided smaller) on the number of juveniles compared to the control group were recorded at concentrations of 77.2, 139 and 250 mg test item/kg soil d.w.

### Effects of GLOB1811F on *Eisenia fetida* in a 56-day reproduction study

Endpoint	Treatment group (mg test item/kg soil d.w.)								
	Control	4.1	7.4	13.2	23.8	42.9	77.2	139	250
Mortality of adult worms after 4 weeks (%)	0.0	2.5	0.0	0.0	0.0	0.0	0.0	2.5	5.0
Mean biomass change after 4 weeks (%)	28.1	28.8	31.1	26.9	27.9	30.2	29.5	27.7	19.3*
Mean number of juveniles after 8 weeks	274.5	280.5	260.0	272.0	276.3	252.5	206.8*	155.8*	84.3*
Reduction of reproduction compared to control (%)	-	-2.2	5.3	0.9	-0.6	8.0	24.7	43.3	69.3
Endpoint (mg test item/kg soil d.w.)									
NOEC (mortality)	250								
NOEC (biomass)	139								
NOEC (reproduction)	42.9								
LC <sub>50</sub> (mortality) <sup>1</sup>	> 250								
EC <sub>10</sub> (reproduction) <sup>2</sup>	45.4 (95 % confidence limits 36.0 – 57.2)								
EC <sub>20</sub> (reproduction) <sup>2</sup>	71.9 (95 % confidence limits 61.4 – 84.2)								
EC <sub>50</sub> (reproduction) <sup>2</sup>	158 (95 % confidence limits 143 – 175)								

Not statistically significantly different to control regarding mortality (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm,  $\alpha = 0.05$ , one-sided greater)

\* statistically significantly different compared to control (Williams t test for biomass change and reproduction,  $\alpha = 0.05$ , one-sided smaller)

Negative values = increase, relative to control

<sup>1</sup> based on estimation of the data,

<sup>2</sup> Logit analysis

The validity criteria for the control group were met:

- Adult mortality:  $\leq 10$  % (being 0.0 % after 4 weeks)
- Number of juveniles per replicate:  $\geq 30$  (being 237 to 321)
- Coefficient of variation of reproduction:  $\leq 30$  % (being 11.4 %)

## Conclusion

In a 56-day earthworm reproduction study with GLOB1811F, no statistically significant effect on survival of the adult *Eisenia fetida* in artificial soil were determined up to and including 250 mg test item/kg soil dry weight, i.e. the highest concentration tested. The NOEC for mortality was determined to be 250 mg test item/kg soil dry weight. The NOEC for biomass change and reproduction was determined to be 139 and 42.9 mg test item/kg soil d.w., respectively. The EC<sub>10</sub>, EC<sub>20</sub> and EC<sub>50</sub> values for reproduction were calculated to be 45.4, 71.9 and 158 mg test item/kg soil dry weight

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

Comments of zRMS:	<p>The study was performed according to OECD TG 232 and principles of GLP. The validity criteria are met. For the control group:</p> <ul style="list-style-type: none"> <li>- Mean adult mortality: <math>\leq 20\%</math> (observed: 2.5 %)</li> <li>- Mean number of juveniles per test vessel: <math>\geq 100</math> (observed: average of 994/vessel)</li> <li>- Coefficient of variation for the mean number of juveniles: <math>&lt; 30\%</math> (observed: 10.2 %).</li> </ul> <p>The study is considered acceptable and suitable for the risk assessment.</p>
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Reference:	KCP 10.4.2-01
Report	Effects of GLOB1811F on the reproduction of the collembolan <i>Folsomia candida</i> , XXX S., 2020b, 20 48 TCC 0070, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (OECD 232 (2016))
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

### Materials and methods

Name of the test item:	GLOB1811F
Batch No.:	180511
Active ingredient/ content:	Boscalid 500 g/kg (nominal), 497.2 g/kg (analysed)
Test species:	Collembola ( <i>Folsomia candida</i> ), age: 9 - 12 days; source: in-house culture.

### Results

No statistically significant effects on parental mortality (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm,  $\alpha = 0.05$ , one-sided greater) and on the number of juveniles (Williams-t-test,  $\alpha = 0.05$ , one-sided smaller) compared to the control group were found at any concentration tested.

Results are summarised in Table 1.

Table 1: Chronic effects of GLOB1811F on *Folsomia candida* in a 28-day reproduction study

Endpoint	Treatment group [mg test item/kg soil dry weight]								
	Control	8.2	14.7	26.5	47.6	85.7	154	278	500
Mean adult mortality [%]	2.5	2.5	2.5	2.5	0.0	5.0	0.0	2.5	2.5
Mean number of juveniles	994	1000	1008	973	998	986	1027	972	957



Reduction of reproduction [%] compared to control	-	-0.7	-1.5	2.0	-0.5	0.8	-3.3	2.2	3.7
	Endpoints [mg test item/kg soil dry weight]								
NOEC (mortality)	500								
NOEC (reproduction)	500								
LC <sub>50</sub> (mortality) <sup>1</sup>	> 500								
EC <sub>10</sub> (reproduction) <sup>1</sup>	> 500								
EC <sub>20</sub> (reproduction) <sup>1</sup>	> 500								
EC <sub>50</sub> (reproduction) <sup>1</sup>	> 500								

Not statistically significantly different to control regarding mortality (Multiple Sequentially-rejective Fisher Test after Bonferoni-Holm,  $\alpha = 0.05$ , one-sided greater) and reproduction (Williams-t-test,  $\alpha = 0.05$ , one-sided smaller)

Calculations were done using unrounded values

Negative values = increase, relative to control

<sup>1</sup> based on estimation of the data

In a separate study (BioChem project No. 20 48 TCC 0064, dated 14 September 2020), the EC<sub>50</sub> (reproduction) of the reference item boric acid was calculated to be 107 mg/kg soil dry weight. The results of the reference test demonstrate the sensitivity of the test system

The validity criteria for the control group were met:

- Mean adult mortality:  $\leq 20 \%$  (observed: 2.5 %)
- Mean number of juveniles per test vessel:  $\geq 100$  (observed: average of 994/vessel)
- Coefficient of variation for the mean number of juveniles:  $< 30 \%$  (observed: 10.2 %)

## Conclusion

In a 28-day *Folsomia candida* reproduction study with GLOB1811F, the NOEC for mortality of the parental collembolans was determined to be 500 mg test item/kg soil dry weight. The LC<sub>50</sub> could not be calculated, but it can be concluded that the LC<sub>50</sub> is higher than 500 mg test item/kg soil d.w., the highest concentration tested.

The NOEC for reproduction was determined to be 500 mg test item/kg soil dry weight. The EC<sub>10</sub>, EC<sub>20</sub> and EC<sub>50</sub> values for reproduction could not be calculated, but it can be concluded that these values are higher than 500 mg test item/kg soil d.w., the highest concentration tested.

Comments of zRMS:	The study was performed according to OECD TG 226 and principles of GLP. The validity criteria are met. The study is considered acceptable and suitable for the risk assessment.
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Reference: KCP 10.4.2-02

Report Effects of GLOB1811F on the reproduction of the predatory mite *Hypoaspis aculeifer*, XXX L., 2020, 20 48 THC 0055, BioChem agrar  
Labor für biologische und chemische Analytik GmbH

Guideline(s): Yes (OECD 226 (2016))



Deviations: No  
GLP: Yes  
Acceptability: Yes

### Materials and methods

Name of the test item: GLOB1811F

Batch No.: 180511

Active ingredient/content: boscalid 500 g/kg (nominal)  
497.2 g/kg (analysed)

Test species: *Hypoaspis aculeifer* (CANESTRINI)  
age: adult female mites with an age difference of 2 days  
source: Katz Biotech AG, Baruth

Test system: Exposure of female mites to different concentrations of the test item mixed into artificial soil substrate

Test design: The effects of the test item on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* (CANESTRINI) were investigated in a chronic laboratory experiment over a time period of 14 days according to OECD 226.  
Each of the eight different test item concentrations were homogeneously mixed into artificial soil and filled into glass vessels. Subsequently, the soil mites were introduced on top of the soil and the vessels were covered. Four replicates were performed for the test item groups and eight replicates for the control group; each replicate consisted of ten female soil mites. The mites were fed with *Tyrophagus putrescentiae* (SCHRANK) at the beginning and every two to three days during the whole test period. For the main measured variables, the number of juveniles per test vessel and additionally the mortality of the adult female mites were determined. Mortality and reproductive output of the mites exposed to the test item were compared to that of the control in order to determine the no observed effect concentration (NOEC).  
Assessment of adult mortality and reproduction effects was carried out after 14 days.

Endpoints: Mortality of adults and number of juveniles

Reference item: Dimethoate 400 EC (400 g/L, nominal).  
Test concentrations: 0.9, 1.3, 2.0, 3.0, 4.4, 6.7 10.0, 15.0 mg a.s./kg soil dry weight (d.w.) nominally equivalent to 2.3, 3.5, 5.3, 7.9, 11.9, 17.8, 26.7, 40.1 mg reference item/kg soil d.w. (spacing factor 1.5)  
The effects of the reference item were investigated in a separate study.

Test concentrations: 16, 29, 53, 95, 171, 309, 556 ,1000 mg test item/kg soil dry weight (spacing factor: 1.8)

Test conditions: Artificial soil according to OECD 226, pH 6.3 - 6.5 at test start, pH 6.2 - 6.4 at test end; water content at test start 47.15 - 49.15 % of maximum

Endpoint	Treatment group [mg test item/kg soil dry weight]								
	Control	16	29	53	95	171	309	556	1000
Mean adult mortality [%] (day 14)	0.0	5.0	5.0	2.5	0.0	0.0	10.0	2.5	2.5
Mean number of juveniles (day 14)	262.1	277.3	274.0	273.0	257.5	252.0	244.8	247.0	245.8
Coefficient of variation [%]	6.5	4.3	12.3	3.0	5.7	3.8	10.8	6.4	5.1
Reproduction in [%] of control	100	106	105	104	98	96	93	94	94
	Endpoint [mg test item/kg soil dry weight]								

NOEC (mortality)	≥ 1000
NOEC (reproduction)	≥ 1000
LC <sub>50</sub> (mortality) <sup>1</sup>	> 1000
EC <sub>10</sub> (reproduction) <sup>1</sup>	> 1000
EC <sub>20</sub> (reproduction) <sup>1</sup>	> 1000
EC <sub>50</sub> (reproduction) <sup>1</sup>	> 1000

Not statistically significantly different compared to the control (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm for mortality,  $\alpha = 0.05$ , one-sided greater and Williams Multiple Sequential t-test Procedure,  $\alpha = 0.05$ , one-sided smaller)

<sup>1</sup> based on estimation of the data

## Conclusion

In a 14-day *Hypoaspis aculeifer* reproduction study with GLOB1811F, the LC<sub>50</sub>, EC<sub>10</sub>, EC<sub>20</sub> and EC<sub>50</sub> values could not be calculated, but it can be concluded, that these values are higher than 1000 mg test item/kg soil dry weight. The NOEC for mortality and reproduction was determined to be equal or higher than 1000 mg test item/kg soil d.w.

## A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. All the validity criterion was met. The study is considered to be reliable and suitable for the risk assessment.
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Reference:	KCP 10.5
Report	Effects of GLOB1811F on the activity of soil microflora (Nitrogen transformation test), XXX L., 2020b, 20 48 SMN 0061, BioChem agrar Labor für biologische und chemische Analytik GmbH
Guideline(s):	Yes (OECD 216 (1998), OECD 214 (1998))
Deviations:	No
GLP:	YES
Acceptability:	Yes

## Materials and methods

Test item:	GLOB1811F
Batch No.:	180511
Formulation type:	Water dispersible formulation
Active ingredient:	Boscalid
Content:	500 g/kg (nominal) 497.2 g/kg (analysed)

Test soil:	Biologically active agricultural soil: loamy sand (DIN 4220) / loam (USDA), pH 6.3, 1.42 % Corg, WHC: 38.20 g/100 g dry soil.
Test design:	The test was performed in accordance with the OECD Guideline 216 (2000). Aim of the study was the determination of the nitrogen transformation (NO <sub>3</sub> -nitrogen-production) in soil enriched with lucerne meal (concentration in soil 0.5 %) by comparison of nitrogen transformation in test item treated soil with a non-treated soil. Three replicates per treatment and concentration. NH <sub>4</sub> -nitrogen, NO <sub>3</sub> - and NO <sub>2</sub> -nitrogen were determined by using the Autoanalyzer (SEAL Analytical). Sampling scheme: 0, 7, 14 and 28 days after treatment.
Test concentrations:	Control, 1.5 mg test item/kg soil dry weight and 15 mg test item/kg soil dry weight. Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm <sup>3</sup> .
Endpoints:	Effects on NO <sub>3</sub> -nitrogen-production after 28 days of exposure.
Reference item:	Dinoterb (purity: 99.28 % (g/g) analysed). The reference item was tested in a separate study (20 48 SMO 0001) at concentrations of 6.80, 13.60 and 27.20 mg/kg soil dry weight.
Test conditions:	Water content: approximately 45 % of its maximum water holding capacity; water content: 17.19 - 17.61 g/100 g dry soil; pH: 6.1 - 6.2 Soil samples were incubated at 19.4 - 20.7 °C, while stored in test vessels in the dark.
Statistics:	Calculation of mean values per treatment, standard deviations, coefficients of variation.
Dates of work:	Experimental start: 16.09.2020  Experimental end: 14.10.2020

## Results and discussions

No adverse effects of the test item on nitrogen transformation in soil could be observed at both test concentrations (1.5 mg/kg soil dry weight and 15 mg/kg soil dry weight) after 28 days (time interval 14-28).

The results are summarised in the table below.

Table 1: Effects on nitrogen transformation in soil after treatment with the test item

Time interval (days)	Control	1.5 mg GLOB1811F/kg soil dry weight		15 mg GLOB1811F/kg soil dry weight	
	NO <sub>3</sub> -N/day [mg/kg soil d.w.]	NO <sub>3</sub> -N/day [mg/kg soil d.w.]	% difference to control <sup>1</sup>	NO <sub>3</sub> -N/day [mg/kg soil d.w.]	% difference to control <sup>1</sup>
0-7	3.71	3.42	-7.8	3.08	-17.2
7-14	1.34	1.68	+25.3	1.50	+11.7
14-28	1.26	1.26	±0.0	1.46	+16.3

The calculations were performed with unrounded values

1) based on NO<sub>3</sub>-N-production; - = inhibition; + = stimulation

In a separate study the reference item Dinoterb caused stimulations of nitrogen transformation of +59.9 %, +216.3 % and +238.5 % at 6.80, 13.60 and 27.20 mg Dinoterb per kg soil dry weight, respectively, determined 28 days after application (time interval 14-28). For details see Appendix 6, page 22.

## **Conclusion**

The test item GLOB1811F (tested at 1.5 mg/kg soil dry weight and 15 mg/kg soil dry weight) caused no adverse effects (deviation from control <25%, OECD 216) on soil nitrogen transformation (measured as NO<sub>3</sub>-N production) at the end of the 28-day incubation period.

<b>A 2.6</b>	<b>KCP 10.6</b>	<b>Effects on terrestrial non-target higher plants</b>
<b>A 2.6.1</b>	<b>KCP 10.6.1</b>	<b>Summary of screening data</b>
<b>A 2.6.2</b>	<b>KCP 10.6.2</b>	<b>Testing on non-target plants</b>
<b>A 2.6.3</b>	<b>KCP 10.6.3</b>	<b>Extended laboratory studies on non-target plants</b>
<b>A 2.7</b>	<b>KCP 10.7</b>	<b>Effects on other terrestrial organisms (flora and fauna)</b>
<b>A 2.8</b>	<b>KCP 10.8</b>	<b>Monitoring data</b>