

REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB1911F

Product name(s): **CURRANDO/ SUBIGON/ COLLECTOR**

Chemical active substance:

Difenoconazole, 500 g/L

Central Zone

Zonal Rapporteur Member State: PL

NATIONAL ASSESSMENT PL

Applicant: Globachem NV

Submission date: April 2020

Update: August 2020

MS Finalisation date: May 2021

Revision date: October 2021

Version history

When	What
April 2020	Version submitted by the applicant
August 2020	Applicant's update
May 2021	Version evaluated by PL zRMS
October 2021	Version revised to take into account comments of cMSs and responses of the applicant

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This part of dRR of the product CURRANDO/ SUBIGON/ COLLECTOR has been evaluated based on request of Ministry of Agriculture and Rural Development in Poland expressed in a letter of 27 July 2020 with a case mark KS.rs.8208.1.11.2020.

PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Globachem NV in April 2020.

The application is for approval of GLOB1911F (trade names: Currando, Subigon, Collector), an suspension concentrate (SC) containing 500 g/L Difenoconazole for use as a fungicide in potatoes, sugar/fodder beet and oilseed rape for which Poland was designated zRMS.

1.2 Letters of Access

The Annex III dossier contains a letter of access from the company Syngenta.

1.3 Justification for submission of tests and studies

The application is for approval of authorization for a new product. It follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 for the new studies of Globachem NV submitted in support of this application and listed in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	GLOB1911F
Product name in MS	Currando/ Subigon/ Collector
Authorization number	/
Function	Fungicide
Applicant	Globachem N.V.
Active substance(s)	Difenoconazole, 500 g/L

(incl. content)	
Formulation type	Suspension concentrate [Code: SC]
Packaging	250, 500 mL and 1, 2, 3 L bottle, HDPE, HDPE/PA, HDPE/F, HDPE/EVOH 5, 10, 15, 20 L canisters, HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	Not Applicable
Recommended tank mixtures	Not Applicable

2.2 Conclusion

The evaluation of the application for GLOB1911F resulted in the decision to grant the authorization. All uses applied for were authorised.

2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Eye Irrit. 2, H319 Aquatic Chronic 1, H410
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is **formatted bold**:

Hazard pictograms:	GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	H319 Causes serious eye irritation H410 Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P264 Wash hands and face thoroughly after handling P270 Do not eat, drink or smoke when using this product P273 Avoid release to the environment P280 Wear eye protection eye/face protection. P391 Collect spillage P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P501 Dispose of contents/ containers to ...
Additional labelling phrases:	EUH401 To avoid risks to man and the environment, comply with the instructions for use. EUH208 Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction

Special rule for labelling of plant protection product (PPP):

EUH401	To avoid risks to man and the environment, comply with the instructions for use.
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2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms, respect following risk mitigation measures: Potato 4 x 0.125 kg a.s./ha: - 10m vegetated buffer strip with 10 m non sprayed buffer zone Sugar beet 2 x 0.125 kg a.s./ha: - 10m vegetated buffer strip with 10 m non sprayed buffer zone Winter oilseed rape 2 x 0.125 kg a.s./ha: - 10m vegetated buffer strip with 10 m non sprayed buffer zone Spring oilseed rape 2 x 0.125 kg a.s./ha: - 10m vegetated buffer strip with 10 m non sprayed buffer zone Or other option:

	In case the restriction sentence “To protect aquatic organisms from run off in surface water do not apply on run off endangered areas” is included on the label, respect following risk mitigation measures, To protect aquatic organisms: potato, sugar beet, spring and winter oilseed rape: 50% drift reducing nozzles or a 5m no-spray bufferzone.
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
	Based on AOEM model: No PPE required But, Personal eye protection need to be used – relating to classification (H319).
Worker protection:	
	no PPE required
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
P501	Dispose of contents/container in accordance with local/regional/national regulation.
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>To protect aquatic organisms, respect following risk mitigation measures:</p> <p>Potato 4 x 0.125 kg a.s./ha:</p> <ul style="list-style-type: none"> - 10m vegetated buffer strip with 10 m non sprayed buffer zone <p>Sugar beet 2 x 0.125 kg a.s./ha:</p> <ul style="list-style-type: none"> - 10m vegetated buffer strip with 10 m non sprayed buffer zone <p>Winter oilseed rape 2 x 0.125 kg a.s./ha:</p> <ul style="list-style-type: none"> - 10m vegetated buffer strip with 10 m non sprayed buffer zone <p>Spring oilseed rape 2 x 0.125 kg a.s./ha:</p> <ul style="list-style-type: none"> - 10m vegetated buffer strip with 10 m non sprayed buffer zone <p>Or other option:</p> <p>In case the restriction sentence “To protect aquatic organisms from run off in surface water do not apply on run off endangered areas” is included on the label, respect following risk mitigation measures, To protect aquatic organisms: potato, sugar beet, spring and winter oilseed rape: 50% drift reducing nozzles or a 5m no-spray bufferzone.</p>
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

Integrated pest management (IPM)/sustainable use:	
	-

2.5.2 Specific restrictions linked to the intended uses

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

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

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2021-05

PPP (product name/code): Currando/ Subigon/ Collector / GLOB1911F
 Active substance: Difenoconazole
 Safener: /
 Synergist: /
 Applicant: Globachem NV
 Zone(s): Central^(d)
 Verified by MS: Yes

Formulation type: SC
 Conc. of as: 500 g/L
 Conc. of safener: / ^(c)
 Conc. of synergist: / ^(c)
 Professional use: ☒
 Non professional use: ☐

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Potatoes SOLTU <i>Solanum tuberosum</i>	F	<i>Alternaria</i> sp. (ALTESP)	Normal downward spraying	BBCH 65-99	a) 1-4 b) 1-4	10	a) 0.250 L/ha b)1.0 L/ha	a) 0.125 kg as/ha b) 0.500 kg as/ha	250-400	14	
2	PL	Sugar beet BEAVA <i>Beta vulgaris</i>	F	<i>Cercospora beticola</i> (CERCBE)	Normal downward spraying	After BBCH 39 till 49	A) 1-2 B) 1-2	14	a)0.250 L/ha b)0.500 L/ha	a) 0.125 kg as/ha b) 0.250 kg as/ha	100-400	21	
3	PL	Winter oilseed rape BRSNW <i>Brassica napus</i>	F	<i>Alternaria brassicae</i> (ALTEBA) <i>Sclerotinia sclerotiorum</i> (SCLESC)	Normal downward spraying	BBCH 60-65	A) 1 B) 1	-	A) 0.250 L/ha B) 0.250 L/ha	A) 0.250 L/ha B) 0.250 L/ha	100-400	56	

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

The product GLOB1911F is a suspension concentrate. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white opaque liquid, with a musty type odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature higher than 400 °C. In aqueous solution, it has a pH value around 6.39 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE, HDPE/F, HDPE/PA or HDPE/EVOH bottles. Its technical characteristics are acceptable for a *Suspension concentrate* formulation. The intended concentration of use is 0.0625% to 0.25%.

No tank mixes are required for GLOB1911F.

3.2 Efficacy (Part B, Section 3)

The efficacy of GLOB1911F (referred to as Difenoconazole 500 SC in the efficacy section) at a dose rate of 0.25 L/ha was compared to the already registered (identical) products containing 250 g/L difenoconazole (Difcor 250 EC and Narita 250 EC) at their registered dose rate of 0.5 L/ha via bridging trials. These bridging trials demonstrate the equivalence of both products at the tested dose rates for the use on sugar beets, oilseed rape and potatoes.

To support registration of the new formulation Difenoconazole 500 SC, data of Difcor 250 EC were provided to show comparability of both products and their performance across conducted trials and a new product based on a 'bridging' approach does not have an adverse impact on the effectiveness. Difcor 250 EC containing difenoconazole, is also produced by Globachem N.V., therefore premise that there is appropriate data access to the existing formulation. The applicant has stated that they hold authorizations in all MS included in this GAP table. The zRMS has not validated this and therefore can only confirm the efficacy status of PL authorization. In this case, bridging trials are presented across a representative range of uses where the dose of active substance per hectare for both products is the same in all comparative (side-by-side) trials. The trials have been conducted with Difenoconazole 500 SC at a dose rate of 0,25 L/ha and reference product Difcor 250 EC at a dose rate of 0,5 l/ha, against pathogens on potato, sugar beet and oilseed rape in 24 efficacy trials carried out between 2018 and 2019.

Minimum effective dose tests

No specific minimum effective dose trial has been carried out. However, based on results from the bridging trials provided under section 3.2.3., the dose of 0,25 l/ha of Difenoconazole 500 SC provided the optimum overall control and should be considered as an effective solution against the claimed major diseases. Thus, the proposed rate of 0.25 l/ha should be considered the minimum effective dose to deliver broad-spectrum control under a wide range of environmental conditions.

Efficacy tests

MARITIME EPPO Zone

The efficacy of Difenoconazole 500 SC is mostly comparable between requested uses, so the data should be evaluated as a complete package representing moderate to good control against a range of pathogens on potato, sugar beet and oilseed. These results allow the basic Difcor 250 EC dossier to be used in the registration process for the new product Difenoconazole 500 SC as a complement to the new product test results. In some cases, both products have lower levels of control than expected e.g., oilseed rape trials.

The differences observed were mostly related to adverse weather conditions that were generally not conducive to the development of diseases with little or no rainfall throughout the critical infection period.

The individual cMS perhaps has specific guidance describing registration new product based on EPPO Guideline 1/307(2). Therefore, cMS based on extensive national experience should consider whether presented data there is an appropriate data package to support the registration of Difenconazole 500 SC based on a 'bridging' approach.

NORTH - EAST EPPO Zone

Comparative (side by side) trials was used to demonstrate that the new product Difenconazole 500 SC efficacy is equivalent to the original, already registered product. Comparability of both products regarding the active substance, mode of action and dose rate can be considered as a suitable package with a reduced number of trials for each crop for the claim of use of Difenconazole 500 SC. According to the presented results, it can be concluded that the results of the tested product Difenconazole 500 SC are comparable with the results of products Difcor 250 EC/Narita 250 EC tested at the same amount of active substance per hectare. It is acceptable that trials available for Difcor 250 EC/Narita 250 EC can be used as bridging trials to cover the requested uses as follow:

Crop	Application rate L/ha	Pests	Timing / Growth stage of crop & season	Max. number per use
Potatoes	0,25	<i>Alternaria</i> sp. (AL-TESP)	BBCH 65-91	1-4
Sugar beet	0,25	<i>Cercospora beticola</i> (CERCBE)	After BBCH 39 till 49	1-2
Winter oilseed rape	0,25	<i>Alternaria brassicae</i> (ALTEBA), <i>Sclerotinia sclerotiorum</i> (SCLESC)	BBCH 60-65	1

Registration in Poland of DIFCOR 250 EC/Narita 250 EC does not cover application against *Ramularia beticola*, *Erysiphe betae* on sugar beet and *Phoma lingam*, *Erysiphe cruciferarum* and *Pyrenopeziza brassicae* on oilseed rape. For the above-requested uses, the number of trials included by the applicant is insufficient for their registration in the context of guideline EPPO PP 1/226(2).

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

The applicant has provided a resistance risk analysis according to guideline EPPO. Overall, the risk of resistance can be estimated as low to medium for the difenconazole. The management strategy presented by the applicant should be implemented in cMS based on the latest FRAC recommendations and consideration in that cMS conditions.

Phytotoxicity to host crop

Based on the known crop safety of application of difenconazole on crops and no effects on crop vigour and phytotoxicity across selectivity assessment gathered in the efficacy trials it is reasonable to conclude that Difenconazole 500 SC has no adverse effects to host crop when applied at the proposed label rates and according to label recommendations.

Effect on yield of treated plants or plant product

Difenconazole 500 SC applied at a proposed dose rate of 0,25 L/ha had no negative effects on crop yield and quality when applied in oilseed rape, potato and sugar beet and could actually increase total mean yield slightly compared to untreated control.

Impact on succeeding crops

There is no risk of the appearance of the adverse effect of the fungicide Difenconazole 500 SC on succeeding crops even in the event of crop failure on a field that has been treated with this product.

Impact on other plants including adjacent crops

Difenconazole 500 SC will not have unacceptable effects on non-target terrestrial plants when applied at

a maximum application rate of 0.25 L/HA.

3.2.1 Information on the occurrence or possible occurrence of the development of resistance

Reference is made to the original submission of Difcor 250 EC (= Narita 250 EC).

3.2.2 Adverse effects on treated crops

Treatment with GLOB1911F had no biological effects on the different quality parameters or yield compared to the untreated control. Crop safety of GLOB1911F was assessed in the bridging trials at the N dose rate according to EPPO Guideline PP 1/135(4). No significant adverse effects were recorded at the proposed dose rates in sugar beet, oilseed rape or potato.

3.2.3 Observations on other undesirable or unintended side-effects

No adverse effects on beneficial and other non-target and other non-target organisms were observed in any of the trials.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for determination of Difenconazole and impurity and relevance of CIPAC methods in GLOB1911F were not evaluated as part of the EU review of Difenconazole. Therefore all relevant data are provided and are considered adequate. A HPLC-DAD method was submitted to analyse the active ingredient content and one impurity in the formulation. The method was validated.

3.3.2 Analytical methods for residues

As these analytical methods for the determination of residues in crops are active substance data and the studies used in the EU review of Difenconazole are out of protection, reference can be made to these active substance data for Difenconazole.

However, new residue studies were performed in which a new analytical method was developed and validated For Difenconazole, apart from the method provided during the EU review.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

The toxicological classification of GLOB1911F was based on theoretical calculations according to Regulation (EC) 1272/2008 as amended. Based on the classification of the active ingredient and co-formulants, GLOB1911F is classified as Eye Irrit. 2, H319.

zRMS: GLOB1911F/Currando requires classification for eye irritation: Eye Irrit.2 H319 Causes serious eye irritation - based on calculations taking into account hazards posed by its ingredients and their con-

centrations in the product according to Regulation (EC) 1272/2008. In addition, since the concentration of 1,2-benzisothiazol-3(2H)-one in the product Currando (GLOB1911F) is above this elicitation limit, thus elicitation on the label of this product with the statement EUH208 - 'Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction' is required.

3.4.2 Operator exposure

Operator exposure to GLOB1911F was not evaluated as part of the EU review of Difenconazole. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Operator exposure for Difenconazole was assessed against the AOEL agreed in the EU review (0.16 mg a.s./kg bw/d). For Difenconazole, the default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) were used for the concentrate (10%) as well as for the spray dilution (50%). Operator exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using GLOB1911F on potatoes, sugar beet and oilseed rape is acceptable without the use of personal protective equipment. However, due to the classification of GLOB1911F (H319), personal eye protection need to be used.

zRMS: The exposure to difenconazole of operator wearing the adequate work clothing (with arms, body and legs covered) and applying the product Glob1911f / Currando/Subigon/Collector on oilseeds or sugar beet or potato at dose 0.125 kg a.s./ha (0.25L product/ha), using tractor-mounted/trailed boom sprayer with hydraulic nozzles, calculated with the EFSA AOEM amounted to 26.33 % of AOEL of difenconazole. It is thus concluded that the application of product Glob1911f / Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of operator wearing the adequate work clothing (with arms, body and legs covered) for its intended use and dose within good agricultural practice.

Noting that the product is classified Eye Irrit. 2 thus to protect eye operators should wear protective goggles or face protection.

3.4.3 Worker exposure

Worker exposure to GLOB1911F was not evaluated as part of the EU review of Difenconazole. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Worker exposure for Difenconazole was assessed against the AOEL agreed in the EU review (0.16 mg a.s./kg bw/d). For Difenconazole, the default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) were used for the concentrate (10%) as well as for the spray dilution (50%). Worker exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the worker entering a field treated with GLOB1911F is acceptable without the use of personal protective equipment.

zRMS:

The exposure to difenconazole of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of oilseeds treated with the product Glob1911f / Currando/ Subigon/ Collector treated 2 times at a dose of 0.125 kg a.s./ha with interval 14d or a field of root and tuber vegetables treated 4 times at a dose of 0.125 kg a.s./ha with interval 10d, as foreseen in GAP, calculated with the EFSA AOEM amounted respectively to 9.43 % of AOEL or 15.99

% of AOEL, therefore the application of product Glob1911f / Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of worker wearing adequate work clothing for its intended use within good agricultural practice.

The exposure to difenoconazole of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of root and tuber vegetables treated 4 times at a dose of 0.125 kg a.s./ha with interval 10d, as foreseen in GAP, calculated with EUROPOEM II amounted respectively to 66 % of AOEL, but for worker wearing additionally protective gloves amounted to 13 % of AOEL. Thus, according to exposure estimated with EUROPOEM II the application of product Glob1911f / Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of worker wearing adequate work clothing and protective gloves for its intended use within good agricultural practice.

The exposure to difenoconazole of worker not wearing PPE but wearing a work clothing (long sleeved shirt, long trousers) and entering for 8 hours for removal of bolting beets a field of beets treated with the product Glob1911f / Currando/ Subigon/ Collector 4 times at a dose of 0.125 kg a.s./ha, interval 10d as foreseen in GAP, calculated with the EFSA AOEM using acceptable input data, amounted respectively to **116.88 %** of AOEL thus is posing an unacceptable health risk. However, when worker is wearing additionally protective gloves the exposure is equal 13% of AOEL, thus is not causing an unacceptable risk.

3.4.4 Bystander and resident exposure

Bystander and resident exposure to GLOB1911F was not evaluated as part of the EU review of Difenoconazole. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Bystander and resident exposure resulting from use of GLOB1911F on potatoes, sugar beet and oilseed rape was calculated according to the AOEM model.

It is concluded that there is no unacceptable risk anticipated for any resident after long-term exposure to GLOB1911F.

In the absence of AAOEL determined for Difenoconazole, it is considered that the risk assessment for the bystander is covered by the resident risk assessment.

zRMS:

The exposure of residents (adult and child) to difenoconazole, an active substance of a product Glob1911f /Currando/ Subigon/ Collector, applied on oilseeds 2 times at a dose of 0.125 kg a.s./ha with interval 14d or on a field of root and tuber vegetables treated 4 times at a dose of 0.125 kg a.s./ha with interval 10d, as foreseen in GAP, using tractor-mounted/trailed boom sprayer with hydraulic nozzles, calculated with the EFSA AOEM demonstrates that such an exposure for child and adult resident is equal respectively to 16.30% - 23.17% (child) and 6.71% - 10.44% (adult) of AOEL for difenoconazole, thus the application of product Glob1911f /Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of child and adult residents. Thus it is concluded that the application of product Glob1911f /Currando/ Subigon/ Collector does not pose an unacceptable risk to the health of adult and child resident due to its intended use within good agricultural practice.

No bystander acute exposure estimation is required since no acute acceptable operator exposure value (AAOEL) has been set for difenoconazole, the active substance of a product Glob1911f /Currando/ Subigon/ Collector. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to difeno-

conazole as a result of application of Glob1911f /Currando/ Subigon/ Collector with accordance with intended use within good agricultural practice.

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

3.5.1 Residues

New bridging studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Bridging studies were performed on the intended uses potato, sugar beet and oilseed rape with a side-by-side comparison of the products GLOB1911F and Difenoconazole 250 EC. Difenconazole 250 EC is already authorised in many Member States for the use on potato, sugar beet and oilseed rape. Dependent on the Member State and crop, this product is authorised under product name 'Difcor 250 EC', 'Difcor' or 'Narita'. It was concluded that the residues found from the new formulation GLOB1911F are comparable to those from the formulation Difenconazole 250 EC and therefore no additional data on GLOB1911F was required and the complete residue data set established for Difenconazole 250 EC was used in this application. The data submitted show that no exceedance of the EU MRL will occur. The uses are considered acceptable.

3.5.2 Consumer exposure

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals when taking into account sugar beet tops in ruminants diet, and regarding available feeding data, there is a clear risk for animal MRL to be exceeded. However, nowadays it is common practice that at harvest sugar beet tops are cut, chopped and spread back onto the field by the harvester for fertilization. It is therefore unlikely they will be fed to livestock and no restriction sentence on the label is required.

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.01 mg/kg bw/day and ARfD of 0.16 mg/kg bw for Difenconazole. It can therefore be concluded that acceptable margins of safety exist for consumers.

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

No new studies are presented; all data were reviewed in the EU review of Difenconazole. Appropriate endpoints from the EU review were used to calculate PECs for Difenconazole the relevant metabolites in soil, surface water, ground water and air for the intended use patterns.

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

The PEC of GLOB1911F, the active substances Difenconazole and its metabolites CGA205375 and CGA71019 in soil have been assessed with the FOCUS model and the focus groundwater interception values and the DT₅₀ values established in the EU review.

Although field DT₅₀ > 3 months and field DT₉₀ > 1 year were observed for Difenconazole, soil accumulation studies with annual applications showed no accumulation of Difenconazole after up to 10 years use. However for the sake of completeness, PEC_{accumulation} was calculated for Difenconazole at it metabolites.

The results for PEC_{accumulation} in soil for the active substances and its metabolites were used for the ecotoxicological risk assessment.

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

PEC ground water calculations are provided for the intended use of GLOB1911F on potatoes, sugar beet and oilseed rape (winter and spring). The direct leaching into the groundwater of Difenoconazole and its metabolites CGA205375 and CGA71019 have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models.

The results of the leaching models PEARL 4.4.4 and PELMO 5.5.3 show that when used according to the intended use on potatoes, sugar beet and oilseed rape (winter and spring) in the Central Zone, Difenoconazole and its metabolites leach in acceptable amounts ($< 0.1 \mu\text{g/L}$) to groundwater in every European scenario.

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

PEC surface water calculations are provided for the intended use of GLOB1911F on potatoes, sugar beet and oilseed rape (winter and spring). The PEC of Difenoconazole and relevant metabolites in surface water and sediment (PEC_{sw} and PEC_{sed}) have been assessed for the use of GLOB1911F with the FOCUS SW models (STEP 1 to 4) and the DT50 water/sediment values established in the EU review. PEC_{sed accumulation} was also calculated.

The results for PEC surface water and PEC_{sediment, accumulation} for the active substance and its metabolites were used for the eco-toxicological risk assessment.

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

The fate and behaviour in air of Difenoconazole was evaluated during the EU review of Difenoconazole. No additional studies have been performed.

The vapour pressure of Difenoconazole was determined to be $3.32 \times 10^{-8} \text{ Pa}$ at 25°C . The Henry's Law Constant was determined as $9.0 \times 10^{-7} \text{ Pa.m}^3/\text{mol}$ (25°C). Both values indicate a low potential for volatility. No volatilization of Difenoconazole from moist soil surface was observed in experiment with measurement of volatile radioactivity over 24 hours. In study with measurement of volatility as percentage loss of radioactivity from plant and soil only a small loss ($<9\%$ of initial radioactivity) was observed over 24 hours. Based on the presented data, no significant volatilisation of Difenoconazole is expected. Photochemical oxidative degradation was rapid with a calculated half-life of 5 hours and any residue that may occur in the atmosphere are therefore expected to be rapidly degraded.

CGA71019 has a relatively high vapour pressure of 0.34 Pa at 25°C . The value of Henry's Law Constant is $3 \times 10^{-5} \text{ Pa m}^3/\text{mol}$. No volatile products were observed in soil degradation study on CGA71019. Therefore no significant volatilisation of CGA71019 formed in soil is expected.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds and Terrestrial vertebrates (other than birds)

Effects on birds and mammals for GLOB1911F were not evaluated as part of the EU review of Difenoconazole. However further data on GLOB1911F are not relevant as active substance data on toxicity to

birds and mammals is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review.

The risk assessment for effects on birds is carried out according to the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009)¹.

The acute, short-term and long-term risks of GLOB1911F to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with Difenoconazole, the metabolite CGA131013 and maximum residues occurring on food items following applications according to the proposed use pattern.

The TERa and TERlt values exceed the triggers of 10 and 5 for the acute and long-term assessment respectively, indicating that Difenoconazole and metabolite CGA131013 does not pose an acute nor a long-term risk to wild birds and mammals after the use of GLOB1911F according to the intended GAP.

The ratio of the effective application rate and acute and reproductive endpoints for Difenoconazole do not exceed the threshold value of 3000 as given by EFSA/2009/1438 for more sorptive substances ($K_{oc} \geq 500$ L/kg). Therefore, there is low risk of acute/long term toxicity to birds and mammals from the uptake of contaminated drinking water and no further assessment is required.

Difenoconazole has a log P_{OW} value of 4.36, hence the risk from secondary poisoning was considered. The long-term TERs for secondary poisoning via earthworms and fish based on 21 days TWA PEC_{soil} and 21 days TWA PEC_{sw} values were all above the Annex VI trigger of 5, indicating acceptable risks. Therefore, the risk for birds and mammals through secondary poisoning from the intended use of GLOB1911F according to the proposed GAP is acceptable.

3.7.2 Effects on aquatic species

Effects on aquatic organisms for GLOB1911F were not evaluated as part of the EU review of Difenoconazole. During the EU review of Difenoconazole, it was quoted that Member States must pay particular attention to the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate. A new risk assessment was performed for the critical GAP of GLOB1911F using the toxicity data of GLOB1911F, the active substances as well as the metabolites CGA205375 and CGA71019.

The TER using worst-case PEC_{sw} and $PEC_{sed,accu}$ values for the active substance and the metabolites exceed the relevant triggers, indicating that Difenoconazole and the metabolites pose an unacceptable risk to aquatic organisms following the use of GLOB1911F on potatoes, sugar beet and oilseed rape (winter and spring) according to the recommended use pattern.

To protect aquatic organisms, following risk mitigation measures should be applied:
(when D3, D4, R1 FOCUS scenarios are relevant)

Potato 4 x 0.125 kg a.s./ha:

- 10m vegetated buffer strip with 10 m non sprayed buffer zone

Sugar beet 3 x 0.125 kg a.s./ha:

- 10m vegetated buffer strip with 10 m non sprayed buffer zone

Winter oilseed rape 2 x 0.125 kg a.s./ha:

¹ EFSA (2009). Guidance of EFSA – Risk assessment for Birds and Mammals. EFSA Journal 2009; 7(12):1438.

- 10m vegetated buffer strip with 10 m non sprayed buffer zone

Spring oilseed rape 2 x 0.125 kg a.s./ha:

- 10m vegetated buffer strip with 10 m non sprayed buffer zone

A study of the acute toxicity of GLOB1911F for algae showed that this product should be labelled as very toxic for aquatic life with long lasting effects. Hence, phrase H410 should be mentioned on the label.

3.7.3 Effects on bees

Effects on bees of GLOB1911F were not evaluated as part of the EU assessment of Difenconazole. Therefore all relevant data and assessments are provided here and are considered adequate.

Testing for effects of GLOB1911F on bees was carried out. Both acute (oral and contact) and chronic (oral adult and larvae) toxicity were tested.

The acute risk of GLOB1911F to honey-bees was assessed from hazard quotients between toxicity end-points, estimated from the acute oral and contact studies and the maximum single application rate of 125 g a.s./ha. All the hazard quotients are considerably less than 50, indicating that Difenconazole and GLOB1911F pose a low acute risk to bees.

3.7.4 Effects on other arthropod species other than bees

Effects on non-target arthropods of GLOB1911F were not evaluated as part of the EU assessment of Difenconazole. Therefore all relevant data and assessments are provided here and are considered adequate.

The in-field HQ values for exposure to maximum residues on leaves are all less than the trigger value of 1 for the Tier II studies for the species *Aphidius rhopalosiphii*, *Poecilus cupreus* and *Chrysoperla carnea*, except for the species *Typhlodromus pyri* for which the HQ is slightly above the trigger of 1. A higher-tier study under semi-field conditions was therefore conducted with *Typhlodromus pyri* where the predatory mite protonymphs were exposed to aged residues of GLOB1911F, demonstrating the potential for in-field recovery of *Typhlodromus pyri*. In consequence, it can be concluded that GLOB1911F does not pose an unacceptable risk to non-target arthropods in in-field areas following application according to the intended GAP.

The off-field HQ values for *T. pyri*, *A. rhopalosiphii*, *P. cupreus* and *C. carnea*, A. are lower than the trigger value of 1, indicating acceptable risk to non-target arthropods in off-field areas following the use of GLOB1911F according to the intended GAP.

3.7.5 Effects on soil organisms

Earthworms

The acute and long-term risk of GLOB1911F to earthworms was assessed from acute and long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for the active ingredient and relevant metabolites, and the maximum $PEC_{\text{soil, accumulation}}$.

The acute-term TER values for earthworms exceed the Annex VI acute-term trigger values of 10, indicating that GLOB1911F 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 GLOB1911F to earthworms is acceptable in accordance with the intended GAP.

Effects on other soil non-target macro-organisms

The long-term TER values for *Folsomia candida* and *Hypoaspis aculeifer* exceed the Annex VI long-term trigger values of 5, indicating that GLOB1911F poses a low long-term risk to other non-target soil organisms when applied according to the intended GAP.

Effect on micro-organisms

As the $PEC_{\text{soil, accumulation}}$ of Difenoconazole and its metabolites and the formulation are all lower than the concentration at which no significant effects are detected, it can be concluded that the risk of GLOB1911F to soil micro-organisms is acceptable in accordance with the intended GAP.

3.7.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants of GLOB1911F were not evaluated as part of the EU assessment of Difenoconazole. Therefore all relevant data and assessments are provided here and are considered adequate.

The potential effects of GLOB1911F on vegetative vigour and seedling emergence of six non-target terrestrial plants has been tested.

First tier risk assessment indicates that there is no unacceptable risk from GLOB1911F for non-target plants when applied according to the proposed use rates.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.8 Relevance of metabolites (Part B, Section 10)

The Difenoconazole metabolites CGA71019 and CGA205375 are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B Section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore **not** required.

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

GLOB1911F contains Difenoconazole which is approved as a candidate for substitution because Difenconazole is considered to be persistent and toxic.

As a conclusion of the comparative assessment, use 1 to 5 from GAP table in 2.6 is not suitable for substitution because there are no alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

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

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

The Letters of Access will be provided separately.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3 (filled in Part C)	Divens, J.	2020	MSDS of GLOB1911F and its co-formulants Globachem NV, document GLOB1911F Not GLP or GEP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.1 2.3.1 2.3.3 2.4.1 2.4.2 2.5.1 2.5.2 2.6.1 2.7.1 2.7.3 2.7.4 2.8.2 2.8.3.1 2.8.3.2 2.8.5.1.2 2.8.7.2 4.2	Sowle, J.	2019	Determination of storage stability and shelf life specification data for a suspension concentrate formulation GLOB1911F containing 500g/L Difenoconazole, stored at 54 °C ± 2 °C for two weeks, in compliance with good laboratory practice. Laboratory: David Norris Analytical Laboratories Ltd. Study number: DNA5103 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.1 and 2.2.2 (filed in Part C)	Sowle, J.	2020	Theoretical certificate of explosive and oxidizing properties for a soluble concentrate formulation containing Difenoconazole. Laboratory: David Norris Analytical Laboratories Ltd. Not GLP, unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.1	Sowle J.	2020a	Validation of the methods of determination of Difenoconazole and a specified impurity in a suspension concentrate formulation GLOB1911F containing 500 g/L Difenoconazole, in compliance with good laboratory practice. Study Number: DNA5105 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2-01a	Jonchère F.	2011a	Validation of the Analytical Method for the Determination of Difenoconazole Residues in potato (tubers) and wheat (grain and straw) Laboratory: Anadiag Study number: R B0128 GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of Narita (R-36/2016)	Globachem NV
KCP 5.2-01b	Jonchère F.	2013a	Amendment No. 1 to final Report Number R B0128: Validation of the Analytical Method for the Determination of Difenoconazole Residues in potato (tubers) and wheat (grain and straw) Laboratory: Anadiag Study number: R B0128 GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of Narita (R-36/2016)	Globachem NV
KCP 5.2-02	Faessel V.	2012a	Validation of the analytical method for the	N	N	Study report already submitted to PL to	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			determination of Difenconazole residue in Apricot, sugar beet (roots and leaves), carrot (roots) and celery (leaves) Laboratory: Anadiag Study number: R B2196 GLP Unpublished			support the authorisation of DIFCOR 250 EC (R-612/2015)	
KCP 5.2-03a	xxxxxx.	2008a	Validation of the Analytical Methods for the Determination of Difenconazole (and its metabolites) Residues in vegetables, fruits, cereals and animal matrices Laboratory: xxxxxx Study number: R A8143 GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-03b	xxxxxx	2008b	Amendment No. 1 to final Report Number R A8143: Validation of the Analytical Methods for the Determination of Difenconazole (and its metabolites) Residues in vegetables, fruits, cereals and animal matrices Laboratory: xxxxxxxx Study number: R A8143 GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-03c	xxxxxx	2013a	Amendment No. 2 to final Report Number R A8143: Validation of the Analytical Methods for the Determination of Difenconazole (and its metabolites) Residues in vegetables, fruits, cereals and animal matrices Laboratory: xxxxxx	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study number: R A8143 GLP Unpublished				
KCP 5.2-04a (submitted as KCA 6.3-07a)	Jonchère F.	2011d	Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2011. Lab: Anadiag SA, France Study Number: R B1114 GLP not published	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-04b (submitted as KCA 6.3-07b)	Jonchère F.	2013b	Amendment No. 1 to final Report Number R B1114: Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2011. Lab: Anadiag SA, France Study Number: R B1114 GLP not published	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-05	Austin R.	2009a	Independent Laboratory Validation of a Method for the determination of difenoconazole in crops Laboratory: CEM Analytical Service (CEMAS) Study number: CEMS-4180 GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-06	xxxxxxx	2009b	Independent Laboratory Validation of a Method for the determination of difenoconazole and its metabolite CGA205375 in bovine liver, kidney, muscle and fat, milk and eggs Laboratory: xxxxxxxx	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study number: CEMS-4181 GLP Unpublished				
KCP 5.2-07	Faessel V.	2013a	Validation of the Analytical Method for the Determination of Difenconazole Residues in milk. Lab: Anadiag SA, France Study Number: R B2295 GLP not published	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-08	Eberhard Z.	2008	Validation of an Analytical Method for the Determination of Difenconazole and its Metabolite CGA 205375 in Soil Laboratory: SGS INSTITUT FRESENIUS GmbH Study number: IF-08/01135942 GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-09	Faessel V.	2013b	Validation of the Analytical Method for the Determination of Difenconazole Residues in ground and surface water. Lab: Anadiag SA, France Study Number: R B2299 GLP not published	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 5.2-10	Gätschenberger H.	2017	Difenconazole and Paclobutrazol – Residues in honey following exposure of bees to treated winter oilseed rape in Germany during 2016. Study Number: S16-01988 GLP not published	N	Y (dependent on data protection already claimed by Syngenta)	Globachem N.V. has access to this study via a letter of access from Syngenta.	Syngenta*
KCP 5.2-11	Juckeland, D.	2020a	Effects of GLOB1911F on <i>Pseudokirchneriella</i>	N	Y	Data/study report never submitted be-	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(submitted as KCP 10.2.1/01)			<i>subcapitata</i> in an algal growth inhibition test BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 AAL 0002 GLP Unpublished			fore to PL.	
KCP 5.2-12 (submitted as 10.6.2/01)	Kästner K.,	2020a	Effect of GLOB1911F on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 46 PSE 0002 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2-13 (submitted as 10.6.2/02)	Kästner K.,	2020b	Effect of GLOB1911F on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 46 PVV 0002 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2-14 (Submitted as KCP 10.3.1.1.1/02 10.3.1.1.2/02)	Amsel, K.	2020	Acute toxicity of GLOB1911F to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BBA 0010 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2-15 (Submitted as KCA)	Eckenstein H.,	2014	Difenoconazole - Effects on the Development of Sediment-Dwelling Larvae of <i>Chironomus riparius</i> in Water-Sediment Systems with Spiked Sediment	N	Y (dependent on data)	Globachem N.V. has access to this study via a letter of access from Syngenta.	Syngenta*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
8.2.5.3/01)			Harlan Laboratories Ltd, Zelgliweg 1, 4452 Itingen, Switzerland Report Number D81747. Syngenta File No. CGA169374_10839 GLP Unpublished		protection already claimed by Syngenta)		
KCP 5.2-16 (Submitted as KCP 10.3.1.2/01)	Dreßler, K.	2020	Chronic toxicity of GLOB1911F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BAC 0003 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2-17 (Submitted as KCP 10.3.1.2/02)	Schmidt, K.	2020	GLOB1911F - Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BLC 0004 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-11	Rivet, J-P	2011	Efficacy of fungicides against <i>Uromyces betae</i> on Sugarbeets Report number: 1107F06 Laboratory: Essais + Sponsor: Globachem N.V. GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-12	Rivet, J-P	2011	Efficacy of fungicides against <i>Uromyces betae</i> on Sugarbeets Report number: 1107F07 Laboratory: Essais + Sponsor: Globachem N.V. GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-13	Karniewicz, V.	2011	Determination of Efficacy of Difenconazole 150 + Propiconazole 150 EC against fungal diseases in sugar beet, 1 Site in France 2011 Report number: S11-02726-01 Laboratory: Eurofins Agroscience Services Sponsor: Globachem N.V. GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-14	Karniewicz, V.	2011	Determination of Efficacy of Difenconazole 150 + Propiconazole 150 EC against fungal diseases in sugar beet, 1 Site in France 2011 Report number: S11-02726-02 Laboratory: Eurofins Agroscience Services Sponsor: Globachem N.V. GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-15	Karniewicz, V.	2011c	Determination of Efficacy of Difenconazole 150 + Propiconazole 150 EC against fungal diseases in sugar beet, 1 Site in France 2011 Report number: S11-02726-03 Laboratory: Eurofins Agroscience Services Sponsor: Globachem N.V. GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-16	Karniewicz, V.	2011	Determination of Efficacy of Difenconazole 150 + Propiconazole 150 EC against fungal diseases in sugar beet, 1 Site in France 2011 Report number: S11-02726-04 Laboratory: Eurofins Agroscience Services Sponsor: Globachem N.V. GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-21	Toth, F.	2010	Trial report of Plant Protection Products. Report number: 22/F/2010RS Laboratory: Gemerprodukt Valice, OVD Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-22	Toth, F.	2010	Trial report of Plant Protection Products. Report number: 28/F/2010RS	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) /	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Laboratory: Gemerprodukt Valice, OVD Sponsor: Globachem NV GEP, not published			Narita 250 EC (R - 36/2016)	
KCP 6.2-23	Schmidt, I.	2009	Efficacy and selectivity of Difenconazole 250 EC against SCLESC (Sclerotinia sclerotiorum / Cottony rot), ALTEBA (Alternaria brassicae / Black spot of rape) on BRSNW (Brassica napus napus (winter) / Winter rape-seed). Registration purpose. Poland 2009. Report number: 25-01/2009 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-24	Schmidt, I.	2009	Efficacy and selectivity of Difenconazole 250 EC against SCLESC (Sclerotinia sclerotiorum / Cottony rot), ALTEBA (Alternaria brassicae / Black spot of rape) on BRSNW (Brassica napus napus (winter) / Winter rape-seed). Registration purpose. Poland 2009. Report number: 25-02/2009 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-25	Schmidt, I.	2009	Efficacy and selectivity of Difenconazole 250 EC against SCLESC (Sclerotinia sclerotiorum / Cottony rot), ALTEBA (Alternaria brassicae / Black spot of rape) on BRSNW (Brassica napus napus (winter) / Winter rape-seed). Registration purpose. Poland 2009. Report number: 25-03/2009 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-26	Schmidt, I.	2009	Efficacy and selectivity of Difenconazole 250 EC against SCLESC (Sclerotinia sclerotiorum / Cottony rot), ALTEBA (Alternaria brassicae / Black spot of rape) on BRSNW (Brassica napus napus (winter) / Winter rape-seed). Registration purpose. Poland 2009.	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report number: 25-04/2009 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published				
KCP 6.2-27	Maurer, B.	2010	Determination of efficacy and selectivity of Tebucur, Difenoconazole 250 EC, Difenoconazole 125 + tebuconazole 250 against SCLESC (Sclerotinia sclerotiorum / cottony rot), ALTEBA (Alternaria brassicae / black spot of rape) on BRSNW (Brassica napus napus (winter) / winter rapeseed). Registration purpose. Poland 2010 Report number: 25-18/2010 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-28	Maurer, B.	2010	Determination of efficacy and selectivity of Tebucur, Difenoconazole 250 EC, Difenoconazole 125 + tebuconazole 250 against SCLESC (Sclerotinia sclerotiorum / cottony rot), ALTEBA (Alternaria brassicae / black spot of rape) on BRSNW (Brassica napus napus (winter) / winter rapeseed). Registration purpose. Poland 2010 Report number: 25-19/2010 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-29	Maurer, B.	2010	Determination of efficacy and selectivity of Tebucur, Difenoconazole 250 EC, Difenoconazole 125 + tebuconazole 250 against SCLESC (Sclerotinia sclerotiorum / cottony rot), ALTEBA (Alternaria brassicae / black spot of rape) on BRSNW (Brassica napus napus (winter) / winter rapeseed). Registration purpose. Poland 2010 Report number: 25-20/2010 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-30	Ridgway, J.	2011	Determination of Efficacy of Tebuconazole and Difeno-	N	N	Data/study already submitted for regis-	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			conazole against Alternaria leaf and pod spot and Sclerotinia stem rot in winter oilseed rape, 1 Site in the UK, 4 Sites in France and 1 Site in Germany, 2010 Report number: S10-01762 Laboratory: Eurofins Agroscience Services Ltd Sponsor: Globachem NV GEP, not published			tration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	
KCP 6.2-31	Ciesla, M.	2011	Determination of efficacy and selectivity of Difenconazole 250 EC, DIFCOR 250 EC, Difenconazole 125 + Tebuconazole 250 EW against LEPTMA (Leptosphaeria maculans/Black leg of crucifers) on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2011. Report number: 8633/01/2011 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-32	Ciesla, M.	2011	Determination of efficacy and selectivity of Difenconazole 250 EC, DIFCOR 250 EC, Difenconazole 125 + Tebuconazole 250 EW against LEPTMA (Leptosphaeria maculans/Black leg of crucifers) on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2011. Report number: 8633/02/2011 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-33	Ciesla, M.	2011	Determination of efficacy and selectivity of Difenconazole 250 EC, DIFCOR 250 EC, Difenconazole 125 + Tebuconazole 250 EW against LEPTMA (Leptosphaeria maculans/Black leg of crucifers) on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2011. Report number: 8633/03/2011 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP, not published				
KCP 6.2-34	Ciesla, M.	2011	Determination of efficacy and selectivity of Difenconazole 250 EC, DIFCOR 250 EC, Difenconazole 125 + Tebuconazole 250 EW against LEPTMA (Leptosphaeria maculans/Black leg of crucifers) on BRSNW (Brassica napus napus (winter) / Winter rapeseed). Registration purpose. Poland 2011. Report number: 8633/04/2011 Laboratory: Agrostat Sp. z.o.o. Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-35	Marocchi, A.	2011	GEP trial report. Evaluate efficacy and selectivity of Glob 4.20, DIFCOR and TEBUCUR against Phoma lingam on Oil Seed Rape. Germany 2010. Report number: 10 OSR F GBM 001-07 Laboratory: SGS Agri Min Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-36	Marocchi, A.	2011	GEP trial report. Evaluate efficacy and selectivity of Glob 4.20, DIFCOR and TEBUCUR against Phoma lingam on Oil Seed Rape. France 2010. Report number: 10 OSR F GRM TS 002 Laboratory: SGS Agri Min Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-37	Marocchi, A.	2011	GEP trial report. Evaluate efficacy and selectivity of Glob 4.20, DIFCOR and TEBUCUR against Phoma lingam on Oil Seed Rape. France 2010. Report number: 10 OSR F GBM 004 Laboratory: SGS Agri Min Sponsor: Globachem NV GEP, not published	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	Globachem NV
KCP 6.2-39	Eberhardt, A.	2011	Determination of efficacy of Difenconazole against Phoma lingam in winter oilseed rape, 3 sites in Northern Europe 2009/2010.	N	N	Data/study already submitted for registration of Difcor 250 EC (R – 40/2015) / Narita 250 EC (R - 36/2016)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report number: S09-00934 Laboratory: Eurofins Agroscience Services Sponsor: Globachem NV GEP, not published				
KCP 6.2-40	Tomas Spitzer	2019	Efficacy of Difenoconazole against diseases in OSR. Report number: FE-19-B-DifcorSC-CZ01 Laboratory: Zemedelsky vyzkumny ustav Kromeriz, s.r.o., Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-41	Uwe Gerdau	2019	Efficacy of Difenoconazole against diseases in OSR. Report number: FE-19-B-DifcorSC-DE02 Laboratory: Agrartest GmbH Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-42	Chenevall-Pallud Sylvie	2019	Efficacy of Difenoconazole against diseases in OSR. Report number: FE-19-B-DifcorSC-FR03 Laboratory: Promo-Vert SAS Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-43	Duncan Carr	2019	Efficacy of Difenoconazole against diseases in OSR. Report number: FE-19-B-DifcorSC-UK07 Laboratory: Oxford Agricultural Trials Limited Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-44	Andy Hunt	2019	Efficacy of Difenoconazole against diseases in OSR. Report number: FE-19-B-DifcorSC-UK08 Laboratory: Oxford Agricultural Trials Limited Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-45	Mateusz Ćwiek	2019	Efficacy of Difenoconazole against diseases in OSR. Report number: FE-19-B-DifcorSC-PL06 Laboratory: SynTech Research Poland Sp. z o.o. Sponsor: Globachem NV	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP, not published				
KCP 6.2-47	Lenka Vasatkova-Stanclova	2019	Efficacy of Difenconazole against CERCBE in sugar beet. Report number: FE-19-D-DifcorSC-CZ01 Laboratory: Zkušební stanice Nechanice s.r.o. Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-48	Sören Hötzel	2019	Efficacy of Difenconazole against CERCBE in sugar beet. Report number: FE-19-D-DifcorSC-DE02 Laboratory: Field Research Support Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-49	Doug Slater	2019	Efficacy of Difenconazole against CERCBE in sugar beet. Report number: FE-19-D-DifcorSC-UK06 Laboratory: Oxford Agricultural Trials Limited Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-50	Andy Hunt	2019	Efficacy of Difenconazole against CERCBE in sugar beet. Report number: FE-19-D-DifcorSC-UK07 Laboratory: Oxford Agricultural Trials Limited Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-51	Adrian Skorczyk	2019	Efficacy of Difenconazole against CERCBE in sugar beet. Report number: FE-19-D-DifcorSC-PL04 Laboratory: Field Research Support Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-52	Agnieszka Faligowska	2019	Efficacy of Difenconazole against CERCBE in sugar beet. Report number: FE-19-D-DifcorSC-PL05	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Laboratory: Poznań University of Life Sciences Sponsor: Globachem NV GEP, not published				
KCP 6.2-53	Ing. Jitka Mareckova	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: FE-18-B-DIF-NARITA-CZ01 Laboratory: Ing. Jitka Mareckova, ZS Krasne Udoli Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-54	Katrin Torkler	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: FE-18-B-DIF-NARITA-DE04 Laboratory: Quintus GmbH Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-55	Henk de Vries	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: FE-18-B-DIF-NARITA-NL06 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-56	Henk de Vries	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: 181363 FE-18-B-DIF-NARITA-NL06_2 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-57	Henk de Vries	2019	Efficacy and selectivity of difenconazole against ALTESP in potato. Report number: FE-19-C-DifcorSC-BE04 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-58	Henk de Vries	2019	Efficacy and selectivity of difenconazole against	N	Y	Data/study report never submitted be-	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			ALTESP in potato. Report number: FE-19-C-DifcorSC-NL05 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem NV GEP, not published			fore to PL.	
KCP 6.2-59	Lisa Conrad	2019	Efficacy and selectivity of difenoconazole against ALTESP in potato. Report number: FE-19-C-DifcorSC-SE03 Laboratory: HS Skåne HUSEC Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-60	Mateusz Cieřła	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: FE-18-A-DIF-NARITA-PL01 Laboratory: Field Research Support Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-61	Mateusz Cieřła	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: FE-18-A-DIF-NARITA-PL02 Laboratory: Field Research Support Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-62	Anna Jarecka-Boncera	2018	Efficacy and selectivity of Difenconazole 250 SC and Narita against Alternaria sp. in potato. Report number: FE-18-A-DIF-NARITA-PL03 Laboratory: Instytut Ogrodnictwa Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-63	Hubert Olejnik	2019	Efficacy and selectivity of difenoconazole against ALTESP in potato. Report number: FE-19-C-DifcorSC-PL06 Laboratory: Field Research Support Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-64	Grzegorz Dąbrowski	2019	Efficacy and selectivity of difenoconazole against ALTESP in potato. Report number: FE-19-C-DifcorSC-PL07 Laboratory: SynTech Research Poland Sp. z o.o. Sponsor: Globachem NV GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3-01	Ertus C.	2020a	Determination of Difenconazole residues in potato following four foliar applications with Difenconazole 250 EC and GLOB1911F under field conditions in Northern Europe in 2019. Lab: Anadiag SA, France Study Number: R B9108 GLP not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3-02	Jonchère F.	2011b	Determination of Difenconazole residues in potato following treatment with Difenconazole 250 EC under field conditions in Northern and Southern Europe in 2010. Lab: Anadiag SA, France Study Number: R B0126 GLP not published	N	N	Study report already submitted to PL to support the authorisation of Narita (R-36/2016)	Globachem NV
KCA 6.3-03	Ertus C.	2020b	Determination of Difenconazole residues in sugar beet following three foliar applications with Difenconazole 250 EC and GLOB1911F under field conditions in Northern Europe in 2019. Lab: Anadiag SA, France Study Number: R B9106 GLP not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3-04	Ertus C.	2013a	Determination of Difenconazole residues in sugar beet following treatment with Difenconazole 250	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			EC under field conditions in Northern Europe in 2012. Lab: Anadiag SA, France Study Number: R B2185 GLP not published				
KCA 6.3-05	Ertus C.	2020c	Determination of Difenconazole residues in winter oilseed rape following two foliar applications with Difenconazole 250 EC and GLOB1911F under field conditions in Northern and Southern Europe in 2019. Lab: Anadiag SA, France Study Number: R B9107 GLP not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3-06	Jonchère F.	2011c	Determination of Difenconazole residues in oilseed rape following treatment with Difenconazole 250 EC under field conditions in Northern Europe in 2010. Lab: Anadiag SA, France Study Number: R B0119 GLP not published	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCA 6.3-07a	Jonchère F.,	2011d	Determination of Difenconazole residues in oilseed rape following treatment with Difenconazole 250 EC under field conditions in Northern and Southern Europe in 2011. Lab: Anadiag SA, France Study Number: R B1114 GLP not published	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCA 6.3-07b	Jonchère F.,	2013b	Amendment No. 1 to final Report Number R	N	N	Study report already submitted to PL to	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			B1114: Determination of Difenconazole residues in oilseed rape following treatment with Difenconazole 250 EC under field conditions in Northern and Southern Europe in 2011. Lab: Anadiag SA, France Study Number: R B1114 GLP not published			support the authorisation of DIFCOR 250 EC (R-612/2015)	
KCA 6.10.1	Gätschenberger H.	2017	Difenconazole – Residues in honey following exposure of bees to treated winter oilseed rape in Germany during 2017. Study Number: S17-01051 GLP	N	Y (dependent on data protection already claimed by Syngenta)	Globachem N.V. has access to this study via a letter of access from Syngenta.	Syngenta*
KCP 9.2.4.1-01	Ploem, J-P.	2020a	Difenconazole 500 SC - Estimations of the predicted environmental concentration in groundwater (PEC _{gw}) of Difenconazole and relevant metabolites following the application of GLOB1911F on potatoes, sugar beet and oilseed rape. Globachem NV, Report GLOB1911F – GW – Central EU Not GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 9.2.5-01	Ploem, J-P.	2020b	Difenconazole 500 SC – Estimation of the Predicted Environmental concentrations in surface water (PEC _{SW}) and sediments (PEC _{SED}) for Difenconazole and relevant metabolites following the application of GLOB1911F on potatoes, sugar beet and oilseed rape. Globachem NV, Report GLOB1911F – SW/SED –	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Central EU Not GLP Unpublished				
KCP 10.2.1/01	Juckeland, D.	2020a	Effects of GLOB1911F on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 AAL 0002 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 8.2.5.3 (summarized in KCP 10.2.1)	Eckenstein, H.	2014	Difenoconazole - Effects on the Development of Sediment-Dwelling Larvae of <i>Chironomus riparius</i> in Water-Sediment Systems with Spiked Sediment Harlan Laboratories Ltd, Zelgliweg 1, 4452 Itingen, Switzerland Report Number D81747. Syngenta File No. CGA169374_10839 GLP Unpublished	N	Y (dependent on data protection already claimed by Syngenta)	Globachem N.V. has access to this study via a letter of access from Syngenta.	Syngenta*
KCP 10.3.1.1.1- 10.3.1.1.2	Franke, M.	2020	Acute toxicity of GLOB1911F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BAA 0011 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.1.1/02 10.3.1.1.2/02	Amsel, K.	2020	Acute toxicity of GLOB1911F to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BBA 0010 GLP	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.3.1.2/01	Dreßler, K.	2020	Chronic toxicity of GLOB1911F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BAC 0003 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.2/02	Schmidt, K.	2020	GLOB1911F - Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 BLC 0004 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2/01	Röhlig, U.	2020a	Effects of GLOB1911F on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in an extended laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 NTE 0001 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2/02	Röhlig, U.	2020b	Effects of GLOB1911F on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) in an extended laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 NAE 0001 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2/03	Röhlig, U.	2020c	Effects of GLOB1911F on the carabid beetle <i>Poecilus cupreus</i> L. in an extended laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 NLE 0001 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2/04	Röhlig, U.	2020d	Effects of GLOB1911F on the green lacewing <i>Chrysoperla carnea</i> STEPH. in an extended laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 NCE 0001 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2/05	Röhlig, U.	2020e	Effects of GLOB1911F on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in an extended laboratory test (under semi-field conditions aged residues) BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 NTR 0003 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 8.4.1-01 (summarized in KCP 10.4.1.1)	Sacker, D.	2009a	The effect of difenoconazole technical on the reproduction of <i>Eisenia fetida</i> . Chemex Environmental International Limited report ENV8407/070803 GLP Unpublished.	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCA 8.4.1-02 (summarized)	Sacker, D.	2009b	The effect of CGA205375 (difenoconazole metabolite 2) on the reproduction of <i>Eisenia fetida</i> .	N	N	Study report already submitted to PL to support the authorisation of DIFCOR	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
in 10.4.1.1)			Chemex Environmental International Limited report ENV8401/050824 GLP Unpublished.			250 EC (R-612/2015)	
KCP 10.4.1.1/01	Friedrich., S.	2020a	Effects of GLOB1911F on the reproduction of the earthworm <i>Eisenia Andrei</i> in artificial soil BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 TEC 0012 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.1.1/02	Servajean, E.	2009	Earthworm reproduction test with Difenconazole 250 g/L EC (OECD 222, April 2004). Phytosafe report 09-99-048-ES GLP Unpublished	N	N	Study report already submitted to PL to support the authorisation of DIFCOR 250 EC (R-612/2015)	Globachem NV
KCP 10.4.1.2	Schulz, L.	2015	Effects of Difenconazole 250 g/L EC on earthworms under field conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 14 10 48 007 F GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2/01	Schulz, L.	2020a	Effects of GLOB1911F on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 THC 0009 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2/02	Friedrich., S.	2020b	Effects of GLOB1911F on the reproduction of the	N	Y	Data/study report never submitted be-	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			collembolan <i>Folsomia candida</i> BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 TCC 0011 GLP Unpublished			fore to PL.	
KCP 10.5	Schulz, L.	2020b	Effects of GLOB1911F on the activity of soil microflora (Nitrogen transformation test) BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 48 SMN 0005 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.6.2/01	Kästner K.,	2020a	Effect of GLOB1911F on seedling emergence and seedling growth of six non-target terrestrial plant species under greenhouse conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 46 PSE 0002 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.6.2/02	Kästner K.,	2020b	Effect of GLOB1911F on vegetative vigour of six non-target terrestrial plant species under greenhouse conditions BioChem agrar, Labor für biologische und chemische Analytik GmbH Report number 20 46 PVV 0002 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV

*Globachem N.V. has a Letter of Access to this study from Syngenta.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.4.1-6.4.3	xxxxxx	1989	Metabolism of triazole and phenyl-14C-CGA-169374 in laying hens dosed daily for fourteen consecutive days. ABR-89051 (plus Amendment 1), SAM No. 0270 xxxxxxx GLP Unpublished	Y	N	/ (out of data protection)	/ (out of data protection)
KCA 6.4.1-6.4.3	xxxxxx	1990	[14C]-CGA-169374 phenyl and triazole label distribution, elimination, and metabolism in Hens. ABR-89101 (plus Amendment 1), SAM No. 0364 xxxxxxx GLP Unpublished	Y	N	/ (out of data protection)	/ (out of data protection)
KCA 6.4.1-6.4.3	xxxxxx	2000	Residue of difenoconazole (CGA 169374) and its metabolite CGA 205375 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of difenoconazole at three dose levels. 202/99, SAM No. 2039 xxxxxxx GLP Unpublished	Y	N	/ (out of data protection)	/ (out of data protection)
KCA 6.6.2	Heyer R.	1995a	Determination of difenoconazole and triazolylalanine in field soil and rotational crop (carrot); 488002, SAM No. 1215 RCC Umweltchemie GmbH, D-64380 Rossdorf, Germany GLP Unpublished	Y	N	/ (out of data protection)	/ (out of data protection)
KCA 6.6.2	Heyer, R	1995b	Determination of difenoconazole and triazolylalanine in field soil and rotational crop (spinach); 488001, SAM No. 1216 RCC Umweltchemie GmbH, D-64380 Rossdorf, Germany GLP Unpublished	Y	N	/ (out of data protection)	/ (out of data protection)

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner