

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GLOB1911F

Product name: **CURRANDO/ SUBIGON/ COLLECTOR**

Chemical active substance(s):

Difenoconazole, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: August 2020

MS Finalisation date: May 2021

Revision date: October 2021

Version history

When	What
August 2020	Version submitted by the applicant
May 2021	Version evaluated by zRMS
October 2021	Version revised to take into account comments of MSs

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for a new product GLOB1911F, containing 500 g/L of Difenoconazole, and formulated as a suspension concentrate (SC). Three trade names are proposed depending on the distributor and are Currando, Subigon and Collector. 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. GLOB1911F was not the representative formulation during the EU Review of the active substance.

Poland is the zRMS of GLOB1911F for the Central zone and Czech Republic, Belgium, Germany and the Netherlands are the cMS.

The data on Difenoconazole are out of data protection at the EU level.

Technical equivalence data of the intended sources of the active ingredient are owned by Globachem and are available. The intended sources are already approved in the EU, the evaluation reports can be found on CIRCA.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applica- ble)
Central zone	Poland, CURRANDO/ SUBIGON/ COLLECTOR	Belgium, CURRANDO/ SUBIGON/ COLLECTOR Czech Republic, CURRANDO/ SUBIGON/ COLLECTOR Germany, CURRANDO/ SUBIGON/ COLLECTOR The Netherlands, CURRANDO/ SUBIGON/ COLLECTOR

0.1.3 Regulatory history of the active Difenoconazole

Table 0.1-2: Summary of regulatory history of CAS No: 119446-68-3

Status	
Approved in EU	Y
Original Inclusion Directive	Commission Implementing Regulation (EU) No 540/2011

Status	
RMS	ES + UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2013
Current expiration of approval	31.12.2020 31.12.2021
Low risk substance or Candidate for Substitution?	CfS

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

In this overall assessment Member States must pay particular attention to the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate.

The SANCO report for Difenconazole (SANCO/830/08 – 10/03/2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 17/12/2010.

Table 0.1-3: Information on minimum purity of Difenconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
940 g/kg	Two different sources for Difenconazole are considered in this dossier both with min. purity : 960 g/kg Equivalence report available: Y RMS: Spain and Germany

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

Endpoint	Difenconazole	
	EU agreed endpoint from EFSA Journal 2011;9(1):1967	Endpoint used*
Purity of active substance	94%	96% (Globachem NV)

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

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

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

zRMS to insert overall summary of the assessment focusing on the main conclusions only, including a grouping of safe uses, non-safe uses and uses for which the safety could only be established following additional risk mitigation at a national (non-core) level or the safety is to be confirmed by cMS.

Section 1, 2 and 4. Identity, physical and chemical properties and further information

Two-year shelf life is accepted for the PPP.

Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy

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. (ALTESP)	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 as well as requested use on spring oilseed rape. For the above-requested uses, the number of trials included by the applicant is insufficient for their registration in the context of EPPO standard PP 1/226(2).

Section 5. Analytical methods

The analytical method used for analysing active substance and toluene in the plant protection product meets the SANCO/3030/99 rev. 5.

Section 6. Mammalian Toxicology

Regarding health hazards and risks the formulation is accepted for all intended use.

Section 7. Metabolism and Residues

The intended GAP is accepted. The respective analytical methods for residues determination are available. An exceedance of the currently adopted MRLs is not expected. The estimated consumer exposure is not a public health concern.

Section 8. Fate and behaviour.

In accordance with proposed pattern use, an exposure assessment for the formulation of GLOB1911F was submitted.

The mitigation measures were proposed, and final decision will be made in ecotoxicological section.

Section 9. Ecotoxicology.

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of GLOB1911F as a fungicide on: potatoes, sugar and fodder beets, winter and spring oilseed rapes poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. To protect the aquatic organisms. the mitigation measures were considered.

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

Uses 1- 6

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

None

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

Uses 1- 6

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

All uses/ GAPs are covered by established MRLs except for use in **crop**. An application for amending the MRL has been submitted by **MS** to EFSA **EFSA Project Number** (if applicable).

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

Appendix 1 ALL intended uses

PPP (product name/code):	Currando/ Subigon/ Collector/ GLOB1911F	Formulation type:	SC
Active substance 1:	Difenoconazole	Conc. of as 1:	500 g/L
Active substance 2:	/	Conc. of as 2:	/
Active substance 3:	/	Conc. of as 3:	/
Safener:	/	Conc. of safener:	/
Synergist:	/	Conc. of synergist:	/
Applicant:	Globachem NV	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central	Non professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp 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 safener/ synergist per ha, other dose rate expression, dose range (min- max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product / 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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Potatoes SOLTU <i>Solanum tu- berosum</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		
4	CZ, BE, DE, NL	Potatoes SOLTU <i>Solanum tu- berosum</i>	F	<i>Alternaria</i> sp. (ALTESP)	Normal downward spraying	BBCH 40-99	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	100-400	14		
5	CZ, BE, NL	Sugar beet/ fodder beet BEAVA <i>Beta vulgaris</i>	F	Rust (UROMBE), <i>Ramularia beticola</i> (RAMUBE), powdery mildew (ERYSBE), <i>Cercospora beticola</i> (CERCBE)	Normal downward spraying	After BBCH 31 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		
6	DE	Sugar beet/ fodder beet BEAVA <i>Beta vulgaris</i>	F	Rust (UROMBE), <i>Ramularia beticola</i> (RAMUBE), powdery mildew (ERYSBE), <i>Cercospora beticola</i> (CERCBE)	Normal downward spraying	After BBCH 31 till 49	A) 1-2 B) 1-2	14	A) 0.200-0.250 L/ha B) 0.400-0.500 L/ha	A) 0.100-0.125 kg as/ha b) 0.200-0.250 kg as/ha	100-400	21		
7	CZ, BE, DE	Winter oilseed rape BRSNW <i>Brassica napus</i>	F	<i>Phoma lingam</i> (LEPTMA), <i>Alternaria brassicae</i> (ALTEBA), <i>Sclerotinia sclerotiorum</i> (SCLESC), <i>Erysiphe cruciferarum</i> (ERYSCR) <i>Pyrenopeziza brassicae</i> (PYRPBR)	Normal downward spraying	BBCH 19-69	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	56	Max. 1 application in autumn	

8	NL	Winter oilseed rape BRSNW <i>Brassica napus</i>	F	<i>Phoma lingam</i> (LEPTMA), <i>Alternaria brassicae</i> (ALTEBA), <i>Sclerotinia sclerotiorum</i> (SCLESC), <i>Erysiphe cruciferarum</i> (ERYSCR) <i>Pyrenopeziza brassicae</i> (PYRPBR)	Normal downward spraying	BBCH 19-69	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	56	Application timing according to NL-specific conditions	
9	CZ, BE, DE, NL	Spring oilseed rape BRSNS <i>Brassica napus spring</i>	F	<i>Phoma lingam</i> (LEPTMA), <i>Alternaria brassicae</i> (ALTEBA), <i>Sclerotinia sclerotiorum</i> (SCLESC), <i>Erysiphe cruciferarum</i> (ERYSCR) <i>Pyrenopeziza brassicae</i> (PYRPBR)	Normal downward spraying	BBCH 19-69	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	56	Max. 1 application before BBCH 21	

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

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

Column 15: zRMS conclusion.

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

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/m³ 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