REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GLOB182F

Product name(s): SURRENDER

Chemical active substance:

Fludioxonil, 100 g/L

Interzonal

Zonal Rapporteur Member State: PL

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: January 2021

MS Finalisation date: October 2021(initial assessment)

March 2022 (final Core Assessment)

Version history

When	What
January 2021	Initial dRR - Globachem NV.
August 2021	Dossier update by the applicant: corrected water volume for the seed treatment, and separate dose rate established for sunflower in Germany, due to different seed planting rate (DE was removed from the use no 4, the use no 6 was added for DE alone).
October 2021	Initial izRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the izRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
March 2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the izRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

Table of Contents

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 named GLOB182F, containing 100 g/L Fludioxonil, and formulated as a flowable concentrate for seed treatment (FS). This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. GLOB182F was not the representative formulation during the EU Review of the active substances.

Poland is the zRMS of GLOB182F for all zones as it concerns a seed treatment product. In this case, the EU is considered to be a single zone where one single Member State can evaluate the PPP on behalf of the entire EU. The cMS are Austria, France, Germany, Hungary, Italy, Latvia, Romania, Slovenia and Spain.

The data on Fludioxonil are out of data protection at the EU level. The Specification and 5 batch analysis data are owned by Globachem. The source is already approved in the EU, the evaluation report can be found on CIRCA.
With regard to the Annex III data, all necessary data is owned by the company Globachem NV itself.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	Not applicable	Not applicable
Central zone	Not applicable	Not applicable
Southern zone	Not applicable	Not applicable
Inter-zonal	zRMS: Poland Product code: GLOB182F Product name: Surrender Authorization number: /	cMS: Austria, France, Germany, Hungary, Italy, Latvia, Romania, Slovenia, Spain Product code: GLOB182F Product name: Surrender Authorization number: /

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 131341-86-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	FR ES
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2008
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.04.2009
Date of final Commission (re-registration) deadline (Step 2)	31.10.2012
Current expiration of approval	31.10.~~2018~~ 2022
Low risk substance or Candidate for Substitution?	CfS

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

On the basis of the proposed uses and the supported uses (as listed in Appendix II), for uses other than seed treatment, Member States, in the framework of any authorisations to be granted, varied or withdrawn, must pay particular attention to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA339833 and CGA192155, in vulnerable zones and must pay particular attention to the protection of fish and aquatic invertebrates. Conditions of authorisation should include risk mitigation measures, where appropriate.

The SANCO report for Fludioxonil (SANCO/2818/07 – 10/09/2007) 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 17/08/2007.

Table 0.1-3: Information on minimum purity of Fludioxonil

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
95%	98% Equivalence report available: Y RMS: Czech Republic and Germany

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

Endpoint	Active Substance	
	EU agreed endpoint from EFSA Scientific Report 2007;110:1-85	Endpoint used
Purity of active substance	95%	98% (Globachem NV)

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

For the overview of accepted uses see the Complete GAP table in Appendix 1 of this document.
For detailed information see the GAP tables in the individual relevant sections.

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

See column 17 of the Complete GAP table presented in Appendix 1 of this document.

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

See column 17 of the Complete GAP table presented in Appendix 1 of this document.

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:

See column 17 of the Complete GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 2, date: 2022-03

PPP (product name/code):	GLOB182F	Formulation type:	Flowable concentrate for seed treatment (FS)
Active substance:	Fludioxonil	Conc. of as:	100 g/L
Safener:	/	Conc. of safener:	/
Synergist:	/	Conc. of synergist:	/
Applicant:	Globachem NV	Professional use:	☒
Zone(s):	Interzonal	Non professional use:	☐
Verified by MS:	~~No~~ Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17							
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: developmental stages of the pest or pest group)	**Application**				**Application rate**					**PHI** (days)	**Remarks:** Min-Max. TGW (thousand grain weight, g/1000 seeds) Min-Max. Sowing density per ha (seeds/ha)	**Overall conclusion**							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L/ton seeds a) max. rate per appl. b) max. total rate per crop/season	Kg a.s./ton seeds a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Sowing rate (kg seeds/ha) min/ max	Water L/ton seeds min/ max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & bevaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy

Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																								
1	~~zRMS + all cMS*~~ PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	Maize (forage) (ZEAMX)	I (treatment seeds) F (sowing)	*Fusarium* sp. (FUSASP) Pythium sp. (PYTHSP)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	a) 1.2-2.375 b) 1.2-2.375	24-47.5	4-8L (incl. product)	N/A	TGW: 240-380 Sowing density: 100,000-125,000 12-23.75 mL product/ha	A	A	A	A	A	A	A	A FUSASP PL N PYTHSP FR, PL C both targets, other cMSs
2	~~zRMS + all cMS*~~ PL, LV, HU, RO, AT, SI, DE, FR, IT, ES	Maize (grain) (ZEAMX)	I (treatment seeds) F (sowing)	*Fusarium* sp. (FUSASP) Pythium sp. (PYTHSP)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	a) 0.96-1.71 b) 0.96-1.71	19.2-34.2	4-8L (incl. product)	N/A	TGW: 240-380 Sowing density: 80,000-90,000 9.6-17.1 mL product/ha	A	A	A	A	A	A	A	A FUSASP PL N PYTHSP FR, PL C both targets, other cMSs
3	~~zRMS + all cMS*~~ PL, LV, HU, RO,	Sweet corn (ZEAMS)	I (treatment seeds) F (sowing)	*Fusarium* sp. (FUSASP) Pythium sp. (PYTHSP)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 0.050 b) 0.050	a) 0.2925-0.825 b) 0.2925-0.825	5.9-16.5	4-8L (incl. product)	N/A	TGW: 90-220 Sowing density: 65,000-75,000	A	A	A	A	A	A	A	N sweet corn PL

	AT, SI, DE, FR, IT, ES														2.93-8.25 mL product/ha							C other cMSs
4	PL, AT, FR, IT, LV, ES	Sunflower (HELAN)	I (treatment seeds) F (sowing)	*Botrytis cinerea* (BOTRCI) *Fusarium* sp. (FUSASP) ~~Downy mildew~~ *Plasmopara halstedii* (PLASHA)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.5 b) 1.5	a) 0.150 b) 0.150	a) 0.525-1.6875 b) 0.525-1.6875	3.5-11.3	4-8L (incl. product)	N/A	TGW: 20-50 Sowing density: 175,000-225,000 5.25-16.88 mL product/ha	A	A	A	A	A	A	A	A
4 5 (at higher rate)	PL, AT, FR, IT, LV, ES, HU, RO, SI	Sunflower (HELAN)	I (treatment seeds) F (sowing)	*Botrytis cinerea* (BOTRCI) *Fusarium* sp. (FUSASP) ~~Downy mildew~~ *Plasmopara halstedii* (PLASHA)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.5 b) 1.5	a) 0.150 b) 0.150	a) 0.525-1.6875 b) 0.525-1.6875	3.5-11.3	4-8L (incl. product)	N/A	TGW: 20-50 Sowing density: 175,000-225,000 5.25-16.88 mL product/ha	A	A	A	A	A	C Birds A Other species	A	A C PLASHA HU
5 (at lower rate)	HU, RO, SI	Sunflower (HELAN)	I (treatment seeds) F (sowing)	*Botrytis cinerea* (BOTRCI) *Fusarium* sp. (FUSASP) ~~Downy mildew~~ *Plasmopara halstedii* (PLASHA)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.25~~-1.5~~ b) 1.25~~-1.5~~	a) 0.125~~-0.150~~ b) 0.125~~-0.150~~	a) 0.4375~~-1.6875~~ b) 0.4375~~-1.6875~~	3.5-11.3	4-8L (incl. product)	N/A	TGW: 20-50 Sowing density: 175,000-225,000 4.375-16.88 mL product/ha Higher application rate excluded due to unacceptable risk to birds	A	A	A	A	A	A	A	A C PLASHA HU

6	DE	Sunflower (HELAN)	I (treatment seeds) F (sowing)	*Botrytis cinerea* (BOTRCI) *Fusarium* sp. (FUSASP) ~~Downy mildew~~ *Plasmopara halstedii* (PLASHA)	Seed treatment	BBCH 00	a) 1 b) 1	/	a) 1.5 b) 1.5	a) 0.150 b) 0.150	a) 1.15 b) 1.15	4.5- 7.7	4-8L (incl. product)	N/A	TGW: 60-90 Sowing density: 75,000-85,000 seeds/ha 6.75-11.48 mL product/ha	A	A	A	A	A	C Birds A Other species	A	A

*zRMS: Poland
cMS: Austria, France, Germany, Hungary, Italy, Latvia, Romania, Slovenia, Spain

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).
14 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
15 PHI - minimum pre-harvest interval
16 Remarks may include: Extent of use/economic importance/restrictions
17 Overall conclusion - explanation for the column 17 is below ***

***** Explanation for column 17 "Overall conclusion"**

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible