

REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB182F

Product name(s): SURRENDER

Chemical active substance:

Fludioxonil, 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(Authorization)

Applicant: Globachem NV

Submission date: January 2021

MS Finalisation date: October 2021(initial National 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.
October 2021	Initial izRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern is struck through and shaded.
March 2022	Final report (National 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.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Globachem N.V. in January 2021.

The application was for GLOB182F, a FS formulation containing 100 g/L Fludioxonil for use as a seed treatment with fungicidal activity in maize seeds at a dose rate of 0.5 L/ton seeds and sunflower seeds at a dose rate of 1.5 L/ton seeds.

1.2 Letters of Access

The Annex III dossier for GLOB182F contains no letters of access.

1.3 Justification for submission of tests and studies

As GLOB182F was not the lead formulation during the Annex I inclusion of Fludioxonil, it is not possible to refer to the DAR and the EFSA conclusion on Fludioxonil with regard to the formulation studies. Therefore, studies on the plant protection product GLOB182F had to be generated for authorisation purposes in all zones.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	GLOB182F
Product name in MS	SURRENDER
Authorization number	-
Function	fungicide
Applicant	Globachem N.V.
Active substance(s) (incl. content)	Fludioxonil; 100 g/L
Formulation type	Flowable concentrate for seed treatment [Code: FS]
Packaging	1 – 5 – 10 – 15 – 20 – 200 – 1000 L HDPE, HDPE/PA, HDPE/F, HDPE/EVOH containers
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

Based on performed evaluation, authorisation of GLOB182F/Surrender in Poland can be granted **only** for **both intended** uses in maize **and sunflower**. ~~For uses in sunflower at 1.5 L/ton seeds further data enabling refinement of the long-term risk to birds is deemed necessary.~~

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 as amended:

Hazard class(es), categories:	Eye Damage 1, H318 Skin Sens.1A, H317 Aquatic Chronic 1, H410 Aquatic Chronic 2, H411
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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:	GHS05, GHS07, GHS09
Signal word:	Warning Danger
Hazard statement(s):	H317, H318, H410 H411
Precautionary statement(s):	P261, P280, P302+352, P305+P351+P338, P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
Hazard determining components for labelling of toxicological properties ¹⁾ :	2-methyl-2H-isothiazol-3-one; 1,2-benzisothiazol-3(2H)-one;

See Part C for justifications of the classification and labelling proposals.

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).
SPe5	To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
SPe6	To protect birds/wild mammals remove spillages.
	For professional uses. If accompanied by a leaflet: Read accompanying instructions before use.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

In accordance with directives 92/85/EEC and 94/33/EC as amended, work with this plant protection product is forbidden to pregnant workers, workers who are breastfeeding and young people.

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:	
	<p>PPE:</p> <p>Protective clothing and protective gloves against liquid chemicals - relating to classification (<i>H318</i>, <i>H317</i>), and to the exposure estimate for the concentrated product.</p> <p>Personal eye-protection (chemical goggles or face shield) during mixing/loading and handling the contaminated surfaces - relating to classification (<i>H318</i>, <i>H317</i>). Personal eye-protection need not be used during the bagging process.</p>
Worker protection:	
	<p>PPE:</p> <p>Protective clothing and protective gloves during handling of treated seeds - relating to classification (<i>H317</i>).</p>
Integrated pest management (IPM)/sustainable use:	
	/
Environmental protection	
P391	Collect spillage.
P501	Dispose of contents/container in accordance with local/regional/national regulation.
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).
SPe5 (phrase required on package of treated seeds)	To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
SPe6 (phrase required on package of treated seeds)	To protect birds/wild mammals remove spillages.
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. 2.0, date:
2022-03

PPP (product name/code):
GLOB182F

Formulation type: Flowable concentrate
for seed treatment
(FS)

Active substance 1: Fludioxonil
Safener: /
Synergist: /
Applicant: Globachem NV
Zone(s): Interzonal
Verified by MS: Yes
Field of use: Fungicide

Conc. of as 1: 100 g/L
Conc. of safener: /
Conc. of synergist: /
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17						
Use No. (e)	Mem ber state (s)	Crop and/ or situation (crop destination / purpose of crop)	F Fn Fn G Gn Gp n or I	Pests or Group of pests controlled (additionally : development al 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. inter val betw een appli cations (days)	L/ton seeds a) max. rate per appl. b) max. total rate per crop/se ason	Kg a.s./ton seeds a) max. rate per appl. b) max. total rate per crop/seaso n	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 & beaviour	Ecotoxicology	Relevance of metabolites in groundwater

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	PL	Maize (forage) (ZEAMX)	I (treatment seeds) F (sowing)	<i>Fusarium</i> 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 N PYTHSP	
2	PL	Maize (grain) (ZEAMX)	I (treatment seeds) F (sowing)	<i>Fusarium</i> 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 N PYTHSP	
3	PL	Sweet corn (ZEAMS)	I (treatment seeds) F (sowing)	<i>Fusarium</i> 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 2.93-8.25 mL product/ha	A	A	A	A	A	A	A	A	N	
4	PL	Sunflower (HELAX)	I (treatment seeds) F (sowing)	<i>Botrytis cinerea</i> (BOTRCI) Downy mildew (PLASHA) <i>Fusarium</i> sp. (FUSASP)	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 Birds	A	A	A	A Other species

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	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.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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

3 Background of authorization decision and risk management

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

The product GLOB182F is a flowable concentrate for seed treatment. 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 uniform bright red liquid, with a sweet solvent like odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of more than 400 °C. In aqueous solution, it has a pH value around 6.58 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 stored in HDPE bottles, neither the active ingredient content nor the technical properties were changed. The two years storage stability study is ongoing and should be available in July 2022. The packaging claimed in the section 4 (HDPE, f-HDPE, HDPE/PA or HDPE/EVOH) is acceptable as a storage stability study at elevated temperature during 14 days was carried out in the HDPE material and can be extrapolated. Its technical characteristics are acceptable for a flowable concentrate formulation.

The intended concentration of use is 6.25-37.5% (0.5-1.5L product in 4-8L water).

No tank mixes are required for GLOB182F.

3.2 Efficacy (Part B, Section 3)

The product GLOB182F contains 100 g/L fludioxonil, a well-known active registered in many EU countries and used as both a seed treatment product and as a fungicide in foliar sprays in a myriad of crops. In most EU countries, one or more products based on fludioxonil are approved.

This registration report is based on 50 efficacy trials carried out on maize (23 trials) and sunflower (27 trials) between 2018 and 2020 to assess the biological performance and safety of GLOB182F. The trials were carried out across the Maritime, North-East and South-East and Southern EPPO Zones (9 performed in the Maritime zone, 10 in the North-East, 10 in the South-East and 21 in the Mediterranean EPPO Zone, in Italy and in Spain. Twenty three trials were performed as greenhouse experiments. Out of the remaining 27 field trials 7 were carried out in the Maritime zone, 1 – in the North-East zone, 9 – in the South-East zone and 10 trials – in the Mediterranean zone. Contractors responsible for carrying out the trials were authorized by relevant local authorities and in possession of GEP certificates.

3.3 Efficacy data

Fludioxonil has been widely and successfully used in plant protection practice in many European countries and beyond on a wide variety of crops. The properties of the active substance are well-known and practically tested. Providing preliminary range-finding tests is not regarded essential for this submission.

In the first part of the BAD it is demonstrated that a dose rate of 0.5 L/ton of GLOB182F is required for maize and provides a much higher efficacy compared to lower dose rates. In the case of sunflower, it is demonstrated that a minimum dose rate of 1.50 L/ton is required to reach a good efficacy and provides a much higher efficacy compared to the lower dose rate. However, in countries of the South-East EPPO zone, a range of 1.25 – 1.50 L/ton seeds can be sufficient in less severe and challenging situations.

The other parts of the efficacy section demonstrate the efficacy of GLOB182F against fungal pathogens on seeds of maize and sunflower, which is on average comparable to that of the reference products. Furthermore, no negative effect on the quality parameters caused by GLOB182F or the reference product were observed.

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

The combined risk of resistance development can be concluded low for the use in maize and medium for the use in sunflower. As no foliar uses of fludioxonil are registered for any of the two crops, the resistance management strategy seems presently unnecessary. However, in the case when foliar applications of the

same active are proposed in maize or sunflower in the future, the risk of resistance development should be reconsidered carefully, particularly with respect to sunflower, the host to the high-risk *Botrytis cinerea*.

3.3.2 Adverse effects on treated crops

In addition to the 50 efficacy trials, all of which assessed for phytotoxic effects and sometimes collected additional selectivity data (yield, germination), 18 selectivity trials were performed, 10 in maize and 8 in sunflower, where a higher dose rate of GLOB182F was tested. With one exception (See Part B3, 3.4.1 Adverse effects on treated crops), in none of the remaining selectivity trials performed with double the maximum requested dose rate or in the efficacy trials performed with the maximum requested dose rate any negative effects on plant growth were recorded. The data collected demonstrates that GLOB182F is safe for use on maize and sunflower. No negative impact on yield amount or yield quality was observed.

3.3.3 Observations on other undesirable or unintended side-effects

No unintended or undesirable side-effects were observed in any of the trials provided in this dossier. For the impact on succeeding and adjacent crops reference is made to the core dossier, Part B3.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for determination of Fludioxonil, impurities and relevance of CIPAC methods in GLOB182F were not evaluated as part of the EU review of Fludioxonil. Therefore, all relevant data are provided and are considered adequate. A HPLC-PDA method was submitted to analyse the active ingredient content in the formulation. The method was validated.

3.4.2 Analytical methods for residues

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

In EFSA Scientific Report (2007) 110, 1-85, Conclusion on the peer review of fludioxonil it is stated that *“Adequate analytical methods are available for the determination of fludioxonil residues in food of plant origin (grapes and wheat), soil, water, air. Recently submitted studies, regarding the validation of multi-residue method DFG S19 as the enforcement method for the determination of residues of fludioxonil in different plant matrices with LC-MS/MS detection and the independent laboratory validation of the DFG S19 method for the determination of residues of fludioxonil in plant matrices were summarised and accepted by the RMS in an addendum to the DAR (October 2006, B.5) and discussed in the PRAPeR 06 expert meeting.*

A confirmatory method for the determination of residues in soil by LC-MS/MS has also been evaluated by the RMS and discussed in the PRAPeR 06 expert meeting.

An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed. Analytical methods for the determination of residues in body fluids and tissues are not required.”

According to the EFSA Journal 2011;9(8):2335 the relevant residue for enforcement is proposed as parent fludioxonil. For risk assessment, the residue was defined as the sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil. Validated analytical methods for enforcement of the residue definition in foods of plant origin are available with a LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities. During the peer review under Directive 91/414/EEC, an analytical method using HPLC-UV, confirmed by the use of an alternative column in the HPLC system, and its ILV were evaluated and validated for the determination of the sum of fludioxonil and its metabolites that can be oxidised to metabolite CGA 19215513, expressed as fludioxonil, with a LOQ of 0.01 mg/kg in milk and meat and a LOQ of 0.05 mg/kg in liver, kidney, fat and eggs (FAO, 2004; Denmark, 2005). However, as the method is very

complex, involving a laborious extraction method, the development of a more efficient method is still desirable.

In EFSA Journal 2019;17(8):5812 it is stated that “*In the framework of the MRL review, a possible simplification of the enforcement residue definition for certain animal products (muscle, fat and liver) was discussed. EFSA noted that a livestock feeding study would be required where fludioxonil and metabolites containing the 2,2-difluorobenzo[1,3]dioxole-4 carboxylic moiety are reported separately (EFSA, 2011). Since the new feeding study used the common moiety method (see Section 2.3), the residue definitions for enforcement and risk assessment set during the MRL review are still valid.*

Comparing the residue definition recommended by EFSA in the MRL review with the residue definition for enforcement established in Regulation (EC) No 396/2005, EFSA noted an inaccuracy, which should be corrected when the MRL regulation is updated, following the current assessment:

- *Current residue definition established in Regulation (EC) No 396/2005 (applicable to animal products, except honey): sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluorobenzo[1,3]dioxole-4 carboxylic acid*
- *Residue definition recommended by EFSA (2011): sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil.”*

According to the current Regulation (EU) 2021/4098 1807 the residue definition for animal products, except honey is established as sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluorobenzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil.

Note:

The active substance fludioxonil were evaluated on EU level according to the old data requirements. Now not Commission Regulation (EU) 545/2011 but the Commission Regulation (EU) No 284/2013 is applicable. Therefore, general:

- an independent laboratory validation (ILV) for the method for the determination of residues of fludioxonil in drinking water is missing;
- an analytical method for the residues of fludioxonil in body fluids and tissues is required.

Conclusions:

1. The current values of MRL for eggs and fat for fludioxonil were decreased and equal 0.02 mg/kg for eggs and 0.01 mg/kg for fat (Reg. (EU) 2021/4098 1807). The LOQ of the analytical method AG-616B equals 0.05 mg/kg in eggs and fat, so this method is not appropriate for post-authorization control and monitoring purposes.

Additionally, since HPLC-UV method for the determination of fludioxonil in animal matrices uses a two column switching system, which is considered as not “commonly available”, it cannot be validated according to SANCO/825/00/rev.8.1.

Taking the above into account new method for the determination of residues of fludioxonil in animal matrices and ILV should be provided for the present product registration.

Applicants answer:

The applicant likes to mentioned that the dossier of Surrender was submitted well before the entrance into force of Reg. (EU) 2020/1633, amending the MRLs (25 May 2021). In consequence, the applicant should not be forced to comply with this regulation. Additionally, residues in commodities of animal origin after the use of Surrender are not expected (residue trials for the intended uses show a no residue situation and the dietary burden calculations are well below the trigger of 0.004 mg/kg bw/d) and, in any case, a new analytical method for monitoring compliant with the new MRLs is already available to the authorities so they would be capable to analyse Fludioxonil residues in this matrices.

However, the applicant acknowledges this issue and has already contacted several laboratories capable to match the available study. however not all necessary information on the extraction procedures is available (volumes and concentrations of reagents), which is the most important part of the methodology in order to mimic the metabolism data to prove extractability of the analytes, and therefore significant method development work would be required to make sure the method is fit for purpose before the validation can commence. It is also worth noting that, the new method validation guideline that came into

force earlier this year (SANTE/2020/12830, Rev.1 Feb 2021) prohibits the use of dichloromethane in new studies and therefore a new extract purification step will also be required.

The applicant is therefore open to submit a new analytical method and ILV for commodities from animal origin, but request to be able to do it as a post-registration requirement.

zRMS-PL agrees with the Applicant's proposal: new method for the determination of residues of fludioxonil in animal matrices and ILV should be provided for the present product registration - post registration requirement.

It should be noted that the final report of the new validation method is available and ILV for determination of residues in animal matrices is currently ongoing.

2. zRMS considers that the data requirement for

- ILV for the method for the determination of residues of fludioxonil in high water content matrices,
 - complete demonstrations of the extraction efficiencies,
 - an ILV of the method of determination of fludioxonil in drinking water,
 - a method for determination of fludioxonil in body fluids and tissues
- should be provided at the renewal of the active substance.

It should be noted that the report of the primary and confirmatory method for drinking and surface water (the same method is used for both matrices) is expected by the end of May/mid-June 2022. The ILV will start soon after.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

The toxicological classification of GLOB182F was based on theoretical calculations according to Regulation (EC) 1272/2008 as amended. Based on the classification of the co-formulants, GLOB182F is classified as Eye Dam. 1, H318; Skin Sens. 1A, H317.

3.5.2 Operator exposure

Operator exposure to GLOB182F was not evaluated as part of the EU review of Fludioxonil. Therefore all relevant data and risk assessments are provided here and are considered adequate.

Operator exposure was assessed against the AOEL agreed in the EU review (0.59 mg/kg bw/d). The default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) were used for the concentrate as well as for the dilution (1:8). Operator exposure was modelled using the SeedTROPEX model.

Operator exposure was also modelled using the SeedTROPEX model (75th values) for seed treatment and loading and sowing of treated seeds.

The French SeedTROPEX model for seed treatment activities was derived from the original SeedTROPEX database, but adopted the following changes, which were in line with the comments from the Methodology group of the Advisory Committee on Pesticides of the French Ministry of Agriculture.

In the French SeedTROPEX model for seed treatment four different scenarios regarding personal protective equipment (PPE) are considered. In "Scenario 1" no protection is worn during any of the seed treatment activities. "Scenario 2" considers gloves worn during all phases except bagging. For "Scenario 3" gloves are worn during all phases except bagging and respiratory protection worn (level P2 minimum) during the cleaning phase. In "Scenario 4" gloves and non-woven clothing is considered during all phases except gloves during bagging and respiratory protection (level P2 minimum) during the cleaning and bagging phases. A body weight of 70 kg and 60 kg is taken into account.

According to the French Advisory Council on Pesticides for evaluation the 75th percentile of the SeedTROPEX database will be used. The 75th percentile of the exposure data will be compared to the AOEL; this ratio will be used as criterion for a decision of acceptability of the risk.

Calculations for industrial seed treatment according to the Seed-TROPEX model predict acceptable levels of exposure to fludioxonil for operators wearing a long-sleeved work jacket and long trousers. The degree of protection defined is considered to be appropriate for operators working with on-farm treatment equipment

~~According to the model calculations, it is concluded that the risk for the operator using GLOB182F at 0.5/ton seeds for maize seed treatment is acceptable provided the appropriate PPE/risk mitigation measures are applied.~~

Based on the calculation of operator exposure with the SeedTROPEX model (geometric mean values), it is concluded that the risk for the operator using GLOB182F on maize and sunflower is acceptable without PPE, when loading and sowing seeds treated with 0.5 or 1.5 L GLOB182F/ton.

Based on the calculation of operator exposure with the French SeedTROPEX model (75th percentile), it is concluded that the risk for the operator using GLOB182F on sunflower, at up to 1.5 L/ton, and maize, at up to 0.5 L/ton, is acceptable without the use of PPE normal workwear (Long-sleeved jacket and long trousers as usual work wear) for the undiluted product and the dilution, when loading and sowing seeds treated with GLOB182F.

3.5.3 Worker exposure

Worker exposure to GLOB182F was not evaluated as part of the EU review of Fludioxonil. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Worker exposure was assessed against the AOEL agreed in the EU review (0.59 mg/kg bw/d). The default dermal absorption values defined in the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) were used for the concentrate as well as for the spray dilution. Worker exposure was modelled using the SeedTROPEX model.

Based on the calculation of worker exposure with the SeedTROPEX model, it is concluded that there is no unacceptable risk anticipated for workers wearing adequate work clothing (but no PPE) when loading and sowing seeds treated with 0.5 L GLOB182F/ton. But specific PPEs (see point 2.5.1) are necessary with respect to classification PPP.

3.5.4 Bystander and resident exposure

Bystander exposure to GLOB182F was not evaluated as part of the EU review of Fludioxonil. However, a product based on Fludioxonil (Celest 025 FS) was one of the lead formulations during the EU review of Fludioxonil. In this review, the bystander exposure to Fludioxonil in a seed treatment product was evaluated. It was concluded that bystander exposure in stationary seed treatment facilities was rare. If an incidental presence of bystanders would occur at a seed treatment facility, it is assumed to be a short duration of exposure and normally lower than that of seed treatment operators who are occupationally exposed longer. Therefore, it was assumed that there would be no risk to persons being incidentally exposed during seed treatment operations with a seed treatment product containing Fludioxonil. As GLOB182F is a seed treatment formulation also containing Fludioxonil, the same conclusions are applicable to Fludioxonil 100 FS.

As GLOB182F is a product for seed treatment and treatment of seeds occurs indoor in stationary seed treatment facilities, there is no risk for exposure of residents living in close vicinity of seed treatment facilities.

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

3.6.1 Residues

Maize and sunflower are the major crops in northern Europe (SANTE/2019/12752). Seed treatments in general lead to lower residues in the harvested crops and often residues are below the LOQ.

According to the SANTE/2019/12752 when a non-systemic active substance is applied to seeds, no quantifiable residues are expected in plants or plant products (zero residue situation). In case of zero residue situation for seed treatments 3 residue trials are required for major crops.

In accordance with SANTE/2019/12752 for seed treatments 3 residue trials on immature maize can be extrapolated to sweet corn (minor crop, <LOQ situation). Therefore the immature maize data cover the use on sweet corn.

No new data were submitted in the framework of this application by the Applicant.

Applicant makes reference to existing data that had supported the registration of a seed treatment PPPs (Fludioxonil 025 FS and Maxim ML 035 FS) containing fludioxonil.

Information submitted by the Applicant is sufficient and zRMS-Poland agrees with conclusions presented in point 7.2.3.1:

„Residue trials in sweet corn, maize and rape seed (extrapolation to sunflower seeds possible according to SANTE/2019/12752) for seed dressing with Fludioxonil in Northern and Southern EU countries were evaluated and accepted during the EU review of the maximum residue levels (MRLs) for Fludioxonil according to Article 12 of regulation (EC) No 396/2005. A suitable number of trails for both Northern and Southern EU according to the GAP were evaluated. Fludioxonil residues were always found to be below 0.02 mg/kg. A summary of the data evaluated during the EU review of the maximum residue levels (MRLs) for Fludioxonil according to Article 12 of regulation (EC) No 396/2005 is provided in table 7.2-9 below. These trials can we referred for GLOB182F since they have been used to support the intended uses of the reference products (Fludioxonil 025 FS and Maxim ML 035 FS) in the zRMS and all CMs for more than 10 years and are therefore out of protection.”

Sufficient residue trials are available to support the intended uses for Surrender on seed treatment for sunflower, maize and sweet corn. According to the EFSA Journal 2011;9(8):2335 - „Review of the existing MRLs for fludioxonil”:

1. Maize grain:

Trials GAP: 10 x GAP compliant (5.0 g a.s./100 kg seed)

7 **10** x <0.02 mg/kg,

2. Sweet corn:

Trials GAP: 3 x GAP compliant (5.0 g a.s./100 kg seed)

3 x <0.02 mg/kg,

3. Sunflower seed (extrapolation from rape seed)

Trials GAP: 7 x GAP compliant (15.00 g a.s./100 kg seed)

7 x <0.02 mg/kg.

The studies on the magnitude of residues are valid with regard to storage stability.

In the EFSA Journal 2011;9(8):2335 it is concluded that oilseeds, cereals grains and sweet corn: *there is a lack of residues trials compliant with the LOQ for enforcement (0.01 mg/kg). However, residues resulting from the seed treatment are expected to be below this LOQ (supported by the metabolism studies). In these cases MRLs are set at 0.01* mg/kg.*

Available results show that the in force MRL on sunflower seed, maize and corn of 0.01* mg/kg (~~Reg. 2021/1098~~ **Reg. 2021/1807**) will not be exceeded.

Since fludioxonil was applied to oilseed rape, maize and sweet corn seeds before sowing, a PHI is not considered to be relevant.

3.6.2 Consumer exposure

Consumer risk assessment calculations were performed taking into account all the crops for which an MRL has been set for Fludioxonil under EU Regulation No. ~~2021/1098~~ **2021/1807**. Where the MRL for a particular crop is below the LOQ, calculations have been made with the LOQ for that crop.

Chronic exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo, rev.3.1). **A conversion factor of 2.8 was applied for root and tuber vegetables.**

Chronic intakes for all consumer groups are below the ADI. With the current EFSA model the highest chronic risk assessment was calculated for NL toddler with ~~52~~ 63% of ADI. For this diet, the highest contributor is apples potatoes with ~~15~~ 16% of ADI. Therefore the intended uses will not result in a consumer chronic exposure exceeding the ADI.

Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

The proposed uses of fludioxonil in the product GLOB182F / Surrender do not represent unacceptable chronic and acute risks for the consumer.

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

No new studies were presented; all data were reviewed in the EU review of fludioxonil. Appropriate endpoints from the EU review were used to calculate PECs for fludioxonil and the relevant metabolites in soil, surface water and groundwater for the intended use patterns. Risk to air was also evaluated based on the EU agreed data.

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

The PEC of GLOB182F and the active substance fludioxonil in soil have been assessed with the FOCUS model and the focus groundwater interception values and the DT₅₀ values established in the EU review. Based on the use of GLOB182F as a seed treatment in maize and sunflower, the maximum environmental concentration in soil (PECs) of fludioxonil will be 0.00882 mg/kg, covering all intended uses.

The results for PEC soil for Fludioxonil were used for the ecotoxicological risk assessment.

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

PEC groundwater calculations were provided for the intended use of GLOB182F as a seed treatment in maize and sunflower. The direct leaching into the groundwater of fludioxonil has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and the K_{oc} values established in the EU review. Due to PEC_{gw} <0.001 µg/L, FOCUS MACRO simulations were not required.

The results of the leaching models PEARL 4.4.4 and PELMO 5.5.3 show that when used according to the intended use in maize and sunflower in the EU, Fludioxonil is not expected to migrate to groundwater at unacceptable concentrations.

Based on these results, it is concluded that fludioxonil is not expected to exceed the threshold level in groundwater (0.1 µg/L) when GLOB182F is used at the intended GAP in the intended crops.

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

PEC surface water calculations were provided for the intended use of GLOB182F as a seed treatment in maize and sunflower. The PEC of fludioxonil and its relevant metabolites in surface water (PEC_{sw} and PEC_{sed}) have been assessed for the use of GLOB182F with the FOCUS SW models (STEP 1 to 2) and the DT₅₀ water/sediment values established in the EU review.

The results for PEC surface water for the active substance and its metabolite were used for the ecotoxicological risk assessment.

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

Studies on the fate and behaviour in air with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance fludioxonil.

The vapour pressure at 20 °C of the active substance fludioxonil is < 10⁻⁵ Pa. Hence the active substance

Fludioxonil is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance fludioxonil due to volatilization with subsequent deposition should not be considered. Due to DT₅₀ in the atmosphere <2 days it is not expected that fludioxonil would be a subject of the short- or long-ranger transport.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

Performed risk assessment demonstrated acceptable acute and long-term risk to birds from seeds and seedlings scenario following uses of GLOB182F as a seed treatment in maize and sunflower at application rates equivalent to 50 and 125 mg a.s./kg seeds, respectively.

For intended uses in sunflower at rate equivalent to 150 mg a.s./kg seeds acceptable acute risk could be concluded for seeds and seedling scenario and acceptable long-term risk for seedling scenario. However, the long-term TER for granivorous birds feeding on seeds was below the trigger of 5 indicating potentially unacceptable risk from this use. ~~No risk refinement options were available, since application to sunflower was not considered in the Applicants' calculations and further data needs to be provided in order to resolve the risk from the intended uses in sunflower at the higher rate.~~

During the commenting period the Applicant provided the LoA to the additional study on reproductive toxicity of fludioxonil to bobwhite quail performed by the authorisation holder (Syngenta) for purposes of the renewal process. The study has been already evaluated and agreed during the ongoing fludioxonil renewal process. Although the substance was not yet renewed, it is not expected that conclusions from evaluation of the study and the endpoints would change since they were not questioned during the peer-review or the expert meeting. For this reason the evaluator is of the opinion that re-evaluation of the study at the inter-zonal level is not necessary and the endpoint as agreed by the RMS at the EU level may be considered valid.

The new study was performed at higher doses of fludioxonil comparing to the study available during the first EU review (when the maximum dose of 62.8 mg a.s./kg bw/d was tested) and resulted with much higher endpoint for bobwhite quail (NOAEL of 384 mg a.s./kg bw/d, the maximum dose tested). This demonstrated that the initially agreed NOAEL of 62.8 mg a.s./kg bw/d is overconservative and that from the whole dataset the NOAEL of 126 mg a.s./kg bw/d derived for the mallard duck is currently the lowest and may be used to refine the risk for uses in sunflower at higher rate. Please note that based on the data available during the renewal process, the same endpoint has been agreed by the RMS for the risk assessment purposes, but due to slightly different approach in calculation of the dietary dose, the endpoint of 134 mg a.s./kg bw/d is reported in Vol. 3CA, B.9 (2019), where the detailed summary of the study may be found.

Due to the restrictions indicated in the LoA by the owner of the study, its results may be considered only in support of authorisation of GLOB182F in Poland, while use of these data in other Member States and countries is not possible without the prior consent of Syngenta. Taking this into account, the additional risk assessment performed with consideration of endpoint derived from this new study has been presented only in Part A relevant for Poland, while in the Part B. Section 9 respective reference has been made with indication that conclusions of presented below evaluation may be considered by the cMS only when the Applicant for GLOB182F presents respective Syngenta consent at the national level.

Additional risk assessment is presented in table below.

Intended use	Sunflower (large seeds)
Active substance	Fludioxonil
Nominal application rate (mg a.s./kg seed)	1 × 150 mg as/kg

Residues in seedlings (mg a.s./kg)		30 (based on NAR/5)				
Reprod. toxicity (mg/kg bw/d)		126				
TER criterion		5				
Crop scenario Growth stage	Indicator species	NAR¹ (mg a.s./kg)	FIR/bw	TWA	Short-cut value² = DDD (mg/kg bw/d)	TER_{It}
Large seeds	Large granivorous bird	150	0.1	1	15	8.4
Seedlings	Small omnivorous bird	30	0.5	0.53	7.95	15.8
	Large herbivorous bird	30	0.3	0.53	4.77	26.4

With the NOAEL of 126 mg a.s./kg bw/d, acceptable long-term risk may be concluded for birds from sunflower seeds treated with higher rate of GLOB182F and no further data or assessments are deemed necessary.

Calculations performed for uses in maize were not repeated with consideration of the higher NOAEL of 126 mg a.s./kg bw/d, since acceptable risk could be concluded already with the lower endpoint of 62.8 mg a.s./kg bw/d.

Overall, acceptable acute and long-term risk to birds may be concluded in both relevant scenarios (treated seeds and seedlings) from all intended uses of GLOB182F as a seed treatment in maize and sunflower.

The ratio of the effective application rate to the acute and long term toxicity endpoint is less than 3000 for fludioxonil. Therefore it is considered that 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.

Fludioxonil has a log P_{ow} value of 4.12. It was therefore necessary to consider the risk from secondary poisoning further. The risk assessments for earthworm and fish-eating birds and mammals show that there is no unacceptable long-term risk for these birds and mammals after exposure to GLOB182F when used according to the proposed GAP. Evaluation of the risk of secondary poisoning was not required for fludioxonil soil metabolites since in the regulatory studies they were formed only in presence of light while due to the type of application (seed treatment) photolysis will not play a major role in degradation of fludioxonil in soil. For this reason metabolites formed via photolysis in soil may not be taken into account in the risk assessment for the intended uses of GLOB182F. Nevertheless, due to potential migration of fludioxonil to surface water bodies and subsequent degradation, aquatic photolytic metabolites ((CGA339833, CGA344623 and A5) are considered relevant for the risk assessment together with metabolite CGA192155 formed in water/sediment studies. In the course of the EU review photolytic metabolites CGA344623 and A5 were considered to be minor metabolites since they were detected only in the sterile photolysis study and not in the water/sediment study performed under light conditions. Therefore, only photolytic aquatic metabolite CGA339833 should be taken into account in the evaluation. However, according to information available in the DAR (Vol. 3, B.8 of January 2005), log Pow values for CGA192155 and CGA339833 are <3, hence the evaluation of the risk of secondary poisoning was not triggered for these compounds.

Terrestrial vertebrates (other than birds)

The TER_a and TER_{It} values exceed the triggers of 10 and 5 for the acute and long-term risk assessment respectively, indicating that fludioxonil does not pose an acute and a long-term risk to wild birds and mammals after the use of GLOB182F according to the intended GAP.

The ratio of the effective application rate to the acute and long-term toxicity endpoint is less than 3000 for fludioxonil. Therefore, it is considered that there is low risk of acute/long term toxicity to mammals from the uptake of contaminated drinking water and no further assessment is required.

Fludioxonil has a log POW value of 4.12. It was therefore necessary to consider the risk from secondary poisoning further. The risk assessments for earthworm and fish-eating mammals show that there is no

unacceptable long-term risk for these mammals after exposure to GLOB182F when used according to the proposed GAP. As in case of birds, evaluation of the risk of secondary poisoning was either not triggered or not required for fludioxonil metabolites.

3.8.2 Effects on aquatic species

An acceptable acute and long-term risk to aquatic organisms was identified for the intended use of GLOB182F in sunflower and maize seeds. No risk mitigation measures are required.

3.8.3 Effects on bees

The hazard quotients after oral and contact exposures are below the trigger value of 50. According to SANCO/10329/2002 (final, 2002), it can therefore be concluded that the intended use of GLOB182F gives a low acute oral and contact risk to honey bees.

The chronic TER's for honey bee adults and larvae are higher than the respective trigger values defined by the EFSA guidance on bees (2013) indicating that the proposed use of GLOB182F as seed treatment on sunflower and maize poses an acceptable chronic risk to honey bee adults and larvae.

The acute TER's for bumblebees at screening step are higher than the respective trigger values defined by the EFSA guidance on bees (2013) indicating that the proposed use of GLOB182F as seed treatment poses an acceptable acute risk to bumblebees.

3.8.4 Effects on other arthropod species other than bees

The in-field and off-field HQ values for *A. rhopalosiphi*, *T. pyri*, *Aleochara bilineata* and *Poecilus cupreus* fall below the trigger values indicating that GLOB182F does not pose an unacceptable risk to non-target arthropods in in-field and off-field areas following application according to the proposed use patterns. No risk mitigation measures are deemed necessary for the off-crop habitats.

3.8.5 Effects on soil organisms

Earthworms

The long-term risk of GLOB182F to earthworms was assessed from long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for the active ingredient and the formulation, and the maximum soil PEC.

The chronic TER values for Fludioxonil and GLOB182F were greater than the Annex IV trigger of 5, indicating an acceptable risk to earthworms following application of GLOB182F for the proposed use.

Effects on other soil non-target macro-organisms

The long-term risk of GLOB182F to *Folsomia candida* and *Hypoaspis aculeifer* was assessed from long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for the formulation and the maximum soil PEC.

The chronic TER values for GLOB182F are greater than the Annex IV triggers of 5, indicating an acceptable risk to soil non-target macro-organisms following application of GLOB182F for the proposed use.

Effects on soil non-target micro-organisms

The risk of GLOB182F to soil micro-organisms was evaluated by comparison of concentrations resulting with effects <25%, derived from laboratory tests on fludioxonil, with the soil PECs for the relevant use. In a study performed with GLOB182F, this product had no significant effect on soil micro-organisms at up to 10 mg/kg in the soil nitrogen transformation study.

As the PEC_{soil} of fludioxonil and the formulation are all much lower than the concentration at which no significant effects are detected, it can be concluded that the risk of GLOB182F to soil micro-organisms is acceptable in accordance with the intended use.

3.8.6 Effects on non-target terrestrial plants

Since GLOB182F is applied as a seed treatment, it is of no risk to non-target plants and therefore no assessment was required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

3.9 Relevance of metabolites (Part B, Section 10)

Following the use of Fludioxonil as a seed treatment product, only the degradation in the dark has to be considered as the treated seeds are incorporated into the soil. As the metabolites of Fludioxonil are only formed in the light by photolysis, they are not relevant for the use of Fludioxonil as seed treatment product (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)

GLOB182F contains Fludioxonil which is approved as a candidate for substitution because it has two PBT criteria.

As a conclusion of the comparative assessment, the uses from the GAP table in section 2.6 are not suitable for substitution because there are not enough alternative modes 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

Following information is required to finalise the evaluation:

- the two years storage stability study is ongoing and should be available in July 2022;
- new method for the determination of residues of fludioxonil in animal matrices and ILV should be provided for the present product registration - post registration requirement.

~~In order to authorise uses in sunflower at 1.5 L product/ton seeds, further data enabling refinement of the long term risk to birds must be provided.~~

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem.

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 letnie badania stabilności są w toku, termin zakończenia planowany jest na lipiec 2022 r. Możliwe jest wydanie zgody warunkowo, na podstawie zaakceptowanych wyników 14-dniowego badania przyspieszonego starzenia w temperaturze 54°C środka przechowywanego w opakowaniach wykonanych z HDPE (Pomeroy D., 2020a). Zgodnie z zapisami aktualnie obowiązującej wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 17/10/2019 możliwa jest ekstrapolacja wyników badań stabilności z opakowań wykonanych z HDPE na HDPE/PA, HDPE/EVOH i F-HDPE. W związku z powyższym, wszystkie opakowania wymienione, w punkcie 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Środek nie jest przewidziany do łącznego stosowania.
5. Brak uwag do zapisu nazwy grupy chemicznej, do której przyporządkowano substancję czynną. Dodano zawartość substancji czynnej wyrażoną w procentach (została obliczona w oparciu o gęstość produktu 1,0490 g/mL zgodnie z punktem 2.6.1 Sekcji 1).

Sekcja skuteczność:

1. Uzupełniono opis mechanizmu działania fludioksnilu, oraz skorygowano opis zakresu stosowania w rozdziale OPIS DZIAŁANIA.
2. W obydwu zastosowaniach poprawiono objętość wody zalecaną do wykonania zabiegu zaprawiania, zgodnie z korektą dostarczoną przez wnioskodawcę podczas trwania oceny.
3. Wprowadzono nieznaczne korekty kolejności i uzupełnienie treści w rozdziale „SPORZĄDZANIE ZAWIESINY DO ZAPRAWIANIA I TECHNIKA ZAPRAWIANIA”.
4. Skorygowano rażące błędy semantyczne i fleksyjne, oraz ortografię tekstu.
5. W toku odpowiedzi na komentarze analizowano ponownie zasadność wcześniejszego zaakceptowania zastosowania przeciwko grzybom z rodzaju *Pythium* na kukurydzy. Wcześniej, tj. podczas oceny, ekspert zaakceptował to zastosowanie, uważając, iż uznanie zastosowania przeciwko *Fusarium* sp. spowoduje tak czy inaczej wprowadzenie środka na rynek i ekspozycję *Pythium* sp. na działanie jego substancji aktywnej. Obecnie jednak uznano takie podejście za błędne, i zastosowanie to usunięto z projektu etykiety z powodu zbyt niskiej liczby przedłożonych badań skuteczności z udziałem patogenów z tej grupy (cztery badania), i niskiego poziomu skuteczności jaki one demonstrują (średnia < 50%). Wspomniane badania nie dają podstaw dla deklarowania skuteczności wnioskowanego preparatu przeciwko grzybom z rodzaju *Pythium*. Niemniej jednak sugerujemy, że zastosowanie to może być przedmiotem rejestracji w trybie art. 51 w kukurydzy cukrowej, która jest w Polsce gatunkiem małoobszarowym (patrz niżej).
6. Z etykiety usunięto zastosowanie w kukurydzy cukrowej, gdyż z uwagi na brak badań selektywności na tej roślinie, przy jednoczesnym wystąpieniu objawów fitotoksyczności w 1/10 badań selektywności wykonanych w kukurydzy na ziarno, nie może ono być zarejestrowane w trybie art. 33. Uważamy, że zastosowanie w kukurydzy cukrowej może być jednak zarejestrowane w trybie art. 51.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. Zaproponowane przez wnioskodawcę środki ostrożności dla osób wykonujących zabieg agrochemiczny (zaprawianie nasion) są odpowiednie do uzyskanego wyniku szacowanie NDE obliczonego zgodnie z modelem SeedTROPEX oraz właściwości toksykologiczne formulacji (Uwaga: brak jest zharmonizowanych zasad/wytycznych dotyczących osobistych środków bezpieczeństwa dla wykonujących zabieg zaprawiania nasion).

2. Brak uwag do klasyfikacji zagrożeń.

Sekcja pozostałości:

1. Wprowadzono do etykiety zapis dotyczący roślin uprawianych następnie. „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: Nie dotyczy”.

Sekcja los i zachowanie w środowisku:

1. Brak uwag.

Sekcja ekotoksykologia:

1. Przy zwrocie P391 dodano informację, że rozsypane nasiona zaprawione środkiem muszą zostać zebrane.

2. Dodano zwrot P501.

3- **Przywrócono zastosowanie w słoneczniku.** ~~Z zakresu stosowania wykreślono słonecznik.~~

4. Poprawiono brzmienie zwrotów, które muszą znaleźć się na opakowaniach zaprawionych nasion w celu ochrony ptaków i ssaków.

Załącznik do zezwolenia MRiRW nr R -

Posiadacz zezwolenia:

GLOBACHEM N.V., Brustem Industriepark, Lichtenberglaan 2019, 3800 Sint-Truiden, Królestwo Belgii, tel.: +32 11 78 57 17, fax: +32 11 68 15 65, e-mail: globachem@globachem.com.


SURRENDER

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

fludioksonil (związek z grupy fenylopiroli) – 100 g/litr (9,53%)

Zezwolenie nr R-

	
Niebezpieczeństwo	
H317	Może powodować reakcję alergiczną skóry.
H318	Powoduje poważne uszkodzenie oczu.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261	Unikać wdychania rozpylonej cieczy.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P305 + P351 + P338/P310	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać/ Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem okulistą.
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
P333 + P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/ zgłosić się pod opiekę lekarza.
P273	Unikać uwolnienia do środowiska.
P391	Zebrać wyciek/zebrać rozsypane nasiona zaprawione środkiem

P501	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach
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OPIS DZIAŁANIA

FUNGICYD - zaprawa nasienna, w formie płynnego koncentratu (FS) o działaniu powierzchniowym, przeznaczony do zaprawiania ziarna siewnego ~~zboż~~ kukurydzy i słonecznika w zaprawiarkach przystosowanych do zapraw ciekłych i zawieszinowych, ~~ziarna siewnego zboż~~ w celu zwalczania chorób powodowanych przez grzyby.

Substancją czynną środka jest fludioksonil (związek fenylopirolowy (PP) – z grupy inhibitorów kinazy histydyny w procesie transdukcji sygnału osmotycznego, wg FRAC Grupa 12).

STOSOWANIE ŚRODKA

Kukurydza na ziarno, kukurydza na zielonkę i cukrowa

fuzaryjna zgorzel siewek (powodowana ~~grzybami~~ przez grzyby z rodzajów *Fusarium* oraz *Pythium*)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 50 ml środka z dodatkiem 50 400-800 ml wody na 100 kg nasion. Niższe objętości wody mogą być stosowane w przemysłowych systemach zaprawiania, o ciągłym przepływie zaprawy i nasion.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Słonecznik

Mączniak rzekomy słonecznika, szara pleśń, fuzaryjna zgorzel siewek

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 150 ml środka z dodatkiem 150 ml wody 100 kg nasion.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Nie wymagany

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):

Zaprawionego ziarna nie wolno przeznaczać go na cele konsumpcyjne, ani na paszę.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy.

1. Zaprawiać tylko dobrze oczyszczony materiał siewny.
2. Zaprawiony materiał powinien być dokładnie i równomiernie pokryty środkiem.
3. Zaprawianie wykonać najlepiej bezpośrednio przed siewem.
4. Zaprawione nasiona pozostawić po zaprawieniu w otwartych workach do momentu przeschnięcia.
5. Jeżeli zachodzi konieczność przechowywania zaprawionego ziarna do następnego sezonu, należy zbadać przed siewem zdolność kiełkowania.
6. Zaprawione nasiona przechowywać w grubych, oznakowanych i szczelnie zamkniętych workach, w oddzielnych, chłodnych, suchych i dobrze wentylowanych pomieszczeniach, z dala od żywności i pasz.
7. Zaprawionego materiału siewnego można używać wyłącznie do siewu. Nie wolno przeznaczać go na cele konsumpcyjne, ani na paszę.

Na opakowaniach zaprawianych nasion powinny zostać umieszczone następujące zwroty:

1. Zaprawionego ziarna można używać wyłącznie do siewu. Nie wolno przeznaczać go na cele konsumpcyjne, ani na paszę.
2. Jeżeli zachodzi konieczność przechowywania zaprawionego ziarna do następnego sezonu, należy zbadać przed siewem zdolność kiełkowania.
3. Zaprawione nasiona przechowywać w grubych, oznakowanych i szczelnie zamkniętych workach, w oddzielnych, chłodnych, suchych i dobrze wentylowanych pomieszczeniach, z dala od żywności i pasz.
4. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.
5. W celu ochrony ptaków i wolno żyjących ssaków:
 - zaprawione nasiona muszą być całkowicie przykryte glebą – **zapewnić** ~~upewnić się~~, że zaprawione nasiona są również całkowicie przykryte na końcach rzędów,
 - zebrać przypadkowo rozsypane nasiona.

SPORZĄDZANIE ZAWIESINY DO ZAPRAWIANIA I TECHNIKA ZAPRAWIANIA

Ściśle przestrzegać właściwego dawkowania środka.

Przed użyciem wstrząsnąć.

Zawiesinę do zaprawiania sporządzić w zbiorniku zaprawiarki lub w oddzielnym naczyniu.

Do połowy wymaganej ilości wody dodać odpowiednią ilość zaprawy. Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika zaprawiarki z cieczą użytkową. Uzupełnić wodą do potrzebnej ilości, dokładnie mieszając. Gotowa zaprawa może być użyta w czasie 24 godzin od momentu jej sporządzenia. Zaprawiać z włączonym mieszadłem.

Zaprawiać w zaprawiarkach mechanicznych o ruchu ciągłym lub porcjowych, zgodnie z instrukcją obsługi danej zaprawiarki. Przed rozpoczęciem zaprawiania zaprawiarkę poddać kalibracji.

ilość ~~ilość~~ **Objętość** wody jest związana z typem zaprawiarki oraz wilgotnością ziarna. Większa ~~ilość~~ **objętość** wody na ogół poprawia wyrównanie pokrycia ziarna zaprawą, natomiast niższe objętości wody mogą być stosowane w przemysłowych systemach zaprawiania, o ciągłym przepływie zaprawy i nasion. Zaprawiony materiał siewny powinien być dokładnie i równomiernie pokryty środkiem.

POSTĘPOWANIE Z RESZTKAMI ZAWIESINY I MYCIE APARATURY

Resztki zawiesiny oraz wodę użytą do mycia zaprawiarki należy:

- jeżeli jest to możliwe, zużyć do sporządzenia zawiesiny podczas kolejnego zaprawiania lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania zaprawy, w trakcie wykonywania zabiegu zaprawiania oraz pakowania i wysiewu zaprawionych nasion.

W trakcie załadunku środka do zaprawiarki lub innego bezpośredniego narażenia na płynny środek operator lub pracownik powinni dodatkowo nosić okulary ochronne lub ochronę twarzy zabezpieczającą przed działaniem żrącym na oczy.

Zanieczyszczoną odzież ochronną nie wносить poza miejsce pracy.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie dotyczy

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C-30°C.

Chronić przed światłem słonecznym.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z ośrodkiem zatruc/lekarzem okulistą.

W przypadku kontaktu ze skórą: umyć dużą ilością wody.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not relevant.

Appendix 4 Lists of data considered for national authorization

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 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- 2.7.4- 2.8.2- 2.8.3.1- 2.8.5.1.2- 2.8.7.2	Pomeroy, D.	2020a	Determination of Storage Stability and Shelf Life Specification Data for a Flowable Concentrate for Seed Treatment FS Formulation Containing Fludioxonil Stored at 54°C±2°C for 2 weeks, in Compliance with Good Laboratory Practice. Laboratory: David Norris Analytical Laboratories Ltd. Study number: DNA5607 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.2.1- 2.2.2 (filled in Part C)	Pomeroy, D.	2020b	Theoretical certificate of explosive and oxidizing properties for a formulation containing fludioxonil. Laboratory: David Norris Analytical Laboratories Ltd. Not GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.10.1- 2.10.2	De Vos P.	2021a	Fludioxonil 100 FS. Adhesion to and distribution on treated maize and sunflower seeds. Laboratory: CRA-W – Centre wallon de Recherches agronomiques Study number: 25152 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.11/01	De Vos P.	2021b	Fludioxonil 100 FS. Residues in dust of on treated maize and sunflower seeds. Laboratory: CRA-W – Centre wallon de Recherches agronomiques Study number: 25155 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.11/02	Daniel Fernández Fuego	2021	Statement: Description of the effectiveness of the washing procedure for GLOB182F. Not GLP Unpublished	N	Y	Data 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 5.1.1	Pomeroy, D.	2020	Validation of the methods of determination of Fludioxonil in a FS formulation, in compliance with good laboratory practice. DNA5609 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2 (submitted as KCP 2.10.1-2.10.2)	De Vos P.	2021a	Fludioxonil 100 FS. Adhesion to and distribution on treated maize and sunflower seeds. Laboratory: CRA-W – Centre wallon de Recherches agronomiques Study number: 25152 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2 (submitted as KCP 2.11)	De Vos P.	2021b	Fludioxonil 100 FS. Residues in dust of on treated maize and sunflower seeds. Laboratory: CRA-W – Centre wallon de Recherches agronomiques Study number: 25155 GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2 (submitted as KCP 10.2.1)	Renner, P.	2021a	Acute toxicity of GLOB182F to <i>Daphnia magna</i> in a 48-hour static test. 20 48 ADL 0012 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2 (submitted as KCP 10.2.1)	Renner, P.	2021b	Effects of GLOB182F on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test. 20 48 AAL 0015 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2 (submitted as KCP 10.3.1.1)	Amsel, K.	2020	Acute toxicity of Fludioxonil 100 FS to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions, 20 48 BBA 0026. BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.2	Schmidt, K.	2021	GLOB182F – Repeated exposure of honey bee (<i>Apis mellifera</i>)	N	Y	Data/study report never submitted	Globachem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(submitted as KCP 10.3.1.2)			larvae under laboratory conditions. 20 48 BLC 0050 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished			before to PL.	NV
KCP 5.2 (submitted as KCP 10.3.1.2)	Deßler, K.	2020	Chronic toxicity of GLOB182F to the honey bee <i>Apis mellifera</i> L. under laboratory conditions. 20 48 BAC 0051 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-01	H. de Vries	2018	Efficacy of Fludioxonil 25 FS, Difenoconazole 30 FS and DIF 25 + FDLX 25 FS against Fusarium in maize Report number: SFE-18-B-FDLX25FS-NL01 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-02	H. de Vries	2018	Efficacy of Fludioxonil 25 FS, Difenoconazole 30 FS and DIF 25 + FDLX 25 FS against Fusarium in maize Report number: SFE-18-B-FDLX25FS-NL02 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-03	P. Pouquet	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-A-FDXLMIX-FR02 Laboratory: Promo-Vert Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-04	H. de Vries	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-A-FDXLMIX-NL03 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-05	A. Czajka	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-B-FDXLMIX-PL04 Laboratory: Inhort Sponsor: Globachem N.V.	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 6.2-06	Z. Nagy	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-B-FDXLMIX-HU02 Laboratory: Syntech Research HU Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-07	H. de Vries	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-B-FDXLMIX-NL01 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-08	M. Hambáľková	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-C-FDXLMIX-CZ01 Laboratory: Zeměděľský výzkumný ústav Kroměříž Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-09	H. de Vries	2019	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-19-C-FDXLMIX-NL02 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-10	I. Ferrero Herrero	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-A-FDXLMIX-ES01 Laboratory: GMW Bioscience Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-11	S. Gaudino	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-A-FDXLMIX-IT02 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-12	F. Mazzi	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-A-FDXLMIX-IT03 Laboratory: Staphyt Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-13	S. Németh	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-B-FDXLMIX-HU01 Laboratory: CPR	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
			Sponsor: Globachem N.V. GEP, not published				
KCP 6.2-14	J. Ritecz	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-B-FDXLMIX-HU02 Laboratory: CPR Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-15	A. Włodarek	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-C-FDXLMIX-PL01 Laboratory: InHort Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-16	B. Ciupa-Wyleżalek	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-C-FDXLMIX-PL02 Laboratory: Institute of Plant Protection - National Research Institute Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-17	B. Ciupa-Wyleżalek	2020	Efficacy of Fludioxonil for seed treatment in maize. Report number: SFE-20-C-FDXLMIX-PL03 Laboratory: Institute of Plant Protection - National Research Institute Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-18	C. Oostingh	2019	Efficacy and selectivity of propamocarb against seed-borne diseases in corn. Report number: SFE-19-A-PPCMB-NL01 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-19	B. Krzyżińska	2019	Efficacy and selectivity of propamocarb against seed-borne diseases in corn. Report number: SFE-19-A-PPCMB-PL02 Laboratory: Institute of Plant Protection - National Research Institute Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-20	B. Krzyżińska	2019	Efficacy and selectivity of propamocarb against seed-borne diseases in corn.	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Report number: SFE-19-A-PPCMB-PL03 Laboratory: Institute of Plant Protection - National Research Institute Sponsor: Globachem N.V. GEP, not published				
KCP 6.2-21	G. Castella	2020	Efficacy of seed-treatments against diseases in glasshouse. Report number: SFE-20-A-PPMCB-ZOX-IT03 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-22	B. Krzyżińska	2020	Efficacy of seed-treatments against diseases in glasshouse. Report number: SFE-20-A-PPMCB-ZOX-PL01 Laboratory: Institute of Plant Protection - National Research Institute Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-23	B. Krzyżińska	2020	Efficacy of seed-treatments against diseases in glasshouse. Report number: SFE-20-A-PPMCB-ZOX-PL02 Laboratory: Institute of Plant Protection - National Research Institute Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-24	G. Castella	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-B-PPMCB-ZOX-IT01 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-25	G. Castella	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-B-PPMCB-ZOX-IT02 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-26	I. Makó	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-C-PPMCB-ZOX-HU03 Laboratory: CPR Europe Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-27	P. Occhetti	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-C-PPMCB-ZOX-IT04	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published				
KCP 6.2-28	I. Ferrero Herrero	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-C-PPMCB-ZOX-ES05 Laboratory: GMW Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-29	I. Ferrero Herrero	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-C-PPMCB-ZOX-ES06 Laboratory: GMW Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-30	A. Włodarek	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-A-FDXL100FS-PL01 Laboratory: Inhort Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-31	A. Włodarek	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-A-FDXL100FS-PL02 Laboratory: Inhort Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-32	I. Ferrero	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-A-FDXL100FS-ES03 Laboratory: GMW Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-33	C. Oostingh	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-A-FDXL100FS-NL04 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-34	A. Vilotic	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-A-FDXL100FS-IT05 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-35	A. Vilotic	2020	Efficacy of seed-treatments against diseases in glasshouse	N	Y	Data/study report never submitted	Globachem

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			Report number: SFE-20-A-FDXL100FS-IT06 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published			before to PL.	NV
KCP 6.2-36	H. Zagi	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-B-FDXL100FS-HR02 Laboratory: Pest Pro Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-37	H.Zagi	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-B-FDXL100FS-HR03 Laboratory: Pest Pro Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-38	G. Lőrinczné Izsányi	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-B-FDXL100FS-HU04 Laboratory: CPR Europe Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-39	F. Magliano	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-B-FDXL100FS-IT05 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-40	J. Suñer	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-B-FDXL100FS-ES06 Laboratory: GMW Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-41	M. Maidero	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-D-FDXL100FS-ES01 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-42	H. Zagi	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-D-FDXL100FS-HR02 Laboratory: Pest Pro Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.2-43	H. Zagi	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-D-FDXL100FS-HR03 Laboratory: Pest Pro Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-44	F. Magliano	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-D-FDXL100FS-IT04 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-45	F. Magliano	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-D-FDXL100FS-IT05 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-46	F. Magliano	2020	Efficacy of seed-treatments against diseases in field Report number: SFE-20-D-FDXL100FS-IT06 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-47	M. Ciesla	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-C-FDXL100FS-HR01 Laboratory: Pest Pro Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-48	M. Deandrea	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-C-FDXL100FS-IT04 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-49	M. Deandrea	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-C-FDXL100FS-IT05 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-50	M. Deandrea	2020	Efficacy of seed-treatments against diseases in glasshouse Report number: SFE-20-C-FDXL100FS-IT06 Laboratory: Sagea Sponsor: Globachem N.V.	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.4-01	E. Vaitiekienė	2019	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-19-A-FDXLMIX-DK01 Laboratory: Agrolab Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-02	J. Ritecz	2019	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-19-A-FDXLMIX-HU02 Laboratory: SynTech Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-03	J. Rezmerska-Pietka	2019	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-19-A-FDXLMIX-PL03 Laboratory: AgroResearch Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-04	H. de Vries	2019	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-19-A-FDXLMIX-NL04 Laboratory: Proeftuin Zwaagdijk Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-05	O. Machalova	2020	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-20-A-FDXLMIX-CZ01 Laboratory: ZZS Kujavy Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-06	C. Broms	2020	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-20-A-FDXLMIX-SE02 Laboratory: HUSEC Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-07	E. Lay	2020	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-20-A-FDXLMIX-FR03 Laboratory: Staphyt FR Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-08	F. Mazzi	2020	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-20-A-FDXLMIX-IT04 Laboratory: Staphyt IT	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Sponsor: Globachem N.V. GEP, not published				
KCP 6.4-09	O. Treikale	2020	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-20-A-FDXLMIX-LV05 Laboratory: LAAPC Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-10	O. Treikale	2020	Selectivity of Fludioxonil 100 FS in maize. Report number: SFS-20-A-FDXLMIX-LV06 Laboratory: LAAPC Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-11	O. Machalova	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-CZ01 Laboratory: ZZS Kujavy Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-12	J. Safar	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-CZ02 Laboratory: Agritec Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-13	P. Otrhalkova	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-CZ03 Laboratory: InTec Agro Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-14	M. Selig	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-DE04 Laboratory: FRS Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-15	U. Gerdau	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-DE05 Laboratory: Agrartest Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-16	E. Lay	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-FR06	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Laboratory: Staphyt FR Sponsor: Globachem N.V. GEP, not published				
KCP 6.4-17	F. Magliano	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-IT07 Laboratory: Sagea Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-18	B. Ferencz	2020	Selectivity of Fludioxonil 100 FS in sunflower. Report number: SFS-20-A-FDXL100FS-RO08 Laboratory: BioTek Sponsor: Globachem N.V. GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 9.2.4.1	Fernandez, D.	2020a	GLOB182F - Estimations of the PEC _{gw} of Fludioxonil for the intended use as a seed treatment formulation in maize and sunflower. GLOB182F-GW non GLP Unpublished	N	N	-	Globachem NV
KCP 9.2.5	Fernandez, D.	2020b	GLOB182F - Estimations of the PEC _{sw} and PEC _{sed} of Fludioxonil and relevant metabolites for the intended use as a seed treatment formulation in maize and sunflower. GLOB182F-GW non GLP Unpublished	N	N	-	Globachem NV
KCP 10.1.1/01	xxxxxxxxxxxxxxxxxx	2015	Fludioxonil - A reproduction study with the Northern Bobwhite xxxxxxxxxxxxx xxxxxxxxxxxxx GLP Unpublished	Y	Y	Data/study report never submitted before to PL.	Syngenta (Globachem access via LoA, valid in PL only)
KCP 10.2.1	Renner, P.	2020a	Acute toxicity of GLOB182F to <i>Daphnia magna</i> in a 48-hour static test. 20 48 ADL 0012 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	Renner, P.	2020b	Effects of GLOB182F on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test.	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			20 48 AAL 0015 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished				
KCP 10.3.1.1	Franke, M.	2020	Acute toxicity of GLOB182F to the honeybee <i>Apis mellifera</i> L. under laboratory conditions. 20 48 BAA 0079 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.1	Amsel, K.	2020	Acute toxicity of Fludioxonil 100 FS to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions, 20 48 BBA 0026. BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.2	Schmidt, K.	2020	GLOB182F – Repeated exposure of honey bee (<i>Apis mellifera</i>) larvae under laboratory conditions. 20 48 BLC 0050 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.2	Deßler, K.	2020	Chronic toxicity of GLOB182F to the honey bee <i>Apis mellifera</i> L. under laboratory conditions. 20 48 BAC 0051 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2	Röhlig, U.	2020a	Effects of GLOB182F on the parasitic wasp <i>Aphidius rhopalosiphii</i> (DEStEFANI-PEREZ) in a laboratory test. 20 48 NAL 0009. BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 10.3.2	Röhlig, U.	2020b	Effects of GLOB182F on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test. 20 48 NTL 0008. BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2	Röhlig, U.	2020c	Effects of Fludioxonil 25 FS on the rove beetle <i>Aleochara bilineata</i> GYLL. in an extended laboratory test. 20 48 NKE 0007 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Study submitted earlier for registration of another Fludioxonil-based seed treatment PPP (R-44/2020). Protected 10 years from the 1 st authorization in PL (28/04/2020).	Globachem NV
KCP 10.3.2	Röhlig, U.	2018a	Effect of Fludioxonil 480 FS on the rove beetle <i>Aleochara bilineata</i> GYLL. in an extended laboratory test. 18 48 NKE 0003 Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2	Röhlig, U.	2020d	Effects of Fludioxonil 25 FS on the carabid beetle <i>Poecilus cupreus</i> L. in an extended laboratory test. 20 48 NLE 0005 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Study submitted earlier for registration of another Fludioxonil-based seed treatment PPP (R-44/2020). Protected 10 years from the 1 st authorization in PL (28/04/2020).	Globachem NV
KCP 10.3.2	Röhlig, U.	2018b	Effects of Fludioxonil 480 FS on the carabid beetle <i>Poecilus cupreus</i> L. in an extended laboratory test 18 48 NLE 0001 BioChem agrar Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.1.1	Friedrich, S.	2017a	Sublethal effects of Fludioxonil 25 FS on the earthworm <i>Eisenia andrei</i> in artificial soil. 17 48 TEC 0025 BioChem agrar, Labor für biologische und chemische Analytik GmbH	N	Y	Study submitted earlier for registration of another Fludioxonil-based seed treatment PPP (R-44/2020). Protected 10 years from the 1 st authorization in PL	Globachem NV

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			GLP Unpublished			(28/04/2020).	
KCP 10.4.1.1	Friedrich, S.	2017b	Sublethal effects of Fludioxonil 480 FS on the earthworm <i>Eisenia andrei</i> in artificial soil 17 48 TEC 0041 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2	Friedrich, S.	2017c	Effects of Fludioxonil 25 FS on the reproduction of the collembolan <i>Folsomia candida</i> . 17 48 TCC 0024 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Study submitted earlier for registration of another Fludioxonil-based seed treatment PPP (R-44/2020). Protected 10 years from the 1 st authorization in PL (28/04/2020).	Globachem NV
KCP 10.4.2	Friedrich, S.	2017d	Effects of Fludioxonil 480 FS on the reproduction of the collembolan <i>Folsomia candida</i> 17 48 TCC 0041 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2	Schulz, L.	2017a	Effects of Fludioxonil 25 FS on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> . 17 48 THC 0020 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Study submitted earlier for registration of another Fludioxonil-based seed treatment PPP (R-44/2020). Protected 10 years from the 1 st authorization in PL (28/04/2020).	Globachem NV
KCP 10.4.2	Schulz, L.	2017b	Effects of Fludioxonil 480 FS on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> 17 48 THC 0037 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.5	Schulz, L.	2020	Effects of GLOB182F on the activity of soil microflora (Nitrogen transformation test).	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			20 48 SMN 0041 BioChem agrar, Labor für biologische und chemische Analytik GmbH GLP Unpublished				

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
-	-	-	-	-	-	-	-

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
-	-	-	-	-	-	-	-

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

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-	-	-	-	-	-	-	-