

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: GLOB2111F**

**Product name(s): Starinta**

**Chemical active substance(s):**

**Bixafen, 125 g/L**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT Poland**  
**(authorization)**

**Applicant: Globachem NV**

**Submission date: December 2023**

**zRMS Assessment: 09/08/2024**

**Version after commenting : 15/11/2024**

**MS Finalisation date: 12/12/2024 corrected 29/04/2025**

**corrected 27/05/2025**

## Version history

When	What
August 2024	zRMS assessment
November 2024	After commenting period
December 2024	Final report
April 2025	Correction in terms of effectiveness
May 2025	Correction in terms of aquatic organisms

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application was submitted by Globachem NV in December 2023.

The application is for approval of GLOB2111F, an emulsifiable concentrate (EC) containing 125 g/L bixafen for use as a fungicide in winter and spring cereals in the Central Zone for which the Poland was designated zRMS.

#### 1.2 Letters of Access

The dossier contains no letters of access.

#### 1.3 Justification for submission of tests and studies

This application was made in accordance with the article 33 of the Regulation 1107/2009. It follows the data requirements for the active substances laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

#### 1.4 Data protection claims

Data protection is claimed for all documents and data included in this dossier. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Globachem NV.

### 2 Details of the authorization decision

#### 2.1 Product identity

Product code	GLOB2111F
Product name in MS	Starinta
Authorization number	/
Function	Fungicide
Applicant	Globachem NV.
Active substance(s) (incl. content)	Bixafen– 125 g/L
Formulation type	Emulsifiable Concentrate (EC)

Packaging	0.250, 0.500, 1, 2, 3, 5, 10, 15, 20 L HDPE/PA, HDPE/F
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

## 2.2 Conclusion

The evaluator also verified whether the co-formulants contained in plant protection product Starinta (Product code: GLOB2111F) are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Starinta (Product code: GLOB2111F) does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product Starinta (Product code: GLOB2111F) meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

**Efficacy:** The evaluation of the application for Starinta resulted in the decision to grant conditional authorization. Acceptable evidence was only provided against SEPTTR on wheat and RHYNSE on barley, with the possibility to extrapolate the data to other crops (see GAP table for details). This is because there are not enough efficacy trials that fit the proposed uses with one application. Typically, two treatments of GLOB2111F have been made, exceeding the recommendations proposed in the GAP. Where possible, results obtained after the first application (0-DAB) were included in this evaluation. Like all other SDHIs, GLOB2111F must only be used as a tank-mix partner with no cross-resistance to this product. For PL, further data are required for the use of GLOB2111F in combination with other fungicides (tank-mix partners) according to the claimed uses. This would consist of at least three fully supportive trials for each tank-mix partner, demonstrating acceptable levels of infestation and disease control of SEPTTR on wheat and RHYNSE on barley.

## 2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.



## 2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin Irrit. 2, Eye Irrit. 2, Aquatic Chronic 1, Aquatic Acute 1, Dam. 1.,
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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
Signal word:	Danger
Hazard statement(s):	<b>H315 - Causes skin irritation</b> <b>H318 - Causes serious eye damage</b>
Precautionary statement(s):	<b>P264 - Wash hands, forearms and face thoroughly after handling</b> <b>P280 - Wear protective gloves, protective clothing, eye protection/face protection</b> <b>P302+P352 - IF ON SKIN: Wash with plenty of water/soap</b> <b>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</b> <b>P310 - Immediately call a POISON CENTER or doctor</b> <del>P321</del> <b>P332+P313 - If skin irritation occurs: Get medical advice/attention</b> <b>P362+P364 - Take off contaminated clothing and wash it before reuse</b>
Additional labelling phrases:	<b>To avoid risks to man and the environment, comply with the instructions for use. [EUH401]</b> <b>Contains: N-Octyl-2-pyrrolidone</b>

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies or 50% drift reduction nozzle.

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

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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

Operator protection:	
P280	Wear protective gloves, protective clothing, eye protection/face protection.
Worker protection:	

	<del>Wear protective gloves, working clothing, arms/legs covered.</del>
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
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).
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.
SPe3	50% drift reduction nozzles or 5 m buffer zone	All uses



## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2023-November-28

PPP (product name/code): Starinta / GLOB2111F  
 Active substance 1: Bixafen  
 Active substance 2: /  
 Safener: /  
 Synergist: /  
 Applicant: Globachem NV  
 Zone(s): central (d)  
 Verified by MS: yes/no

Formulation type: EC (a, b)  
 Conc. of as 1: 125 g/L (c)  
 Conc. of as 2: / (c)  
 Conc. of safener: / (c)  
 Conc. of synergist: / (c)  
 Professional use: ☒  
 Non professional use: ☐

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter wheat <i>Triticum aestivum</i> winter / <i>Triticum durum</i> winter (TRZAW/TRZDW)	F	<i>Puccinia striiformis</i> (PUCCST) <i>Zymoseptoria tritici</i> (SEPTTR) <i>Parastagonospora nodorum</i> (LEPTNO) <i>Puccinia recondita</i> (PUCCRE) <i>Blumeria graminis</i> (ERYSGR)	Normal down- ward spraying	BBCH 30 – 61 <del>BBCH 30 – 33</del>	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
2	PL	Winter wheat <i>Triticum aestivum</i> winter / <i>Triticum</i>	F	<i>Fusarium</i> sp. (FUSASP)	Normal down- ward	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 – 300	/	

		<i>durum-winter</i> (TRZAW/TRZDW)			spraying								
3	PL	Winter barley <i>Hordeum vulgare</i> winter (HORVW)	F	<i>Puccinia hordei</i> (PUCCHD) <i>Pyrenophora teres</i> (PYRNTE) <i>Rhynchosporium secalis</i> (RHYNSE) <i>Blumeria graminis</i> (ERYSGR) <i>Ramularia collo-cygni</i> (RAMUCC)	Normal down- ward spraying	BBCH 30 – 61 <del>BBCH 30—33</del>	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
4	PL	Winter barley <i>Hordeum vulgare</i> winter (HORVW)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
5	PL	Winter rye <i>Secale cereale</i> winter (SECCW)	F	<i>Rhynchosporium secalis</i> (RHYNSE) <i>Puccinia recondita</i> (PUCCRE) <i>Blumeria graminis</i> (ERYSGR)	Normal down- ward spraying	BBCH 30 – 61 <del>BBCH 30—33</del>	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
6	PL	Winter-rye <i>Secale cereale</i> -winter (SECCW)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61—69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
7	PL	Triticale winter <i>Triticale sp.</i> winter (TTLWI)	F	<i>Rhynchosporium secalis</i> (RHYNSE) <i>Parastagonospora nodorum</i> (LEPTNO) <i>Puccinia striiformis</i> (PUCCST) <i>Zymoseptoria tritici</i> (SEPTTR) <i>Blumeria graminis</i> (ERYSGR)	Normal down- ward spraying	BBCH 30 – 61 <del>BBCH 30—33</del>	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
8	PL	Triticale-winter <i>Triticale sp.</i> -winter (TTLWI)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61—69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
9	PL	Oats winter <i>Avena sativa</i> (AVESW)	F	<i>Blumeria graminis</i> (ERYSGR) <i>Puccinia coronata</i> var.	Normal down- ward	BBCH 30—61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	

				<i>avenae</i> (PUCCCA) <i>Pyrenophora chaetomioides</i> (PYRNAV)	spraying								
10	PL	Oats-winter <i>Avena sativa</i> (AVESW)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
11	PL	Spring-wheat <i>Triticum aestivum</i> spring/ <i>Triticum</i> <i>durum</i> spring- (TRZAS/TRZDS)	F	<i>Puccinia striiformis</i> (PUCCST) <i>Zymoseptoria tritici</i> (SEPTTR) <i>Parastagonospora nodorum</i> (LEPTNO) <i>Puccinia recondita</i> (PUCCRE) <i>Blumeria graminis</i> (ERYSGR)	Normal down- ward spraying	BBCH 30 – 61 BBCH 30 – 33	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
12	PL	Spring-wheat <i>Triticum aestivum</i> spring/ <i>Triticum</i> <i>durum</i> spring- (TRZAS/TRZDS)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
13	PL	Spring barley <i>Hordeum vulgare</i> spring (HORVS)	F	<i>Puccinia hordei</i> (PUCCHD) <i>Pyrenophora teres</i> (PYRNTE) <i>Rhynchosporium secalis</i> (RHYNSE) <i>Blumeria graminis</i> (ERYSGR) <i>Ramularia collo-cygni</i> (RAMUCC)	Normal down- ward spraying	BBCH 30 – 61 BBCH 30 – 33	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
14	PL	Spring-barley <i>Hordeum vulgare</i> spring (HORVS)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	
17	PL	Triticale spring <i>Triticale sp.</i> spring (TTLSO)	F	<i>Rhynchosporium secalis</i> (RHYNSE) <i>Parastagonospora nodorum</i> (LEPTNO) <i>Puccinia striiformis</i> (PUCCST) <i>Zymoseptoria tritici</i>	Normal down- ward spraying	BBCH 30 – 61 BBCH 30 – 33	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100– 300	/	

				(SEPTTR) <i>Blumeria graminis</i> (ERYSGR)									
18	PL	Triticale spring <i>Triticale sp. spring</i> (TTLSP)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61—69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
19	PL	Oats spring <i>Avena sativa</i> (AVESP)	F	<i>Blumeria graminis</i> (ERYSGR) <i>Puccinia coronata var.</i> <i>avenae</i> (PUCCCA) <i>Pyrenophora chaetomioides</i> (PYRNAV)	Normal down- ward spraying	BBCH 30—61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
20	PL	Oats spring <i>Avena sativa</i> (AVESP)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
21	PL	Spelt <i>Triticum spelta</i> (TRZSP)	F	<i>Puccinia recondita</i> (PUCCRE) <i>Puccinia striiformis</i> (PUCCST) <i>Pyrenophora teres</i> (PYRNTE) <i>Rhynchosporium secalis</i> (RHYNSE) <i>Zymoseptoria tritici</i> (SEPTTR) <i>Puccinia triticina</i> (PUCCRT) <i>Blumeria graminis</i> (ERYSGR)	Normal down- ward spraying	BBCH 30 – 61 BBCH 30—33	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
22	PL	Spelt <i>Triticum spelta</i> (TRZSP)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61—69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
<b>Minor uses according to Article 51 (zonal uses)</b>													
33	PL	Spring rye <i>Secale cereale spring</i> (SECCS)	F	<i>Rhynchosporium secalis</i> (RHYNSE) <i>Puccinia recondita</i> (PUCCRE) <i>Blumeria graminis</i> (ERYSGR)	Normal down- ward spraying	BBCH 30 – 61	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	

34	PL	Spring rye <i>Secale cereale spring</i> (SECCS)	F	<i>Fusarium sp.</i> (FUSASP)	Normal down- ward spraying	BBCH 61 – 69	a) 1 b) 1	/	a) 1 b) 1	a) 0.125 b) 0.125	100 - 300	/	
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**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

**Remarks columns:**

1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
8 The maximum number of application possible under practical conditions of use must be provided.  
9 Minimum interval (in days) between applications of the same product  
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  
13 PHI - minimum pre-harvest interval  
14 Remarks may include: Extent of use/economic importance/restrictions

### **3 Background of authorization decision and risk management**

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

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 a brownish yellow liquid, with a mild aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 361.1 °C. In aqueous solution, it has a pH value around 5.76 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE/PA*, *HDPE/F*. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation.

The intended concentration of use is 0.33% to 1.0%.

#### **3.2 Efficacy (Part B, Section 3)**

##### **3.2.1 Efficacy data**

GLOB2111F contains 100 g/L of the active substance bixafen. It is formulated as an emulsifiable concentrate (EC). It is to be used as a fungicide on cereals. Bixafen is a well-known active substance, used for many years in cereals, either in straight formulation or in ready mixtures.

The maximum proposed label rate for GLOB2111F is 1 L/ha with maximum 1 application at BBCH stages according to the target diseases. From the presented results it can be clearly concluded that GLOB2111F at the recommended rates provides control of various fungal diseases, equivalent to a range of commercial standards being crop safe as well. For increased control levels and in order to avoid resistance build-up, the use is recommended in mixture with active substances with different mode of action.

##### **3.2.2 Information on the occurrence or possible occurrence of the development of resistance**

GLOB2111F is based on a single active substance: Bixafen. Bixafen belongs to SDHI fungicides (FRAC group 7). All fungicides of this group inhibit complex II of the fungal mitochondrial respiration by binding and blocking SDH-mediated electron transfer from succinate to ubiquinone.

According to the FRAC Code List (2020) Resistance to SDHI fungicides is known for several fungal species in field populations and lab mutants. Target site mutations in *sdh* gene, e.g. H/Y (or H/L) at 257, 267, 272 or P225L, dependent on fungal species. Members of the SDHI group of fungicides require resistance management. Also according to FRAC, the application of fungicides with different modes of action in mixtures (both ready formulations and tank mixtures) and the alternation between non-cross-resistant fungicide classes are both suitable approaches to minimize the risk of resistance development alongside good agronomic practices.

Based on this information, it is considered that the risk of resistance development is medium for GLOB2111F. The limitation of one application per season and combination of GLOB2111F with a mixing partner decreases the agronomic risk and can be regarded as resistance risk modifiers. Thus, if the resistance management strategy is respected, resistance can be kept under control, bringing the risk to an

acceptable level.

### 3.2.3 Adverse effects on treated crops

Plant protection products containing bixafen have been applied to a wide variety of crops in different countries for many years without any reports of damage symptoms to the crops. Consequently, reference is made to the efficacy trials (KCP 6.2).

Enough data to study the adverse effects on treated crops of GLOB2111F has been submitted and demonstrate the safe use of GLOB2111F. No significant adverse effects were recorded at the proposed dose rates in any trial on the target cereals.

GLOB2111F contains 125g/L of the active substance bixafen. It is formulated as an emulsifiable concentrate (EC). It is to be used as a fungicide in cereals. The proposed maximum rate of the product is 1.0 L/ha with a maximum of one applications per crop/season with a water content of 100 – 300 L/ha.

#### **Minimum effective dose:**

Based on the results of trials in North East zone, the 1.0 l/ha dose of GLOB2111F provided the optimum overall reduction and should be considered an acceptable solution for the major cereal diseases claimed.

#### **Efficacy tests**

Acceptable evidence was only provided against SEPTTR on wheat and RHYNSE on barley, with the possibility to extrapolate the data to other crops (see GAP table for details). Like all other SDHIs, GLOB2111F must only be used as a tank-mix partner with no cross-resistance to this product. For PL, further data are required for the use of GLOB2111F in combination with other fungicides (tank-mix partners) according to the claimed uses. This would consist of at least three fully supportive trials for each tank-mix partner demonstrating acceptable levels of infestation and disease control of SEPTTR on wheat and RHYNSE on barley.

#### **Yield and Yield parameters:**

The data summarized across all EPPO climatic zones confirmed that GLOB2111F applied at the proposed label rate of 1.0 L/ha with a maximum of one application per season had no adverse effect on yield and yield quality parameters

#### **Information on possible occurrence of the development of resistance:**

The applicant addresses all points of the EPPO Standard PP 1/213 (Resistance risk analysis) to evaluate the possible actual resistance risk of Bixafen. Based on FRAC assessment the applicant stated the risk of resistance for bixafen as medium to high and a special resistance management system must be used for the application of the product.

As with all SDHIs, GLOB2111F must only be used as a tank-mix partner with no cross-resistance to this product.

#### **Phytotoxicity to host crop:**

Phytotoxicity symptoms in crops tested caused by the application of GLOB2111F were not observed in any of the efficacy trials reported by the applicant.

#### **Adverse effects on succeeding or adjacent crops:**

GLOB2111F had no adverse effects on the crops tested as observed in germination or vegetative vigour tests with any of the plant species. GLOB2111F does not pose a risk to succeeding or adjacent crops and justifies the recommendation of no restrictions on succeeding or adjacent crops when using GLOB2111F.

### **3.2.4 Observations on other undesirable or unintended side-effects**

Based on the presented results and on the experience with the active substance, it is highly unlikely that the product will cause any damage to succeeding or adjacent crops and no mitigation measures are therefore proposed.

There were no adverse effects on beneficial and other non-target organisms observed in any of the effectiveness trials conducted.

## **3.3 Methods of analysis (Part B, Section 5)**

Analytical methods for bixafen in plant, animal, water, air, soil and in the formulation GLOB2111F are available.

### **3.3.1 Analytical method for the formulation**

Analytical methods for determination of bixafen in GLOB2111F were not evaluated as part of the EU review of the active substances. Therefore, all relevant data are provided and are considered adequate. An HPLC-DA method was submitted to analyse the active ingredient content in the formulation. This method was successfully validated in terms of specificity, linearity, accuracy and repeatability according to SANCO/3029/99 rev. 5.

### **3.3.2 Analytical methods for residues**

All analytical methods are active substance data and were provided in the EU review of bixafen and were considered adequate.

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions [EFSA Scientific Report (2008) 140, 1-74; EJ 2010; 8(3):1523; EJ 2010; 8(4):1565)]. All details with the overall conclusion are included in part B Section 5 of the present Registration Report.

## **3.4 Mammalian toxicology (Part B, Section 6)**

### **3.4.1 Acute toxicity**

The toxicological classification of GLOB2111F is based on theoretical calculations according to Regulation 1272/2008 as well as an *in vitro* testing carried out with the closely related formulation GLOB2020aF. Reference is made to the Part C for theoretical calculations and the dRR part B6 for the *in vitro* test. Based on data provided, product GLOB2111F should be classified as Skin Irrit. 2 H315, Eye Dam. 1 H318.

### **3.4.2 Operator exposure**

Operator exposure to GLOB2111F was not evaluated as part of the EU review of bixafen. Therefore, all relevant data and risk assessments are provided here and are considered adequate.



Operator exposure for bixafen was assessed against the AOEL agreed in the EU review of 0.13 mg a.i./kg bw/d using the online calculator tool provided by EFSA (calculator version: opex v 1.0.1)..

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.

According to the model calculations, it can be concluded that the risk for the operator using GLOB2111F on cereals is acceptable under conditions of intended use when the workwear is worn. Wearing adequate work clothing, ~~no PPE~~, the risk is 94.7% of systemic AOEL and with PPE (gloves during mixing, loading and application), the risk is 11.0% of systemic AOEL. Based on hazard classification of the product it is recommended for operator to wear workwear, protective gloves, eye protection or face protection during mixing/loading.

### 3.4.3 Worker exposure

Worker exposure to GLOB2111F was not evaluated as part of the EU review of bixafen. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Worker exposure for bixafen was assessed against the AOEL agreed in the EU review of 0.13 mg a.i./kg bw/d using the online calculator tool provided by EFSA (calculator version: opex v 1.0.1)..

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.

According to the model calculations, it can be concluded that the risk for the worker ~~using~~ during re-entry activities on area treated with GLOB2111F on cereals is acceptable under conditions of intended use without PPE, but the worker should wear an adequate workwear within good agricultural practice. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried. Without workwear the risk is 84.1 % of systemic AOEL. Wearing adequate work clothing, ~~no PPE~~, the risk is 9.4%.

### 3.4.4 Bystander and resident exposure

Resident exposure to GLOB2111F was not evaluated as part of the EU review of bixafen. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

Resident exposure for bixafen was assessed against the AOEL agreed in the EU review of 0.13 mg a.i./kg bw/d using the online calculator tool provided by EFSA (calculator version: opex v 1.0.1).

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.

According to the revised model calculations, it is concluded that there is no undue risk to any resident after longer-term exposure to bixafen. The risk is ~~15.4%~~ 20.4% of systemic AOEL for children and ~~6.6%~~ to 7.6% for adults.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

It is concluded that there is no undue risk to bystanders and residents after exposure to GLOB2111F.

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

#### 3.5.1 Residues

For the applied use of GLOB2111F in cereals, reference is made to the data that were submitted for the EU review of bixafen, as the active substance data sufficiently address aspects of the residue situation that might arise from the use of GLOB2111F.

Compliance with the EU MRLs of bixafen is met for the intended use of GLOB2111F.

#### 3.5.2 Consumer exposure

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.02 mg/kg bw/day and ARfD of 0.2 mg/kg bw/day for bixafen. It can therefore be concluded that acceptable margins of safety exist for consumers. An assessment of consumer intake levels was presented by the applicant.

For bixafen, Chronic and acute exposure calculations for all crops were performed using the EFSA Pesticide Residues Intake Model (PRIMO) (revision 3.1) model. ~~As no acute reference has been set for the active substance, there is no need to evaluate the acute risk.~~

Based on the different calculations made to estimate the risk for consumer through diet and other means, it can be concluded that the proposed use of bixafen in the product GLOB2111F do not lead to an unacceptable risk for consumers.

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

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

#### 3.6.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

The PEC of bixafen and GLOB2111F in soil has been assessed with the FOCUS model and the focus groundwater interception values and the DT<sub>50</sub> values established in the EU review.

Maximum PEC<sub>soil accumulation</sub> value for bixafen was 0.0462 mg/kg, following the application rate of 1 x 125 g as./ha to winter and spring cereals at BBCH 30 (80% crop interception).

The results for PEC<sub>soil</sub> for the active substance were used for the ecotoxicological risk assessment.

#### 3.6.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

PEC<sub>gw</sub> has been determined for bixafen and its relevant metabolite in groundwater M44 e, using the FOCUS PELMO 6.6.4, and FOCUS PEARL 5.5.5 and FOCUS MACRO 5.5.4 models and EU agreed endpoints (SANCO/3919 /2007-rev. 5). the results of the leaching calculations show that when bixafen is used according to the critical GAP in winter and spring cereals in the EU, it leaches in acceptable amounts (< 0.1 µg/L) to groundwater in every European scenario. However for the metabolite M44, the concentration in groundwater exceeds the trigger of 0.1 µg/L in most European scenarios. A non-

relevance assessment of M44 according to SANCO/221/2000 – rev.11 (Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances regulated under Council Directive 91/414/EEC) has been performed, showing that this metabolite is not relevant (and therefore subject to other limits than 0.1 µg/L). Therefore, the risk is acceptable when exposed to the concentrations calculated in this report.

### 3.6.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

The PEC of bixafen and the formulation GLOB2111F in surface water (PEC<sub>sw</sub> and PEC<sub>sed</sub>) have been assessed with the standard FOCUS scenarios using the endpoints established in the EU review.

The results for PEC<sub>sw</sub> for the active substances, the metabolites and the formulation were used for the ecotoxicological risk assessment.

### 3.6.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)

The vapour pressure at 20 °C of the active substance bixafen is < 10<sup>-5</sup> Pa. Hence the active substance bixafen is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance bixafen due to volatilization with subsequent deposition should **not** be considered.

## 3.7 Ecotoxicology (Part B, Section 9)

### 3.7.1 Effects on terrestrial vertebrates

The TER<sub>a</sub> value is greater than the Annex VI trigger of 10, indicating low acute risk to mammals from bixafen following application of GLOB2111F at the intended GAP. The TER<sub>lt</sub> value for bixafen is greater than the Annex VI trigger of 5, indicating that GLOB2111F presents no unacceptable long-term risk to mammals when applied according to the proposed GAP.

The risk assessment for secondary poisoning, required for bixafen, showed that the risk for earthworm-eating and fish-eating mammals is acceptable following use of GLOB2111F according to the proposed use pattern. Furthermore, the risk assessment for exposure *via* drinking water also showed an acceptable risk.

### 3.7.2 Effects on aquatic species

**For winter cereals** the calculated FOCUS Steps 1 to 4 PEC/RAC ratios for GLOB2111F and the active substance bixafen are all **below the trigger value of 1** ~~above the Annex VI trigger values~~, indicating that GLOB2111F poses low acute and chronic risk to aquatic organisms when the following risk mitigation measures are respected:

- 5 meters no-spray buffer zone or the use of 50% drift-reduction nozzle.

**For spring cereals**, taking into account winter cereals as surrogate crop for R1 scenario, the calculated FOCUS Steps 1 to 4 PEC/RAC ratios for GLOB2111F and the active substance bixafen are all below the trigger value of 1, indicating that GLOB2111F poses low acute and chronic risk to aquatic organisms when the following risk mitigation measures are respected:

- 5 meters no-spray buffer zone or the use of 50% drift-reduction nozzle.

### 3.7.3 Effects on bees

Risk assessment based on SANCO/10329/2002 rev. 2 (final): HQ values for oral and dermal exposure are below the relevant trigger. Therefore, it can be assumed that the intended uses of GLOB2111F represent low risk exposure to honey bees and bumble bees.

~~Risk assessment based on EPP0 (2010): The chronic TERs for honey bee adults and larvae are higher than the trigger of 1, indicating that the proposed uses according to the intended GAP of GLOB2111F poses an acceptable chronic risk to honey bee larvae and adults.~~

Risk assessment based on EFSA bee GD (EFSA Journal 2013;11(7):3295): Acceptable chronic risk was demonstrated for adult honey bees, and larvae for all intended uses.

### 3.7.4 Effects on other arthropod species other than bees

The hazard quotients for in-field and off-field risk are below the trigger value. Therefore an acceptable acute risk to arthropods other than bees is expected from the application of GLOB2111F according to the intended GAP.

### 3.7.5 Effects on soil organisms

The TER values ~~together with the higher tier field study~~ indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2111F.

As both the  $PEC_{soil, accumulation}$  of bixafen and the formulation are lower than the concentration at which no significant effects are detected, it can be concluded that the risk of GLOB2111F to soil micro-organisms is acceptable in accordance with the intended use.

### 3.7.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for GLOB2111F shows that the Annex VI trigger value of 5 is not exceeded, indicating that GLOB2111F poses a low risk to non-target terrestrial plants when applied according to the proposed use rates.

### 3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

## 3.8 Relevance of metabolites (Part B, Section 10)

The metabolite of bixafen M44 is predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B, Section 8, Chapter 8.8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is was performed. M44 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.11.

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

Bixafen is no candidate for substitution.

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

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

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

## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.

## Appendix 2 Copy of the product label

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

Zezwolenie MRiRW nr R - z dnia

Posiadacz zezwolenia:

Globachem nv, Brustem Industriepark, Lichtenberglaan 2019, B-3800 Sint Truiden, Belgia,  
tel.: +32 – 11785717, fax.: +32 – 1168 1565, e-mail: globachem@globachem.com


### STARINTA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

biksafen (związek z grupy karboksamidów) – 125 g/l ( %)

Zezwolenie MRiRW nr R- z dnia

	
<b>Niebezpieczeństwo</b>	
H315 H318 H410	Działa drażniąco na skórę. Powoduje poważne uszkodzenie oczu. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P264 P273 P280	Dokładnie umyć ręce po użyciu. Unikać uwolnienia do środowiska. Stosować rękawice ochronne, odzież ochronną, ochronę oczu/ochronę twarzy.
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody/ mydłem.
P305 + P351 + P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P310	Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.
P332 + P313	W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P362 + P364 P391	Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem. Zebrać wyciek.

Zawiera: N-(n-oktylo)-2-pirolidon

## OPIS DZIAŁANIA

FUNGICYD w formie rozpuszczalnego koncentratu (EC) do sporządzania roztworu wodnego o działaniu układowym do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego.

Zgodnie z klasyfikacją FRAC substancja czynna biksafen zaliczana jest do grupy 7 (fungicydy SDHI).

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego. **Środek przeznaczony jest wyłącznie do stosowania łącznego (tank-mix) z innymi środkami grzybobójczymi zalecanymi do zwalczania tych samych chorób w tych samych uprawach.** Środki te powinny zawierać substancje czynne z innej grupy niż grupa FRAC 7. Odnosnie zalecanych środków do łącznego stosowania ze środkiem STARINTA przed wykonaniem zabiegu wskazana jest konsultacja z posiadaczem zezwolenia lub jego przedstawicielem.

### Pszenica ozima

~~Rdza żółta-zbóż, septorioza paskowana liści, septorioza plew pszenicy, rdza brunatna, mączniak prawdziwy-zbóż i traw~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).

~~fuzarioza kłosów~~

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha~~

~~Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki do końca fazy kwitnienia (BBCH 61-69).~~

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

### Jęczmień ozimy, jęczmień jary

~~Rdza jęczmienia, plamistość siatkowa jęczmienia, rynchosporioza zbóż, mączniak prawdziwy-zbóż i traw, ramularia jęczmienia~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).

~~fuzarioza kłosów~~

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha~~

~~Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki (BBCH 61).~~

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

### Żyto ozime, żyto jare

~~Rynchosporioza zbóż, rdza brunatna, mączniak prawdziwy-zbóż i traw~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).



*fuzarioza kłosów*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki do końca fazy kwitnienia (BBCH 61–69).

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

**Pszenżyto ozime, pszenżyto jare**

*Rynchosporioza zbóż, septorioza plew, rdza żółta zbóż, septorioza paskowana liści, mączniak prawdziwy zbóż i traw*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).

*fuzarioza kłosów*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki do końca fazy kwitnienia (BBCH 61–69).

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

**Owies ozimy, owies jary**

*Septorioza paskowana liści, rdza koronowa owsa, helmintosporioza owsa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).

*fuzarioza kłosów*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki (BBCH 61).

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

**Pszenica jara**

*Rdza żółta zbóż, septorioza paskowana liści, septorioza plew pszenicy, rdza brunatna pszenicy, mączniak prawdziwy zbóż i traw*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).

*fuzarioza kłosów*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki do końca fazy kwitnienia (BBCH 61–69).

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste  
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

#### **Pszenica orkisz**

*Rdza brunatna pszenicy, rdza żółta zbóż, plamistość siatkowa, ~~rnychosporioza zbóż~~, septorioza paskowa-na liści, mączniak prawdziwy zbóż i traw*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób, od początku wzrostu źdźbła do początku fazy kwitnienia (BBCH 30-61).

#### *fuzarioza kłosów*

*Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 l/ha*

*Termin stosowania: Środek stosować zaraz po wykłoszeniu, gdy widoczne są pierwsze pylniki do końca fazy kwitnienia (BBCH 61–69).*

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

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 dotyczy

1. Zabieg wykonywać dokładnie, aby wszystkie części rośliny były pokryte cieczą użytkową.
2. Podczas stosowania środka nie dopuścić do:
  - znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
  - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
3. Środek zawiera substancję czynną biksafen z grupy karboksamidów (SDHI - grupa FRAC 7). W ramach strategii antyodpornościowej należy m. in. stosować środek wyłącznie w zalecanej dawce jeden raz w sezonie wegetacyjnym. Zaleca się również włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania (stosowanie przemienne).

#### **NASTĘPSTWO ROŚLIN**

Środek nie stwarza zagrożenia dla roślin uprawianych następczo nawet w przypadku wcześniejszej likwidacji uprawy.

#### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

#### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, 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 wyczyścić.

### **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, ~~odzież ochronną~~, ochronę oczu oraz ochronę twarzy, ~~odzież ochronną~~ zabezpieczającą przed oddziaływaniem środków ochrony roślin oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

~~Zanieczyszczoną odzież ochronną nie wносить poza miejsce pracy.~~

Unikać zanieczyszczenia skóry i oczu.

Dokładnie umyć ręce i twarz po użyciu.

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

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

### **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.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie ~~zadaniowej~~ strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych lub zastosowanie technik redukujących znoszenie cieczy użytkowej o 50% .

### **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
- w dobrze wentylowanym pomieszczeniu.

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 połknięcia: W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc lub z lekarzem. Wypłukać usta.~~

W przypadku kontaktu ze skórą: Umyć dużą ilością wody/ mydłem.

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 lub lekarzem.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.

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

~~W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.~~

~~Wskazówki dla lekarza: leczenie symptomatyczne (dekontaminacja, funkcje vitalne). Płukanie żołądka.~~

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

### **Appendix 3 Letter of Access**

No letter of access submitted.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 1.4.3 (Confidential - Part C)	Anonymous	2023	MSDS of GLOB2111F and its formulants Globachem N.V. Not GLP Unpublished	N	N	-	Globachem NV
KCP 2.1, KCP 2.4.1, KCP 2.4.2, KCP 2.7.1, KCP 2.8.6.1	Kishora, K. S.	2023a	Accelerated storage stability test of GLOB2111F AG-G0103 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.2.1, KCP 2.2.2 (Confidential - Part C)	Kishora, K. S.	2023b	Theoretical certificate of explosive and oxidizing properties for an EC formulation containing 125 g/L Bixafen Eurofins Advinus Agrosiences Services India Private Limited Non-GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.3.1	Kishora, K. S.	2023c	Determination of flash point of GLOB2111F AG-G0106 Eurofins Advinus Agrosiences Services India Private Limited Non-GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.3.3	Kishora, K. S.	2023d	Determination of auto ignition temperature of GLOB2111F AG-G0113 Eurofins Advinus Agrosiences Services India Private Limited Non-GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.5.1	Kishora, K. S.	2023e	Determination of viscosity of GLOB2111F	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
			AG-G0107 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished			before to PL	NV
KCP 2.5.2	Kishora, K. S.	2023f	Determination of surface tension of GLOB2111F AG-G0108 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.6.1	Kishora, K. S.	2023g	Determination of relative density of GLOB2111F AG-G0109 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.7.4	Kishora, K. S.	2023h	Low temperature stability of GLOB2111F AG-G0110 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 2.8.2	Kishora, K. S.	2023i	Determination of presintence foam of GLOB2111F AG-G0111 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 4.2	Kishora, K. S.	2023j	Determination of the effectiveness of cleaning for GLOB2111F AG-G0112 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 5.1.1	Kishora, K.S.	2023	Purity analysis of GLOB2111F AG-G0105 Eurofins Advinus Agrosiences Services India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 5.1.2	Ciorga, B.	2023a	Validation of analytical method for the determination of active substance bixafen concentration in aqueous media solutions of the test item GLOB2111F 0064/0023/FA	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
			SORBOLAB Research Laboratory LLC GLP Unpublished				
KCP 5.1.2	Ciorga, B.	2023b	Validation of analytical method for the determination of active substance bixafen concentrations in aqueous media solutions of the test item GLOB2111F 0064/0035/FA SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 5.1.2	Ballai, C.	2023	Validation of Analytical Method for the Determination of GLOB2111F from Feeding Solutions FPBSTUDY-272-VAL1 FumoPrep Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 5.1.2	Ballai, C.	2023	Validation of Analytical Method for the Determination of GLOB2111F from Surface-treat Solution FPBSTUDY-272-VAL5 FumoPrep Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 5.2	Sam, N.	2023	Validation of analytical method for the determination of bixafen and bixafen-desmethyl residues in animal body fluid and tissues by LC-MS/MS. Report No.: AG-G2321 Eurofins Advinus Agroservices India Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-01	T. McCabe	2021	Efficacy of triazoles in cereals FE-21-B-GLOB2020F-2111F-IE01 Crop Research Limited GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-03	S. Camuñez	2021	Efficacy of triazoles in cereals. Version 2 FE-21-B-GLOB2020F-2111F-PL03	N	Y	Data protection started with: R-161/2024 (22/11/2024)	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
			STAPHYT GEP Unpublished				
KCP 6.2-04	S. Drzewiecki	2021	Efficacy of triazoles in cereals FE-21-B-GLOB2020F-2111F-PL04 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-05	P. Umiński	2022	Efficacy of fungicides in cereals FE-22-L-GLOB2020F-GLOB2111F-PL01 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-06	S. Camuñez	2022	Efficacy of fungicides in cereals. Version 1 FE-22-L-GLOB2020F-GLOB2111F-PL02 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-07	A. Szymura	2022	Efficacy of fungicides in cereals FE-22-L-GLOB2020F-GLOB2111F-PL03 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-08	Z. Sawinska	2022	Efficacy of fungicides in cereals FE-22-L-GLOB2020F-GLOB2111F-PL04 University of Life Sciences ZDD Gorzyń GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-09	M. Koppel	2022	Efficacy of fungicides in cereals FE-22-M-GLOB2020F-GLOB2111F-EE01 Estonian Crop Research Institute GEP	N	Y	Data/study report never submitted before to PL	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2-10	A. Zaluma	2022	Efficacy of fungicides in cereals FE-22-M-GLOB2020F-GLOB2111F-LV02 SIA Agrolab Baltic GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-11	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-M-GLOB2020F-GLOB2111F-LV03 LAAPC GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-12	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-M-GLOB2020F-GLOB2111F-LV04 LAAPC GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-13	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-M-GLOB2020F-GLOB2111F-LV05 LAAPC GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-14	A. Zaluma	2022	Efficacy of fungicides in cereals FE-22-M-GLOB2020F-GLOB2111F-LV06 SIA Agrolab Baltic GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-15	J. Sanders	2021	Efficacy of triazoles in cereals FE-21-B-GLOB2020F-2111F-PT05 Syntech Research Portugal GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-16	H. Zagi	2022	Efficacy of fungicides in cereals	N	Y	Data/study report never submitted	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
			FE-22-S-GLOB2020F-GLOB2111F-HR02 Pest Pro d.o.o. GEP Unpublished			before to PL	
KCP 6.2-17	M. Savvidis	2022	Efficacy of fungicides in cereals FE-22-T-GLOB2020F-GLOB2111F-GR01 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-18	H. Zagi	2022	Efficacy of fungicides in cereals FE-22-T-GLOB2020F-GLOB2111F-HR02 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-19	H. Zagi	2022	Efficacy of fungicides in cereals FE-22-T-GLOB2020F-GLOB2111F-HR03 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-20	S. Lopez Alvarez	2022	Efficacy of fungicides in cereals FE-22-T-GLOB2020F-GLOB2111F-PT05 Syntech Research Portugal GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-21	M. Chourdas	2022	Efficacy of fungicides in cereals. FE-22-S-GLOB2020F-GLOB2111F-GR01 MAGMA-AGRO S.A. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-22	M. Savvidis	2022	Efficacy of fungicides in cereals FE-22-S-GLOB2020F-GLOB2111F-GR03 Agri 2000 Hellas Ltd.	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 Unpublished				
KCP 6.2-23	M. Savvidis	2022	Efficacy of fungicides in cereals FE-22-T-GLOB2020F-GLOB2111F-GR04 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-24	M. Holaschke	2022	Efficacy of fungicides in cereals FE-22-K-GLOB2020F-GLOB2111F-SI01 EAS Austria GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-25	M. Holaschke	2022	Efficacy of fungicides in cereals FE-22-K-GLOB2020F-GLOB2111F-SI03 EAS Austria GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-26	T. Barasits	2022	Efficacy of fungicides in cereals FE-22-N-GLOB2020F-GLOB2111F-HU02 CPR Europe Kft. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-27	B. Lang	2022	Efficacy of fungicides in cereals FE-22-N-GLOB2020F-GLOB2111F-HU01 Plant-Art Research Kft. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-28	K. Hill	2021	Efficacy of fungicides in cereals FE-21-C-GLOB2020F-2111F-IE02 EAS Ireland GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-29	T. McCabe	2021	Efficacy of fungicides in cereals - Winter Barley FE-21-C-GLOB2020F-2111F-IE03 Crop Research Limited GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-30	M. Lenane	2021	Efficacy of fungicides in cereals FE-21-A-GLOB2020F-2111F-IE03 SGS Ireland Ltd GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-31	T. McCabe	2021	Efficacy of fungicides in cereals - Winter Wheat FE-21-A-GLOB2020F-2111F-IE04 Crop Research Limited GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-32	A. Ficke	2022	Efficacy of fungicides in cereals FE-22-F-GLOB2020F-GLOB2111F-NO02 NIBIO GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-34	M. Koppel	2022	Efficacy of fungicides in cereals FE-22-U-GLOB2020F-GLOB2111F-EE01 Estonian Crop Research Institute GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-35	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-U-GLOB2020F-GLOB2111F-LV02 LAAPC GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-36	P. Umiński	2022	Efficacy of fungicides in cereals FE-22-U-GLOB2020F-GLOB2111F-PL03	N	Y	Data/study report submitted to PL along with the submission of Pirlan-	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
			Field Research Support GEP Unpublished			ko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-37	G. Piotrowski	2022	Efficacy of fungicides in cereals FE-22-U-GLOB2020F-GLOB2111F-PL04 SynTech Research Poland Sp.z.o.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlan-ko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-38	K. Gulbis	2021	Efficacy of fungicides in cereals FE-21-C-GLOB2020F-2111F-LV04 Latvian Plant Protection Research Centre Ltd GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-39	S. Camuñez	2021	Efficacy of fungicides in cereals. Version 2 FE-21-C-GLOB2020F-2111F-PL05 STAPHYT GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-40	S. Drzewiecki	2021	Efficacy of fungicides in cereals FE-21-C-GLOB2020F-2111F-PL06 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-41	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-C-GLOB2020F-GLOB2111F-LV01 LAAPC GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlan-ko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-42	P. Umiński	2022	Efficacy of fungicides in cereals FE-22-C-GLOB2020F-GLOB2111F-PL02 Field Research Support GEP	N	Y	Data/study report submitted to PL along with the submission of Pirlan-ko. The product is not registered yet. Data protection to start with the first	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			authorization.	
KCP 6.2-43	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-D-GLOB2020F-GLOB2111F-LV01 LAAPC GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-44	S. Camuñez	2022	Efficacy of fungicides in cereals. Version 1 FE-22-D-GLOB2020F-GLOB2111F-PL02 STAPHYT GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-45	K. Gulbis	2021	Efficacy of fungicides in cereals FE-21-A-GLOB2020F-2111F-LV05 Latvian Plant Protection Research Centre Ltd GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-46	P. Umiński	2021	Efficacy of fungicides in cereals FE-21-A-GLOB2020F-2111F-PL06 Field Research Support GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-47	S. Camuñez	2021	Efficacy of fungicides in cereals. Version 2 FE-21-A-GLOB2020F-2111F-PL07 STAPHYT GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-48	P. Umiński	2022	Efficacy of fungicides in cereals FE-22-H-GLOB2020F-GLOB2111F-PL01 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-49	M. Koppel	2022	Efficacy of fungicides in cereals	N	Y	Data/study report never submitted	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
			FE-22-I-GLOB2020F-GLOB2111F-EE01 Estonian Crop Research Institute GEP Unpublished			before to PL	
KCP 6.2-50	M. Koppel	2022	Efficacy of fungicides in cereals FE-22-I-GLOB2020F-GLOB2111F-EE02 Estonian Crop Research Institute GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-51	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-I-GLOB2020F-GLOB2111F-LV03 LAAPC GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-52	K. Gulbis	2022	Efficacy of fungicides in cereals FE-22-I-GLOB2020F-GLOB2111F-LV04 LAAPC GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-53	H. Zagi	2022	Efficacy of fungicides in cereals. FE-22-P-GLOB2020F-GLOB2111F-HR02 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-55	M. Holaschke	2022	Efficacy of fungicides in cereals. FE-22-P-GLOB2020F-GLOB2111F-SI01 EAS Austria GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-56	H. Zagi	2022	Efficacy of fungicides in cereals. FE-22-R-GLOB2020F-GLOB2111F-HR02 Pest Pro d.o.o.	N	Y	Data/study report submitted to Poland along with the submission of Pirlanko. The product is not regis-	Globachem NV



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished			tered yet. Data protection to start with the first authorization.	
KCP 6.2-57	H. Zagi	2022	Efficacy of fungicides in cereals. FE-22-R-GLOB2020F-GLOB2111F-HR03 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report submitted to Poland along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-58	L. Figuera	2022	Efficacy of fungicides in cereals. FE-22-R-GLOB2020F-GLOB2111F-PT04 AGROLIS CONSULTING GEP Unpublished	N	Y	Data/study report submitted to Poland along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-59	S. Lopez Alvarez	2022	Efficacy of fungicides in cereals. FE-22-R-GLOB2020F-GLOB2111F-PT05 Syntech Research Portugal GEP Unpublished	N	Y	Data/study report submitted to Poland along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-60	M. Holaschke	2022	Efficacy of fungicides in cereals. FE-22-R-GLOB2020F-GLOB2111F-SI01 EAS Austria GEP Unpublished	N	Y	Data/study report submitted to Poland along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-61	M. Chourdas	2021	Efficacy evaluation of the fungicides GLOB1911F, GLOB1813F, GLOB2020aF and GLOB2111F in winter wheat. FE-21-A-GLOB2020F-2111F-GR08 MAGMA-AGRO S.A. GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-62	H. Zagi	2021	Efficacy of fungicides in cereals FE-21-A-GLOB2020F-2111F-HR01 Pest Pro d.o.o. GEP	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2-63	H. Zagi	2022	Efficacy of fungicides in cereals FE-22-O-GLOB2020F-GLOB2111F-HR02 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-64	M. Savvidis	2022	Efficacy of fungicides in cereals FE-22-Q-GLOB2020F-GLOB2111F-GR04 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-65	H. Zagi	2022	Efficacy of fungicides in cereals FE-22-Q-GLOB2020F-GLOB2111F-HR02 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-66	H. Zagi	2022	Efficacy of fungicides in cereals FE-22-Q-GLOB2020F-GLOB2111F-HR03 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-67	S. Lopez Alvarez	2022	Efficacy of fungicides in cereals FE-22-Q-GLOB2020G-GLOB2111F-PT05 Syntech Research Portugal GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-68	M. Chourdas	2022	Efficacy of fungicides in cereals. FE-22-O-GLOB2020F-GLOB2111F-GR01 MAGMA-AGRO S.A. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-69	M. Savvidis	2022	Efficacy of fungicides in cereals	N	Y	Data/study report never submitted	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
			FE-22-O-GLOB2020F-GLOB2111F-GR03 Agri 2000 Hellas Ltd. GEP Unpublished			before to PL	
KCP 6.2-70	M. Savvidis	2022	Efficacy of fungicides in cereals FE-22-Q-GLOB2020F-GLOB2111F-GR01 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-71	B. Lang	2021	Efficacy of fungicides in cereals FE-21-C-GLOB2020F-2111F-HU01 Plant-Art Research Kft. GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-72	B. Lang	2022	Efficacy of fungicides in cereals FE-22-E-GLOB2020F-GLOB2111F-HU01 Plant-Art Research Kft. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-73	T. Barasits	2022	Efficacy of fungicides in cereals FE-22-E-GLOB2020F-GLOB2111F-HU02 CPR Europe Kft. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-74	B. Lang	2021	Efficacy of fungicides in cereals FE-21-A-GLOB2020F-2111F-HU02 Plant-Art Research Kft. GEP Unpublished	N	Y	Data protection started with: R-161/2024 (22/11/2024)	Globachem NV
KCP 6.2-75	M. Holaschke	2022	Efficacy of fungicides in cereals FE-22-F-GLOB2020F-GLOB2111F-SI01 EAS Austria	N	Y	Data/study report never submitted before to PL	Globachem NV

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			GEP Unpublished				
KCP 6.2-76	L. Mihály	2022	Efficacy of fungicides in cereals FE-22-J-GLOB2020F-GLOB2111F-HU01 Agrofil-SZMI Kft. GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-77	P. Sipos	2022	Efficacy of fungicides in cereals FE-22-J-GLOB2020F-GLOB2111F-HU02 EUROFINS AGROSCIENCE SERVICES GEP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 6.2-101	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-T-GLOB2020F-2111F-2021F-CZ01 Agricultural research institut Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-103	L. Jorgensen	2023	Efficacy of fungicides in cereals. FE-23-B-GLOB2020F-2111F-2021F-DK01 Institute of Agroecology, Aarhus University GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-104	L. Møller	2023	Efficacy of fungicides in cereals. FE-23-A-GLOB2020F-2111F-2021F-DK01 VKST Field Trials GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-105	L. Ewaldz	2023	Efficacy of fungicides in cereals. FE-23-A-GLOB2020F-2111F-2021F-SE02 Hushållningssällskapet Skåne GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-106	L. Møller	2023	Efficacy of fungicides in cereals. FE-23-B-GLOB2020F-2111F-2021F-DK02 VKST Field Trials GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-107	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB2020F-2111F-2021F-CZ01 Agricultural research ins GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-108	L. Frydrych	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB2020F-2111F-2021F-CZ02 OSEVA PRO Zubří GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-109	L. Mareckova	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB2020F-2111F-2021F-CZ03 Testing station Krasne Udoli GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-110	L. Bernardová	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB2020F-2111F-2021F-CZ04 Zkusebni stanice Kluky GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-111	L. Trnka	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB2020F-2111F-2021F-CZ05 Zemservis zkusebni stanice Domaninek s.r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-112	L. Bauer	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB2020F-2111F-2021F-CZ06	N	Y	Data/study report submitted to PL along with the submission of Pirlan-	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
			InTec Agro Trials, s.r.o. GEP Unpublished			ko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-113	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-CZ02 Agricultural research institut Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-114	L. Safar	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-CZ03 AGRITEC Research, Breeding and Services, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-115	L. Trnka	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-CZ04 Zemservis zkusebni stanice Domaninek s.r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-116	L. Fiala	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-CZ01 Zkušební stanice Kluky spol. s r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-117	L. Krupa	2023	Efficacy of fungicides in cereals. FE-23-H-GLOB2020F-2111F-2021F-DK02 Ytteborg Field Trials GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-119	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-A-GLOB1811F-2021F-BXN-CZ02 Agricultural research ins GEP	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			authorization.	
KCP 6.2-121	L. Møller	2023	Efficacy of fungicides in cereals. FE-23-H-GLOB2020F-2111F-2021F-DK01 VKST Field Trials GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-124	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-I-GLOB2020F-2111F-2021F-CZ01 Agricultural research institut Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-125	L. Fiala	2023	Efficacy of fungicides in cereals. FE-23-I-GLOB2020F-2111F-2021F-CZ02 Zkušební stanice Kluky spol. s r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-126	L. Mareckova	2023	Efficacy of fungicides in cereals. FE-23-I-GLOB2020F-2111F-2021F-CZ03_ Testing station Krasne Udoli GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-127	L. Trnka	2023	Efficacy of fungicides in cereals. FE-23-I-GLOB2020F-2111F-2021F-CZ04 Zemservis zkusebni stanice Domaninek s.r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-128	L. Safar	2023	Efficacy of fungicides in cereals. FE-23-I-GLOB2020F-2111F-2021F-CZ05 AGRITEC Research, Breeding and Services, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-130	L. Ewaldz	2023	Efficacy of fungicides in cereals.	N	Y	Data/study report submitted to PL	Globachem NV

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			FE-23-N-GLOB2020F-2111F-2021F-SE02 HS Konsult AB GEP Unpublished			along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-131	L. Vaitiekienė	2023	Efficacy of fungicides in cereals. FE-23-N-GLOB2020F-2111F-2021F-SE05 Agrolab Sverige AB GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-132	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-O-GLOB2020F-2111F-2021F-CZ01 Agricultural research institut Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-133	L. Fiala	2023	Efficacy of fungicides in cereals. FE-23-O-GLOB2020F-2111F-2021F-CZ02 Zkušební stanice Kluky spol. s r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-134	L. Subr	2023	Efficacy of fungicides in cereals. FE-23-O-GLOB2020F-2111F-2021F-CZ03 Zkusebni stanice Trutnov s.r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-135	L. Bauer	2023	Efficacy of fungicides in cereals. FE-23-O-GLOB2020F-2111F-2021F-CZ04 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-136	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-S-GLOB2020F-2111F-2021F-CZ01 Agricultural research institut Kromeriz, Ltd.	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet.	Globachem NV



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			GEP Unpublished			Data protection to start with the first authorization.	
KCP 6.2-137	L. Safar	2023	Efficacy of fungicides in cereals. FE-23-S-GLOB2020F-2111F-2021F-CZ02 AGRITEC Research, Breeding and Services, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-138	L. Tvaruzek	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-CZ01 Agricultural research institut Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-139	L. Safar	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-CZ02 AGRITEC Research, Breeding and Services, Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-140	L. Frydrych	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-CZ03 OSEVA PRO Zubří GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-141	L. Trnka	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-CZ04 Zemservis zkusebni stanice Domaninek s.r.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-143	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-T-GLOB2020F-2111F-2021F-LV04 Latvian Plant Protection Research Centre GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-144	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-T-GLOB2020F-2111F-2021F-LV05 Latvian Plant Protection Research Centre GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-145	L. Strzeliński	2023	Efficacy of fungicides in cereals. FE-23-T-GLOB2020F-2111F-2021F-PL06 UP Poznań ZDD URiR Gorzyń GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-146	L. Drzewiecki	2023	Efficacy of fungicides in cereals. FE-23-C-GLOB2020F-2111F-2021F-PL02 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-147	L. Piotrowski	2023	Efficacy of fungicides in cereals. FE-23-C-GLOB2020F-2111F-2021F-PL03 SynTech Research Poland Sp. z o.o. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-148	L. Umiński	2023	Efficacy of fungicides in cereals. FE-23-C-GLOB2020F-2111F-2021F-PL01 Field Research Support GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-149	L. Koppel	2023	Efficacy of fungicides in cereals. FE-23-E-GLOB2020F-2111F-2021F-EE01 Centre of Estonian Rural Research and Knowledge GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-150	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-E-GLOB2020F-2111F-2021F-LV02	N	Y	Data/study report submitted to PL along with the submission of Pirlanko.	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
			Latvian Plant Protection Research Centre GEP Unpublished			ko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-151	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-LV05 Latvian Plant Protection Research Centre GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-152	L. Umiński	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-PL06 Field Research Support GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-153	L. Drzewiecki	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-PL07 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-154	L. Treikale	2023	Efficacy of fungicides in cereals. FE-23-B-GLOB1811F-2021F-BXN-LV010 GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-155	L. Umiński	2023	Efficacy of fungicides in cereals. FE-23-B-GLOB1811F-2021F-BXN-PL02 Field Research Support GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-156	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-I-GLOB2020F-2111F-2021F-LV07 Latvian Plant Protection Research Centre GEP	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first	Globachem NV

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			Unpublished			authorization.	
KCP 6.2-157	L. Umiński	2023	Efficacy of fungicides in cereals. FE-23-J-GLOB2020F-2111F-2021F-PL01 Field Research Support GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-158	L. Rembisz	2023	Efficacy of fungicides in cereals. FE-23-J-GLOB2020F-2111F-2021F-PL02 Green & Property GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-159	L. Koppel	2023	Efficacy of fungicides in cereals. FE-23-N-GLOB2020F-2111F-2021F-EE03 Centre of Estonian Rural Research and Knowledge GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-160	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-N-GLOB2020F-2111F-2021F-LV04 Latvian Plant Protection Research Centre GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-161	L. Umiński	2023	Efficacy of fungicides in cereals. FE-23-P-GLOB2020F-2111F-2021F-PL01 Field Research Support GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-162	L. Drzewiecki	2023	Efficacy of fungicides in cereals. FE-23-P-GLOB2020F-2111F-2021F-PL02 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-163	L. Szemendera	2023	Efficacy of fungicides in cereals.	N	Y	Data/study report submitted to PL	Globachem NV

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			FE-23-M-GLOB2020F-2111F-2021F-PL08 Fertico GEP Unpublished			along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-164	L. Koppel	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-EE05 Centre of Estonian Rural Research and Knowledge GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-165	L. Gulbis	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-LV06 Latvian Plant Protection Research Centre GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-166	L. Strzeliński	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-PL07 UP Poznań ZDD U RiR Gorzyń GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-167	L. Szemendera	2023	Efficacy of fungicides in cereals. FE-23-P-GLOB2020F-2111F-2021F-PL03P Fertico GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-168	L. Savvidis	2023	Efficacy of fungicides in cereals. FE-23-F-GLOB2020F-2111F-2021F-GR03 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-169	L. Savvidis	2023	Efficacy of fungicides in cereals. FE-23-F-GLOB2020F-2111F-2021F-GR04 Agri 2000 Hellas Ltd.	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet.	Globachem NV

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			GEP Unpublished			Data protection to start with the first authorization.	
KCP 6.2-170	L. Žagi	2023	Efficacy of fungicides in cereals. FE-23-F-GLOB2020F-2111F-2021F-HR01 Pest Pro doo GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-171	L. Žagi	2023	Efficacy of fungicides in cereals. FE-23-F-GLOB2020F-2111F-2021F-HR02 Pest Pro doo GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-172	L. Godinho	2023	Efficacy of fungicides in cereals. FE-23-F-GLOB2020F-2111F-2021F-PT05 SAGEA Lda GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-173	L. Žagi	2023	Efficacy of fungicides in cereals. FE-23-R-GLOB2020F-2111F-2021F-HR08 Pest Pro doo GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-174	L. Godinho	2023	Efficacy of fungicides in cereals. FE-23-C-GLOB1811F-2021F-BXN-PT01 SAGEA Lda GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-175	L. Savvidis	2023	Efficacy of fungicides in cereals. FE-23-C-GLOB1811F-2021F-BXN-GR02 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-176	L. Savvidis	2023	Efficacy of fungicides in cereals. FE-23-L-GLOB2020F-2111F-2021F-GR01 Agri 2000 Hellas Ltd. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-177	L. Godinho	2023	Efficacy of fungicides in cereals. FE-23-L-GLOB2020F-2111F-2021F-PT02 SAGEA Lda GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-178	L. Chourdas	2023	Efficacy of fungicides in cereals. FE-23-N-GLOB2020F-2111F-2021F-GR06 MAGMA-AGRO S.A. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-179	L. Alvarez Silvia	2023	Efficacy of fungicides in cereals. FE-23-N-GLOB2020F-2111F-2021F-PT07 Syntech Research Portugal GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-180	L. Žagi	2023	Efficacy of fungicides in cereals. FE-23-M-GLOB2020F-2111F-2021F-HR09 Pest Pro doo GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-181	L. Lang	2023	Efficacy of fungicides in cereals. FE-23-G-GLOB2020F-2111F-2021F-HU01 Plant-Art Research Kft. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-182	L. Sipos	2023	Efficacy of fungicides in cereals. FE-23-G-GLOB2020F-2111F-2021F-HU02	N	Y	Data/study report submitted to PL along with the submission of Pirlanko.	Globachem NV

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			EAS Hungary, Székesfehérvár GEP Unpublished			ko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-183	L. Ferencz	2023	Efficacy of fungicides in cereals. FE-23-G-GLOB2020F-2111F-2021F-RO03 Syntech Research Agrico SRL GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-184	L. Ene	2023	Efficacy of fungicides in cereals. FE-23-G-GLOB2020F-2111F-2021F-RO04 Sagea Agromania GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-185	L. Holaschke	2023	Efficacy of fungicides in cereals. FE-23-G-GLOB2020F-2111F-2021F-SI05 EAS Austria GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-186	L. Sipos	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB1811F-2021F-BXN-HU02 EAS Hungary, Székesfehérvár GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-187	L. Ferencz	2023	Efficacy of fungicides in cereals. FE-23-D-GLOB1811F-2021F-BXN-RO01 Syntech Research Agrico SRL GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-188	L. Lang	2023	Efficacy of fungicides in cereals. FE-23-K-GLOB2020F-2111F-2021F-HU01 Plant-Art Research Kft. GEP	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first	Globachem NV



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			Unpublished			authorization.	
KCP 6.2-189	L. Mihály	2023	Efficacy of fungicides in cereals. FE-23-K-GLOB2020F-2111F-2021F-HU02 Agrofil-SZMI Kft. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-190	L. Barasits	2023	Efficacy of fungicides in cereals. FE-23-K-GLOB2020F-2111F-2021F-HU04 CPR Europe Kft. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-191	L. Ferencz	2023	Efficacy of fungicides in cereals. FE-23-K-GLOB2020F-2111F-2021F-RO03 Syntech Research Agrico GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-192	L. Holaschke	2023	Efficacy of fungicides in cereals. FE-23-K-GLOB2020F-2111F-2021F-SI05 EAS Austria GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-193	L. Policnik	2023	Efficacy of fungicides in cereals. FE-23-K-GLOB2020F-2111F-2021F-SI06 Slovenian Institute of Hop Research and Brewing GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-194	L. Hajnal	2023	Efficacy of fungicides in cereals. FE-23-Q-GLOB2020F-2111F-2021F-HU01 Field Test Hungary Kft. GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 6.2-195	L. Ferencz	2023	Efficacy of fungicides in cereals.	N	Y	Data/study report submitted to PL	Globachem NV

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			FE-23-Q-GLOB2020F-2111F-2021F-RO02 Syntech Research Agrico GEP Unpublished			along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	
KCP 6.2-196	L. Holaschke	2023	Efficacy of fungicides in cereals. FE-23-Q-GLOB2020F-2111F-2021F-SI03 EAS Austria GEP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Pirlanko. The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 7.1.4	Ashwini, C.	2023	GLOB2020aF: in vitro skin corrosion: reconstructed human epidermis (RhE) test method AD-G1189 Adgyl Lifesciences Private Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 9.2.4	Fernandez D.	2023	Estimation of the Predicted Environmental Concentration of bixafen in groundwater following the application of GLOB2111F to winter and spring cereals GLOB2111F-Bixf-GW Globachem NV Non-GLP Unpublished	N	N	-	Globachem NV
KCP 9.2.5	Fernandez D.	2023	Estimation of the Predicted Environmental Concentration of bixafen in surface water following the application of GLOB2111F to winter and spring cereals GLOB2111F-Bixf-SW Globachem NV Non-GLP Unpublished	N	N	-	Globachem NV
KCP 10.2.1	Zaworska, K.	2023	<i>Daphnia magna</i> acute immobilization test of the test item GLOB2111F according to OECD guideline 202.0064/0025/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.2.1	Domagała, J.	2023	Freshwater algae ( <i>Raphidocelis subcapitata</i> ) growth inhibition	N	Y	Data/study report never submitted	Globachem

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			test of the test item GLOB2111F according to OECD 201 guideline. 0064/0024/E SORBOLAB Research Laboratory LLC GLP Unpublished			before to PL	NV
KCP 10.3.1.1	Orosz, I.	2023	A GLP acute contact and oral toxicity study with GLOB2111F on honey bees ( <i>Apis mellifera</i> ). 22/139-116MT Charles River Laboratories Hungary Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.3.1.1	Orosz, I.	2024	A GLP acute contact and oral toxicity study with GLOB2111F on bumblebees ( <i>Bombus terrestris</i> ). 22/139-116MTB. Charles River Laboratories Hungary Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.3.1.2	Orosz, I.	2024	A GLP 10-day chronic oral toxicity study with GLOB2111F on honey bees ( <i>Apis mellifera</i> ). 22/139-134MT Charles River Laboratories Hungary Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.3.1.2	Woźniak, A	2023	Honey bee larval toxicity test following repeated exposure of the test item GLOB2111F according to OECD GD 239 ENV/JM/MONO(2016)34. 0064/0026/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.3.2	Kulec-Płoszczycza, E.	2024	Extended laboratory residual contact test with the predatory mite <i>Typhlodromus pyri</i> for regulatory testing of GLOB2111F. ETOX-2023-30 EcoTox Alliance Sp. z o. o. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.3.2	Balász, O	2023	Effect of GLOB2111F on the parasitic wasp ( <i>Aphidius</i>	N	Y	Data/study report never submitted	Globachem

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			<i>rhopalosiphi</i> ) in an extended laboratory trial. 22/139-351FD Charles River Laboratories Hungary Kft. GLP Unpublished			before to PL	NV
KCP 10.3.2	Kubisiak, K.	2023	Extended laboratory test to determine the effects of the test item GLOB2111F on the green lacewing ( <i>Chrysoperla carnea</i> ). 0064/0028/E SORBOLAB Research Laboratory LLC. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.3.2	Domagała, J.	2023	Extended laboratory test to determine the effects of the test item GLOB2111F on the ladybird beetle ( <i>Coccinella septempunctata</i> ). 0064/0027/E SORBOLAB Research Laboratory LLC. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.4.1.1	Orosz, I.	2023	A GLP reproduction study of GLOB2111F on earthworms ( <i>Eisenia fetida</i> ). 22/139-211G Charles River Laboratories Hungary Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.4. 2	Orosz, I.	2023	A GLP Reproduction Test of GLOB2111F in Soil with Collembolan ( <i>Folsomia candida</i> ). 22/139-130CO Charles River Laboratories Hungary Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.4. 2	Orosz, I.	2024	A GLP Reproduction Test of GLOB2111F in Soil with Predatory mite ( <i>Hypoaspis (Geolaelaps) aculeifer</i> ). 22/139-389TLA Charles River Laboratories Hungary Kft. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.5	Adamesik, B.	2024	A GLP Soil Microorganisms Nitrogen Transformation Study of GLOB2111F. 22/139-055AN	N	Y	Data/study report never submitted before to PL	Globachem NV

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			Charles River Laboratories Hungary Kft. GLP Unpublished				
KCP 10.6.2	Woźniak, A.	2024	Terrestrial plant test: vegetative vigour test of the test item GLOB2111F according to OECD 227 guideline. 0064/0044/E SORBOLAB Research Laboratory LLC. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV
KCP 10.6.2	Woźniak, A.	2024	Terrestrial plant test: seedling emergence and seedling growth test of the test item GLOB2111F according to OECD 208 Guideline. 0064/0043/E SORBOLAB Research Laboratory LLC. GLP Unpublished	N	Y	Data/study report never submitted before to PL	Globachem NV

**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
KCP 5.1.2	Schoening, R.	2006	Analytical method 01012 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on plant matrices by HPLC-MS/MS Report No.: 01012 Bayer CropScience AG GLP Unpublished	N	N		BCS
KCP 5.1.2	Schoening, R., Willmess, J.	2007	Analytical method 01036 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on animal tissues by HPLC-MS/MS Report No.: 01036 Bayer CropScience AG	N	N		BCS

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			GLP Unpublished				
KCP 5.1.2 KCP 5.2	Bardel, P.; Schoening, R.	2006	Analytical method 00983 for the determination of residues of BYF00587 in/on plant matrices by HPLC-MS/MS Report No.: 00983 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 5.1.2 KCP 5.2	Billian, P.; Druskus, M.	2007	Analytical method 01063 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on animal tissues, milk and eggs by HPLC-MS/MS Report No.: 01063 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 5.1.2 KCP 5.2	Brumhard, B.; Freitag, T	2006	Analytical method 00952 for the determination of residues of BYF 00587 in soil by HPLC-MS/MS Bayer CropScience AG, Report No.: 00952, Edition Number: M-281557-01-1 Date: 11.12.2006 GLP, unpublished GLP Unpublished	N	N	-	BCS
KCP 5.1.2 KCP 5.2	Krebber, R.; Braune, M.	2008	Analytical method 01073 for the determination of bixafen (BYF 00587) in drinking and surface water by HPLCMS/MS Report No.: 01073 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 5.1.2 KCP 5.2	Class, T	2007	BYF 00587: Analytical method for the determination of BYF 00587 in air PTRL Europe, Ulm, Germany Report No.: P605077505 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 5.2	Ballesteros, C.; Portet, M.	2008	Independent laboratory validation of the analytical method 00983 for the determination of residues of BYF 00587 in/on Plant Matrices by HPLC-MS/MS Report No.: MR-08/005 Bayer CropScience S.A., Lyon, France Bayer CropScience AG	N	N	-	BCS

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
			GLP Unpublished				
KCP 5.2	Ballesteros, C.	2007	Independent Laboratory Validation of the Analytical method 01063 for the determination of residues of BYF00587 and its metabolite BYF00587-desmethyl in/on animal tissues, milk and eggs by HPLC-MS/MS Report No.: MR-08/004 Bayer CropScience S.A., Lyon, France Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 6.4	Schulz, M.; Landsiedel, R.	2007	Reg.No. 5435595 (metabolite of BAS 700 F) - <i>Salmonella typhimurium</i> / <i>Escherichia coli</i> reverse mutation assay (standard plate test and preincubation test). 2007/1051931 BASF AG GLP Unpublished	✗ N	N	-	BASF
KCP 6.4	Schulz, M.; Landsiedel, R.	2008a	Reg.No. 5435595 (metabolite of BAS 700 F) - In vitro chromosome aberration assay in V79 cells. 2008/1002741 BASF SE GLP Unpublished	✗ N	N	-	BASF
KCP 6.4	Schulz, M.; Landsiedel, R.	2008b	Reg.No. 5435595 (metabolite of BAS 700 F) - In vitro gene mutation test in CHO cells (HPRT locus assay). 2008/1014199 BASF SE GLP Unpublished	✗ N	N	-	BASF
KCP 6.4	██████████	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Micronucleus test in bone marrow cells of the mouse. ██████████ GLP Unpublished	Y	N	-	BASF
KCP 6.4	██████████	2009	Reg.No. 5435595 (metabolite of BAS 700 F) - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage). ██████████	Y	N	-	BASF

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
			GLP Unpublished				
KCP 6.4		2009	Reg.No. 5069089 (metabolite of BAS 700 F) - Repeated dose 90-day oral toxicity study in Wistar rats - Administration in the diet GLP Unpublished	Y	N	-	BASF
KCA 6.1	Billian, P.	2008	Storage stability of BYF 00587 and its metabolite BYF00587-desmethyl in/on wheat (grain, straw, green material), potato tuber, lettuce head and oil seed rape for 24 months. Report No.: MR-06/141 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.2.1	Miebach, D.; Bon-gartz, R.	2007a	Metabolism of [pyrazole-5- <sup>14</sup> C]BYF00587 in wheat after spray application Report No.: MEF-06/347 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.2.1	Miebach, D.; Bon-gartz, R.	2007b	Metabolism of [dichlorophenyl-UL- <sup>14</sup> C]BYF00587 in wheat after spray application Report No.: MEF-06/348 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.2.1	Spiegel, K.	2007a	Metabolism of [pyrazole-5- <sup>14</sup> C]BYF00587 in soybeans after spray application Report No.: MEF-07/069 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.2.1	Spiegel, K.	2007b	Metabolism of [dichlorophenyl-UL- <sup>14</sup> C]BYF00587 in soybeans after spray application Report No.: MEF-07/068 Bayer CropScience AG GLP	N	N	-	BCS



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.2.2		2007a	Metabolism of [pyrazole-5- <sup>14</sup> C]BYF 00587 in the laying hen GLP Unpublished	Y	N	-	BCS
KCA 6.2.2		2007b	Metabolism of [dichlorophenyl-UL- <sup>14</sup> C]BYF 00587 in the laying hen GLP Unpublished	Y	N	-	BCS
KCA 6.2.3		2007a	Metabolism of [pyrazole-5- <sup>14</sup> C]BYF 00587 in the lactating goat GLP Unpublished	Y	N	-	BCS
KCA 6.2.3		2007b	Metabolism of [dichlorophenyl-UL- <sup>14</sup> C]BYF 00587 in the lactating goat GLP Unpublished	Y	N	-	BCS
KCA 6.3.1	Schoening, R.; Raecker, T.; Erler, S.	2007	Determination of the residues of BYF 00587 in/on spring wheat and winter wheat after spraying of BYF 00587 (125 EC) in the field in Northern France, Sweden, the United Kingdom and Germany Report No.: RA-2320/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.3.1	Schoening, R.; Reincke, A.	2008	Determination of the residues of BYF 00587 in/on winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Northern France, the United Kingdom, Sweden and Germany Report No.: RA-2006/07 Bayer CropScience AG GLP	N	N	-	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.3.1	Schoening, R.; Raecker, T.; Lorenz, S.	2007	Determination of the residues of BYF 00587 in/on winter wheat, wheat, durum and spring wheat after spraying of BYF 00587 (125 EC) in the field in Greece, Italy, Southern France and Spain Report No.: RA-2321/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.3.1	Schoening, R.; Reincke, A.	2008b	Determination of the residues of BYF 00587 in/on spring wheat, wheat, durum and winter wheat after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy, Spain and Portugal Report No.: RA-2005/07 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.3.2	Schoening, R.; Raecker, T.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Northern France, Sweden, the United Kingdom and Germany Report No.: RA-2322/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.3.2	Schoening, R.; Reincke, A.	2008	Determination of the residues of BYF 00587 in/on spring barley after spraying of BYF 00587 (125 EC) in the field in Northern France, Germany, the United Kingdom and Belgium Report No.: RA-2003/07 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.3.2	Schoening, R.; Raecker, T.; Erler, S	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy, Spain and Portugal Report No.: RA-2323/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.2	Schoening, R.; Reincke, A.	2007	Determination of the residues of BYF 00587 in/on spring barley and winter barley after spraying of BYF 00587 (125 EC) in the field in Southern France, Italy and Spain Report No.: RA-2004/07 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.4.1	[REDACTED]	2007	Bixafen: Feeding study laying hens ( <i>Gallus gallus domesticus</i> ) [REDACTED] GLP Unpublished	Y	N	-	BCS
KCA 6.4.2	[REDACTED]	2008	Bixafen: Feeding study with dairy cows [REDACTED] GLP Unpublished	Y	N	-	BCS
KCA 6.5.1	Justus, K.; Kuhnke, G.	2008	BYF 00587: Aqueous hydrolysis under conditions of processing studies Report No.: MEF-07/437 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.5.3	Schoening, R.; Billian, P.; Wolters, A.	2007	Determination of the residues of BYF 00587 in/on spring barley grain and the processed fractions (brewers's malt; malt culms; ... ) after spraying of BYF 00587 (125 EC) in the field in Sweden, Germany and Northern France. Report No.: RA-3324/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.6.2	Weber, E.; Spiegel, K.; Koehn, D.	2007a	Metabolism of [pyrazole-5- <sup>14</sup> C]BYF 00587 in confined rotational crops Report No.: MEF-07/071 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.6.2	Weber, E.; Spiegel,	2007b	Metabolism of [dichlorophenyl-UL- <sup>14</sup> C]BYF 00587 in confined	N	N	-	BCS

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
	K.; Koehn, D.		rotational crops Report No.: MEF-07/070 Bayer CropScience AG GLP Unpublished				
KCA 6.6.3	Schoening, R.; Erler, S	2008a	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Germany Report No.: RA-2139/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.6.3	Schoening, R.; Erler, S.	2008b	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Northern France Report No.: RA-2143/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCA 6.6.3	Schoening, R.; Erler, S.	2008c	Determination of the residues of BYF 00587 in/on the field rotational crops turnip, lettuce, winter wheat and spring wheat after spraying of BYF 00587 (125 EC) in the field in Germany Report No.: RA-2144/06 Bayer CropScience AG GLP unpublished	N	N	-	BCS
KCA 6.6.3	Schoening, R.; Erler, S.	2008d	Determination of the residues of BYF 00587 in/on the field rotational crops carrot, lettuce and winter wheat after spraying of BYF 00587 (125 EC) in the field in Spain Report No.: RA-2145/06 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 9.1.1.1	Sneikus, J. ; Koehn, D.	2005	[Pyrazole-5-14C] and [dichlorophenyl-UL14C]BYF00587: Aerobic soil metabolism in 4 EU soils Bayer Crop Science AG Report No.: MEF-05/172	N	N	-	BCS

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
			GLP Unpublished				
KCP 9.1.1.1	Unold, M.; Bayer, H.	2009	Rate of degradation of M700F002 (metabolite of BAS 700 F) in aerobic soil. BASF SE 2009/1070322 GLP Unpublished	N	N	-	BASF
KCP 9.1.1.1	Simmonds, M.; Lowden, P.	2006	[Dichlorophenyl-UL-14C] and [pyrazole-5-14C]-BYF00587: Anaerobic soil degradation Battelle UK Ltd. / Bayer Crop Science AG Report No.: CX/05/045 GLP Unpublished	N	N	-	BCS
KCP 9.1.1.2	Heinemann, O.	2007	Determination of the residues of BYF 00587 and BYF 00587-desmethyl in/on soil after spraying of BYF 00587 (450 SC) in the field in Germany, United Kingdom, Sweden, France, Spain and Italy Bayer Crop Science AG, Report No.: RA-2056/05 GLP Unpublished	N	N	-	BCS
KCP 9.1.1.2	Unold, M.; <i>et al.</i>	2009	Field soil dissipation study of M700F002 (metabolite of BAS 700 F) in the formulation EXP 5435595 on bare soil at four different locations in Europe, 2008-2009. BASF SE; 2009/1070325 GLP Unpublished	N	N	-	BASF
KCP 9.1.1.2	Hardy, I.A.J.	2009a	BAS 700 F: Kinetic modelling analysis of M700F002 data from field soil residue studies conducted in Europe. Battelle UK Ltd Non-GLP Unpublished	N	N	-	BASF
KCP 9.1.1.2	Hardy, I.A.J.	2009b	BAS 700 F: Timestep normalisation analysis of M700F002 data from field soil residue studies conducted in Europe. Battelle UK Ltd 2009/1093281 Non-GLP	N	N	-	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 9.1.2.1	Koehn, D.; Haas, M	2005	BYF00587: Adsorption/desorption on five soils Bayer Crop Science AG Report No.: MEF-04/455, GLP Unpublished	N	N	-	BCS
KCP 9.1.2.1	Hassink, J.; Stephan, A.	2009	Determination of the adsorption/desorption behaviour of M700F002 (metabolite of BAS 700 F) on different soils BASF SE 2009/1070296 GLP Unpublished	N	N	-	BASF
KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3	Oddy, A.; Doble, M.	2006	[Dichlorophenyl-UL-14C] and [pyrazole-5-14C]-BYF 00587: Degradation and retention in two water/sediment systems Battelle UK Ltd. / Bayer Crop Science AG Report No.: CX/05/060 GLP Unpublished	N	N	-	BCS
KCP 10.1.1		2005	Acute oral toxicity for bobwhite quail ( <i>Colinus virginianus</i> ) with BYF 00587 techn. a.s.. GLP Unpublished	Y	N	-	BCS
KCP 10.1.1		2007	BYF 00587: Effects of a subchronical dietary exposure to northern bobwhite quails including effects on reproduction and behaviour. GLP Unpublished	Y	N	-	BCS
KCP 10.1.1		2009	Toxicity of Bixafen (BYF 00587) Technical on the 6-Week Reproduction to the Bobwhite Quail ( <i>Colinus virginianus</i> ). GLP Unpublished	Y	N	-	BCS
KCP		2005	BYF 00587 - Acute toxicity in the rat after oral administration.	Y	N	-	BCS

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
10.1.2			GLP Unpublished				
KCP 10.1.2		2007	Technical grade BYF 00587: A two generation reproductive toxicity study in the Wistar rat. GLP Unpublished	Y	N	-	BCS
KCP 10.2.1		2006	Acute toxicity of BYF 00587 (tech.) to fish ( <i>Oncorhynchus mykiss</i> ) under static conditions. GLP Unpublished	Y	N	-	BCS
KCP 10.2.1	Bruns, E.	2006	Acute toxicity of BYF 00587 tech. to the waterflea <i>Daphnia magna</i> in a static laboratory test system Report No.: EBDP004 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 10.2.1	Dorgerloh, M.	2006a	<i>Pseudokirchneriella subcapitata</i> growth inhibition test with BYF 00587 AG. Report No.: EBDP005 Bayer CropScience GLP Unpublished	N	N	-	BCS
KCP 10.2.2		2006b	Early-life Stage toxicity of BYF 00587 tech. to fish ( <i>Pimephales promelas</i> ) GLP Unpublished	Y	N	-	BCS
KCP 10.2.2	Bruns, E.	2007	Influence of BYF00587 (tech.) on development and reproductive output of the waterflea <i>Daphnia magna</i> in a static renewal laboratory test system. Report No.: EBDP064 Bayer CropScience AG GLP	N	N	-	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.2.2	Dorgerloh, M.	2007	<i>Chironomus riparius</i> 28-day chronic toxicity test with bixafen (tech.) in a watersediment system using spiked water. Report No.: EBDP088 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 10.2.2	Bruns, E.	2009	<i>Chironomus riparius</i> 28-day chronic toxicity test with bixafen (tech.) in a watersediment system using spiked sediment. Report No.: EBDP155 Bayer CropScience AG GLP Unpublished	N	N	-	BCS
KCP 10.3.1.1	Schmitzer, S.	2005	Effects of BYF 00587 (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory Report No.: 24481035 IBACON GmbH GLP Unpublished	N	N	-	BCS
KCP 10.4.1	Luehrs, U.	2006a	BYF 00587: Acute toxicity (14 days) to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat Report No.: 29612021 IBACON GmbH GLP Unpublished	N	N	-	BCS
KCP 10.4.1.1	Luehrs, U.	2006b	BYF 00587: Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil with 5% pea Report No.: 29611022 IBACON GmbH GLP Unpublished	N	N	-	BCS
KCP 10.4.2	Luehrs, U.	2007	BYF 00587 EC 125: effects on reproduction of the collembola <i>Folsomia candida</i> in artificial soil with 5% peat Report No.: 36952016 IBACON GmbH GLP Unpublished	N	N	-	BCS
KCP	Kratz, M. A.	2007	Bixafen EC 125: Influence on mortality and reproduction on the	N	N	-	BCS



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10.4.2			soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat Bayer CropScience AG Report No.: KRA-HR-4/07 GLP Unpublished				
KCP 10.5	Leicher, T.;	2007	Determination of effects on nitrogen transformation in soil. Report No.: LRT-N-79/07 Bayer CropScience AG GLP Unpublished	N	N	-	BCS

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

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

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

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