

# REGISTRATION REPORT

## Part A

### Risk Management

Product code: GLOB1912H

Product name: **Jura Max**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland  
(authorization)

Applicant: Globachem NV

Submission date: November 2021

Evaluation date: August 2022

MS Finalisation date: December 2022

## Version history

When	What
November 2021	Initial dossier submission by the applicant for approval of new product.
August 2022	Version evaluated by zRMS PL
December 2022	Revised version taking into account comments of cMSs and the applicant
July 2023	Version revised taking into account comments of cMSs

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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 November 2021.

The application was for approval of GLOB1912H, a suspension concentrate containing 667 g/L prosulfocarb and 14 g/L diflufenican for use as a herbicide in winter cereals, potato and sunflower for which Poland was designated zRMS.

#### 1.2 Letters of Access

A Letter of Access for a worker exposure study related to prosulfocarb from Syngenta was submitted.

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

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

#### 1.4 Data protection claims

Data protection is claimed 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	GLOB1912H
Product name in MS	Jura Max
Authorization number	/
Function	Herbicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Prosulfocarb: 667 g/L Diflufenican: 14 g/L
Formulation type	Emulsifiable concentrate (EC)
Packaging	0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 20 L HDPE-F;HDPE-EVOH;HDPE/PA

Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

## 2.2 Conclusion

The evaluation of the application for product JURA MAX (GLOB1912H) resulted in the decision to grant the authorization.

All uses applied for were authorised.

## 2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

## 2.4 Classification and labelling

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

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

Hazard class(es), categories:	<del>Acute Tox. 4</del> , Eye Dam. 1, Skin Sens. 1, STOT SE3, Aquatic Acute 1, Aquatic Chronic 1 <sup>2</sup>
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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:	<b>GHS05, GHS07, GHS09</b>
Signal word:	<b>Danger</b>
Hazard statement(s):	<del>H302</del> , <b>H317, H318, H336, H411, H410</b>
Precautionary statement(s):	P261, <del>P264</del> , P270, P271, P272, <del>P273</del> , P280, <del>P301+P312</del> , P302+P352, P304+P340, P305+P351+P338, P310, P312, P321, <del>P330</del> , P333+P313, <del>P362+P364</del> , P403+P233, P405, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] <b>EUH066 Repeated exposure may cause skin dryness or cracking</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.
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### 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application
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	equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<del>To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.</del> To protect aquatic organisms respect an unsprayed buffer zone of 10 m to surface water bodies including a 10 m vegetated filter strip
SPe3	To protect non-target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 5 m in combination <del>with 75% drift reducing nozzles or an unsprayed buffer zone of 3 m in combination</del> with 50% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non-agricultural land. (3.2 L/ha)
SPe3	<del>To protect non-target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 3 m in combination with 50% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non-agricultural land. (3.0 L/ha)</del>

### 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:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
<del>P264</del>	<del>Wash hands, forearms and face thoroughly after handling.</del>
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well ventilated area.
P272	Contaminated work clothing should not be allowed to out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
<del>P301+P312</del>	<del>IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.</del>
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor.
P312	Call a POISON CENTER or doctor if you feel unwell.
P321	Specific treatment (see supplemental first aid instruction on this label).
<del>P330</del>	<del>Rinse mouth.</del>
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+ <del>P364</del>	Take off contaminated clothing and wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

P405	Store locked up.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
<del>P273</del>	<del>Avoid release to the environment.</del>
P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
SPe3	<del>To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.</del> To protect aquatic organisms respect an unsprayed buffer zone of 10 m to surface water bodies including a 10 m vegetated filter strip
SPe3	To protect non-target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 5 m in combination <del>with 75% drift reducing nozzles or an unsprayed buffer zone of 3 m in combination</del> with 50% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non-agricultural land. (3.2 L/ha)
SPe3	<del>To protect non target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 3 m in combination with 50% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non agricultural land. (3.0 L/ha)</del>
Other specific restrictions	
EUH401 EUH066	To avoid risks to man and the environment, comply with the instructions for use. Repeated exposure may cause skin dryness or cracking EUH066

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

Integrated pest management (IPM)/sustainable use:	
-	-

## 2.5.2 Specific restrictions linked to the intended uses

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

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

## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	GLOB1912H	Formulation type:	GAP rev. 1, date: 2021-06-11 Emulsifiable concentrate (EC)
Active substance 1:	Prosulfocarb	Conc. of as 1:	667 g/L <sup>(c)</sup>
Active substance 2:	Diflufenican	Conc. of as 2:	14 g/L <sup>(c)</sup>
Safener:	/	Conc. of safener:	/ <sup>(c)</sup>
Synergist:	/	Conc. of synergist:	/ <sup>(c)</sup>
Applicant:	Globachem NV	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	South <sup>(d)</sup>	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		

Field of use:

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, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	/
2	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/
3	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-21	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	/
4	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-21	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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		
		wheat (TRZDW) , Spelt (TRZSP)											
5	PL	Potato (SOLTU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160- 300	/	/
6	PL	Potato (SOLTU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160- 300	/	/
7	PL	Sunflower (HELAN)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a) Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160- 300	/	/
8	PL	Sunflower (HELAN)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160- 300	/	/

**Remarks table heading:**

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

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

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<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

**Overall summary:** 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 light-yellow liquid, with a solvent odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a flash point of 66.0°C. In aqueous solution, it has a pH value around 6.84 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. ~~The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE F, HDPE EVOH or HDPE/PA.~~ The two-year storage stability study is ongoing. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation.

**Implications for labelling:** none

**Compliance with FAO specifications:** The product GLOB1912H complies with the general FAO specifications.

**Compatibility of mixtures:** not applicable as no tank mixtures are mentioned on the label.

**Nature and characteristics of the packaging:** Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

**Nature and characteristics of the protective clothing and equipment:** Information regarding the required protective clothing and equipment for the safe handling of GLOB1912H has been provided and is considered to be acceptable

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

##### 3.2.1 Efficacy data

GLOB1912H is an emulsifiable concentrate formulation (EC) containing the active ingredients prosulfocarb (667 g/L) and diflufenican (14 g/L). It is used for pre- and post-emergence weed control in winter cereals and pre-emergence weed control in potatoes and sunflowers. Both active substances are known and are already present on the market either alone or in mixture with other herbicides. The proposed label rates for GLOB1912H are 3 L/ha and 3.2 L/ha . From the presented results it can be concluded that most of the weeds commonly found on fields where cereals, potatoes or sunflowers are grown can be controlled by GLOB1912H, applied at the proposed dose rates.

GLOB1912H is an emulsifiable concentrate formulation containing prosulfocarb and diflufenican at concentrations of 667 g/L and 14 g/L per l product. It is recommended as a pre-emergence or early post-emergence treatment for the control of some annual grasses and broadleaved weeds in winter cereals and as a pre-emergence application in potatoes and sunflowers. Results referring to the efficacy of GLOB1912H were obtained in 104 efficacy trials carried out in 2019 – 2020. The applicant highly lights that GLOB1912H is similar to the already registered in many countries of UE product Jura (EC). It should be noted that the majority of the data were produced in the Maritime and North-East EPPO zones, with a limited number of trials in the South-East zone. Therefore, cMS based on national experience should consider whether presented data there are appropriate to support the registration of GLOB1912H.

### **Preliminary tests**

No preliminary results are presented in support of GLOB1912H. The applicant claims that the product GLOB1912H contains the same amount of active substances as the already registered product JURA EC. JURA EC was developed with 667 g/l prosulfocarb and 14 g/l diflufenican (ratio 47.6:1) with a target dose of 4 l/ha (2201 g/ha prosulfocarb and 56 g/ha diflufenican). The applicant concluded that the dose rate of GLOB1912H can be reduced by 20% (3.2 l/ha) when applied to winter cereals compared to Jura (EC), while still providing the same level of weed control.

### **Minimum effective dose**

#### **MARITIME EPPO Zone**

##### **Minimum effective dose for the pre-emergence use on potatoes**

To fulfil the requirements of justifying the minimum effective dosage according to EPPO guideline PP1/225 (1) GLOB1912H on potatoes was tested in a range of field efficacy trials at application rates of the intended full application rate of 3,2 L/ha and at the reduced rates of 2 L/ha. Overall, all trials showed a numerical, if not statistically significant efficacy increase if the maximum claimed application rate of 3,2 L/ha for GLOB1912H was applied in comparison to reduced dose rate tested. Especially for CHEAL, POLCO and SOLNI, a dose-response was observed after application of GLOB1912H at a full dose rate of 3,2 L/ha compared to reduced dose rate.

##### **Minimum effective dose for the pre-emergence use on sunflower**

To fulfil the requirements of justifying the minimum effective dosage according to EPPO guideline PP1/225 (1) GLOB1912H on potatoes was tested in a range of field efficacy trials at application rates of the intended full application rate of 3,2 L/ha and at the reduced rates of 2 L/ha. Overall, all trials showed a numerical, if not statistically significant efficacy increase if the maximum claimed application rate of 3,2 L/ha for GLOB1912H was applied in comparison to reduced dose rate tested. Especially for CHEAL, ECHCG, POLCO and POLLA, a dose-response was observed after application of GLOB1912H at a full dose rate of 3,2 L/ha compared to reduced dose rate.

#### **SOUTH-EAST EPPO ZONE**

##### **Minimum effective dose for the pre-emergence use on potatoes**

To fulfil the requirements of justifying the minimum effective dosage according to EPPO guideline PP1/225 (1) GLOB1912H on potatoes was tested in a range of field efficacy trials at application rates of the intended full application rate of 3,2 L/ha and at the reduced rates of 2 L/ha. Overall, all trials showed a numerical, if not statistically significant efficacy increase if the maximum claimed application rate of 3,2 L/ha for GLOB1912H was applied in comparison to reduced dose rate tested. Especially for CHEAL, ECHCG and SOLNI a dose-response was observed after application of GLOB1912H at a full dose rate of 3,2 L/ha compared to reduced dose rate.

##### **Minimum effective dose for the pre-emergence use on sunflower**

To fulfil the requirements of justifying the minimum effective dosage according to EPPO guideline PP1/225 (1) GLOB1912H on potatoes was tested in a range of field efficacy trials at application rates of the intended full application rate of 3,2 L/ha and at the reduced rates of 2 L/ha. Overall, all trials showed a numerical, if not statistically significant efficacy increase if the maximum claimed application rate of 3,2 L/ha for GLOB1912H was applied in comparison to reduced dose rate tested. Especially for AMARE, CHEAL, ECHCG, POALV and POLLA a dose-response was observed after application of GLOB1912H at a full dose rate of 3,2 L/ha compared to reduced dose rate.

#### **NORTH-EAST EPPO ZONE**

##### **Minimum effective dose for the pre-emergence use on potatoes**

To fulfil the requirements of justifying the minimum effective dosage according to EPPO guideline PP1/225 (1) GLOB1912H on potatoes was tested in a range of field efficacy trials at application rates of the intended full application rate of 3,2 L/ha and at the reduced rates of 2 L/ha. Overall, all trials showed a numerical, if not statistically significant efficacy increase if the maximum claimed application rate of 3,2 L/ha for GLOB1912H was applied in comparison to reduced dose rate tested. Especially for CHEAL, GAETE, GASPA, POLCO and VIOAR, a dose-response was observed after application of GLOB1912H at a full dose rate of 3,2 L/ha compared to reduced dose rate.

##### **Minimum effective dose for the pre and post-emergence on winter cereals - all EPPO ZONES**

The applicant claims that GLOB1912H is similar to Jura (EC), which is registered to use on cereal crops in many countries across Europe with a dose rate of 4 L/ha for both the pre-emergence as well as the post-emergence application. Both products contain the same amount of active substances in the same formulation type. The applicant

provided bridging trials to demonstrate that the GLOB1912H applied at a dose rate of 3.2 L/ha can give similar performance to Jura (EC) applied at a dose rate of 4 L/ha. Having considered the results it can be concluded that there is no difference between the performance of the formulations GLOB1912H and Jura EC. Presented data suggest that this rate of 3,2 L/ha GLOB1912H is necessary to control of susceptible weeds in winter cereals crops. Therefore, it can be considered that the MED data are sufficient to indicate that 3,2 L/ha of GLOB1912H is required.

#### Efficacy

The results of 108 trials of using GLOB1912H at a rate of 3.2 l/ha to control annual grasses and dicotyledonous weeds in claimed uses are as follows.

<b>Maritime Eppo zone</b>		
crop	<b>Weed susceptibility</b>	
	Susceptible (S)	Moderately Susceptible (MS)
Winter cereals pre-emergence n=19	<i>Poa annua</i> , <i>Apera spica-venti</i> , <i>Alopecurus myosuroides</i> and annual broadleaved weeds: <i>Viola arvensis</i> , <i>Veronica persica</i> , <i>Stellaria media</i> , <i>Papaver rhoeas</i> , <i>Matricaria chamomilla</i> , <i>Tripleurospermum inodorum</i>	<i>Galium aparine</i>
Winter cereals post-emergence n=14	<i>Poa annua</i> and <i>Apera spica-venti</i> and annual broadleaved weeds: <i>Galium aparine</i> , <i>Geranium pusillum</i> , <i>Matricaria chamomilla</i> , <i>Tripleurospermum inodorum</i> , <i>Papaver rhoeas</i> , <i>Stellaria media</i> , <i>Veronica persica</i> and <i>Viola arvensis</i>	<i>Alopecurus myosuroides</i> and <i>Centaurea cyanus</i>
Potato n=15	<i>Poa annua</i> , <i>Galeopsis tetrahit</i> , <i>Viola arvensis</i> , <i>Persicaria lapathifolia</i> , <i>Thlaspi arvense</i> , and <i>Fallopia convolvulus</i>	<i>Veronica persica</i> , <i>Tripleurospermum inodorum</i> , <i>Chenopodium album</i> , <i>Solanum nigrum</i> , and <i>Mercurialis annua</i>
Sunflower n=7	<i>Chenopodium album</i> , <i>Fallopia convolvulus</i> , <i>Persicaria lapathifolia</i>	<i>Echinochloa crus-galli</i>
<b>North-east Eppo zone</b>		
crop	<b>Weed susceptibility</b>	
	Susceptible (S)	Moderately Susceptible (MS)
Winter cereals pre-emergence n=11+12	<i>Poa annua</i> and <i>Apera spica-venti</i> and annual broadleaved weeds: <i>Viola arvensis</i> , <i>Papaver rhoeas</i> , <i>Tripleurospermum inodorum</i> , <i>Geranium pusillum</i> , <i>Matricaria chamomilla</i> , <i>Stellaria media</i> , and <i>Veronica hederifolia</i>	<i>Alopecurus myosuroides</i> and <i>Galium aparine</i>
Winter cereals post-emergence n=11+10	<i>Poa annua</i> and <i>Apera spica-venti</i> and annual broadleaved weeds: <i>Galium aparine</i> , <i>Tripleurospermum inodorum</i> , <i>Papaver rhoeas</i> , <i>Viola arvensis</i> , <i>Fumaria officinalis</i> , <i>Geranium pusillum</i> , <i>Lamium purpureum</i> , <i>Stellaria media</i> , <i>Veronica hederifolia</i> , <i>Veronica persica</i>	<i>Alopecurus myosuroides</i>
Potato n=15	<i>Poa annua</i> , <i>Fallopia convolvulus</i> , <i>Persicaria lapathifolia</i> , <i>Persicaria maculosa</i> , <i>Polygonum persicarioides</i> , <i>Thlaspi arvense</i> , <i>Viola arvensis</i> , <i>Galeopsis tetrahit</i> , <i>Galinsoga parviflora</i> , <i>Amaranthus retroflexus</i> , and <i>Capsella bursa-pastoris</i>	<i>Veronica persica</i> , <i>Tripleurospermum inodorum</i> , <i>Solanum nigrum</i> , <i>Chenopodium album</i> , <i>Fumaria officinalis</i> and <i>Echinochloa crus-galli</i>
Sunflower n=4	<i>Chenopodium album</i> , <i>Fallopia convolvulus</i> , <i>Persicaria lapathifolia</i>	<i>Echinochloa crus-galli</i>
<b>South-east Eppo zone</b>		
crop	<b>Weed susceptibility</b>	
	Susceptible (S)	Moderately Susceptible (MS)
Winter cereals pre-emergence n=3	<i>Poa annua</i> , <i>Apera spica-venti</i> , <i>Papaver rhoeas</i>	<i>Stellaria media</i>
Winter cereals post-emergence n=3	<i>Apera spica-venti</i> , <i>Poa annua</i> , <i>Papaver rhoeas</i> , and <i>Stellaria media</i> .	

Potato n=3	<i>Chenopodium album</i> , <i>Echinochloa crus-galli</i>	<i>Solanum nigrum</i>
Sunflower n=7		<i>Ambrosia artemisiifolia</i> , <i>Chenopodium album</i> , and annual grass <i>Echinochloa crus-galli</i>

### Phytotoxicity to host crop

#### Winter cereals - Maritime and North East EPPO zone

Phytotoxicity symptoms to cereals occurred in trials using GLOB 1912H at the highest proposed dose (3,2 L/ha) and at 2 N soon after application and at the last assessments. The data also show that phytotoxic symptoms were observed in a similar number of trials following application with the reference products. The values presented indicate that phytotoxicity symptoms caused by GLOB1912H may slightly affect the yield of winter rye, winter wheat, winter triticale, winter spelt and winter durum wheat. A label restriction regarding phytotoxicity should be addressed on the label. Due to phytotoxicity effects in most cereal crops, extrapolation to other cereal crops is not possible.

#### Winter cereals - South-East EPPO Zone.

The applicant did not provide phytotoxicity data in winter cereals. He did not provide justify this approach. Since a close correlation between phytotoxicity symptoms caused by GLOB1912H and cereals yield was observed in the Maritime and North-east EPPO zone, it is not possible to evaluate and draw conclusions on the crop safety of GLOB1912H applied as pre or early post-emergence treatments in winter cereals in South-East EPPO Zone.

#### Phytotoxicity on potatoes and sunflowers all EPPO Zones

Phytotoxicity symptoms on sunflower and potatoes caused by a single application of GLOB1912H applied pre-emergence at the proposed use rate of 3,2 L/ha, were transient. Overall the values presented indicate that phytotoxicity symptoms have no negative effects on yield. Given the possibility of a lower potatoes and sunflower yield with a double dose rate of 6,4 l / ha of GLOB1912H compared to the proposed dose rate of 3,2 l/ha, label warnings regarding phytotoxicity should be included on the label.

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

The applicant addresses all points of EPPO Standard PP 1/213 to evaluate the possible actual risk of resistance to GLOB1912H. The applicant states that weed resistance to prosulfocarb and diflufenican has never been observed together, additionally resistance to diflufenican has never been observed in Europe. Because the product is only applied once per year before there is a very limited selection pressure. This makes resistance unlikely to occur. Overall, zRMS considers that the risk of developing resistance to prosulfocarb and diflufenican of the proposed use of GLOB1912H is low to moderate. The risk is primarily due to the inherent risk of certain target weeds. Given this risk, an overall strategy to prevent and manage such resistance should be adopted following the HRAC.

#### Effects on the quality of plants and plant products

The presented data correspond with the requirements of the EPPO Standards EPPO 1/135(4). The applicant showed that in selectivity trials no negative effects of GLOB1912H on quality parameters could be determined such as:

- number of tubers, % of tubers per weight class, the weight of malformed tubers (kg), starch content (%) in potatoes
- moisture content (%), oil content (%), dry matter content (%) in sunflowers
- Thousand Kernel Weight (g), Moisture content (%), Hectolitre Weight (kg) in winter cereals.

Overall it was demonstrated that the application of GLOB1912H should be considered as safe in potatoes, sunflowers and winter cereals since no significant negative effects on yield quality are to be expected if label recommendations were obeyed.

#### Impact on succeeding crops

From the results presented it can be concluded that there is a risk of adverse effects of GLOB1912H herbicide on succeeding crops. There is a particular risk if crops have to be liquidated. In the case of crop failure, following soil cultivation, oats, cucumber, wheat and salsify may be sown, field beans or broad beans should not be sown within 12 months of application. The recommendation proposed by the applicant is acceptable.

#### Impact on other plants including adjacent crops

The application of GLOB1912H will not have unacceptable effects on tested plants when applied at maximum application rates of 3200 ml product/ha at a spray distance of 1 m except tomato where a minimum buffer zone of 3 m is necessary.

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

Weed resistance to prosulfocarb and diflufenican has never been observed together, additionally resistance to diflufenican has never been observed in Europe.

The fact that resistance to both actives has not been observed together in the many years these substances have been used underscores the importance of GLOB1912H to combat resistant weeds.

Additionally, because GLOB1912 is only applied once per year it has a very limited selection pressure. Based on this information, it is considered that the risk of resistance development is negligible for all target weeds.

### **3.2.3 Adverse effects on treated crops**

GLOB1912H is a formulated product based on active substances already used in straight formulations and/or in mixtures with other active substances and authorized in EU, with no known negative effects. Enough data to study the adverse effects on treated crops of GLOB1912 has been submitted to demonstrate the safe use of GLOB1912H on potatoes and sunflowers up to double the maximum requested dose rate, without negative effects on treated crops. The applicant wishes to add a warning to the label to avoid spray overlap on winter cereals.

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

There were no adverse effects on beneficial and other non-target organisms observed in any of the effectiveness and phytotoxicity trials conducted. Mitigation measures are proposed in order to limit the impact on succeeding and adjacent crops. All details can be found in Part B Section 3 and Part B Section 9 Ecotoxicology.

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

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

Analytical methods for the determination of prosulfocarb and diflufenican in GLOB1912H were not evaluated as part of the EU review of these active substances. Therefore all relevant data are provided here and are considered adequate. An LC-QQQ method was submitted to analyse the active ingredient content in the formulation. The method was successfully validated.

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

All analytical methods are active substance data and were provided in the EU review of prosulfocarb and diflufenican.

#### **zRMS:**

In the context of authorisation request sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

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

#### 3.4.1 Acute toxicity

Acute toxicity studies for GLOB1912H were not evaluated as part of the EU review of prosulfocarb and diflufenican.

Studies to assess the acute oral, dermal and inhalation toxicity, skin/eye irritation and skin sensitisation properties of the plant protection product GLOB1912H were judged to be not necessary in the interest of animal welfare. The assessment has been conducted according to the calculation method outlined in Regulation EC 1272/2008. Full details on composition and classification of formulants are provided in part C of this registration report.

Based on all available data GLOB1912H should be classified as **Acute Tox. 4**; Eye Dam.1, Skin Sens 1 and STOT SE3.

According to Regulation (EC) 1272/2008 (CLP Regulation), GLOB1912H should be labelled as: *GHS05, GHS07; Danger; H302, H317, H318, H336.*

#### 3.4.2 Operator exposure

Operator exposure to GLOB1912H was not evaluated as part of the EU review of prosulfocarb and diflufenican. Therefore all relevant data and risk assessments are provided here and are considered adequate.

Operator exposure was assessed against the AOEL agreed in the EU review of prosulfocarb (0.007 mg a.i./kg bw/d) and diflufenican (0.11 mg/kg bw/d). For dermal absorption of the concentrate 0.26% and for the spray solution 3.3% for prosulfocarb were used as determined in the dermal absorption study. Default values were used for diflufenican. Operator exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using GLOB1912H according to the intended use is acceptable with the use of gloves during mixing, loading and application.

The exposure to Prosulfocarb of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying JURA MAX ( GLOB1912H) on cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha ) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 253,87% of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Prosulfocarb is reduced to 20.48% of AOEL.

The exposure to Diflufenican of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying JURA MAX ( GLOB1912H) on cereals at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 101.35 % of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Diflufenican is reduced to 3.3% of AOEL.

The sum of exposures of operator wearing a work clothing (long sleeved shirt, long trousers) and protective gloves during mixing/loading and application to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product JURA MAX ( GLOB1912H according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator

Summing up, the application of product JURA MAX ( GLOB1912H) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs and protective gloves during mixing/loading and application. Since the product classified as Eye Dam. 1 and Skin Sens. 1 the operator should wear protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

### 3.4.3 Worker exposure

Worker exposure to GLOB1912H was not evaluated as part of the EU review of prosulfocarb and diflufenican. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with GLOB1912H. As a standard rule, it could be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

#### **zRMS evaluation of worker exposure**

The exposure to Prosulfocarb, an active substance of a product JURA MAX ( GLOB1912H) of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product JURA MAX ( GLOB1912H) at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 29.11 % of respective AOEL.

The exposure to Diflufenican, an active substance of a product JURA MAX ( GLOB1912H), of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals treated with a product JURA MAX ( GLOB1912H) at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM amounted 3.99 % of respective AOEL.

The sum of exposures of worker wearing a work clothing (long sleeved shirt, long trousers) to both active substance expressed as percentage of their AOELs is also below 100%, therefore the application of product JURA MAX ( GLOB1912H) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of worker.

Thus, it is concluded that the application of a product JURA MAX ( GLOB1912H) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers).

### 3.4.4 Bystander and resident exposure

Bystander and resident exposure to GLOB1912H was not evaluated as part of the EU review of prosulfocarb and diflufenican. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that there is no undue risk to any bystander after accidental short-term exposure or to any resident after long-term exposure to GLOB1912H when using a 5 m no spray buffer zone or a 50% drift reducing technique.

#### **zRMS:**

The exposure estimation of resident (adult and child) to Prosulfocarb, an active substance of a product JURA MAX ( GLOB1912H) applied on a field of cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is 114.65% of AOEL and for child resident 320%% of AOEL, therefore the risk would be unacceptable, and risk refinement is needed using relevant risk management measures such as increased buffer zone or drift reduction technology.

When product JURA MAX ( GLOB1912H) is applied on a field of cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, assuming buffer zone of 5 m, the estimated exposure to

Prosulfocarb, an active substance of a product JURA MAX ( GLOB1912H) of resident (adult and child) has been reduced to 26.79% and to 88.12% of AOEL respectively, thus is acceptable

When product JURA MAX ( GLOB1912H) is applied on a field of cereals at maximal dose of 3.2 L product/ha (2.134 kg a.s./ha) as foreseen in GAP, assuming use of Drift Reduction Technology and buffer zone of 2-3 m, the estimated exposure to Prosulfocarb, an active substance of a product JURA MAX (GLOB1912H) of resident adult and child amounted to 26.55% and to 80.76% of AOEL respectively, thus is acceptable.

The estimated exposure of resident (adult and child) to Diflufenican, an active substance of a product JURA MAX ( GLOB1912H) applied at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM and assuming buffer zone of 5 m, but not drift reduction technology, amounted 5.89% of AOEL for child resident and 2.56% of respective AOEL for adult resident. .

The estimated exposure of resident (adult and child) to Diflufenican, an active substance of a product JURA MAX ( GLOB1912H) applied at maximal dose of 3.2 L product/ha (0.0448 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM and assuming an use of drift reduction technology and buffer zone of 2-3 m, amounted 5.67% of AOEL for child resident and 2.56% of respective AOEL for adult resident.

No bystander acute exposure estimation for Prosulfocarb and for Diflufenican is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Prosulfocarb and Diflufenican as a result of application of a product JURA MAX ( GLOB1912H)with accordance with intended use within good agricultural practice.

Summing up application of a product JURA MAX ( GLOB1912H) in line with GAP on low crops at maximal dose of 3.2 L product/ha, using tractor-mounted/trailed boom sprayer does not pose an unacceptable health risk for residents and bystanders, providing that risk mitigation measures are used, either buffer zone of 5 m or drift reduction technology – 50%.

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

#### **3.5.1 Residues**

For the applied use of GLOB1912H in winter cereals, potato and sunflower reference is made to the data that were submitted for the EU review of prosulfocarb and diflufenican, as well as to new studies submitted by the applicant. The evaluated GAP is covering the one intended for GLOB1912H.

Compliance with the EU MRLs of prosulfocarb and diflufenican is met for the intended uses of GLOB1912H.

#### **3.5.2 Consumer exposure**

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.005 mg/kg bw/day for prosulfocarb and 0.2 mg/kg bw/d for diflufenican. It can therefore be concluded that acceptable margins of safety exist for consumers.

Chronic and acute exposure calculations were performed using the EFSA PRIMO (rev. 3.1) model.

For prosulfocarb, the maximum calculated exposure values accounted for 47% of ADI (NL toddler). The calculation of the IEDI was not necessary since the calculation of the TMDI has shown that TMDIs were below the ADI. The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.1 mg/kg bw/day (max. 63% for carrots for UK infant).

For diflufenican, the maximum calculated exposure values accounted for 0.7% of ADI (NL toddler). The calculation of the IEDI was not necessary since the calculation of the TMDI has shown that TMDIs were below the ADI. IESTI calculations were not performed since no ARfD is set.

Based on the different calculations made to estimate consumer exposure, it can be concluded that the use of the product GLOB1912H does not lead to an unacceptable acute or chronic risk for consumers when applied according to the recommendations.

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

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

The PEC of prosulfocarb, diflufenican and their metabolites in soil have been assessed with the FOCUS model and the DT<sub>50</sub> values established in the EU review. The maximum initial predicted environmental concentration in soil (PECs) of the active substances and the metabolites as well as for the formulation are provided in the table 3.7-1 below.

**Table 3.7-1: Maximum PEC<sub>soil</sub> values**

Compound	Maximum PECs (mg/kg)	
	3.2 L/ha	3 L/ha
Prosulfocarb	2.8453	2.6680
Prosulfocarb sulfoxide	0.2056	0.1928
Diflufenican (accumulation)*	0.1510	0.1417
AE B107137 (accumulation)*	0.0544	0.0511
AE 0542291(accumulation)*	0.0850	0.0797
<del>AE B107137</del>	<del>0.0215</del>	<del>0.0202</del>
<del>AE 0542291</del>	<del>0.0336</del>	<del>0.0315</del>
GLOB1912H	4.3080	4.0387

\* PEC<sub>accumulation</sub> calculated with factor of 2.53

The PEC<sub>soil</sub> values were used for the ecotoxicological risk assessment.

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

The PEC of prosulfocarb, diflufenican and their metabolites in ground water has been determined with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and MACRO 5.5.4 models.

The PEC<sub>gw</sub> of the active substance and their metabolites did not exceed the threshold of 0.1 µg/L. There-

fore, no unacceptable leaching to groundwater is anticipated for the intended use of GLOB1912H.

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

The PEC values (PEC<sub>sw</sub> and PEC<sub>sed</sub>) resulting from the FOCUS STEP 1 to 4 of prosulfocarb, diflufenican and their metabolites were calculated for the intended use. These were then used for the ecotoxicological risk assessment.

~~FOCUS profiles of diflufenican were analysed using EPAT for use in the refined ecotoxicological risk assessment.~~

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

The fate and behaviour in air of prosulfocarb and diflufenican was evaluated during the EU review of these active substances. No additional studies have been performed.

The active substance prosulfocarb is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance prosulfocarb due to volatilization with subsequent deposition was considered.

The active substance diflufenican is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by diflufenican due to volatilization with subsequent deposition should not be considered.

## **3.7 Ecotoxicology (Part B, Section 9)**

### **3.7.1 Effects on terrestrial vertebrates**

#### **Birds**

Effects on birds for GLOB1912H were not evaluated as part of the EU review of prosulfocarb or diflufenican. Therefore all relevant data and risk assessments are provided here and are considered adequate. The risk assessment for effects on birds is carried out according to the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009)<sup>1</sup>.

The acute and long-term risks of GLOB1912H to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with prosulfocarb and diflufenican, and maximum residues occurring on food items following applications according to the proposed use pattern. Risk of secondary poisoning through contaminated drinking water has also been assessed. The risk of secondary poisoning through bioaccumulation has also been assessed, as both active substances have a log P<sub>ow</sub> > 3.0. Since GLOB1912H contains 2 active ingredients, a combined risk assessment was also performed.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk (including secondary poisoning), thus indicating no unacceptable risk to birds from the proposed uses.

#### **Terrestrial vertebrates (other than birds)**

Effects on terrestrial vertebrates other than birds for GLOB1912H were not evaluated as part of the EU review of prosulfocarb or diflufenican. Therefore all relevant data and risk assessments are provided here and are considered adequate.

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

The acute and long-term risks of GLOB1912H to wild mammals were assessed using the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009) by calculating the toxicity exposure ratios between toxicity endpoints, estimated from studies with prosulfocarb and diflufenican, and maximum residues occurring on food items following applications according to the use pattern.

For prosulfocarb, results of the first-tier assessment were not acceptable for the long-term risk. Refinement of DT<sub>50</sub> for the reproductive assessment for herbivorous mammals was performed using residue decline trials on young cereal plants.

Risk of secondary poisoning through contaminated drinking water has also been assessed. The risk of secondary poisoning through bioaccumulation has also been assessed, as both active substances have a log P<sub>OW</sub> > 3.0. Since GLOB1912H contains 2 active ingredients, a combined risk assessment was also performed.

In conclusion, the TER<sub>A</sub> and TER<sub>LT</sub> values are greater than the Annex VI trigger of 10 and 5 respectively, indicating low acute and long-term risks to mammals following application of GLOB1912H according to the intended uses.

### 3.7.2 Effects on aquatic species

Effects on aquatic organisms for GLOB1912H were not evaluated as part of the EU review of prosulfocarb and diflufenican. A new risk assessment was performed for the intended uses using the toxicity data of GLOB1817H, which has the same composition as GLOB1912H apart from an additional active substance and a safener, the active substances as well as the metabolites.

An acceptable risk is concluded for prosulfocarb at Step 4 ~~3, except in the R4 scenario in winter cereals (post-emergence use only) and sunflower~~, where a 10 m no spray buffer zone including a 10 m vegetated buffer strip is required to obtain an acceptable risk.

~~The risk for the metabolite prosulfocarb sulfoxide is acceptable at Step 3.~~

According to EFSA Scientific Report (2007) 111, 1-81, for aquatic organisms the risk assessment for prosulfocarb sulfoxide is not required.

An acceptable risk is concluded for diflufenican using a 10 m no spray buffer zone including a 10 m vegetated buffer strip ~~5 m no spray buffer zone~~.

The risk for the metabolites of diflufenican is acceptable at Step 1-2.

An acceptable risk for the formulation GLOB1912H following spray drift is concluded using a 5 m no spray buffer zone (using FOCUS Drift Swash Tool).

Based on the mixture toxicity assessment, it can be concluded that the mitigation measures based on the risk assessment of the individual active substances will be sufficient to protect aquatic organisms.

Taking into account the relevant scenarios for Poland, a 10 m no spray buffer zone including a 10 m vegetated buffer strip ~~5 m no spray buffer zone~~ is needed to protect aquatic organisms when using GLOB1912H as recommended.

### 3.7.3 Effects on bees

Effects on bees for GLOB1912H were not evaluated as part of the EU review of prosulfocarb and diflufenican.

The risk of GLOB1912H to honeybees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with the formulated product GLOB1817H, which has the same composition as GLOB1912H apart from an additional active substance and a safener, and the single application rate of 3231 g/ha. All the hazard quotients are considerably less than 50, indicating that GLOB1912H poses a low acute risk to honeybees.

~~The risk of GLOB1912H to bumble bees was assessed according to the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)” (EFSA Journal 2013;11(7):3295), using toxicity endpoints estimated from acute oral and contact toxicity studies with the formulated product GLOB1817H. It was demonstrated that GLOB1912H poses a low acute risk to bumble bees.~~

~~The chronic risk to honeybees (adult and larvae) was assessed according to the modified EPP0 2010 approach according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028) and the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)” (EFSA Journal 2013;11(7):3295), using toxicity endpoints estimated from chronic studies with the formulated product GLOB1817H. It was demonstrated that GLOB1912H poses a low chronic risk to honeybees.~~

No risk mitigation measure is necessary.

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

Effects on non-target arthropods for GLOB1912H were not evaluated as part of the EU review of prosulfocarb or diflufenican.

Extended laboratory studies were conducted on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Aleaochara bilineata* and *Poecilus cupreus*. The in-field hazard quotients for *Aleaochara bilineata* and *Poecilus cupreus* and the off-field hazard quotients for all species are below the trigger values recommended by ESCORT 2. The in-field hazard quotients for *Typhlodromus pyri* and *Aphidius rhopalosiphi* were exceeding the trigger values, so an additional higher-tier risk assessment was needed. The ESCORT 2 guidance document recommends that any initial effects are acceptable if the potential for recovery within one year can be demonstrated. ~~It is possible to model the dissipation of residues over time using simple first order kinetics and determine the time after the treatment application that the foliar residues would drop to a level that demonstrate an acceptable risk to non target arthropods. Using the default foliar DT<sub>50</sub> of 10 days (according to EFSA Guidance Document on the Risk Assessment of Birds and Mammals, 2009), it was demonstrated that~~

In zRMS opinion, the in-field risk for NTA is acceptable based on following assumptions:

1. for main active substance in GLOB1912H – prosulfocarb, DT<sub>50</sub> in plants and soil (based on field studies) are 1.83 and 13 days, respectively. Therefore, recolonization can take place in short time after application due to rapid decrease in toxicity;
2. the GLOB1912H, based on tests performed on *T. pyri* and *A. rhopalosiphi* indicated only acute toxicity (mortality), without effects on reproduction. For pesticides sublethal effects on arthropod physiology and behavior must be considered for a complete analysis of their impact;
3. the GLOB1912H is a selective herbicide, applied foliar, which actively acts on weeds during their germination, which causes the lack of their emergence or the production of deformed sprouts or young seedlings that quickly die. Thus, the exposure of foliar-dwelling arthropods is likely to be very limited.

4. the GLOB1912H, is a herbicide and therefore has indirect negative impact on folivorous insects population by removing arable weeds. This effect is unrelated to the toxicity of the product itself. It should be highlighted that there are few examples of direct toxic effects of herbicides on invertebrates (including GLOB1912H), with many of those only being demonstrated in the laboratory bioassays and high application rates. Most effects of herbicides are through the indirect effects on the host plants which not germinate or will be destroyed within few days after product application. Thus, effects mediated via plant food resources or habitat modification will result in negative impact on arthropods population, especially of foliar species regardless of the toxicity of the product. This is an effect emphasized in the context of biodiversity,

5. the GLOB1912H has a low toxicity to spiders and ground dwelling beetles which recolonization takes more time comparing to foliar species;

6. only one application per season is recommended;

7. no adverse effects on off-field arthropods are likely and therefore rapid recolonization can take place.

Moreover, additional data for prosulfocarb toxicity to several species of NTA are available in LoEP (laboratory, extended laboratory and semi-field studies), which can be used to confirm acceptable in-field risk.

In conclusion, in zRMS opinion based on WoE approach, the acceptable in-field risk can be concluded.

The potential recovery of in-field populations by arthropod immigration from the off-field habitat can occur well within 1 season and in less than 1 year. As evidenced by the off-field risk assessment, no adverse effects on off-field arthropods are likely and therefore rapid recolonization can take place.

The risk to non-target arthropods following application of GLOB1912H is considered acceptable. No risk mitigation measure is necessary.

### 3.7.5 Effects on soil organisms

Effects on earthworms and other soil macro-organisms for GLOB1912H were not evaluated as part of the EU review of prosulfocarb or diflufenican.

#### Earthworms

The long-term risk of GLOB1912H to earthworms was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the formulation GLOB1817H, which has the same composition as GLOB1912H apart from an additional active substance and a safener, and the maximum PEC<sub>soil</sub>.

The TER<sub>t</sub> due to exposure to prosulfocarb (at both dose rates) and GLOB1912H (at the highest dose rate only) are below the trigger of 5. However, an earthworm field study is available where no adverse effects on earthworm abundance or biomass over a period of one year were observed at an application rate of 4000 g prosulfocarb/ha on bare soil.

No risk mitigation measure is necessary.

#### Effects on other soil non-target macro-organisms

The long term risk of GLOB1912H to *Hypoaspis aculeifer* and *Folsomia candida* was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the formulation GLOB1817H and the maximum PEC<sub>soil</sub>.

The chronic TER value for *Hypoaspis aculeifer* is greater than the Annex IV trigger of 5, indicating an acceptable risk to other soil non-target macro-organisms following application of GLOB1912H for the intended uses.

The TER<sub>t</sub> for Collembola due to exposure to prosulfocarb and GLOB1912H at the highest dose rate are slightly below the trigger of 5. However, the performed risk assessment is very worst case taking into account that the study was performed with GLOB1817H, a formulation containing an additional active substance and a safener in comparison to GLOB1912H. Moreover, the endpoint of the study was corrected by a factor 2 because of the log Pow of prosulfocarb and diflufenican, although the study was already performed on a soil with only 5% peat content.

In zRMS opinion the acceptable risk for collembola can be concluded based on WoE approach.

- The TER values are only slightly below the trigger of 5;
- Prosulfocarb DT<sub>50</sub> in soil (based on field studies) is 13 days;
- Only one application per season is recommended;
- In PECsoil calculation 0% interception factor was considered, based on crop growth stage. Nevertheless, it should be noted that the GLOB1912H is a selective herbicide, applied foliar. Thus, the arable weed community gives some, additional reduction of soil organisms exposure.

Therefore, the risk to Collembola from exposure to GLOB1912H is regarded as acceptable.

#### Effects on soil non-target micro-organisms

Effects on soil microbial activity of GLOB1912H were not evaluated as part of the EU review for prosulfocarb or diflufenican. Therefore all relevant data and assessments were provided.

They show that GLOB1912H application according to the intended use has no significant effect on soil micro-organisms.

### 3.7.6 Effects on non-target terrestrial plants

Effects on non-target plants for GLOB1912H were not evaluated as part of the EU review of prosulfocarb or diflufenican.

The potential effect of GLOB1912H on vegetative vigour and seedling emergence has been tested through studies performed with GLOB1817H which has the same composition as GLOB1912H apart from an additional active substance and a safener, on non-target terrestrial plants. The most sensitive species in pre-emergence was *Daucus carota* with an ER<sub>50</sub> of 335.65 mL/ha. In post-emergence, the most sensitive species was *Lycopersicon esculentum* with an ER<sub>50</sub> of 75.93 mL/ha.

A buffer zone of 1 m in combination with 90% drift reducing techniques, a buffer zone of 3 m in combination with 75% drift reducing techniques, a buffer zone of 5 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction is needed to protect non-target plants after application of GLOB1912H at the dose rate of 3.2 L/ha.

A buffer zone of 1 m in combination with 90% drift reducing techniques, a buffer zone of 3 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction is needed to protect non-target plants after application of GLOB1912H at the dose rate of 3.0 L/ha.

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

Not required.

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

The metabolites prosulfocarb sulfoxide, AE 0542291 and AE B107137 are predicted to occur in ground-water at concentrations below 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

GLOB1912H contains diflufenican which is approved as a candidate for substitution because two of PBT.

As a conclusion of the comparative assessment, the uses from GAP table in 2.6 are not suitable for substitution because there are not more than 4 alternative modes of action available amongst alternative products and thus the chemical diversity remaining is not sufficient.

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

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

The three-year storage stability study is ongoing. This study has to be assessed when available.

## **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.

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

A Letter of Access for a worker exposure study related to prosulfocarb from Syngenta was 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 2.1-2.8, KCP 4.2	Sowle J.	2020a	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, and Diflufenican stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. DNA5955 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.2.1 and 2.2.2 <i>Confidential – submitted in Part C.</i>	Sowle J.	2020b	Theoretical certificate of explosive and oxidizing properties for an EC formulation containing 667 g/L prosulfocarb and 14g/L diflufenican. DNA6103 David Norris Analytical Laboratories Ltd. Not GLP Unpublished	N	N	-	Globachem NV
KCP 2.7.2	Sowle J.	2023	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, and Diflufenican stored at ambient temperature for 3 Years, in Compliance with Good Laboratory Practice.	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
			DNA5957 David Norris Analytical Laboratories Ltd. GLP Unpublished				
KCP 2.7.5	Sowle J.	2022	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, and Diflufenican stored at ambient temperature for 2 Years, in Compliance with Good Laboratory Practice. DNA5956 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.1	Sowle J.	2020	Validation of the Methods of Determination of Prosulfocarb and Diflufenican in an EC Formulation, in Compliance with Good Laboratory Practice DNA5958 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.2.1</i>	Juckeland D.	2021a	Acute toxicity of GLOB1817H to <i>Daphnia magna</i> in a 48-hour semi-static test 20 48 ADL 0015 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.2.1</i>	Juckeland D.	2021b	Effects of GLOB1817H on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 20 48 AAL 0019 Biochem Agrar GmbH	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data pro-	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
			GLP Unpublished			tection to start with the first authorization.	
KCP 5.1.2 Submitted as KCP 10.2.1	Juckeland D.	2021c	Effects of GLOB1817H on Lemna gibba in a growth inhibition test under semi-static test conditions 20 48 ALE 0017 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.2.1	Juckeland D.	2021d	Effect of GLOB1817H on <i>Myriophyllum spicatum</i> in a semi-static water-sediment system 20 48 AMS 0010 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.1	Juckeland, D.	2012a	Effects of Prosulfocarb sulfoxide on <i>Chlamydomonas reinhardtii</i> in an algal growth inhibition test 12-10-48-057-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.1	Juckeland, D.	2012b	Effects of Prosulfocarb sulfoxide on <i>Chlorella vulgaris</i> in an algal growth inhibition test 12-10-48-059-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.2	Juckeland, D.	2012e	Effects of Prosulfocarb sulfoxide on <i>Anabaena flos-aquae</i> in an algal growth inhibition test 12-10-48-058-W Biochem Agrar GmbH	N	N	Data protection started with: R-31/2016	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.1.2 Submitted as KCA 8.2.6.2	Juckeland, D.	2012d	Effects of Prosulfocarb sulfoxide on <i>Navicula pelliculosa</i> in an algal growth inhibition test 12-10-48-053-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.2	Juckeland, D.	2012e	Effects of Prosulfocarb sulfoxide on <i>Skeletonema costatum</i> in an algal growth inhibition test 12-10-48-060-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 Submitted as KCP 10.3.1.1.1	Amsel, K.	2021	Acute toxicity of GLOB1817H to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions 20-48-BBA-0029 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.3.1.2	Ruhland, S.	2021	Chronic toxicity of GLOB1817H to the honey bee <i>Apis mellifera</i> L. under laboratory conditions 20-48-BAC-0071 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.3.1.3	Schmidt, K.	2021	GLOB1817H – Repeated exposure of the honey bee ( <i>Apis mellifera</i> L.) larvae under laboratory conditions 20-48-BLC-0052 Biochem Agrar GmbH	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first author-	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
			GLP Unpublished			ization.	
KCP 5.1.2 <i>Submitted as KCP 10.4.1.2</i>	Schulz, L.	2015	Effects of prosulfocarb 800 g/L EC on earthworms under field conditions. Biochem Agrar Report Number 14 10 48 008 F GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
<del>KCP 5.1.2 <i>Submitted as KCA 8.1.3</i></del>	<del>Sacker, D.</del>	<del>2008</del>	<del>The bioaccumulation potential of prosulfocarb in earthworm (<i>Eisenia foetida foetida</i>). ENV8333/040822 Chemex Environmental International Ltd GLP Unpublished</del>	<del>N</del>	<del>N</del>	<del>Data protection started with: R-31/2016</del>	<del>Globachem NV</del>
KCP 5.1.2 <i>Submitted as KCP 10.6</i>	Lewington-Gower, M.	2021	GLOB1817H: terrestrial plant test: vegetative vigour test STC/20/E1409 Stockbridge Technology Center Ltd GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 5.1.2	Jonchère F.	2010a	Validation of the Analytical Method for the Determination of Prosulfocarb Residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant + Amendment 1 to final report No. R A9085 (2014) Anadiag R A9085 GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2	Laguna O.	2021a	Validation of analytical method for the determination of residues of prosulfocarb in	N	Y	Data/study report never submitted before to PL.	Globachem NV

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			sunflower seeds. E21024 Laboratoire Phytocontrol GLP Unpublished				
KCP 5.1.2	Jonchère F.	2011	Validation of the analytical method for the determination of diflufenican residues in potato (tubers) B0133 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2	Laguna O.	2021b	Diflufenican – Validation of analytical methods for the determination of diflufenican and its metabolites on potato tubers E21003 Laboratoire Phytocontrol GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2	Jonchère F.	2010b	Validation of the analytical method for the determination of diflufenican residues in oilseed rape seeds. A9259 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2	Laguna O.	2021c	Validation of analytical method for the determination of residues of diflufenican and its metabolites and conjugates in sunflower seeds. E21023 Laboratoire Phytocontrol GLP	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 5.2	Turnbull G.	2008	Development and validation of a method for the determination of diflufenican and two metabolites in surface water and drinking water. PGD-307 Central Science Laboratory GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Sapac Group & Globachem NV & Punjab Chemicals and Crop Protection Ltd.
KCP 5.2	Figueiredo H.	2016	Validation of an analytical method for the determination of diflufenican in drinking water, ILV. VAL10/16 Laboratório de residuos Sapac Agro S.A. GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Sapac Agro S.A. & Globachem NV
KCP 5.2	xxx	2015	Validation of the analytical method for the analysis of diflufenican in fat and blood. B6276 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Sapac Agro S.A. & Globachem NV
KCP 6.2-01	Lora M.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied pre-emergence in winter cereals. HE-19-A-GLOB1319H-1912H-ES01 Promo-Vert ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-02	Junglee S.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied pre-emergence in winter cereals HE-19-A-GLOB1319H-1912H-FR02 Promo-Vert FR	N	Y	Data/study report never submitted before to PL.	Globachem NV

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			GEP, not published				
KCP 6.2-03	Zagi H.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied pre-emergence in winter cereals HE-19-A-GLOB1319H-1912H-HR03 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-04	Muscarà A.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied pre-emergence in winter cereals. Italy 2020. HE-19-A-GLOB1319H-1912H-IT04 Agricola 2000 GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-05	Lora M.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied post-emergence in winter cereals HE-19-B-GLOB1319H-1912H-ES01 Promo-Vert ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-06	Junglee S.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied post-emergence in winter cereals HE-19-B-GLOB1319H-1912H-FR02 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-07	Zagi H.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied post-emergence in winter cereals HE-19-B-GLOB1319H-1912H-HR03 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-08	Muscarà A.	2019	Efficacy and selectivity of GLOB1319H and GLOB1912H against weeds applied post-emergence in winter cereals	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
			HE-19-B-GLOB1319H-1912H-IT04 Agricola 2000 GEP, not published				
KCP 6.2-09	de Vries H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-A-GLOB1912H-1913H-NL01 Verify (Zwaagdijk) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-10	Tvaruzek L.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1912H-1913H-CZ01 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-11	Friedrich F.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1912H-1913H-DE02 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-12	Zöllner H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1912H-1913H-DE03 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-13	Sørensen S.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-C-GLOB1912H-1913H-DK01 Aarhus University GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-14	Sørensen S.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-C-GLOB1912H-1913H-DK02 Aarhus University GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-15	Broms C.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-C-GLOB1912H-1913H-SE03 HUSEC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-16	Gulbis K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-D-GLOB1912H-1913H-LV01 LAAPC	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.2-17	Umiński P.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-E-GLOB1912H-1913H-PL01 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-18	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-E-GLOB1912H-1913H-PL02 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-19	Umiński P.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-E-GLOB1912H-1913H-PL03 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-20	Piotrowski G.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-E-GLOB1912H-1913H-PL04 Syntech PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-21	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1912H-1913H-ES01 Staphyt ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-22	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1912H-1913H-FR02 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-23	Zagi H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1912H-1913H-HR03 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-24	Russo A.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1912H-1913H-IT04 Agri2000 GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-	Zagi H.	2020	Efficacy of autumn herbicides in winter cereals.	N	Y	Data/study report never submitted	Globachem NV

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26			HE-20-G-GLOB1912H-1913H-HR02 Pest-Pro GEP, not published			before to PL.	
KCP 6.2-27	Zagi H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-G-GLOB1912H-1913H-HR03 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-28	Ferencz B.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-G-GLOB1912H-1913H-RO04 Biotek RO GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-29	de Vries H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-H-GLOB1912H-1913H-NL01 Verify (Zwaagdijk) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-30	Mareckova J.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-I-GLOB1912H-1913H-CZ01 ZS Krasne Udoli GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-31	Friedrich F.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-I-GLOB1912H-1913H-DE02 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-32	Zöllner H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-I-GLOB1912H-1913H-DE03 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-33	Sørensen S.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-J-GLOB1912H-1913H-DK01 Aarhus University GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-34	Bank Arikan K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-J-GLOB1912H-1913H-DK02 VKST	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.2-35	Usinskiene A.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-J-GLOB1912H-1913H-SE03 Agrolab GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-36	Gulbis K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-K-GLOB1912H-1913H-LV01 LAAPC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-37	Umiński P.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-L-GLOB1912H-1913H-PL01 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-38	Chermula L.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-L-GLOB1912H-1913H-PL02 Eurofins PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-39	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-L-GLOB1912H-1913H-PL03 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-40	Piotrowski G.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-L-GLOB1912H-1913H-PL04 Syntech PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-41	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-M-GLOB1912H-1913H-ES01 Staphyt ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-42	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-M-GLOB1912H-1913H-FR02 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-	Zagi H.	2020	Efficacy of autumn herbicides in winter cereals.	N	Y	Data/study report never submitted	Globachem NV

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43			HE-20-M-GLOB1912H-1913H-HR03 Pest-Pro GEP, not published			before to PL.	
KCP 6.2-44	Russo A.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-M-GLOB1912H-1913H-IT04 Agri2000 GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-45	de Vries H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-A-GLOB1925H-1907bH-NL01 Verify (Zwaagdijk) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-46	Spurova R.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1925H-1907bH-CZ01 ZS Trutnov GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-47	Tvaruzek L.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1925H-1907bH-CZ02 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-48	Zickart U.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1925H-1907bH-DE03 Biochem DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-49	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-B-GLOB1925H-1907bH-DE04 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-50	Umiński P.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-C-GLOB1925H-1907bH-PL01 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-51	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-C-GLOB1925H-1907bH-PL02 Staphyt PL	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.2-52	Gajek D.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-C-GLOB1925H-1907bH-PL03 ARC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-54	Zagi H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-D-GLOB1925H-1907bH-HR02 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-55	Russo A.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-D-GLOB1925H-1907bH-IT03 Agri2000 GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-56	de Vries H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-E-GLOB1925H-1907bH-NL01 Verify (Zwaagdijk) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-57	Spurova R.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1925H-1907bH-CZ01 ZS Trutnov GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-58	Tvaruzek L.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1925H-1907bH-CZ02 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-59	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1925H-1907bH-DE03 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-60	Szrama K.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-F-GLOB1925H-1907bH-DE04 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-	Głazek M.	2020	Efficacy of autumn herbicides in winter cereals.	N	Y	Data/study report never submitted	Globachem NV

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61			HE-20-G-GLOB1925H-1907bH-PL01 IOR Gliwice GEP, not published			before to PL.	
KCP 6.2-62	Idziak R.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-G-GLOB1925H-1907bH-PL02 UP Poznań GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-63	Umiński P.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-G-GLOB1925H-1907bH-PL03 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-64	Junglee S.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-H-GLOB1925H-1907bH-FR01 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-65	Zagi H.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-H-GLOB1925H-1907bH-HR02 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-66	Forte G.	2020	Efficacy of autumn herbicides in winter cereals. HE-20-H-GLOB1925H-1907bH-IT03 Agrigeos GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-67	Dana P.	2018	Efficacy of Aclonifen / Prosulfocarb + DFF in potato applied pre-emergence. HE-18-A-GLOB1319H-CZ01 ZS Kujawy GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-68	Denuelle J.	2018	Efficacy of Aclonifen / Prosulfocarb + DFF in potato applied pre-emergence. HE-18-A-GLOB1319H-FR03 Anadiag GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-	Uminski P.	2019	Efficacy of aclonifen and prosulfocarb against	N	Y	Data/study report never submitted	Globachem NV

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69			weeds in potato applied pre-emergence. HE-19-A-ACN-DFF-PRO-PL01 FRS PL GEP, not published			before to PL.	
KCP 6.2-70	Piotrowski G.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-A-ACN-DFF-PRO-PL02 Syntech GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-71	Camuñez S.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-B-ACN-DFF-PRO-PL01 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-72	Camuñez S.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-B-ACN-DFF-PRO-PL02 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-73	Mareckova J.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-C-ACN-DFF-PRO-CZ01 ZS Krasne Udoli GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-74	Šafář J.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-C-ACN-DFF-PRO-CZ02 Agritec GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-75	Zöllner H.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-D-ACN-DFF-PRO-DE01 Field Research Support (FRS) DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.2-76	Lopez-Alvarez S.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-D-ACN-DFF-PRO-FR02 Promovert GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-77	Camuñez S.	2019	Efficacy of aclonifen and prosulfocarb against weeds in potato applied pre-emergence. HE-19-D-ACN-DFF-PRO-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-78	Uminski P.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-A-Jura-PRO-PL01 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-79	Piotrowski G.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-A-Jura-PRO-PL02 Syntech GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-80	Camuñez S.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-B-Jura-PRO-PL01 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-81	Camuñez S.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-B-Jura-PRO-PL02 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-82	Mareckova J.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-C-jura-PRO-CZ01 ZS Krasne Udoli	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.2-83	Šafář J.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-C-Jura-PRO-CZ02 Agritec GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-84	Zöllner H.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-D-Jura-PRO-DE01 Field Research Support (FRS) DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-85	Lopez-Alvarez S.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-D-Jura-PRO-FR02 Promovert GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-86	Camuñez S.	2019	Efficacy of prosulfocarb and DFF against weeds in potato applied pre-emergence. HE-19-D-Jura-PRO-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-88	de Vries H.	2020	Efficacy of aclonifen and prosulfocarb in potatoes. HE-20-A-GLOB1319H-PRO900-NL02 Verify (Zwaagdijk) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-89	Bauer T.	2020	Efficacy of aclonifen and prosulfocarb in potatoes HE-20-B-GLOB1319H-PRO900-CZ01 InTec GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-90	Friedrich F.	2020	Efficacy of aclonifen and prosulfocarb in potatoes. HE-20-B-GLOB1319H-PRO900-DE02	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Quintus GEP, not published				
KCP 6.2-91	Koppel M.	2020	Efficacy of aclonifen and prosulfocarb in potatoes HE-20-C-GLOB1319H-PRO900-EE01 ETKI GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-92	Gulbis K.	2020	Efficacy of aclonifen and prosulfocarb in potatoes. HE-20-C-GLOB1319H-PRO900-LV02 LAAPC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-93	Umiński P.	2020	Efficacy of aclonifen and prosulfocarb in potatoes. HE-20-D-GLOB1319H-PRO900-PL01 Field Research Support (FRS) PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-94	Piotrowski G.	2020	Efficacy of aclonifen and prosulfocarb in potatoes. HE-20-D-GLOB1319H-PRO900-PL02 Syntech GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-95	Zagi H.	2020	Efficacy of aclonifen and prosulfocarb in potatoes HE-20-E-GLOB1319H-PRO900-HR01 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-96	Barasits T.	2020	Efficacy of aclonifen and prosulfocarb in potatoes HE-20-E-GLOB1319H-PRO900-HU02 CPRP GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-98	Ferencz B.	2020	Efficacy of aclonifen and prosulfocarb in potatoes	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			HE-20-E-GLOB1319H-PRO900-RO04 Biotek FR GEP, not published				
KCP 6.2-99	Ströbele U.	2019	Efficacy of Aclonifen and prosulfocarb against weeds in sunflower applied pre-emergence. HE-19-A-ACNxDFF-PRO-DE01 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-100	Barasits T.	2019	Efficacy of Aclonifen and prosulfocarb against weeds in sunflower applied pre-emergence. HE-19-A-ACNxDFF-PRO-HU02 Syntech HU GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-102	Desogus S.	2019	Efficacy of aclonifen and prosulfocarb against weeds in sunflower applied pre-emergence. HE-19-A-ACNxDFF-PRO-IT04 Sagea IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-103	Dorotea Nagy C.	2019	Efficacy of aclonifen and prosulfocarb against weeds in sunflower applied pre-emergence. HE-19-A-ACNxDFF-PRO-RO05 Biotek RO GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-104	Camuñez S.	2019	Efficacy of aclonifen and prosulfocarb against weeds in sunflower applied pre-emergence. HE-19-A-ACNxDFF-PRO-ES06 Staphyt ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-105	Machalova O.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-A-GLOB1319H-1907bH-CZ01 ZS Kujavy GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-	Spitzer T.	2020	Efficacy of aclonifen, DFF and prosulfocarb in	N	Y	Data/study report never submitted	Globachem NV

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106			sunflower. HE-20-A-GLOB1319H-1907bH-CZ02 Zvu Kromeriz GEP, not published			before to PL.	
KCP 6.2-107	Mareckova J.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-A-GLOB1319H-1907H-CZ03 ZS Krasne Udoli GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-110	Camuñez S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower HE-20-A-GLOB1319H-1907H-FR06 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-111	Camuñez S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower HE-20-A-GLOB1319H-1907H-FR07 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-112	Rivet J.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-A-GLOB1319H-1907bH-FR08 Essais+ GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-113	Camuñez S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower HE-20-B-GLOB1319H-1907bH-ES01 Staphyt ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-114	Tetuan B.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-B-GLOB1319H-1907bH-ES02 GMW Biosciences GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.2-115	Camuñez S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower HE-20-B-GLOB1319H-1907bH-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-116	Camuñez S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower HE-20-B-GLOB1319H-1907bH-FR04 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-117	Zagi H.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-B-GLOB1319H-1907bH-HR05 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-118	Desogus S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-B-GLOB1319H-1907bH-IT06 Sagea IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-119	Desogus S.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-B-GLOB1319H-1907bH-IT07 Sagea IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-120	D'Annunzio G.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-B-GLOB1319H-1907bH-IT08 Agri 2000 (Net) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-121	Zagi H.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-C-GLOB1319H-1907bH-HR01 Pest-Pro	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.2-122	Barasits T.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-C-GLOB1319H-1907bH-HU02 CPRP GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-123	Molnár Z.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-C-GLOB1319H-1907bH-HU03 County Vas GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-124	Ferencz B.	2020	Efficacy of aclonifen, DFF and prosulfocarb in sunflower. HE-20-C-GLOB1319H-1907bH-RO04 Biotek RO GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-125	Tvaruzek L.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-CZ01 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-126	Zöllner H.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-DE02 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-127	Ströbele U.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-DE03 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.2-128	Lopez-Alvarez S.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-FR04 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-129	Lopez-Alvarez S.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-FR05 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-130	Valli F.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-IT06 Agri2000 GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-131	Umiński P.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-PL07 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-132	Gajek D.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied pre-emergence in winter cereals. 2018 HE-18-C-Roxy-Jura-PL08 ARC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-133	Tvaruzek L.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals. 2018 HE-18-D-Roxy-Jura-CZ01	N	Y	Data/study report never submitted before to PL.	Globachem NV

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			Zvu Kromeriz GEP, not published				
KCP 6.2-135	Ströbele U.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals. 2018 HE-18-D-Roxy-Jura-DE03 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-136	Lopez-Alvarez S.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals. 2018 HE-18-D-Roxy-Jura-FR04 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-137	Camuñez S.	2018	Efficacy and visual selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals. 2018 HE-18-D-Roxy-Jura-FR05 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-138	Camuñez S.	2018	Efficacy and visual selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals. 2018 HE-18-D-Roxy-Jura-ES06 Staphyt ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-139	Umiński P.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals. 2018 HE-18-D-Roxy-Jura-PL07 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-140	Gajek D.	2018	Efficacy and selectivity of Roxy and Jura against weeds applied post-emergence in winter cereals.	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
			2018 HE-18-D-Roxy-Jura-PL08 ARC GEP, not published				
KCP 6.2-141	Hrabovský J.	2019	Efficacy and selectivity of GLOB1907aH, GLOB1907bH, Jura CS, Jura EC against weeds applied pre-emergence in winter cereals. HE-19-A-GLOB1907H-Jura-CZ01 ZS Kujavy GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-142	Zöllner H.	2019	Efficacy and selectivity of GLOB1907aH, GLOB1907bH, Jura CS and Jura EC against weeds applied pre emergence in winter cereals. HE-19-A-GLOB1907H-Jura-DE02 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-144	Umiński P.	2019	Efficacy and selectivity of GLOB1907aH, GLOB1907bH, Jura CS, Jura EC against weeds applied pre and post-emergence in winter cereals. HE-19-A-GLOB1907H-Jura-PL04 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.2-145	Umiński P.	2019	Efficacy and selectivity of GLOB1907aH, GLOB1907bH, Jura CS, Jura EC against weeds applied pre and post-emergence in winter cereals. HE-19-A-GLOB1907H-Jura-PL05 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-01	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-A-GLOB1912H-1913H-BE01 Staphyt BE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-	Szrama K.	2020	Selectivity of autumn herbicides in winter cere-	N	Y	Data/study report never submitted	Globachem NV

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02			als. HS-20-A-GLOB1912H-1913H-FR02 Staphyt FR GEP, not published			before to PL.	
KCP 6.4-03	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-A-GLOB1912H-1913H-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-04	Junglee S.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-A-GLOB1912H-1913H-FR04 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-05	de Vries H.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-A-GLOB1912H-1913H-NL05 Verify GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-06	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-A-GLOB1912H-1913H-UK06 Staphyt UK GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-07	Bauer T.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-CZ01 InTec GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-08	Hrabovsky J.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-CZ02 ZZS Kujavy GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 6.4-09	Mareckova J.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-CZ03 ZS Krasne Udoli GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-10	Tvaruzek L.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-CZ04 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-11	Zöllner H.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-DE05 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-12	Friedrich F.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-DE06 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-13	Zickart U.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-DE07 BioChem agrar GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-14	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-B-GLOB1912H-1913H-DE08 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-28	Chermula L.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-E-GLOB1912H-1913H-PL01 Eurofins PL	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.4-29	Umiński P.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-E-GLOB1912H-1913H-PL02 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-30	Chermula L.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-E-GLOB1912H-1913H Eurofins PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-31	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-E-GLOB1912H-1913H-PL04 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-32	Tetuan B.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-F-GLOB1912H-1913H-ES01 GMW Biosciences GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-33	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-F-GLOB1912H-1913H-FR02 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-34	Zagi H.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-F-GLOB1912H-1913H-HR03 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-35	Russo A.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-F-GLOB1912H-1913H-IT04	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Agri 2000 (Net) GEP, not published				
KCP 6.4-36	Desogus S.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-F-GLOB1912H-1913H-IT05 Sagea IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-37	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-F-GLOB1912H-1913H-IT06 Staphyt IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-38	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-G-GLOB1912H-1913H-BE01 Staphyt BE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-39	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-G-GLOB1912H-1913H-FR02 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-40	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-G-GLOB1912H-1913H-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-41	Junglee S.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-G-GLOB1912H-1913H-FR04 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-42	de Vries H.	2020	Selectivity of autumn herbicides in winter cereals.	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			HS-20-G-GLOB1912H-1913H-NL05 Verify GEP, not published				
KCP 6.4-43	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-G-GLOB1912H-1913H-UK06 Staphyt UK GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-44	Mareckova J.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-CZ01 ZS Krasne Udoli GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-45	Fiala T.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-CZ02 ZS Kluky GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-46	Ruzicka A.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-CZ03 ZS Rymarov GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-47	Tvaruzek L.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-CZ04 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-48	Friedrich F.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-DE05 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-	Zöllner H.	2020	Selectivity of autumn herbicides in winter cere-	N	Y	Data/study report never submitted	Globachem NV

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49			als. HS-20-H-GLOB1912H-1913H-DE06 FRS DE GEP, not published			before to PL.	
KCP 6.4-50	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-DE07 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-51	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-H-GLOB1912H-1913H-DE08 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-65	Piotrowski G.	2020	Selectivity of autumn herbicides in winter cereals.. HS-20-K-GLOB1912H-1913H-PL01 Syntech PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-66	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals.. HS-20-K-GLOB1912H-1913H-PL02 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-67	Umiński P.	2020	Selectivity of autumn herbicides in winter cereals.. HS-20-K-GLOB1912H-1913H-PL03 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-68	Umiński P.	2020	Selectivity of autumn herbicides in winter cereals.. HS-20-K-GLOB1912H-1913H-PL04 FRS PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.4-69	Tetuan B.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-L-GLOB1912H-1913H-ES01 GMW Biosciences GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-70	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-L-GLOB1912H-1913H-FR02 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-71	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-L-GLOB1912H-1913H-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-72	Zagi H.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-L-GLOB1912H-1913H-HR04 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-73	Russo A.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-L-GLOB1912H-1913H-IT05 Agri 2000 (Net) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-74	Szrama K.	2020	Selectivity of autumn herbicides in winter cereals. HS-20-L-GLOB1912H-1913H-IT06 Staphyt IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-75	Szrama K.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-A-GLOB1310aH-1912H-BE01 Staphyt BE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.4-76	Tvaruzek L.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-A-GLOB1310aH-1912H-CZ02 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-77	Zöllner H.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-A-GLOB1310aH-1912H-DE03 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-78	Szrama K.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-A-GLOB1310aH-1912H-DE04 Staphyt DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-79	Szrama K.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-B-GLOB1310aH-1912H-BE01 Staphyt BE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-80	Tvaruzek L.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-B-GLOB1310aH-1912H-CZ02 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-81	Zöllner H.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-B-GLOB1310aH-1912H-DE03 FRS DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-82	Szrama K.	2020	Selectivity of autumn herbicides in winter spelt. HS-20-B-GLOB1310aH-1912H-UK04 Staphyt UK GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-83	Piotrowski G.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-A-ACN-PROxDFF-PL01 Syntech GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-	Wojtkowiak S.	2019	Selectivity of aclonifen and prosulfocarb applied	N	Y	Data/study report never submitted	Globachem NV

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84			in pre-emergence on potatoes. HS-19-A-ACN-PROxDFF-PL02 FRS PL GEP, not published			before to PL.	
KCP 6.4-85	Gajek D.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-A-ACN-PROxDFF-PL03 ARC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-86	Gajek D.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-A-ACN-PROxDFF-PL04 ARC GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-87	Camuñez S.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-A-ACN-PROxDFF-PL05 Staphyt GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-88	Trojna Z.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-B-ACN-PROxDFF-CZ01 Zemservis GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-89	Šafář J.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-B-ACN-PROxDFF-CZ02 Agritec GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-90	Zöllner H.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-C-ACN-PROxDFF-DE01 Field Research Support (FRS) DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV

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KCP 6.4-91	Camuñez S.	2019	Selectivity of aclonifen and prosulfocarb applied in pre-emergence on potatoes. HS-19-C-ACN-PROxDFF-FR02 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-92	Umiński P.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-D-GLOB1319H-1907bH-PL01 Field Research Support (FRS) PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-93	Szrama K.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-D-GLOB1319H-1907bH-PL02 Staphyt PL GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-94	Spurova R.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-E-GLOB1319H-1907bH-CZ01 ZS Trutnov GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-95	Trnka M.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-E-GLOB1319H-1907bH-CZ02 Zemservis GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-96	Zöllner H.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-E-GLOB1319H-1907bH-DE03 Field Research Support (FRS) DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-97	Friedrich F.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-E-GLOB1319H-1907bH-DE04 Quintus	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			GEP, not published				
KCP 6.4-98	de Vries H.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-E-GLOB1319H-1907bH-NL05 Verify (Zwaagdijk) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-99	Lang B.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-F-GLOB1319H-1907bH-HU01 Plant-Art GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-100	Balázs K.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-F-GLOB1319H-1907bH-HU02 County Somogy GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-101	Borcsik Z.	2020	Selectivity of aclonifen and prosulfocarb in potatoes. HS-20-F-GLOB1319H-1907bH-HU03 County Csongrad GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-102	Lang B.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower HS-20-A-GLOB1319H-1907bH-HU01 Plant-Art GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-103	Takács A.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower HS-20-A-GLOB1319H-1907bH-HU02 County Fejer GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-104	Ferencz B.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower HS-20-A-GLOB1319H-1907bH-RO03	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			Biotek RO GEP, not published				
KCP 6.4-105	Camuñez S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower HS-20-B-GLOB1319H-1907bH-ES01 Staphyt ES GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-106	Tetuan B.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-B-GLOB1319H-1907bH-ES02 GMW Biosciences GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-107	Camuñez S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower HS-20-B-GLOB1319H-1907bH-FR03 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-108	Junglee S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-B-GLOB1319H-1907bH-FR04 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-109	Zagi H.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-B-GLOB1319H-1907bH-HR05 Pest-Pro GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-110	Desogus S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-B-GLOB1319H-1907bH-IT06 Sagea IT GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-111	Desogus S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower.	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			HS-20-B-GLOB1319H-1907bH-IT07 Sagea IT GEP, not published				
KCP 6.4-112	D'Annunzio G.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-B-GLOB1319H-1907bH-IT08 Agri 2000 (Net) GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-113	Spitzer T.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-CZ01 Zvu Kromeriz GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-114	Bauer T.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-CZ02 Intec GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-115	Zöllner H.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-DE03 Field Research Support (FRS) DE GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-116	Friedrich F.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-DE04 Quintus GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-117	Camuñez S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-FR05 Staphyt FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-	Camuñez S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in	N	Y	Data/study report never submitted	Globachem NV

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118			sunflower. HS-20-C-GLOB1319H-1907bH-FR06 Staphyt FR GEP, not published			before to PL.	
KCP 6.4-119	Junglee S.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-FR07 Promo-Vert FR GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.4-120	de Vries H.	2020	Selectivity of aclonifen, DFF and prosulfocarb in sunflower. HS-20-C-GLOB1319H-1907bH-NL08 Verify / Proeftuin Zwaagdijk GEP, not published	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 6.5.1	Rockliff C.	2014	Prosulfocarb 667 + Diflufenican 14 EC GLP Seedling Emergence and Seedling Growth Test Terrestrial Non Target Plants STC/14/E843 Stockbridge Technology Centre Ltd GLP, not published	N	Y	Data protection started with: R-180/2017	Globachem NV
KCP 7.2	Perny A.	2016	Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetry) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe RB424 Anadiag GLP Unpublished	N	N	-	Syngenta <i>Globachem access</i>
KCP 7.3	Hassler S.	2021	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1912H through human skin membranes	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			20200297 Innovative Environmental Services (IES) Ltd. GLP Unpublished				
KCA 6.1	Jonchère F.	2010a	Frozen storage stability of residues of prosulfocarb in sunflower seeds A9086 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.1	Jonchère F.	2012	Frozen storage stability of diflufenican residues in oilseed rape seeds A9260 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.1	Quistad G.B., Bronner K, and Kovatchev A.	2010	A metabolism study with [14C]Diflufenican (3 radiolabels) using oilseed rape 1984W PTRL West, Inc. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3	Jonchère F.	2010b	Determination of prosulfocarb residues in potato following treatment with Prosulfocarb 800 g/L EC under field conditions in southern Europe in 2009 A9050 Anadiag GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 6.3	Jonchère F.	2010c	Determination of prosulfocarb residues in sunflower following treatment with Prosulfocarb	N	N	Data protection started with: R-31/2016	Globachem NV

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			800 g/L EC under field conditions in northern Europe in 2009 A9049 Anadiag GLP Unpublished				
KCA 6.3	Jonchère F.	2010d	Determination of diflufenican residues in potato following treatment with Diflufenican 500 SC under field conditions in Northern Europe in 2010 B0132 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3	Ertus C.	2021a	Determination of diflufenican and its metabolites and conjugates residues in potatoes following soil application with GLOB1912H under field conditions in Northern Europe in 2021 C1238 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3	Ertus C.	2021b	Determination of diflufenican and its metabolites and conjugates residues in potatoes following soil application with GLOB1912H under field conditions in Southern Europe in 2021 C1082 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.3	Jonchère F.	2011	Determination of diflufenican residues in winter oilseed rape following treatment with Diflufenican 500 SC under field conditions in northern and	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			southern Europe in 2009-2010. A9258 Anadiag GLP Unpublished				
KCA 6.3	Ertus C.	2021c	Determination of diflufenican (and its metabolites and conjugates) and prosulfocarb residues in sunflower following soil application with GLOB1912H under field conditions in Southern Europe in 2021 C1081 Anadiag GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCA 6.10	Jonchère F.	2010	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2009-2010. R A9051 Anadiag GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 6.10	Perny A.	2010	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2011-2012. R B1234 Anadiag GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 9.2.4	Truyens, S	2021	Estimations of the PEC <sub>gw</sub> of prosulfocarb, diflufenican and relevant metabolites	N	N	-	Globachem NV

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			GLOB1912HGW Globachem NV non GLP Unpublished				
KCP 9.2.5	Truyens, S	2021	Estimations of the PEC <sub>sw</sub> of prosulfocarb, diflufenican and relevant metabolites GLOB1912HSW Globachem NV non GLP Unpublished	N	N	-	Globachem NV
KCA 8.1.3	Sacker, D.	2008	The bioaccumulation potential of prosulfocarb in earthworm ( <i>Eisenia foetida foetida</i> ). ENV8333/040822 Chemex Environmental International Ltd GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.1	Juckeland, D.	2012a	Effects of Prosulfocarb sulfoxide on <i>Chlamydomonas reinhardtii</i> in an algal growth inhibition test 12-10-48-057-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.1	Juckeland, D.	2012b	Effects of Prosulfocarb sulfoxide on <i>Chlorella vulgaris</i> in an algal growth inhibition test 12-10-48-059-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.2	Juckeland, D.	2012c	Effects of Prosulfocarb sulfoxide on <i>Anabaena flos-aquae</i> in an algal growth inhibition test 12-10-48-058-W	N	N	Data protection started with: R-31/2016	Globachem NV

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			Biochem Agrar GmbH GLP Unpublished				
KCA 8.2.6.2	Juckeland, D.	2012d	Effects of Prosulfocarb sulfoxide on <i>Navicula pelliculosa</i> in an algal growth inhibition test 12-10-48-053-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.2	Juckeland, D.	2012e	Effects of Prosulfocarb sulfoxide on <i>Skeletonema costatum</i> in an algal growth inhibition test 12-10-48-060-W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.3.1.2	Ansaloni, T.	2016a	Chronic toxicity of Diflufenican technical on honeybees ( <i>Apis mellifera</i> L.) TRC16-019BA Trialeamp GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCA 8.3.1.3	Ansaloni, T.	2016b	Toxicity of Diflufenican technical on honey bee larvae ( <i>Apis mellifera</i> L.) after repeated exposure under laboratory conditions TRC16-018BA Trialeamp GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.2.1	Juckeland, D.	2021a	Acute toxicity of GLOB1817H to <i>Daphnia magna</i> in a 48-hour semi-static test 2-48-ADL-0015	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The prod-	Globachem NV

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			Biochem Agrar GmbH GLP Unpublished			uct is not registered yet. Data protection to start with the first authorization.	
KCP 10.2.1	Juckeland, D.	2021b	Effects of GLOB1817H on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 20 48 AAL 0019 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.2.1	Juckeland, D.	2021c	Effects of GLOB1817H on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions 20 48 ALE 0017 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.2.1	Juckeland, D.	2021d	Effect of GLOB1817H on <i>Myriophyllum spicatum</i> in a semi-static water-sediment system 20 48 AMS 0010 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.3.1.1	Franke, M.	2020	Acute toxicity of GLOB1817H to the honeybee <i>Apis mellifera</i> L. under laboratory conditions. 20 48 BAA 0130 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.3.1.1.1	Amsel, K.	2021	Acute toxicity of GLOB1817H to the bumblebee <i>Bombus terrestris</i> L. under laboratory conditions 20 48 BBA 0029	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The prod-	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
			Biochem Agrar GmbH GLP Unpublished			uct is not registered yet. Data protection to start with the first authorization.	
KCP 10.3.1.2	Ruhland, S.	2021	Chronic toxicity of GLOB1817H to the honey bee <i>Apis mellifera</i> L. under laboratory conditions 20 48 BAC 0071 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.3.1.3	Schmidt, K.	2021	GLOB1817H – Repeated exposure of the honey bee ( <i>Apis mellifera</i> L.) larvae under laboratory conditions 20 48 BLC 0052 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.3.2.2	Röhlig, U.	2020a	Effects of GLOB1817H on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Destefani-Perez) in an extended laboratory test. 20 48 NAE 0018 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.3.2.2	Röhlig, U.	2020b	Effects of GLOB1817H on the predatory mite <i>Typhlodromus Pyri</i> Scheuten in an extended laboratory test. 20 48 NTE 0013 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP	Röhlig, U.	2020c	Effects of GLOB1817H on the rove beetle <i>Aleo-</i>	N	Y	Data/study report submitted 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
10.3.2.2			<i>chara bilineata</i> Gyll. in an extended laboratory test. 20 48 NKE 0010 Biochem Agrar GmbH GLP Unpublished			along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	
KCP 10.3.2.2	Röhlig, U.	2020d	Effects of GLOB1817H on the carabid beetle <i>Poecilus cupreus</i> L. in an extended laboratory test. 20 48 NLE 0007 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.4.1.1	Servajean, E.	2012	Earthworm reproduction test with prosulfocarb 800 g/L EC (OECD 222, April 2004). 12-99-012-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.4.1.1	Friedrich, S.	2020	Effects of GLOB1817H on the reproduction of the earthworm <i>Eisenia fetida</i> . 20 48 TEC 0054 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.4.1.2	Schulz, L.	2015	Effects of prosulfocarb 800 g/L EC on earthworms under field conditions. Biochem Agrar Report Number 14 10 48 008 F GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP	Lauvaux, S.	2016	A dose response study to assess the NOEC, EC <sub>10</sub> .	N	Y	Data/study report submitted 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
10.4.2.1			20-50 on reproduction and LR <sub>10-20-50</sub> on mortality of Prosulfocarb 800 EC of the predatory mite <i>Hypoaspis aculeifer</i> on artificial soil in the laboratory. HA04/2016 Walloon Agricultural Research Centre GLP Unpublished			along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	
KCP 10.4.2.1	Taylor, K.	2016	Diflufenican 500 g/L SC: Predatory mite ( <i>Hypoaspis aculeifer</i> ) reproduction test in soil. DF50GM Envigo CRS Limited GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV & Sapec Agro S.A.
KCP 10.4.2.1	Schulz, L.	2020	Effects of GLOB1817H on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> . 20 48 THC 0043 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.4.2.1	Friedrich, S.	2020	Effects of GLOB1817H on the reproduction of the collembolan <i>Folsomia candida</i> 20 48 TCC 0059 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.5	Schulz, L.	2020	Effect of GLOB1817H on the activity of soil microflora (Nitrogen transformation test) 20 48 SMN 0052 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). 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 10.6	Stead, A.	2021	GLOB1817H: terrestrial plant test: seedling emergence and seedling growth test STC/20/E1410 Stockbridge Technology Center Ltd GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	Globachem NV
KCP 10.6	Lewington-Gower, M.	2021	GLOB1817H: terrestrial plant test: vegetative vigour test STC/20/E1409 Stockbridge Technology Center Ltd GLP Unpublished	N	Y	Data/study report submitted to PL along with the submission of Eledura (GLOB1817H). The product is not registered yet. Data protection to start with the first authorization.	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
None							

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
KCA 8.1.3	Sacker, D.	2008	The bioaccumulation potential of prosulfocarb in earthworm ( <i>Eisenia foetida foetida</i> ).	N			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
			ENV8333/040822 Chemex Environmental International Ltd GLP Unpublished				
KCA 8.2.6.1	Juckeland, D.	2012a	Effects of Prosulfocarb sulfoxide on <i>Chlamydomonas reinhardtii</i> in an algal growth inhibition test 12 10 48 057 W Biochem Agrar GmbH GLP Unpublished	N			Globachem NV
KCA 8.2.6.1	Juckeland, D.	2012b	Effects of Prosulfocarb sulfoxide on <i>Chlorella vulgaris</i> in an algal growth inhibition test 12 10 48 059 W Biochem Agrar GmbH GLP Unpublished	N			Globachem NV
KCA 8.2.6.2	Juckeland, D.	2012c	Effects of Prosulfocarb sulfoxide on <i>Anabaena flos-aquae</i> in an algal growth inhibition test 12 10 48 058 W Biochem Agrar GmbH GLP Unpublished	N			Globachem NV
KCA 8.2.6.2	Juckeland, D.	2012d	Effects of Prosulfocarb sulfoxide on <i>Navicula pelliculosa</i> in an algal growth inhibition test 12 10 48 053 W Biochem Agrar GmbH GLP Unpublished	N			Globachem NV
KCA 8.2.6.2	Juckeland, D.	2012e	Effects of Prosulfocarb sulfoxide on <i>Skeletonema costatum</i> in an algal growth inhibition test 12 10 48 060 W Biochem Agrar GmbH GLP Unpublished	N			Globachem NV
KCA 8.3.1.2	Ansaloni, T.	2016a	Chronic toxicity of Diflufenican technical on honeybees ( <i>Apis mellifera</i> L.) TRC16-019BA Trialcamp	N			

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				
KCA 8.3.1.3	Ansaloni, T.	2016b	Toxicity of Diflufenican technical on honey bee larvae ( <i>Apis mellifera</i> L.) after repeated exposure under laboratory conditions TRC16-018BA Trialcamp GLP Unpublished	N			

**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 <b>this MS</b> : Data protection started with: <insert authorization number of first authorization>	Owner