

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: GLOB1913H**

**Product name: Roxy XL**

**Chemical active substances:**

**Prosulfocarb, 900 g/L**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT Poland**

**(authorization)**

**Applicant: Globachem NV**

**Submission date: September 2022**

**After commenting period: 11/30/2023**

**Label correction : 23/05/2024**

## Version history

When	What
September 2022	Initial dossier submission by the applicant for approval of new product.
September 2023	zRMS assessment
November 2023	After commenting period
May 2024	Label correction

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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 September 2022.

The application was for approval of GLOB1913H, an emulsifiable concentrate containing 900 g/L prosulfocarb for use as a herbicide in winter cereals and potato for which Poland was designated zRMS.

#### 1.2 Letters of Access

A Letter of Access for a worker exposure study from Syngenta was submitted, as well as for field monitoring studies of hares from BASF and Bayer.

#### 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	GLOB1913H
Product name in MS	Roxy XL
Authorization number	/
Function	Herbicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Prosulfocarb: 900 g/L
Formulation type	Emulsifiable concentrate (EC)
Packaging	0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 15, 20 L HDPE;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

Authorization can be recommended for proposed use.

From an efficacy aspect, the use of GLOB1913H for pre-emergence and early post-emergence weed control in cereals and pre-emergence in potatoes.

## 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:	Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 2
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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>GHS07, GHS09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H317, H319, H410</b>
Precautionary statement(s):	<b>P261, P272, P280, P302+P352, P305+P351+P338, P321, P333+P313, P337+P313, P363, P362+P364, P391</b>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains: prosulfocarb

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	To protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m vegetated buffer strip to surface water bodies for the use in winter cereals at dose rate of 3.5 L/ha. To protect aquatic organisms respect an unsprayed buffer zone of 12 m including a 10 m vegetated buffer strip to surface water bodies for the use in winter cereals at dose rate of 4 L/ha. To protect aquatic organisms respect an unsprayed buffer zone of 14 m including 10 m vegetated buffer strip to surface water bodies for the use in potato.
SPe3	To protect non-target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 5 m in combination with 50% drift reducing nozzles or an unsprayed buffer zone of 3 m in combination with 75% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non-agricultural land.

### 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.
P272	Contaminated work clothing should not be allowed to out of the workplace.
P280	Wear protective gloves/, protective clothing/, eye protection/, face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment (see supplemental first aid instruction on this label).
P337+P313	If eye irritation persists: Get medical advice/ or attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/ or attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Residents and Bystanders protection:	
	5 m + 50% DRT
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
P391	Collect spillage.
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 10 m including a 10 m

	<p>vegetated buffer strip to surface water bodies for the use in winter cereals at dose rate of 3.5 L/ha.</p> <p>To protect aquatic organisms respect an unsprayed buffer zone of 12 m including a 10 m vegetated buffer strip to surface water bodies for the use in winter cereals at dose rate of 4 L/ha.</p> <p>To protect aquatic organisms respect an unsprayed buffer zone of 14 m including 10 m vegetated buffer strip to surface water bodies for the use in potato.</p>
SPe3	To protect non-target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 5 m in combination with 50% drift reducing nozzles or an unsprayed buffer zone of 3 m in combination with 75% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non-agricultural land.
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

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

## 2.5.2 Specific restrictions linked to the intended uses

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

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



## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Roxy XL/GLOB1913H  
Active substance 1: Prosulfocarb  
Active substance 2: /  
Safener: /  
Synergist: /  
Applicant: Globachem NV  
Zone(s): Central<sup>(d)</sup>  
Verified by MS: yes/no

GAP rev. 1, date: 2022-09-26  
Formulation type: Emulsifiable concentrate (EC)  
Conc. of as 1: 900 g/L <sup>(c)</sup>  
Conc. of as 2: / <sup>(c)</sup>  
Conc. of safener: / <sup>(c)</sup>  
Conc. of synergist: / <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

Field of use:

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, CAPBP, FUMOF, MYOAR, STEME, THLAR, VERPE.	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 4.4 b) 4.4	a) Prosulfocarb: 3.96 b) Prosulfocarb: 3.96	150-300	/	/
2	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	c) 4.0 d) 4.0	a)Prosulfocarb: 3.6 b)Prosulfocarb: 3.6	150-300	/	/
3	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, FUMOF, GERPU, MATCH, STEME, VERHE	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.5 b) 3.5	a)Prosulfocarb: 3.15 b)Prosulfocarb: 3.15	150-300	/	/
4	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, CAPBP, FUMOF, MYOAR, STEME, THLAR, VERPE.	Downward spraying	BBCH 10-29	a) 1 b) 1	/	a) 4.4 b) 4.4	a)Prosulfocarb: 3.96 b)Prosulfocarb: 3.96	150-300	/	/

5	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH 10-29	a) 1 b) 1	/	c) 4.0 d) 4.0	c)Prosulfocarb: 3.6 d)Prosulfocarb: 3.6	150-300	/	/
6	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, POAAN, FUMOF, GERPU, LAMPU, MYOAR, STEME, THLAR, VERHE, VERPE.	Downward spraying	BBCH 10-29	a) 1 b) 1	/	a) 3.5 b) 3.5	a)Prosulfocarb: 3.15 b)Prosulfocarb: 3.15	150-300	/	/
7	PL	Potato (SOLTU)	F	AMARE, CHEAL, GASPA, GERPU, MATIN, POLPE, STEME, THLAR and VIOAR.	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 4.4 b) 4.4	a)Prosulfocarb: 3.96 b)Prosulfocarb: 3.96	150-300	/	/
8	PL	Potato (SOLTU)	F	CAPBP	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.5 b) 3.5	a)Prosulfocarb: 3.15 b)Prosulfocarb: 3.15	150-300	/	/
9	PL	Winter durum wheat (TRZDW)	F	APESV, POAAN, GERPU, VERPE, VERHE)	Downward spraying	Pre-emergence	a) 1 b) 1	/	a) 2.6 b) 2.6	a)Prosulfocarb: 2.34 c)Prosulfocarb: 2.34	150-300	/	/
10	PL	Winter durum wheat (TRZDW)	F	APESV, POAAN, FUMOF, GERPU, LAMPU, MYOAR, THLAR, VERHE, VERPE	Downward spraying	BBCH10-29	a) 1 b) 1	/	a) 2.6 b) 2.6	a)Prosulfocarb: 2.34 d)Prosulfocarb: 2.34	150-300	/	/

### 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 golden yellow coloured liquid, with a sweet odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a flash point of 136.5°C. In aqueous solution, it has a pH value around 6.68 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*, *HDPE-F*, *HDPE-EVOH* or *HDPE/PA*. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation.

##### **zRMS comments**

The proposed by applicant shelf life of at least 2 years is based on the results of accelerated storage test performed according to CIPAC MT 46.4 – 2 weeks test at 54°C. Data from real time storage tests at ambient temperature are additionally required. The ambient temperature shelf life study is ongoing. When the study is completed the data should be submitted to support the proposed by applicant shelf-life of the preparation (2 years).

**Implications for labelling:** none

**Compliance with FAO specifications:** The product GLOB1913H 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 GLOB1913H has been provided and is considered to be acceptable

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

##### 3.2.1 Efficacy data

##### **Preliminary range-finding tests**

The applicant stated that as prosulfocarb is an established active substance, no preliminary studies were conducted, and therefore, no preliminary range-finding tests were submitted in support of GLOB1913H. Efficacy data against individual weed species is presented from two formulations: GLOB1318H (synonym GLOB1913H) and Prosulfocarb 900 CS. Based on the results provided, it can be assumed that the two formulations tested are comparable in terms of efficacy.

##### **Minimum effective dose tests**

### Cereals use

Regardless of EPPO zones and application timings, some weed species did not show a clear dose-response effect, being susceptible to GLOB1913H even at the lowest application rate of 2.6 L/ha (>85%).

### Potatoes use

Regardless of EPPO zones results obtained show that there was no clear increase in weed species susceptibility to GLOB1913H between the 2.6 and 4.4 L/ha rates, but the control achieved with the 4.4 L/ha rate was often higher than the control achieved with the lowest 2.6 L/ha rate.

In the north-eastern zone, where data are available, a dose rate of 4.4 l/ha was much more effective against MATIN and VIOAR than a lower dose rate of 2.6 l/ha.

### Efficacy tests

#### Cereals use

GLOB1913H was tested at 4.4, 3.5 and 2.6 L/ha (3960, 3150, 2340 g of active substance/ha). The requested dose rate of 4.0 L/ha was not been supported by field trials. The applicant states that “all data at 4.4 L/ha dose rate can be used as support a dose rate of 4.0 L/ha on cereals because they differ less than 10%.” This approach is unacceptable as this guidance applies to dose changes of registered products and not as part of a core assessment under Article 33.

Sufficient evidence of effectiveness of the product has been presented from trial data generated in the Maritime, North-East and South-East zones. Data is limited in the South-east zone, so the cMS concerned can extrapolate results from the other EPPO zones. The efficacy data have shown that the tested application rates of 2.6, 3.5 and 4.4 l/ha GLOB1913H will control the following of broad-leaved weed species and some grass weeds when applied to cereals at pre or post-emergence.

Dose rate l/ha	application	North-east zone
2.6	Pre-em	APESV, POAAN, GERPU, VERPE, VERHE
	Post-em	APESV, POAAN, FUMOF, GERPU, LAMPU, MYOAR, THLAR, VERHE, VERPE
3.5	Pre-em	APESV, FUMOF, GERPU, MATCH, STEME, VERHE
	Post-em	APESV, POAAN, FUMOF, GERPU, LAMPU, MYOAR, STEME, THLAR, VERHE, VERPE.
4.4	Pre-em	FUMOF, GALAP.
	Post-em	APESV, CAPBP, FUMOF, MYOAR, STEME, THLAR, VERPE.

The proposed range of application rates would allow dose rates to be applied according to weed pressure and climatic conditions. In practice, the higher dose rate should be used when weed pressure is high or conditions are unfavourable.

#### Potatoes use

In the South-East and Maritime EPPO zones, GLOB1913H was tested at dose rates of 2.6 and 4.4 L/ha. In the North-East EPPO zone, herbicide was tested at a dose rate of 3.6 L/ha. Regardless of EPPO zones, there was no efficacy data available to confirm its efficacy in practice at the requested dose rate of 3.5 L/ha. Data is limited in the South-east zone, so the cMS concerned can extrapolate results from the other EPPO zones. The efficacy data have shown that the tested application rates of 2.6 and 4.4 l/ha GLOB1913H will control the following broad-leaved weed species when applied to potatoes at pre-emergence.

Dose rate l/ha	application	North-east zone
2.6	Pre-em	AMARE, CAPBP, GASPA, GERPU, POLPE, STEME, THLAR

3.5	Pre-em	CAPBP (at dose rate of 3.6 l/ha)
4.4	Pre-em	AMARE, CHEAL GASPA, GERPU, MATIN, POLPE, STEME, THLAR and VIOAR.

### Possible development of resistance or cross-resistance

In terms of resistance risk, the applicant addresses all points of EPPO Standard 1/213 (4). The applicant provided a comprehensive overview of the current resistance status and the risk of resistance developing with prosulfocarb. The zRMS considers that the risk assessment is acceptable. It can be concluded that the overall agronomic resistance risk implemented by GLOB1913H has to be regarded as low to medium under current normal European agricultural practice.

### Adverse effects on treated crops

#### Cereals use

To assess the crop safety of GLOB1913H, specific selectivity trials were conducted under weed-free conditions. The phytotoxicity data indicate that the proposed uses are unlikely to cause significant damage to crops (TRZAW, TRZAWD, HORVW, TTLWI, SECCW). Any injury observed tended to be minor and/or transient. In addition, these trials show that applications of GLOB1913H are unlikely to have a negative impact on yield and quality.

#### Potatoes use

The phytotoxicity data indicate that the proposed uses are unlikely to cause significant injury to the crops. No phytotoxicity was observed in any of the efficacy and phytotoxicity trials, in potatoes in the Maritime and North East EPPO zone. One case of light symptoms of leaf deformation was observed in South East EPPO zone tended to be minor and transient.

The applicant provided acceptable risk assessments in accordance with EPPO to consider the risk to both succeeding and adjacent crops.

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

### 3.3.1 Analytical method for the formulation

Analytical methods for the determination of prosulfocarb in GLOB1913H were not evaluated as part of the EU review of this active substance. Therefore all relevant data are provided here and are considered adequate. An HPLC-DAD 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.

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

### 3.4.1 Acute toxicity

Acute toxicity studies for GLOB1913H were not evaluated as part of the EU review of prosulfocarb. Studies to assess the acute oral, dermal and inhalation toxicity, skin/eye irritation and skin sensitisation properties of the plant protection product GLOB1913H 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 GLOB1913H should be classified as Eye Irrit.2 and Skin Sens 1.

According to Regulation (EC) 1272/2008 (CLP Regulation), GLOB1913H should be labelled as: *GHS07; Warning; H317, H319*.

### **3.4.2 Operator exposure**

Operator exposure to GLOB1913H was not evaluated as part of the EU review of prosulfocarb. 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). For dermal absorption of the concentrate 0.24% and for the spray solution 3% for prosulfocarb were used as determined in the dermal absorption study. Operator exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using GLOB1913H according to the intended use is acceptable with the use of gloves during mixing, loading and application.

### **3.4.3 Worker exposure**

Worker exposure to GLOB1913H was not evaluated as part of the EU review of prosulfocarb. 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 GLOB1913H. 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.

### **3.4.4 Bystander and resident exposure**

Bystander and resident exposure to GLOB1913H was not evaluated as part of the EU review of prosulfocarb. 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 GLOB1913H when using a 5 m no spray buffer zone and 50% drift reducing technique.

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

### **3.5.1 Residues**

For the applied use of GLOB1913H in winter cereals and potato reference is made to the data that were submitted for the EU review of prosulfocarb, as well as to new studies submitted by the applicant. The evaluated GAP is covering the one intended for GLOB1913H.

Compliance with the EU MRLs of prosulfocarb is met for the intended uses of GLOB1913H.

### 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. 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).

Based on the different calculations made to estimate consumer exposure, it can be concluded that the use of the product GLOB1913H 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 and its metabolite 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 3.6-1: Maximum PEC<sub>soil</sub> values**

Compound	Maximum PECs (mg/kg)		
	3.5 L/ha	4 L/ha	4.4 L/ha
Prosulfocarb	4.200	4.800	5.2800
Prosulfocarb sulfoxide	0.3035	0.3469	0.3816
GLOB1913H	4.8413	5.5333	6.0867

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 and its metabolite in ground water has been determined with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 models.

The PEC<sub>gw</sub> of the active substance and its metabolite did not exceed the threshold of 0.1 µg/L. Therefore, no unacceptable leaching to groundwater is anticipated for the intended use of GLOB1913H.

### 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 and its metabolites were calculated for the intended use. These were then used for the ecotoxicological risk assessment.



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

The fate and behaviour in air of prosulfocarb was evaluated during the EU review of this active substance. 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.

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

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

#### **Birds**

Effects on birds for GLOB1913H were not evaluated as part of the EU review of prosulfocarb. 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 GLOB1913H to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with prosulfocarb, and maximum residues occurring on food items following applications according to the proposed use pattern.

The first-tier assessment were not acceptable for the long-term risk for the large herbivorous bird “goose” for the post-emergence use in winter cereals. Refinement of the reproductive risk assessment 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 the active substance has a log P<sub>OW</sub> > 3.0.

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 birds following application of GLOB1913H according to the intended uses.

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

Effects on terrestrial vertebrates other than birds for GLOB1913H were not evaluated as part of the EU review of prosulfocarb. Therefore all relevant data and risk assessments are provided here and are considered adequate.

The acute and long-term risks of GLOB1913H 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 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 the focal species, foliar DT<sub>50</sub> and/or PT values was done.

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

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  $\log P_{ow} > 3.0$ .

In conclusion, the  $TER_A$  and  $TER_{LT}$  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 GLOB1913H according to the intended uses.

### 3.7.2 Effects on aquatic species

Effects on aquatic organisms for GLOB1913H were not evaluated as part of the EU review of prosulfocarb. A new risk assessment was performed for the intended uses using the toxicity data of GLOB1913H.

An acceptable risk is concluded for prosulfocarb at Step 3 for the D4 pond, D5 pond, R1 pond and R4 stream scenario for the dose rate of 3.5 L/ha in winter cereals, the D4 pond, D5 pond and R1 pond scenario for the dose rate of 4 L/ha in winter cereals and the D4 pond and R1 pond scenarios in potatoes.

Taking into account the relevant scenarios for Poland the risk in all other scenarios was acceptable using:

- 10 m no spray buffer zone including 10 m vegetated buffer strip for the pre-emergence and post-emergence use in winter cereals for the dose rate of 3.5 L/ha;
- 10 m no spray buffer zone including 10 m vegetated buffer strip for the pre-emergence and post-emergence use in winter cereals for the dose rate of 4 L/ha
- 10 m no spray buffer zone including 10 m vegetated buffer strip for the use in potatoes.

The risk for the metabolite prosulfocarb sulfoxide is acceptable at Step 3, except for the D2 ditch and R3 stream scenario for the pre-emergence use in winter cereals at a dose rate of 4 L/ha. The risk in the R3 stream scenario can be resolved by using a 10 m no spray buffer zone including a 10 m vegetated filter strip. The risk in D2 ditch remains unresolved, but it represents <1% of the drained cereal growing land in Europe and it is mainly located in areas of the UK. The D2 scenario is therefore of very limited relevance in Member States and, if relevant, can be addressed with a label restriction for heavy clay soils.

An acceptable risk for the formulation GLOB1913H following spray drift is concluded using a 10 m no spray buffer zone for the use in winter cereals at 3.5 L/ha, a 12 m no spray buffer zone for the use in winter cereals at 4 L/ha and a 14 m no spray buffer zone for the use in potatoes.

#### Conclusion:

Taking into account the relevant scenarios for Poland:

- 10 m no spray buffer zone including a 10 m vegetated filter strip is needed to protect aquatic organisms when using GLOB1913H in winter cereals at dose rate of 3.5 L/ha,
- 12 m no spray buffer zone including 10 m vegetated filter strip is needed to protect aquatic organisms when using GLOB1913H in winter cereals at dose rate of 4 L/ha,
- 14 m no spray buffer zone including 10 m vegetated filter strip is needed to protect aquatic organisms when using GLOB1913H in potatoes.

### 3.7.3 Effects on bees

Effects on bees for GLOB1913H were not evaluated as part of the EU review of prosulfocarb.

The risk of GLOB1913H to honeybees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with the formulated product. All the hazard quotients are considerably less than 50, indicating that GLOB1913H poses a low acute risk to honeybees.

The risk of GLOB1913H 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. It was demonstrated that GLOB1913H poses a low acute risk to bumble bees.

The chronic risk to honeybees (adult and larvae) was assessed according to the modified EPPO 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. It was demonstrated that GLOB1913H 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 GLOB1913H were not evaluated as part of the EU review of prosulfocarb.

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 aged residue studies were performed. The ESCORT 2 guidance document recommends that any initial effects are acceptable if the potential for recovery within one year can be demonstrated. It was demonstrated that 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 GLOB1913H 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 GLOB1913H were not evaluated as part of the EU review of prosulfocarb.

#### **Earthworms**

The long-term risk of GLOB1913H to earthworms was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the formulated product and the maximum PECsoil.

The chronic TER value is greater than the Annex IV trigger of 5, indicating an acceptable risk to earthworms following application of GLOB1913H for the intended uses.

In addition, 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 GLOB1913H 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 formulated product 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 GLOB1913H for the intended uses.

The TER<sub>it</sub> for *Folsomia candida* due to exposure to prosulfocarb, prosulfocarb sulfoxide and GLOB1913H is below the trigger of 5. However, a field study is available showing that the risk for *Folsomia candida* is acceptable when using GLOB1913H as intended.

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

Effects on soil microbial activity of GLOB1913H were not evaluated as part of the EU review for prosulfocarb. Therefore all relevant data and assessments were provided.

They show that GLOB1913H 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 GLOB1913H were not evaluated as part of the EU review of prosulfocarb.

The potential effect of GLOB1913H on vegetative vigour and seedling emergence has been tested through studies performed with the formulated product. The most sensitive species in pre- and post-emergence was *Lolium perenne* with an ER<sub>50</sub> of 72.7 mL/ha and 3749 mL/ha, respectively.

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 GLOB1913H.

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

Not required.

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

The metabolite prosulfocarb sulfoxide is predicted to occur in groundwater at concentrations below 0.1 µg/L. Assessment of the relevance of this metabolite 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)**

GLOB1913H does not contain a candidate for substitution.

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

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

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

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

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

## Appendix 2 Copy of the product label

Zezwolenie MRiRW nr R- z dnia r.

### Posiadacz zezwolenia:

Globachem N.V., Brustem Industriepark, Lichtenberglaan 2019, B-3800 Sint-Truiden, Królestwo Belgii, tel.: +32-11 785717, e-mail: [globachem@globachem.com](mailto:globachem@globachem.com)

## ROXY XL

### Środek przeznaczony do stosowania przez użytkowników profesjonalnych

### Zawartość substancji czynnej:

prosulfokarb (związek z grupy karbaminianów) – 900 g/l ( %)

Zezwolenie MRiRW nr R - z dnia r.



### Uwaga

H317 - Może powodować reakcję alergiczną skóry.

H319 – Działa drażniąco na oczy.

EUH 401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P261 – Unikać wdychania rozpylonej cieczy.

P272 - Zanieczyszczoną odzież ochronną nie wyciągać poza miejsce pracy.

P280 - Stosować rękawice ochronne, odzież ochronną, ochronę oczu, ochronę twarzy.

P302 + P352 – W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem.

P305+351+338 – W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

P321 - Zastosować określone leczenie (patrz dodatkowa instrukcja pierwszej pomocy na etykiecie).

P333 + P313 – W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady lub zgłosić się pod opiekę lekarza.

P337 + P313 – W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady lub zgłosić się pod opiekę lekarza.

P362+P364 – Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

P391 – Zebrać wyciek.

Zawiera: prosulfokarb

## OPIS DZIAŁANIA

Roxy XL jest herbicydem w formie koncentratu do sporządzania emulsji wodnej, przeznaczonym do zwalczania niektórych gatunków rocznych chwastów jedno- i dwuliściennych w uprawie pszenicy ozimej i ziemniaków. Idealnymi warunkami działania środka są umiarkowana temperatura i dobre uwilgotnienie gleby.

Roxy XL działa także w warunkach niskiego uwilgotnienia ale jego działanie nie jest tak dobre jak w przypadku optymalnego uwilgotnienia. W niesprzyjających warunkach może dojść do uszkodzeń roślin uprawnych polegających na nieznacznym żółknięciu roślin. Uszkodzenia nie wpływają na wysokość plonu i regenerują się.

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

## DZIAŁANIE NA CHWASTY

Herbicyd jest pobierany przez rośliny w ciągu godziny od zabiegu i zapewnia selektywne zwalczanie chwastów. Opady po tym czasie nie zmniejszają skuteczności zabiegu. Środek jest pobierany przez liście i korzenie chwastów.

### Wrażliwość chwastów na środek w dawce 4,4 l/ha

#### Wrażliwość chwastów na środek w dawce 4,4 l/ha

Zastosowanie przedwiosenne	<b>Chwasty wrażliwe:</b> dymnica pospolita, przytulia czepna
	<b>Chwasty średnio wrażliwe:</b> maruna bezwonna
	<b>Chwasty odporne:</b> fiołek polny
Zastosowanie wiosenne	<b>Chwasty wrażliwe:</b> miotła zbożowa, tasznik pospolity, dymnica pospolita, niezapominajka polna, gwiazdnica pospolita, tobołki polne, przetacznik perski
	<b>Chwasty średnio wrażliwe:</b> przytulia czepna, mak polny
	<b>Chwasty odporne:</b> wyczyniec polny, chaber bławatek, rumianek pospolity

#### Wrażliwość chwastów na środek w dawce 3,5 l/ha

Zastosowanie przedwiosenne	<b>Chwasty wrażliwe:</b> miotła zbożowa, dymnica pospolita, bodziszek drobny, rumianek pospolity, gwiazdnica pospolita, przetacznik bluszczowy
	<b>Chwasty średnio wrażliwe:</b> wyczyniec polny, przytulia czepna, mak polny, przetacznik perski
	<b>Chwasty odporne:</b> Chaber bławatek, fiołek polny
Zastosowanie wiosenne	<b>Chwasty wrażliwe:</b> miotła zbożowa, wiechlina roczna, dymnica pospolita, bodziszek drobny, jasnota purpurowa, niezapominajka polna, gwiazdnica pospolita, tobołki polne, przetacznik perski, przetacznik bluszczowy
	<b>Chwasty średnio wrażliwe:</b> tasznik pospolity, przytulia czepna
	<b>Chwasty odporne:</b> fiołek polny

#### Wrażliwość chwastów na środek w dawce 2,6 l/ha

Zastosowanie przedwiosenne	<b>Chwasty wrażliwe:</b> miotła zbożowa, wiechlina roczna, bodziszek drobny, przetacznik perski, przetacznik bluszczowy
	<b>Chwasty średnio wrażliwe:</b> dymnica pospolita, przytulia czepna, gwiazdnica pospolita
	<b>Chwasty odporne:</b> fiołek polny
Zastosowanie wiosenne	<b>Chwasty wrażliwe:</b> miotła zbożowa, dymnica pospolita, wiechlina roczna, bodziszek drobny, jasnota purpurowa, niezapominajka polna, tobołki polne, przetacznik perski, przetacznik bluszczowy
	<b>Chwasty średnio wrażliwe:</b> tasznik pospolity, przytulia czepna, gwiazdnica pospolita
	<b>Chwasty odporne:</b> fiołek polny

## STOSOWANIE ŚRODKA



### **Pszenica ozima, jęczmień ozimy, żyto ozime, pszenżyto**

Termin stosowania: Stosować po zasiewie od fazy przed wschodami do fazy końca krzewienia zboża (BBCH 10-29). Nasiona zboża muszą być przykryte warstwą gleby o grubości 3 cm.

Maksymalna dawka dla jednorazowego zastosowania: 4 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 3,5 - 4 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 150 – 300 l/ha.

Zalecane opryskiwanie: średniokropliste.

### **pszenica twarda**

Termin stosowania: Stosować po zasiewie od fazy przed wschodami do fazy końca krzewienia zboża (BBCH 10-29). Nasiona zboża muszą być przykryte warstwą gleby o grubości 3 cm.

Maksymalna dawka dla jednorazowego zastosowania: 2,6 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 2,6 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 150 – 300 l/ha.

Zalecane opryskiwanie: średniokropliste

### **Ziemniak**

Termin stosowania: Stosować po sadzeniu przed wschodami ziemniaków, na glebę bez chwastów (BBCH 01-08).

Bulwy ziemniaka muszą być dobrze przykryte glebą aby uniknąć uszkodzeń.

Można także zastosować środek po obredleniu.

Maksymalna dawka dla jednorazowego zastosowania: 4,4 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3,5 - 4,4 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 150 – 300 l/ha.

Zalecane opryskiwanie: średniokropliste.

### **ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ**

Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.

Nie opryskiwać roślin pod wpływem stresu, zaatakowanych przez choroby lub szkodniki albo uszkodzonych przez mróz.

Środka nie stosować przy dużych wahaniami temperatury dobowej. Może wystąpić przejściowe żółknięcie roślin uprawnych, które się regeneruje i nie wpływa na wysokość plonu.

Nie stosować środka w warunkach silnego nasłonecznienia (w godzinach południowych), w warunkach suszy i temperatury powyżej 15 stopni aby uniknąć ewentualnych uszkodzeń roślin uprawnych.

Nie stosować na glebach podmokłych.

Nie stosować na zboża z wsiewkami.

Nie mieszać z glebą.

W ramach strategii antyodpornościowej zaleca się przemienne (w rotacji) stosowanie na danym stanowisku środków chwastobójczych, zawierających substancje czynne z różnych grup chemicznych, o odmiennym mechanizmie działania lub stosowanie mieszanin środków zawierających substancje czynne o różnym mechanizmie działania.

### **NASTĘPSTWO ROŚLIN**

Środek rozkłada się w glebie nie stwarzając zagrożenia dla roślin uprawianych następczo.

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem, rośliny z rodziny selerowatych można siać lub sadzić po upływie 100 dni. W przypadku innych upraw

wskazana jest konsultacja z posiadaczem zezwolenia lub jego przedstawicielem w zakresie doboru roślin do przesiewów.

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem) Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową i uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać. W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

### **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ**

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych, w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub,
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub,
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej

### **WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA**

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

#### **Środki ostrożności dla osób stosujących środek:**

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

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne).

#### **Środki ostrożności związane z ochroną środowiska naturalnego:**

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

W uprawie zbóż dla dawki 3.5L/ha:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych.

W uprawie zbóż dla dawki 4 L/ha

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 12 m zawierającej zadarnioną strefę o szerokości 10 m od zbiorników i cieków wodnych.

W uprawie ziemniaków:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 14 m zawierającej zadarnioną strefę ochronną o szerokości 10 m od zbiorników i cieków wodnych.

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 10 m lub 5 m z zastosowaniem technik redukujących znoszenie cieczy użytkowej o 50% lub 3 m z zastosowaniem technik redukujących znoszenie cieczy użytkowej o 75% od terenów nieużytkowanych rolniczo.

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

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

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

Ziemniaki wczesne – nie dotyczy

Pszenica ozima, jęczmień ozimy, żyto ozime, pszenżyto – nie dotyczy

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

Przed siewem/sadzeniem roślin z rodziny selerowatych – 100 dni

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0-30°C

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza należy pokazać pojemnik lub etykietę.

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

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

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

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

A Letter of Access for a worker exposure study from Syngenta was submitted, as well as for field monitoring studies of hares from BASF and Bayer.

## 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 an Data for Emulsifiable Concentrate Formulation containing Prosulfocarb, stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. DNA5818 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 a formulation containing prosulfocarb. DNA5818 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, stored at ambient temperature for 3 Years, in Compliance with Good Laboratory Practice. DNA5863	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
			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, stored at ambient temperature for 2 Years, in Compliance with Good Laboratory Practice. DNA5819 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 in an EC Formulation, in Compliance with Good Laboratory Practice DNA5820 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 KCA 8.2.6.1</i>	Sacker D.	2008b	The growth inhibition of Prosulfocarb Technical to the algae <i>Scenedesmus subspicatus</i> over a 72 hour exposure period Chemex Environmental International Ltd GLP Unpublished	N	-	-	Syngenta <i>Globachem access</i>
KCP 5.1.2 <i>Submitted as KCP 10.2.1</i>	Siche, O., Wydra V.	2021a	GLOB1913H: Acute toxicity to <i>Daphnia magna</i> in a static 48-hour immobilization test 155401220 Ibacon GmbH GLP Unpublished	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
KCP 5.1.2 Submitted as KCP 10.2.1	Siche, O., Wydra V.	2021b	GLOB1913H: Acute toxicity to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 155401210 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.2.1	Siche, O., Wydra V.	2021c	GLOB1913H: Toxicity to the aquatic plant <i>Lemna gibba</i> in a static growth inhibition test 155401240 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.2.1	Siche, O., Wydra V.	2021d	GLOB1913H: Toxicity to the aquatic plant <i>Myriophyllum spicatum</i> in a static growth inhibition test with a prior rooting phase 155401215 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.2.1	Juckeland, D.	2013a	Effects of Prosulfocarb 800 EC on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static test conditions 13 10 48 018 W Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	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: Jura EC (R-3/2022wu)	Globachem NV



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2 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: Jura EC (R-3/2022wu)	Globachem NV
KCP 5.1.2 Submitted as 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	N	Data protection started with: Jura EC (R-3/2022wu)	Globachem NV
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: Jura EC (R-3/2022wu)	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: Jura EC (R-3/2022wu)	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.7	Juckeland, D.	2013b	Effects of prosulfocarb sulfoxide on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static conditions 13 10 48 017 W Biochem Agrar GmbH GLP Unpublished	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
KCP 5.1.2 Submitted as KCP 10.3.1.1.1	Chwiesko, D.	2021	GLOB1913H: Acute contact and oral toxicity to bumblebees ( <i>Bombus terrestris</i> L.) in the laboratory. 155401105 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.3.1.2	Berg, C.	2021a	GLOB1913H: Chronic oral toxicity test on the honey bee ( <i>Apis mellifera</i> L.) in the laboratory. 155401136 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as KCP 10.3.1.3	Colli, M.	2021	Effects of GLOB1913H on honeybees ( <i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure BT273/20 Biotechnologie BT S.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as 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 never submitted before to PL.	Globachem NV
KCP 5.1.2 Submitted as 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: Roxy 800 EC (R-31/2016 zmienione R-690/2021d)	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2 <i>Submitted as KCP 10.6</i>	Bützler, R.	2021	GLOB1913H: Effects on terrestrial (non-target) plants: seedling emergence and seedling growth test 155401086 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 <i>Submitted as KCP 10.6</i>	Bützler, R.	2021	GLOB1913H: Effects on terrestrial (non-target) plants: vegetative vigour test 155401087 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	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: Roxy 800 EC (R-31/2016 zmienione R-690/2021d)	Globachem NV
KCP 6.2	Roberta Kolberg	2022	Biological Assessment Dossier: GLOB1913H  Globachem NV	N	Y	Data/study report never submitted before to PL.	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	N	N	-	Syngenta <i>Globachem access</i>

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 7.3	Hassler S.	2020	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as Prosulfocarb 900 EC through human skin membranes 20200051 Innovative Environmental Services (IES) Ltd. 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/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: Roxy 800 EC (R-31/2016 zmienione R-690/2021d)	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: Jura EC (R-3/2022wu)	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 9.2.4	Truyens, S	2021	Estimations of the PEC <sub>gw</sub> of prosulfocarb and relevant metabolites for the northern zone GLOB1913HGWNZ Globachem NV non GLP Unpublished	N	N	-	Globachem NV
KCP 9.2.5	Truyens, S	2021	Estimations of the PEC <sub>sw</sub> of prosulfocarb and relevant metabolites for the northern zone GLOB1913HSWNZ 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: Roxy 800 EC (R-31/2016 zmienione R-690/2021d)	Globachem NV
KCA 8.2.6.1	Sacker D.	2008b	The growth inhibition of Prosulfocarb Technical to the algae <i>Scenedesmus subspicatus</i> over a 72 hour exposure period Chemex Environmental International Ltd GLP Unpublished	N	-	-	Syngenta <i>Globachem access</i>
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: Jura EC (R-3/2022wu)	Globachem NV
KCA	Juckeland, D.	2012b	Effects of Prosulfocarb sulfoxide on <i>Chlorella vul-</i>	N	N	Data protection started with: Jura	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
8.2.6.1			garis in an algal growth inhibition test 12 10 48 059 W Biochem Agrar GmbH GLP Unpublished			EC (R-3/2022wu)	
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	N	Data protection started with: Jura EC (R-3/2022wu)	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	N	Data protection started with: Jura EC (R-3/2022wu)	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: Jura EC (R-3/2022wu)	Globachem NV
KCA 8.2.7	Juckeland, D.	2013b	Effects of prosulfocarb sulfoxide on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static conditions 13 10 48 017 W Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP	Schroeer, A.,	2011	Field monitoring of hares and rabbits in cereal fields	N	N	-	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
10.1.2.2	Grimm, T.		RifCon GmbH, Heidelberg, Germany BASF Report No.: M-442679-02-1 Amended: 2012-01-09 Unpublished				<i>Globachem access</i>
KCP 10.1.2.2	Voigt, U., Zaccaroni, M.	2013	Generic field monitoring of hares in a mixed landscape in Germany University of Veterinary Medicine Hannover, Hannover, Germany Bayer Report No.: BAR/FS069 Not GLP Unpublished	N	N	-	Bayer <i>Globachem access</i>
KCP 10.2.1	Siche, O., Wydra V.	2021a	GLOB1913H: Acute toxicity to <i>Daphnia magna</i> in a static 48-hour immobilization test 155401220 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	Siche, O., Wydra V.	2021b	GLOB1913H: Acute toxicity to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 155401210 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	Siche, O., Wydra V.	2021c	GLOB1913H: Toxicity to the aquatic plant <i>Lemna gibba</i> in a static growth inhibition test 155401240 Ibacon GmbH GLP Unpublished	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
KCP 10.2.1	Juckeland, D.	2013a	Effects of Prosulfocarb 800 EC on <i>Myriophyllum spicatum</i> in a growth inhibition test under semi-static test conditions 13 10 48 018 W Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	Siche, O., Wydra V.	2021d	GLOB1913H: Toxicity to the aquatic plant <i>Myriophyllum spicatum</i> in a static growth inhibition test with a prior rooting phase 155401215 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.1	Sekine, T.	2020	GLOB1913H: Effects (acute contact and oral) on honey bees ( <i>Apis mellifera</i> L.) in the laboratory. 155401035 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.1.1	Chwiesko, D.	2021	GLOB1913H: Acute contact and oral toxicity to bumblebees ( <i>Bombus terrestris</i> L.) in the laboratory. 155401105 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.2	Berg, C.	2021a	GLOB1913H: Chronic oral toxicity test on the honey bee ( <i>Apis mellifera</i> L.) in the laboratory. 155401136 Ibacon GmbH GLP Unpublished	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
KCP 10.3.1.3	Colli, M.	2021	Effects of GLOB1913H on honeybees ( <i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure BT273/20 Biotechnologie BT S.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	Leopold, J.	2020a	GLOB1913H: Effects on the predatory mite <i>Typhlodromus Pyri</i> (Acari: Phytoseiidae), extended laboratory study –dose response test- 155401062 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	Leopold, J.	2020b	GLOB1913H: Effects on the parasitoid <i>Aphidius rhopalosiphi</i> ) extended laboratory study –dose response test- 155401002 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	Berg, C.	2021b	GLOB1913H: Effects on the reproduction of rove beetles <i>Aleochara bilineata</i> -extended laboratory study- –dose response test- 155401071 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	Berg, C.	2021c	GLOB1913H: Effects on the carabid beetle <i>Poecilus cupreus</i> -extended laboratory study- –dose response study- 155401007	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
			Ibacon GmbH GLP Unpublished				
KCP 10.3.2.2	Röhlig, U.	2022a	Effects of GLOB1913H on the parasitic wasp <i>Aphidius rhopalosiphi</i> DeStephani-Perez under extended laboratory conditions (under semi-field conditions aged residues on potted barley plants) 22 48 NAR 0003 BioChem agrar GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	Röhlig, U.	2022b	Effects of GLOB1913H on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in an extended laboratory test (under semi-field conditions aged-residues on potted bean plants) 22 48 NTR 0002 BioChem agrar GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.1.1	Straube, D.	2020	GLOB1913H: Effects on reproduction and growth of earthworms <i>Eisenia Andrei</i> in artificial soil. 155401022 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	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 never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.2.1	Straube, D.	2021	GLOB1913H: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil. 155401089 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2.1	Straube, D.	2020	GLOB1913H: Effects on reproduction of the collembola <i>Folsomia candida</i> in artificial soil. 155401016 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2.2	Henkes, G.	2022	Prosulfocarb: GLP-compliant Collembola field study in Germany 2140003 Rifcon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.5	Hammesfahr, U.	2020	GLOB1913H: Effects on the activity of the soil microflora in the laboratory (Nitrogen transformation) 155401080 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.6	Bützler, R.	2021a	GLOB1913H: Effects on terrestrial (non-target) plants: seedling emergence and seedling growth test 155401086 Ibacon GmbH GLP Unpublished	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
KCP 10.6	Bützler, R.	2021b	GLOB1913H: Effects on terrestrial (non-target) plants: vegetative vigour test 155401087 Ibacon GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

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

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

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