

REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB2011I

Product name(s): SANKARI

Chemical active substance:

Pelargonic acid, 650 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland
(authorization)

Applicant: Globachem NV

Submission date: 31/07/2023

RMS Assessment: 17/02/2024

After commenting period: 16/04/2024

Update list studies: 28/05/2024

BBCH correction: 07/10/2024

Version history

When	What
February 2024	Initial dossier submission by applicant for approval of new product. RMS Assessment.
April 2024	After commenting period.
May 2024	Update list studies
October 2024	BBCH correction

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

Low-risk active substance: Pelargonic acid was ascribed on the draft list of low-risk active substance. It was expected to be renewed and officially listed as a low-risk active substance. SANKARI was planned to be submitted according to Article 47 as the active substance does not fulfil the criteria to be excluded as low-risk active substance as defined in point 5 of Annex II of Regulation 1109/2009 and SANKARI would not need specific risk mitigation measures. Nevertheless, renewal is still on-going and the low-risk status still under discussion. In the event the active substance is renewed as a low-risk active substance, then, the evaluation of SANKARI would need to be considered according to Article 47 of Regulation 1107/2009. Actually, it is submitted according to Article 33.

Food-grade quality: Our pelargonic acid does meet criteria to be considered as of food grade quality. Please refer to Part C for further information.

Active renewal status and impact on submission: The active substance renewal is still on-going and the expiry date has been prolonged till December 2024. Thus, endpoints listed in EFSA Journal 2013;11(1):3023 are for now to be used for the risk assessment.

1.2 Letters of Access

Not required as Globachem NV is using either endpoint listed in EFSA Journal 2013;11(1):3023 that are out of data protection, either data generated by Globachem NV with GLOB2011I for which data protection is claimed.

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/referenced 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	GLOB2011I
Product name in MS	SANKARI
Authorization number	/
Function	Insecticide
Applicant	Globachem NV
Active substance(s) (incl. content)	Pelargonic acid
Formulation type	EC
Packaging	<u>Size:</u> 100-150-250-500-600 ml and 1-2-3-5-10-15-20 L <u>Material:</u> HDPE/PA (High Density PolyEthylene Co-extruded with PolyAmide), HDPE-F (Fluorinated High Density PolyEthylene) or HDPE-EVOH (High Density PolyEthylene Co-extruded with Ethylene Vinyl Alcohol)
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	None recommended

2.2 Conclusion

MS-PL conclusion on assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574:

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product (Product code) **GLOB2011I**, Product name(s): **SANKARI** does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** of 3 March 2021 amending **Annex III** to Regulation (EC) No 1107/2009.

According to the current knowledge and available information, none of the co-formulants in the plant protection product **SANKARI** meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products.

The conclusions on efficacy is described in point 3.2.

2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

2.4 Classification and labelling


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

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

Hazard class(es), categories:	Skin Corr. 1C H314 Causes severe skin burns and eye damage Eye Dam 1 H318 Causes serious eye damage.
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	Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	 GHS05
Signal word:	Danger
Hazard statement(s):	H314: Causes severe skin burns and eye damage H412 Harmful to aquatic life with long lasting effects.
Precautionary statement(s):	<u>Precautionary Statement Prevention:</u> P260: Do not breathe spray. P264: Wash hands, forearms and face thoroughly after handling. P280: Wear protective gloves,/eye protection, face protection. <u>Precautionary Statement Response:</u> P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P363: Wash contaminated clothing before reuse. P304 + P340: If INHALED: Remove person to fresh air and keep comfortable for breathing. P310: Immediately call a POISON CENTER or doctor. P321: Specific treatment (see supplemental first aid instruction on this label). P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. <u>Precautionary Statement Storage:</u> P405: Store locked up.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
Contains	2-octadec-9-enoxyethanol;phosphoric acid

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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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:	
	PPE: work wear, gloves and protective goggles or face protection during mixing/loading and application due to the fact that the product is classified as Skin Corr. 1C H314 and Eye Dam. 1 H318. Thus on the labelling must be provided precautionary statement P280 - Wear protective gloves, eye protection, face protection.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
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):	GLOB2011I / SANKARI	Formulation type:	EC ^(a,b)
Active substance 1:	Pelargonic acid	Conc. of as 1:	650 g/L ^(c)
Active substance 2:	/	Conc. of as 2:	/ ^(c)
Safener:	/	Conc. of safener:	/ ^(c)
Synergist:	/	Conc. of synergist:	/ ^(c)
Applicant:	Globachem nv	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		

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, 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)	Conclusion (efficacy)
					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	g 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	Cereals (winter wheat [TRZAW], winter durum wheat [TRZDW], spelt [TRZSP], winter barley [HORVW], winter rye [SECCW], winter tritcale [TTLWI])	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	downward spraying	At first infestation / BBCH 10-29 (autumn: end of September to end of December)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA		winter barley [HORVW] winter wheat [TRZAW] winter durum wheat [TRZDW] spelt [TRZSP], winter rye [SECCW], winter tritcale [TTLWI])

2	PL	Cereals (winter wheat [TRZAW], winter durum wheat [TRZDW], spelt [TRZSP], winter barley [HORVW], winter rye [SECCW], winter tritcale [TTLWI])	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	downward spraying	At first infestation / BBCH 21-49 (spring: March to May)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA		winter barley [HORVW] winter wheat [TRZAW] winter durum wheat [TRZDW], spelt [TRZSP], winter rye [SECCW], winter tritcale [TTLWI])
3	PL	Cereals (winter and spring wheat [TRZAW & TRZAS], winter and spring durum wheat [TRZDW & TRZDS], spelt [TRZSP], winter and spring barley [HORVW & HORVS], winter and spring rye [SECCW & SECCS], winter and spring tritcale [TTLWI & TTLSO])	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	downward spraying	BBCH 51-77 (spring: May to beginning of July)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA		winter and spring wheat [TRZAW & TRZAS] winter and spring durum wheat [TRZDW & TRZDS], spelt [TRZSP], winter and spring barley [HORVW & HORVS], winter and spring rye [SECCW & SECCS], winter and spring tritcale [TTLWI & TTLSO])
4	PL	Cereals (winter wheat [TRZAW], winter durum wheat [TRZDW], spelt [TRZSP], winter barley [HORVW], winter rye [SECCW], winter tritcale [TTLWI])	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	downward spraying	At first infestation / BBCH 10-29 (autumn: end of September to end of December)	a) 2 (14) b) 2 (14)	14	a) 2.0 b) 4.0	a) 1300 b) 2600	200-400	NA		winter barley [HORVW] winter wheat [TRZAW] winter durum wheat [TRZDW], spelt [TRZSP], winter rye [SECCW], winter tritcale [TTLWI])
5	PL	Cereals (winter wheat [TRZAW], winter durum wheat [TRZDW], spelt [TRZSP], winter barley [HORVW], winter rye [SECCW],	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	downward spraying	At first infestation / BBCH 21-49 (spring: March to May)	a) 2 (14) b) 2 (14)	14	a) 2.0 b) 4.0	a) 1300 b) 2600	200-400	NA		winter barley [HORVW] winter wheat [TRZAW] winter durum wheat [TRZDW], spelt [TRZSP], winter rye [SECCW], winter tritcale [TTLWI])

		winter triticale [TTLWI])												
6	PL	Cereals (winter and spring wheat [TRZAW & TRZAS], winter and spring durum wheat [TRZDW & TRZDS], spelt [TRZSP], winter and spring barley [HORVW & HORVS], winter and spring rye [SECCW & SECCS], winter and spring triticale [TTLWI & TTLSO])	F	Aphids / <i>Rhopalosiphum padi</i> [RHOPPA], <i>Sitobion avenae</i> [MACASV]	downward spraying	BBCH 51-77 (spring: May to beginning of July)	a) 2 (14) b) 2 (14)	14	a) 2.0 b) 4.0	a) 1300 b) 2600	200-400	NA		winter and spring wheat [TRZAW & TRZAS] winter and spring durum wheat [TRZDW & TRZDS], spelt [TRZSP], winter and spring barley [HORVW & HORVS], winter and spring rye [SECCW & SECCS], winter and spring triticale [TTLWI & TTLSO]
7	PL	Oilseed rape (winter) [BRNN]	F	Cabbage stem flea beetle / <i>Psylliodes chrysocephala</i> [PSYICH]	downward spraying	At first infestation / BBCH 10-16 (summer-autumn: late August to end of October)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA		
8	PL	Oilseed rape (winter) [BRNNW]	F	Flea beetle / <i>Phyllotreta</i> sp. [PHYESP]	downward spraying	At first infestation / BBCH 10-16 (summer-autumn: late August to end of October)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA		
9	PL	Oilseed rape (winter and spring) [BRNNW and BRNS]	F	Pollen beetle / <i>Meligethes aeneus</i> [MELIAE]	downward spraying	At first infestation / BBCH 50-65 (spring: April to July)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA		
10	PL	Oilseed rape (winter and spring) [BRNNW and BRNS]	F	Cabbage seed - pod weevil / <i>Ceutorhynchus obstrictus</i> [CEUTAS]	downward spraying	At first infestation / BBCH 50-65 (spring: April to July)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200-400	NA	The treatment against pollen beetle also fights the cabbage seed/pod weevil <i>Ceutorhynchus obstrictus</i> (CEUTAS)	

11	PL	Potato [SOLTU]	F	Colorado beetle / <i>Lep- tinotarsa decemline- ata</i> [LPTNDE]	downward spraying	At first infesta- tion / BBCH 35-85 (spring- summer: May to August)	a) 2 (14) b) 2 (14)	14	a) 1.5 b) 3.0	a) 975 b) 1950	200- 400	NA		
12	PL	Maize [ZEAMX]	F	Corn borer / <i>Ostrinia nubilalis</i> [PYRUNU]	downward spraying	At first infesta- tion / BBCH 51- 71 (summer: June to July)	a) 2 (14) b) 2 (14)	14	a) 2.0 b) 4.0	a) 1300 b) 2600	200- 600	NA		
13	PL	Maize [ZEAMX]	F	Corn borer / <i>Ostrinia nubilalis</i> [PYRUNU]	downward spraying	At first infesta- tion / BBCH 51- 71 (summer: June to July)	a) 2 (14) b) 2 (14)	14	a) 3.0 b) 6.0	a) 1950 b) 3900	200- 600	NA		

Remarks table heading:

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

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

Remarks columns:

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

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
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 free-flowing transparent clear yellow liquid, with an oily type odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 360 °C. In aqueous solution, it has a pH value around 3.27 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 (accelerated storage for 14 days at 54°C) indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE-PA*, *HDPE-F* and *HDPE-EVOH*. Its technical characteristics are acceptable for an *emulsifiable concentrate* formulation. The intended concentration of use is 0.333% to 1.5%.

Implication for labelling: The neat pH < 2 triggers a H314 classification.

Compliance with FAO specifications: The product GLOB2011I complies with FAO specifications.

Formulation used for tests: The product GLOB2011I used in the physico-chemical tests has the same composition as the one cited in Part C.

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 GLOB2011I has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

GLOB2011I contains 650 g/L of the active substance pelargonic acid. It is formulated as an emulsifiable concentrate (EC). It is to be used as an insecticide in cereals, oilseed rape, potatoes and maize. Pelargonic acid is a compound of natural occurrence in the environment, having rapid metabolism and degradation in soil with known use for weed control. It has now been found that Pelargonic acid (synonym: Nonanoic acid) used at selected rates is also effective at controlling insect pests. Due to the favorable environmental profile of pelargonic acid and the fact that it provides an alternative mode of action compared to many insecticides currently widely used on arable crops, it represents an important new solution for farmers to control or prevent damage caused by insects.

The proposed maximum label rate is 2 L/ha in cereals, 1.5 L/ha on oilseed rape and potatoes and 3 L/ha on maize. From the presented results it can be concluded that GLOB2011I is able to reduce the damage compared to the untreated control showing a benefit from a product of natural occurrence with low risks and frequently even comparable with conventional pyrethroid reference products.

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

GLOB2011I is based on the active substance pelargonic acid, not yet classified by the IRAC committee. Other fatty acids are known and currently authorized as contact insecticides. Mode of action and classification of those fatty acids by IRAC is unknown (UNE - Botanical essence including synthetic, extracts and unrefined oils with unknown or uncertain MOA). They are believed to penetrate the external layers of the target pest, interacting with multiple vital metabolic processes. Although the mechanisms behind the insecticidal effect of pelargonic acid are still not fully understood, it is proposed that it is associated with suffocation.

There is no known resistance cases to pelargonic acid as an insecticide. The risk to develop resistance to pelargonic acid is considered to be very low, since no inheritable target site modifications are directly involved in the pest/PPP interaction. Considering that the product can be used in an IPM strategy and that according to IRAC, non-specific Modes of Action are good resistance management tools and that resistance is evolving in most target pests of GLOB2011I specially to pyrethroids, GLOB2011I can be a valid alternative with low risks.

Based on the available information, it is considered that the risk of resistance development to GLOB2011I is negligible for all targets.

3.2.3 Adverse effects on treated crops

Submitted data on the adverse effects on treated crops revealed no significant phytotoxicity symptoms caused by GLOB2011I at the maximum proposed dose rates. Based on the submitted data and considering that it's known from experience that pelargonic acid has herbicidal properties at much higher rates, the applicant proposed the following sentence to be inserted on the label: avoid spray overlaps.

3.2.4 Observations on other undesirable or unintended side-effects

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

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

The purpose of this section is to evaluate efficacy data submitted for authorisation of GLOB2011I for insect control on arable crops.

Conclusion – Preliminary range-finding tests

The results presented demonstrate some benefit of pelargonic acid in the mode of action and as effective dose rate of formulations on different insect species and life stages. The results suggest that concentrations between 1/300 and 1/100 provide good control in the laboratory depending on the target pest. ZRMS agrees with the applicant that the level of control in the field needs to be further investigated.

Conclusion – Minimum effective dose

The applicant has made no discussion of this section. The applicant stated that the trials submitted to support the MED of GLOB2011I are the same as the efficacy trials described under section 3.2.3. in which individual trial results including lower dose rates of GLOB2011I are presented. The submitted number of efficacy trials per individual EPPO zone and use to support the approval of individual pest was limited. A definitive conclusion regarding the minimum effective dose per individual EPPO zone cannot be made based on the available data. However, there is a trend suggesting that 1.5 L/ha could serve as the minimum effective dose for use on cereals, oilseed rape and potatoes. At the lower doses, the control was more variable and this resulted in some variation in control between the trials and between EPPO climatic zones. Whereas at the proposed maximum individual dose (975 g a.s./ha) the control was more consistent although it did not prove to be sufficiently effective in all of requested uses.

Conclusion – Efficacy tests

Spring application against ear aphids - *Rhopalosiphum padi* [RHOPPA], *Sitobion avenae* [MACASV].

A conditional registration for this use in wheat may be considered acceptable provided that the applicant submits at least three efficacy trials for each pest as part of the post-registration process. These trials must be carried out in Poland. No data were submitted on winter and spring durum wheat, spelt, winter and spring barley, winter and spring rye, winter and spring triticale. Pelargonic acid as an insecticide is a new use in Poland and therefore full data are needed to demonstrate efficacy on the claimed cereal crops. Extrapolation of data from wheat to other cereals is not acceptable.

Autumn application against aphids as virus vectors - *Rhopalosiphum padi* [RHOPPA], *Sitobion avenae* [MACASV]

A conditional registration for this use may be considered acceptable provided that the applicant submits at least three efficacy trials - autumn application against *Sitobion avenae* on winter barley as part of the post-registration process. These trials have to be conducted in Poland. No data were submitted on wheat, winter rye, winter triticale. Pelargonic acid as an insecticide is a new use in Poland and therefore full data are needed to demonstrate efficacy on the claimed cereal crops. Extrapolation of data from barley to other cereals is not acceptable.

For PL, the applicant has not provided sufficient evidence to demonstrate efficacy of GLOB2011I on potatoes, oilseed rape and maize.

Conclusion - Resistance risk assessment

GLOB2011I is an emulsifiable concentrate formulation (EC) containing the active ingredient pelargonic acid (650 g/L) for insect control on arable crops. The proposed maximum label rate is 2 L/ha in cereals, 1.5 L/ha on oilseed rape and potatoes and 3 L/ha on maize. The applicant has stated that in most crops the product will not be used more than twice a season. No known cases of resistance to pelargonic acid as an insecticide have been recorded. The risk to develop resistance to pelargonic acid is considered to be low, since no inheritable target site modifications are directly involved in the pest/PPP interaction. The resistance risk is considered acceptable.

Conclusion – Phytotoxicity to host crop

It can be concluded that GLOB2011I at the maximum proposed dose rate of 2 L/ha in cereals, 1.5 L/ha on oilseed rape and potatoes and 3 L/ha on maize has no phytotoxic effects on potatoes when applied according to label recommendations and avoiding spray overlaps.

Conclusion – Effect on the yield of treated plants or plant products

Overall, GLOB2011I applied at the proposed maximum dose rates had no adverse effects on crop yield when applied on cereals, oilseed rape, potatoes and maize and could even slightly increase the mean total yield compared to the untreated control.

Conclusion – Effects on the quality of plants or plant products

Overall, GLOB2011I applied at proposed label rate showed no negative effects on quality of cereals, oilseed rape, potatoes and maize. Therefore, no impact of GLOB2011I on quality of yield is to be expected, when applied within proposed label rate range and according to label recommendations.

Conclusion – Impact on succeeding crops

It is concluded that there is negligible risk of pelargonic acid impacting negatively on succeeding crops under normal use and no limitations are proposed. The case presented by the applicant is acceptable and no further data are required.

Conclusion – Impact on other plants including adjacent crops

Overall, it is concluded that the use of GLOB2011I at the proposed maximum recommended dose will not lead to any deleterious effects on adjacent or other crops under normal conditions. No buffer zone or other mitigation measures are needed to protect non-target plants after application of GLOB2011I according to the intended use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of pelargonic acid in GLOB2011I were not evaluated as part of the EU review of this active substance. Therefore, all relevant data are provided here and are considered adequate. A GC-FID method was submitted to analyse the active ingredient content in the formulation. The method was successfully validated.

Analytical methods for the determination of pelargonic acid in sugar solution (from bee study), water stock solutions (from bee larvae study), fortified water (coming from algae study) and fortified blank GLOB2011I formulation (used in NTP studies) were not evaluated as part of the EU review of this active substance. Therefore, all relevant data are provided here and are considered adequate.

3.3.2 Analytical methods for residues

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

3.4 Mammalian toxicology (Part B, Section 6)

Based on data provided, GLOB2011I should be classified as skin corrosion/irritation, Category 1, Sub-Category 1C and labelled as: *GHS05; Danger; H314 - Causes severe skin burns and eye damage.*

No specific risk mitigation measures due to risk assessments are necessary. Nevertheless, based on corrosivity/irritation studies it is recommended to wear suitable protective clothing, protective gloves and safety glasses when using undiluted product.

3.4.1 Acute toxicity

Acute toxicity studies for GLOB2011I were not evaluated as part of the EU review of fatty acids. Therefore, all relevant data were provided and are considered adequate.

No study has been performed for Europe for GLOB2011I as it is possible to extrapolate toxicity from data available on active substance and co-formulants. The assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011). Full details on composition and classification of formulants are provided in part C of this registration report.

Nevertheless, GLP studies were performed to obtain the registration in Brazil and were provided for the sake of completeness in addition to the calculation method. Both data led to the same conclusion.

GLOB2011I containing 650 g/L pelargonic acid, has a low toxicity in respect to acute oral, dermal and inhalation toxicity. It is not a skin sensitizer (calculation and LLNA test). Nevertheless, it is corrosive to skin and causes severe skin burns and eye damage. Taking into account all submitted data and the labelling of active substance and co-formulants, GLOB2011I should be labelled as skin corrosion, Category 1, Sub-Category 1C. According to Regulation (EC) 1272/2008 (CLP Regulation), GLOB2011I should be labelled as: *GHS05; Danger; H314.*

3.4.2 Operator exposure

Operator exposure to GLOB2011I was not evaluated as part of the EU review of fatty acids for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Operator exposure was assessed against the surrogate AOEL (defined as the normal dietary intake of fatty acids i.e. 821 mg/kg bw/day) agreed in the EU review (fatty acids). For dermal absorption of pelargonic acid default values of 25% for the concentrate and 70% for the spray solution were used. Operator exposure was modelled using the EFSA online calculator 2022 v 1.0.0. (OPEX) .

According to the model calculations, it can be concluded that the risk for the operator using GLOB2011I on cereals, oilseed rape, potatoes and maize is acceptable without the use of PPE (i.e. using regular work wear (arms, body and legs covered). Nevertheless, given the skin/eye corrosive potential of GLOB2011I impermeable gloves and eye/face protection should be worn when handling the concentrate and for the maintenance of the sprayer during application. Hence, phrase P280 - Wear protective gloves, eye protection, face protection should be added on the label.

3.4.3 Worker exposure

Worker exposure to GLOB2011I was not evaluated as part of the EU review of fatty acids acid. 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 GLOB2011I. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.4.4 Bystander and resident exposure

Bystander exposure to GLOB2011I was not evaluated as part of the EU review of fatty acids. 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 resident and bystander after accidental short-term exposure to GLOB2011I. This has no labelling implications.

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

The data available are considered sufficient for risk assessment. Pelargonic acid is a naturally occurring compound (also approved as a food additive according to Commission Regulation (EU) No 872/2012) for which no residue definition is set/required. The proposal to maintain pelargonic acid in Annex IV of Regulation (EC) No 396/2005 is supported. No MRL, ArfD, ADI were set/required.

The chronic and the short-term intakes of pelargonic acid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

3.5.1 Residues

Pelargonic acid is a naturally occurring compound (also approved as a food additive according to Commission Regulation (EU) No 872/2012) for which no residue definition is set/required. The proposal to maintain pelargonic acid in Annex IV of Regulation (EC) No 396/2005 is supported. No MRL was

set/required.

3.5.2 Consumer exposure

Pelargonic acid is a naturally occurring compound (also approved as a food additive according to Commission Regulation (EU) No 872/2012) for which no residue definition is set/required. The proposal to maintain pelargonic acid in Annex IV of Regulation (EC) No 396/2005 is supported. No MRL, ArfD, ADI were set/required.

The chronic and the short-term intakes of pelargonic acid residues are unlikely to present a public health concern.

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

No new studies are presented; all data were reviewed in the EU review (fatty acids). Appropriate endpoints from the EU review were used to calculate PECs for GLOB2011I and pelargonic acid in soil, surface water, ground water and air for the intended use patterns.

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

The PEC of GLOB2011I and pelargonic acid in soil has been assessed with the FOCUS model and the focus groundwater interception values and the DT₅₀ values established in the EU review. Based on the recommended use rate of winter cereals at BCH stage 10-29, the maximum initial predicted environmental concentration in soil (PECs) of GLOB2011I and pelargonic acid are provided in the Table 3.6-1. Assuming the same application regime is used year after year, no plateau concentration of pelargonic acid is expected in the soil as degradation is very fast.

Table 3.6-1: Maximum PEC_{soil} values

Compound	Maximum PECs (mg/kg)
	Winter cereals (BBCH 10-29) as worst-case GAP
Pelargonic acid	1.802
GLOB2011I	2.429

The results for PEC soil for GLOB2011I and the active substance were used for the eco-toxicological risk assessment.

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

The PEC of pelargonic acid in groundwater has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS-PELMO 6.6.4 and FOCUS PEARL 5.5.5 models and the Koc values established in the EU review.

Pelargonic acid has a very high mobility in soil and therefore a risk to groundwater could be expected. The predicted environmental concentrations (PEC_{GW}) at 1m depth for pelargonic acid following 26 years for any proposed GAPs (uses 1-13), were less than 0.01 µg/L in all scenarios using FOCUS-PELMO and FOCUS PEARL models and a DT50 of 3 days.

In conclusion, the model(s) predicts that the pelargonic acid will not be found in ground water at concentrations greater than 0.1µg/L. Based on the assessment, the use of pelargonic acid is not expected to lead

to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

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

The PEC of pelargonic acid in surface water (PEC_{sw} and PEC_{sed}) has been assessed with the FOCUS SW the DT50 water/sediment values established in the EU review. Based on the recommended use rate of cereals, oilseed rape, potatoes and maize, the maximum PEC values for surface water and sediment have been calculated according to FOCUS (Step 1, 2 and 3 if necessary) for the parent pelargonic acid.

The results for PEC surface water for the active substance were used for the eco-toxicological risk assessment.

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

The vapour pressure at 20 °C of the active substance pelargonic acid is $> 10^{-4}$ Pa. Hence the active substance pelargonic acid is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance pelargonic acid due to volatilization with subsequent deposition should be considered. However, any exposure to the atmosphere of pelargonic acid is unlikely to be prolonged based on a rapid oxidative photodegradation. Overall, it can be considered that volatilisation to the atmosphere following normal agricultural use of the formulated product will be limited and that any potential for atmospheric exposure will be further limited by the rapid breakdown of pelargonic acid by microbial action in soil. It is considered that pelargonic acid will not be deposited to the terrestrial or aquatic environment by atmospheric routes.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds

In EFSA Journal 2013;11(1):3023, a waiver was concluded for all representative formulations on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals:

“The available toxicity data indicated low acute and short-term (for birds only) toxicity to birds and mammals. Acute and short-term (for birds only) first tier risk assessments for birds and mammals indicated a high risk as the resulting TER values were less than the trigger value. However, given that fatty acids are an essential component of the diet of birds and mammals a low risk was concluded. No reproductive toxicity data were available. However, on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals a low reproductive risk was identified.”

This conclusion can be extrapolated to GLOB2011I especially since doses proposed in this evaluation are far below the doses evaluated for the representative formulations in the EU Review of fatty acids.

The results of the risk assessment indicate an acceptable risk for wildlife birds due to the intended use of GLOB2011I according to the label.

Terrestrial vertebrates (other than birds)

Effects on terrestrial vertebrates other than birds for GLOB2011I were not evaluated as part of the EU review of fatty acids. However further data on GLOB2011I is not relevant as active substance data on toxicity to terrestrial vertebrates other than birds is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU review. Risk assessments for GLOB2011I with the proposed use pattern are provided and are considered adequate.

In EFSA Journal 2013;11(1):3023, a waiver was concluded for all representative formulations on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals:

“The available toxicity data indicated low acute and short-term (for birds only) toxicity to birds and mammals. Acute and short-term (for birds only) first tier risk assessments for birds and mammals indicated a high risk as the resulting TER values were less than the trigger value. However, given that fatty acids are an essential component of the diet of birds and mammals a low risk was concluded. No reproductive toxicity data were available. However, on the basis that fatty acids are readily biodegradable and are an essential component of the diet of birds and mammals a low reproductive risk was identified.”

This conclusion can be extrapolated to GLOB2011I especially since doses proposed in this evaluation are far below the doses evaluated for the representative formulations in the EU Review of fatty acids.

The results of the risk assessment indicate an acceptable risk for wildlife mammals due to the intended use of GLOB2011I according to the label.

3.7.2 Effects on aquatic species

Effects on aquatic organisms for GLOB2011I were not evaluated as part of the EU review of fatty acids. However further data on GLOB2011I is not relevant as active substance data on toxicity to aquatic organisms is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU review. Risk assessments for GLOB2011I with the proposed use pattern are provided here and are considered.

Studies of the acute toxicity of GLOB2011I for daphnia, algae and aquatic plants showed that this product should not be labelled regarding its toxicity to aquatic organisms. Toxicity data available on fish for the active substance and co-formulants lead to the same conclusion.

No risk mitigation measures (buffer zone, drift reduction nozzles or vegetative filter strip) are necessary.

3.7.3 Effects on bees

Effects on bees for GLOB2011I were not evaluated as part of the EU review of fatty acids. However further data on GLOB2011I is not relevant as active substance data on toxicity to bees is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU review. Risk assessments for GLOB2011I with the proposed use pattern were provided and are considered adequate.

Acute risk assessment:

The risks of GLOB2011I to honeybees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and formulated product, and the maximum single application rate of 3000 mL formulation/ha (2732.7 g formulation/ha).

All the hazard quotients are considerably less than 50, indicating that the active ingredient poses a low risk to bees. Therefore, a low risk to bees is expected from the application of GLOB2011I according to the recommended use pattern.

Chronic risk assessment:

The chronic risk of GLOB2011I to honeybee larvae and adults was assessed through the calculation of TER values as set out in SANCO 2002 and the modified EPPO 2010 approach according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028) with active ingredient and formulated product, and the maximum single application rate of 3000 mL formulation/ha (2732.7 g formulation/ha).

All TER are considerably below appropriate HQ value, indicating that the active ingredient and GLOB2011I poses a low risk to honeybee larvae and adults. Therefore, a low risk to bees is expected from the application of GLOB2011I according to the recommended use pattern.

3.7.4 Effects on other arthropod species other than bees

Effects on non-target arthropods for pelargonic acid were not evaluated as part of the EU review of fatty acids.

Extended laboratory studies were conducted on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Orius laevigatus* and *Chrysoperla carnea*. An extended aged residue study was performed on *Typhlodromus pyri*. The in-field and off-field hazard quotients for all species are below the trigger values recommended by ESCORT 2.

The risk to non-target arthropods following application of GLOB2011I 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 GLOB2011I were not evaluated as part of the EU review of fatty acids.

Earthworms

The long-term risk of GLOB2011I to earthworms was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the active substance and formulated product and the maximum PECsoil.

The chronic TER value is greater than the Annex IV trigger of 5 for the worst-case use covering all other uses.

No risk mitigation measure is necessary.

Effects on other soil non-target macro-organisms

The long-term risk of GLOB2011I 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 active substance and formulated product and the maximum PECsoil.

The chronic TER value is greater than the Annex IV trigger of 5, indicating an acceptable risk to other soil non-target macro-organisms following application of GLOB2011I for the intended uses.

Effects on soil non-target micro-organisms

Effects on soil microbial activity of GLOB2011I were not evaluated as part of the EU review of fatty acids. Therefore, all relevant data and assessments were provided.

They show that GLOB2011I 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 GLOB2011I were not evaluated as part of the EU review of fatty acids.

The potential effect of GLOB2011I on vegetative vigour and seedling emergence has been tested through studies performed with the formulated product. All species had an ER₅₀ of more than 8000 ml PPP/ha (> 5200 g a.s./ha).

No mitigation measures are needed to protect non-target plants after application of GLOB2011I.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.8 Relevance of metabolites (Part B, Section 10)

Pelargonic acid is a naturally occurring product and the residue definition in groundwater is pelargonic acid itself. No groundwater metabolites of toxicological concern are expected.

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

GLOB2011I contains pelargonic acid which is not 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

Posiadacz zezwolenia:

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

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej : ...

Podmiot odpowiedzialny za końcowe etykietowanie i pakowanie środka ochrony roślin:....

SANKARI

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Kwas nonanowy (związek z grupy nasyconych kwasów karboksylowych) – **650 g/l**

Zezwolenie MRiRW nr R –



Niebezpieczeństwo

Hasło ostrzegawcze: Niebezpieczeństwo

H314 – Powoduje poważne oparzenia skóry oraz uszkodzenia oczu

H412 - Działa szkodliwie na organizmy wodne, powodując długotrwałe skutki.

EUH401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

Zwroty wskazujące środki ostrożności:

P260 – Nie wdychać rozpylonej cieczy

P264 - Dokładnie umyć ręce i twarz po użyciu.

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

P301 + P333 + P331 - W PRZYPADKU POŁKNIECIA: wypłukać usta. NIE wywoływać wymiotów.

P303 + P361 + P353 - W PRZYPADKU KONTAKTU ZE SKORĄ (lub z włosami): Natychmiast zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody [lub prysznicem].

P363 - Wyprać zanieczyszczoną odzież przed ponownym użyciem.

P304 + P340 - W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania

P305 + P351 + P338 - W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

P310 - Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem

P405 - Przechowywać pod zamknięciem.

Zawiera: Poli(oksy-1,2-etanodiylo), α -9-oktadecenylo- ω -hydroksy- (Z)-, fosforan.

OPIS DZIAŁANIA

INSEKTYCYD w postaci koncentratu do sporządzania emulsji wodnej (EC) o działaniu kontaktowym, przeznaczonym do stosowania zwalczania szkodników. Środek zawiera substancję czynną kwas nonanowy (synonim kwas pelargonowy) z grupy nasyconych kwasów tłuszczowych. Kwasy karboksylowe do których należy substancja aktywna występują naturalnie w przyrodzie a kwasy tłuszczowe są dopuszczone w Unii Europejskiej do stosowania w rolnictwie ekologicznym

Dotychczas nie stwierdzono ryzyka powstawania odporności i substancja czynna kwas nonanowy nie jest klasyfikowana przez IRAC. Nie stwierdzono odporności krzyżowej z innymi grupami insektycydów.

SANKARI ma działanie kontaktowe a jego skuteczność jest uwarunkowana bezpośrednią stycznością szkodników z cieczą użytkową.

W przypadku zwalczania szkodników (zwłaszcza ssących) zabieg wykonać dokładnie, aby wszystkie części roślin były pokryte cieczą użytkową. Środek działa najskuteczniej w wyższych temperaturach. W przypadku konieczności wykonania większej liczby zabiegów, stosować przemiennie z insektycydami z innych grup chemicznych.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Jęczmień ozimy

Mszyca czeremchowo-zbożowa, mszyca zbożowa .

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 2 l/ha

Zalecana dawka do jednorazowego zastosowania : 1,5 – 2 l/ha

Termin stosowania: Środek zastosować natychmiast po zaobserwowaniu pierwszych objawów zerwania szkodników, od fazy szpilkowania do fazy pojawiania się ości z pochwy liścia flagowego (BBCH10-49).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2 (drugi zabieg w przypadku wydłużonego okresu pojawiania się szkodników)

Zalecana ilość wody: 100 - 400 l/ha

Zalecane opryskiwanie: średniokropliste .

Pszenica jara i ozima

Mszyca czeremchowo-zbożowa, mszyca zbożowa .

Maksymalna dawka dla jednorazowego zastosowania: 2 l/ha

Zalecana dawka do jednorazowego zastosowania : 1,5 – 2 l/ha

Termin stosowania: środek stosować od początku fazy kłoszenia do faz dojrzałości późno-mlecznej ziarniaków (BBCH 51- 77).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2 (drugi zabieg w przypadku wydłużonego okresu pojawiania się szkodników)

Zalecana ilość wody: 100 - 400 l/ha

Zalecane opryskiwanie: średniokropliste

Środek wykazuje ograniczone działanie w zwalczaniu mszycy czeremchowo-zbożowej.

ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA

Środek stosować w temperaturze powietrza powyżej 10°C.

Nie stosować na rośliny mokre

Ważne jest dobre pokrycie chronionych upraw cieczą roboczą

Stosować przemiennie ze środkami, zawierającymi substancje czynne z innych grup chemicznych o odmiennych mechanizmach działania.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

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 mieszałem) i uzupełnić wodą do potrzebnej ilości.

Po wlaściu środka do zbiornika opryskiwacza nie wyposażonego w mieszało hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza. Ciecz użytkową należy użyć w dnu przygotowania

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

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.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

Stosować rękawice ochronne, ochronę oczu, ochronę twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin oraz odpowiednie obuwie w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu. Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

OKRESY KARENCJI

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

Nie jest wymagany

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

Kukurydzy oraz zbóż opryskiwanych środkiem SANKARI nie przeznaczają na paszę dla zwierząt

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

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

W czasie kwitnienia roślin uprawnych zaleca się stosowanie środka poza okresami aktywności pszczoł.

Nie jest konieczne wyznaczenie zadarnionej strefy ochronnej od zbiorników i cieków wodnych ani wyznaczanie strefy ochronnej od terenów nieużytkowanych rolniczo

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA ORAZ PIERWSZA POMOC WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać: – w oryginalnych opakowaniach, – w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich, – w temperaturze nieprzekraczającej 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 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 połknięcia: W przypadku złego samopoczucia skontaktować się z Ośrodkiem za-truć lub z lekarzem.

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

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

Okres ważności - 2 lata

Data produkcji - na opakowaniu

Zawartość netto -

Nr partii - na opakowaniu

Appendix 3 Letter of Access

Not required as Globachem NV is using either endpoints listed in EFSA Journal 2013;11(1):3023 that are out of data protection either data generated by Globachem NV with GLOB2011 for which data protection is claimed.

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
KCA 1.11 (filed in Part C)	Sapke, S.	2023	5-batch analysis of pelargonic acid Company Report No UHU-23-0059828/01-1 SGS Chemie, Industrie und Spezialanalytik GmbH non GLP Unpublished	N	N	No data protection claimed since the study is not GLP. Nevertheless, this study is confidential and cannot be disclosed to other parties.	Globachem nv
KCP 1.4.3 (filed in Part C)	Anonymous	2023	MSDS of formulants of GLOB2011I - Globachem NV non GLP unpublished	N	N	No data protection claimed since the study is not GLP. Nevertheless, this study is confidential and cannot be disclosed to other parties.	Globachem nv
KCP 2.1- 2.3.1- 2.4.1- 2.4.2- 2.5.1- 2.5.2- 2.6.1- 2.7.1- 2.7.3- 2.7.4- 2.8.2- 2.8.6.1- 2.8.6.2- 2.8.6.3- 2.11.	Pomeroy, D.	2023a	Determination of Storage Stability and Shelf Life Specification Data for GLOB2011I stored at 54oC±2oC for Two Weeks, in Compliance with Good Laboratory Practice Study number: DNA7165 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	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 2.2.1-2.2.2	Pomeroy, D.	2023b	Theoretical certificate of explosive and oxidising properties for GLOB2011I Study number: DNA7128 David Norris Analytical Laboratories Ltd. Non GLP Unpublished	N	N		Globachem nv
KCP 5.1.1	Pomeroy D.	2023c	Validation of the Methods of Determination of the Active Substance contained in GLOB2011I, in Compliance with Good Laboratory Practice Study number: DNA7168 David Norris Analytical Laboratories Ltd. GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 5.2.1 Submitted as KCP 10.2.1	Börschig C.	2023a	GLOB2011I: Toxicity to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test Study number: 167841210 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 5.2.1 Submitted as KCP 10.2.1	Börschig C.	2023b	GLOB2011I: GLOB2011I: Acute Toxicity to Daphnia magna in a Semi-Static 48-hour Immobilisation Test Study number: 167841220 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 5.2.1 Submitted as KCP 10.2.1	Börschig C.	2023c	GLOB2011I: Toxicity to the Aquatic Plant Myriophyllum spicatum in a Semi-Static Growth Inhibition Test with a Prior Rooting Phase Study number: 167841215 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 5.2.1 Submitted	Schabio S.	2022	GLOB2011I: Chronic Oral Toxicity Test on the Honey Bee (Apis mel-lifera L.) in the Laboratory	N	Y	GLP study necessary according to data requirement 2013 and submitted for the	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
as KCP 10.3.1.2			Study number: 163761136 ibacon GmbH GLP Unpublished			first time at national level.	
KCP 5.2.1 Submitted as KCP 10.3.1.3	Colli M.	2022	Effects of GLOB2011I on honeybees (Apis mellifera L.) 22-day larval toxicity test with repeated exposure Study number: BT256/21 BioTecnologie BT S.r.l. GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 5.2.1 Submitted as KCP 10.6	Bützler R.	2022a	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Study number: 167841086 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 5.2.1 Submitted as KCP 10.6	Bützler R.	2022b	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Study number: 167841087 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 6.2-01	Zöllner, H.	2020	Efficacy of globA (IPU) for aphid control of ear species in cereals FRS044-20-V2 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-02	Svacinova, I.	2021	Efficacy of Sankari on cereals. IE-21-D-GLOB2011I-CZ01 Zemedelsky vyzkumny ustav Kromeriz, s. r. o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-03	de Vries, H.	2021	Efficacy of Sankari on cereals. IE-21-D-GLOB2011I-NL05	N	Y	Data/study report never submitted before to Poland.	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
			Verify GEP Unpublished				
KCP 6.2-04	Spitzer, T.	2022	Efficacy of Sankari on cereals. IE-22-A-GLOB2011I-CZ01 Agricultural Research Institute Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-05	CAMUÑEZ, S.	2022	Efficacy of Sankari on cereals. Version 1 IE-22-A-GLOB2011I-DE02 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-06	Tetuan, B.	2020	Determination of Efficacy of GLOB A Against Aphids in cereals under open field Conditions in One Site in Spain 035E20S GMW Bioscience GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-07	Tetuan, B.	2020	Determination of Efficacy of GLOB A Against Aphids in cereals under open field Conditions in One Site in Spain 062E20S GMW Bioscience GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-08	Russo, A.	2021	Efficacy of Sankari on cereals. IE-21-D-GLOB2011I-IT03 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-09	Russo, A.	2021	Efficacy of Sankari on cereals. IE-21-D-GLOB2011I-IT04 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-10	Milosevic, L.	2022	Efficacy of Sankari on cereals. IE-22-A-GLOB2011I-ES03 SAGEA Centro di Saggio s.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-11	Zagi, H.	2022	Efficacy of Sankari on cereals. IE-22-A-GLOB2011I-HR04 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-12	CAMUÑEZ, S.	2022	Efficacy of Sankari on cereals. Version 2 IE-22-A-GLOB2011I-IT05 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-13	Piotrowski, G.	2021	Efficacy of Sankari on cereals. IE-21-D-GLOB2011I-PL06 Syntech Research Poland Sp. zoo GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-14	Drzewiecki, S.	2021	Efficacy of Sankari on cereals. IE-21-D-GLOB2011I-PL07 Institute of Plant Protection - National Research Institute GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-15	Desogus, S.	2020	Efficacy and selectivity evaluation of the contact effect of the test product GLOBA and GLOBA.M against the aphids on cereals - Serbia 2020 095.I.SAG.SRB20 SAGEA Centro di Saggio s.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-16	Desogus, S.	2020	Efficacy and selectivity evaluation of the contact effect of the test product GLOBE against the aphids on cereals - Serbia and Bulgaria 2020 7003.I.SAG19 SAGEA Centro di Saggio S.r.l.	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2-17	Desogus, S.	2020	Efficacy and selectivity evaluation of the contact effect of the test product GLOBE against the aphids on cereals - Serbia and Bulgaria 2019 7004.ISAG19 Sagea Centro di Saggio s.r.l GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-18	Zöllner, H.	2020	Efficacy of globA (IPU) for aphid control in cereals FRS044-20-V1 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-19	Svacinova, I.	2021	Efficacy of autumn use of Sankari on cereals. IE-21-J-GLOB2011I-CZ01 Zemedelsky vyzkumny ustav Kromeriz, s. r. o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-20	Seifert, M.	2021	Efficacy of autumn use of Sankari on cereals. IE-21-J-GLOB2011I-DE02 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-21	de Vries, H.	2021	Efficacy of autumn use of Sankari on cereals. IE-21-J-GLOB2011I-NL03 Verify GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-22	Spitzer, T.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-CZ01 Agricultural Research Institute Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-23	Bauer, T.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-CZ02 InTec Agro Trials, s.r.o.	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2-24	Burger, P.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-DE03 QUINTUS GmbH GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-25	Seifert, M.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-DE04 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-26	Beyreiss, S.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-UK11 OAT Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-27	Bauer, T.	2022	Efficacy of Sankari on cereals. IE-22-Q-GLOB2011I-CZ01 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-28	LUNZEN-FICHTER, D.	2022	Efficacy of Sankari on cereals (France, 2022). IE-22-Q-GLOB2011I-FR04 QUALIPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-29	Beyreiss, S.	2022	Efficacy of Sankari on cereals. IE-22-Q-GLOB2011I-UK06 OAT Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-30	CAMUÑEZ, S.	2022	Efficacy of Sankari on cereals. Version 1 IE-22-F-GLOB2011I-ES06 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-31	CAMUÑEZ, S.	2022	Efficacy of Sankari on cereals. Version 1 IE-22-F-GLOB2011I-FR07 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-32	Zagi, H.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-HR08 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-33	Zambon, D.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-IT05 SAGEA Centro di Saggio S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-34	Russo, A.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-IT09 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-35	Zambon, D.	2022	Efficacy of Sankari on cereals. IE-22-F-GLOB2011I-IT10 SAGEA Centro di Saggio S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-36	Zagi, H.	2022	Efficacy of Sankari on cereals. IE-22-Q-GLOB2011I-HR05 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-37	Russo, A.	2022	Efficacy of Sankari on cereals. IE-22-Q-GLOB2011I-IT03 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-38	Piotrowski, G.	2021	Efficacy of autumn use of Sankari on cereals. IE-21-J-GLOB2011I-PL04	N	Y	Data/study report never submitted before to Poland.	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
			SynTech Research Poland Sp.zo.o. GEP Unpublished				
KCP 6.2-39	de Vries, H.	2020	efficacy of test compound against meligethes in SORS 201392 Proeftuin Zwaagdijk GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-43	Friedrich, F.	2021	Efficacy of foliar insecticides against pod weevils IE-21-C-GLOB2011I-DE01 QUINTUS GmbH GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-44	CAMUÑEZ, S.	2021	Efficacy of foliar insecticides against pollen beetles. Version 1 IE-21-C-GLOB2011I-FR02 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-47	Trnka, M.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-CZ01 Zemservis Domaninek, zk. st. s.r.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-48	Bauer, T.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-CZ02 InTec Agro Trials, s.r.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-49	Seifert, M.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-DE03 BioChem agrar GmbH Niederlassung Agroplan GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-50	Burger, P.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-DE04 QUINTUS GmbH	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2-51	Spitzer, T.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-J-GLOB2011I-CZ01 Agricultural Research Institute Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-52	Burger, P.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-J-GLOB2011I-DE02 QUINTUS GmbH GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-55	CAMUÑEZ, S.	2022	Efficacy of Sankari on winter oilseed rape. Version 1 IE-22-C-GLOB2011I-ES05 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-56	D'Annunzio, G.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-ES06 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-57	Zagi, H.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-HR08 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-58	Russo, A.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-IT07 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-59	Russo, A.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-IT10 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-60	Milosevic, L.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-IT11 SAGEA Centro di Saggio s.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-65	Gajek, D.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-PL13 Agro Research Consulting GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-66	Szemendera, A.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-PL14 Fertico Sp. z o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-67	Koppel, M.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-J-GLOB2011I-EE03 Estonian Crop Research Institute GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-68	Ozolins-Pole, L.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-J-GLOB2011I-LV04 GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-69	CAMUÑEZ, S.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-J-GLOB2011I-PL05 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-71	Barasits, T.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-C-GLOB2011I-HU09 CPR Europe Kft. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-72	Spitzer, T.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-CZ01	N	Y	Data/study report never submitted before to Poland.	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
			Agricultural Research Institute Kromeriz, Ltd. GEP Unpublished				
KCP 6.2-73	Dana, P.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-CZ03 ZZS Kujavy, s.r.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-74	Burger, P.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-DE04 QUINTUS GmbH GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-75	Zöllner, H.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-DE05 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-76	Beyreiss, S.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-UK15 OAT Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-77	Beyreiss, S.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-UK16 OAT Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-78	Spitzer, T.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-H-GLOB2011I-CZ01 Agricultural Research Institute Kromeriz, Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-79	Bauer, T.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-H-GLOB2011I-CZ02 InTec Agro Trials, s.r.o. GEP	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2-80	CAMUÑEZ, S.	2022	Efficacy of Sankari on winter oilseed rape. Version 1 IE-22-H-GLOB2011I-DE03 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-81	Burger, P.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-H-GLOB2011I-DE04 QUINTUS GmbH GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-82	Safar, J.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-R-GLOB2011I-CZ01 Agritec vyzkum slechteni a sluzby s.r.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-83	Zöllner, H.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-R-GLOB2011I-DE02 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-84	Beyreiss, S.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-R-GLOB2011I-UK05 OAT Ltd. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-85	Haigh, I.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-R-GLOB2011I-UK06 FieldArm Limited GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-86	Bernardová, M.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-CZ02 Zkusebni stanice Kluky GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-	Gajek, D.	2022	Efficacy of Sankari on winter oilseed rape.	N	Y	Data/study report never submitted	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
87			IE-22-G-GLOB2011I-PL13 Agro Research Consulting GEP Unpublished			before to Poland.	
KCP 6.2-88	Umiński, P.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-PL14 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-89	Koppel, M.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-N-GLOB2011I-EE01-1 Estonian Crop Research Institute GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-90	Semaškienė, R.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-N-GLOB2011I-LT02 Institute of Agriculture, LAMMC GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-91	Semaškienė, R.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-O-GLOB2011I-LT01 Institute of Agriculture, LAMMC GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-92	Semaškiene, R.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-O-GLOB2011I-LT02 Institute of Agriculture, LAMMC GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-93	Semaškienė, R.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-O-GLOB2011I-LT03 Institute of Agriculture, LAMMC GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-94	Mitev, A.	2021	Efficacy and selectivity evaluation of Globa against pests in oil seed rape 7495.I.SAG21	N	Y	Data/study report never submitted before to Poland.	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
			Sagea OOD GEP Unpublished				
KCP 6.2-95	Valli, F.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-ES06 Agri 2000 Net Srl GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-96	Ros, A.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-ES07 SAGEA Iberia S.L. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-97	CAMUÑEZ, S.	2022	Efficacy of Sankari on winter oilseed rape. Version 1 IE-22-G-GLOB2011I-FR08 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-98	Zagi, H.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-HR09 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-99	Russo, A.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-IT10 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-100	Zambon, D.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-IT11 SAGEA Centro di Saggio S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-101	Zambon, D.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-G-GLOB2011I-IT12 SAGEA Centro di Saggio S.r.l. GEP	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2-102	CAMUÑEZ, S.	2022	Efficacy of Sankari on winter oilseed rape. Version 1 IE-22-HGLOB2011I-ES05 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-103	CAMUÑEZ, S.	2022	Efficacy of Sankari on winter oilseed rape. Version 1 IE-22-H-GLOB2011I-FR06 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-104	Zagi, H.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-H-GLOB2011I-HR07 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-105	Russo, A.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-H-GLOB2011I-IT08 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-106	Zambon, D.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-H-GLOB2011I-IT09 SAGEA Centro di Saggio S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-107	Zagi, H.	2022	Efficacy of Sankari on winter oilseed rape. IE-22-R-GLOB2011I-HR04 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-108	Muscarà, A.	2022	Efficacy of Sankari on winter oilseed rape. Italy, 2022. IE-22-R-GLOB2011I-IT03 Agricola 2000 S.C.p.A. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-	Trnka, M.	2021	Efficacy of Sankari on potatoes.	N	Y	Data/study report never submitted	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
109			IE-21-F-GLOB2011I-CZ01 Zemservis Domaninek, zk. st. s.r.o. GEP Unpublished			before to Poland.	
KCP 6.2-110	Zöllner, H.	2021	Efficacy of Sankari on potatoes. IE-21-F-GLOB2011I-DE02 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-111	Trnka, M.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-CZ01 Zemservis zkusebni stanice Domaninek s.r.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-112	De Cauwer, Y.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-NL11 Botany B.V. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-113	Umiński, P.	2021	Efficacy of Sankari on potatoes. IE-21-F-GLOB2011I-PL05 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-114	Piotrowski, G.	2021	Efficacy of Sankari on potatoes. IE-21-F-GLOB2011I-PL06 Syntech Research Poland Sp. zoo GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-115	Fiala, T.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-CZ02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-116	Kussinszky, T.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-HU07 EUROFINS AGROSCIENCE SERVICES	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2-117	Suñer Torres, J.	2021	Efficacy of Sankari on potatoes. IE-21-F-GLOB2011I-ES03 GMWBioscience GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-118	Calari, A.	2021	Efficacy of Sankari on potatoes. IE-21-F-GLOB2011I-IT04 SAGEA Centro di Saggio s.r.l GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-119	Milosevic, L.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-ES04 SAGEA Centro di Saggio s.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-120	Barnabè, D.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-FR05 Agri 2000 France SARL GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-121	Zagi, H.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-HR06 Pest Pro d.o.o. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-122	Russo, A.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-IT08 Agri2000 NET GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-123	Calari, A.	2022	Efficacy of Sankari on potatoes. IE-22-D-GLOB2011I-IT09 SAGEA Centro di Saggio s.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-124	Tetuan, B.	2022	Efficacy of Sankari on potatoes. IE-22-K-GLOB2011I-ES01 GMW Bioscience S.L. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-125	Russo, A.	2022	Efficacy of Sankari on potatoes. IE-22-K-GLOB2011I-IT02 Agri2000 NET GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-126	Moizio, M.	2020	Efficacy evaluation of GLOB-A-M against pests in Maize, Italy 2020 408.I.SAG20/e SAGEA Centro di Saggio S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-127	Milosevic, L.	2021	Efficacy of Sankari on maize. IE-21-G-GLOB2011I-ES01 SAGEA Centro di Saggio s.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-128	Navarro Fernandez, D.	2021	Efficacy of Sankari on maize. IE-21-G-GLOB2011I-ES02 GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-129	Russo, A.	2021	Efficacy of Sankari on maize. IE-21-G-GLOB2011I-IT03 Agri 2000 Net S.r.l. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-130	Muscarà, A.	2021	Efficacy of Sankari on maize. IE-21-G-GLOB2011I-IT04 Agricola 2000 S.c.p.A. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-	Milosevic, L.	2022	Efficacy of Sankari on maize.	N	Y	Data/study report never submitted	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
131			IE-22-E-GLOB2011I-ES01 SAGEA Centro di Saggio s.r.l. GEP Unpublished			before to Poland.	
KCP 6.2-132	CAMUÑEZ, S.	2022	Efficacy of Sankari on maize. Version 1 IE-22-E-GLOB2011I-FR02 STAPHYT GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-133	Muscarà, A.	2022	Efficacy of Sankari on maize. Italy, 2022. IE-22-E-GLOB2011I-IT06 Agricola 2000 S.C.p.A. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-134	LANG, B.	2022	Efficacy of Sankari on maize. IE-22-E-GLOB2011I-HU03 Plant-Art Research Kft. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.2-135	Barasits, T.	2022	Efficacy of Sankari on maize. IE-22-E-GLOB2011I-HU05 CPR Europe Kft. GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.4-01	Umiński, P.	2022	Selectivity of Sankari on rye. IS-22-A-GLOB2011I-PL01 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.4-02	Umiński, P.	2022	Selectivity of Sankari on rye. IS-22-A-GLOB2011I-PL02 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.4-03	Umiński, P.	2022	Selectivity of Sankari on triticale. IS-22-A-GLOB2011I-PL03 Field Research Support	N	Y	Data/study report never submitted before to Poland.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.4-04	Umiński, P.	2022	Selectivity of Sankari on tritcale. IS-22-A-GLOB2011I-PL04 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.4-05	Zöllner, H.	2022	Selectivity of Sankari on young OSR. IS-22-B-GLOB2011I-DE01 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 6.4-06	Umiński, P.	2022	Selectivity of Sankari on young OSR. IS-22-B-GLOB2011I-PL03 Field Research Support GEP Unpublished	N	Y	Data/study report never submitted before to Poland.	Globachem NV
KCP 7.1.4	Mecatti Elias, L.	2022a	IN VITRO SKIN IRRITATION TEST FOR GLOB2011I: RECONSTRUCTED HUMAN EPIDERMIS (RHE) TEST METHOD Report No. TX 2284 083 21 B PLANTEC Laboratórios GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 7.1.4	Ammirabile, L.	2022	IN VITRO SKIN CORROSION TEST FOR GLOB2011I: ASSAY WITH RECONSTRUCTED HUMAM EPIDERMIS (RHE) Report No. TX 2284 082 21 B PLANTEC Laboratórios GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 9.2.4	Wyns, G.	2023a	Raw input and output files of PECgw of pelargonic acid following application of GLOB2011I in central Europe Report No.: - Globachem NV non GLP	N	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
			Unpublished				
KCP 9.2.5	Wyns, G.	2023b	Raw input and output files of PECsw of pelargonic acid following application of GLOB2011I in central Europe Report No.: - Globachem NV non GLP Unpublished	N	N		Globachem nv
KCP 10.2.1	Börschig, C.	2023a	GLOB2011I: Acute Toxicity to Daphnia magna in a Semi-Static 48-hour Immobilisation Test Study No. 167841220 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.2.1	Börschig, C.	2023b	GLOB2011I: Toxicity to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test Study No. 167841210 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.2.1	Börschig, C.	2023c	GLOB2011I: Toxicity to the Aquatic Plant Myriophyllum spicatum in a Semi-Static Growth Inhibition Test with a Prior Rooting Phase Study No. 167841215 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.1.1	Schabio, S.	2023	GLOB2011I: Effects (Acute Contact and Oral) on Honey Bees (Apis mellifera L.) in the Laboratory Study No. 163761035 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.1.1	Schabio, S.	2022a	GLOB2011I: Effects (Acute Contact and Oral) on Bumblebees (Bombus terrestris L.) in the Laboratory	N	Y	GLP study necessary according to data requirement 2013 and submitted for the	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
			Study No. 163761105 ibacon GmbH GLP Unpublished			first time at national level.	
KCP 10.3.1.2	Schabio, S.	2022b	GLOB2011I: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory Study No. 163761136 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.1.3	Colli, M.	2022	Effects of GLOB2011I on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure Study No. BT256/21 BioTecnologie BT S.r.l. GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022a	GLOB2011I: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Dose Response Test Study No. 167841062 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022b	GLOB2011I: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended Laboratory Study - Aged Residue Test Study No. 167841060 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022c	GLOB2011I: Effects on the Parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae), Extended Laboratory Study - Dose Response Test Study No. 167841002 ibacon GmbH	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	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 10.3.2.2	Leopold, J.	2022d	GLOB2011I: Effects on the Lacewing Chrysoperla carnea (Neuroptera: Chrysopidae), Extended Laboratory Study - Dose Response Test Study No. 167841047 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.3.2.2	Leopold, J.	2022e	GLOB2011I: Effects on the Predatory Bug Orius laevigatus (Heteroptera, Anthocoridae), Extended Laboratory Study - Dose Response Test Study No. 167841052 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.4.1.1	Hübner, S.	2022a	GLOB2011I: Effects on Reproduction and Growth of Earthworms Eisenia andrei in Artificial Soil Study No. 167841022 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.4.2.1	Hübner, S.	2022b	GLOB2011I: Effects on Reproduction of Collembola (Folsomia candida) in Artificial Soil Study No. 167841016 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.4.2.1	Hübner, S.	2022c	GLOB2011I: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil Study No. 167841089 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	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 10.5	Bauer, J.	2022	GLOB2011I: Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study No. 167841080 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.6.2	Bützler, R.	2022a	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Study No. 167841086 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	Globachem nv
KCP 10.6.2	Bützler, R.	2022b	GLOB2011I: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Study No. 167841087 ibacon GmbH GLP Unpublished	N	Y	GLP study necessary according to data requirement 2013 and submitted for the first time at national level.	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	Owner
KCP 7.1.1	[REDACTED]	2022a	ACUTE ORAL TOXICITY STUDY IN RATS AFTER THE ADMINISTRATION OF GLOB2011I [REDACTED] GLP Unpublished	Y	Globachem NV
KCP 7.1.2	[REDACTED]	2022b	ACUTE DERMAL TOXICITY STUDY IN RATS AFTER THE ADMINISTRATION OF GLOB2011I [REDACTED] GLP Unpublished	Y	Globachem NV
KCP 7.1.3	[REDACTED]	2022c	ACUTE INHALATION TOXICITY STUDY IN RATS AFTER THE ADMINISTRATION OF GLOB2011I [REDACTED] GLP Unpublished	Y	Globachem NV
KCP 7.1.5	Mecatti Elias, L	2022b	BOVINE CORNEAL OPACITY AND PERMEABILITY TEST (BCOP) AFTER APPLICATION OF GLOB2011I Report No. TX 2284 013 21 B PLANTEC Laboratórios GLP Unpublished	N	Globachem NV
KCP 7.1.6	Pampolini, J.	2022d	LOCAL LYMPH NODE ASSAY (LLNA): BRDU-ELISA FOR SKIN SENSITIZATION BY GLOB2011I [REDACTED] GLP Unpublished	Y	Globachem NV

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