REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB1817H

Product name: **Eledura**

Chemical active substances:

Prosulfocarb, 667 g/L
Diflufenican, 14 g/L
Halauxifen-methyl, 1.33 g/L
Cloquintocet-mexyl, 1.33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Globachem NV

Submission date: May 2021

MS Finalisation date: January 2022

Revision date: April 2022

Version history

When	What
May 2021	Initial dossier submission by the applicant for approval of new product.
January 2022	Version evaluated by zRMS PL
April 2022	Version modified to take into account comments of cMS and the applicant

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Globachem NV in May 2021.

The application was for approval of GLOB1817H, a suspension concentrate containing 667 g/L prosulfocarb, 14 g/L diflufenican, 1.33 g/L halauxifen-methyl and 1.33 g/L cloquintocet-mexyl for use as a herbicide in winter cereals for which Poland was designated zRMS.

1.2 Letters of Access

A Letter of Access for a worker exposure study related to prosulfocarb from Syngenta was submitted.
Letters of Access related to halauxifen-methyl and cloquintocet-mexyl will be sent by Corteva Agriscience directly to the authorities.

1.3 Justification for submission of tests and studies

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

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	GLOB1817H
Product name in MS	Eledura
Authorization number	/
Function	Herbicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Prosulfocarb: 667 g/L Diflufenican: 14 g/L Halauxifen-methyl: 1.33 g/L

	Cloquintocet-mexyl: 1.33 g/L
Formulation type	Emulsifiable concentrate (EC)
Packaging	0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 20 L HDPE-F
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for product Eledura (GLOB1817H) resulted in the decision to grant the authorization.

All uses applied for were authorised.

2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, STOT SE3, Aquatic Acute 1, Aquatic Chronic 2

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	**GHS05, GHS07, GHS09**
Signal word:	**Danger**
Hazard statement(s):	~~**H302,**~~ **H317, H318, H336, H400, H411**
Precautionary statement(s):	P261, ~~P264, P270~~, P271, P272, P273, **P280**, **P301+P312**, **P302+P352**, **P304+P340**, **P305+P351+P338**, P310, P312, P321, P330, P333+P313, P362+P364, **P391**, P403+P233, P405, **P501**
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

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

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

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

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands, forearms and face thoroughly after handling.
P270	Do no eat, drink or smoke when using this product.
P271	Use only outdoors or in a well ventilated area.
P272	Contaminated work clothing should not be allowed to out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor.
P312	Call a POISON CENTER or doctor if you feel unwell.
P321	Specific treatment (see supplemental first aid instruction on this label).
P330	Rinse mouth.
P333+P313	If skin irritation or rash occurs: Get medial advice/attention.
P362+P364	Take of contaminated clothing and wash it before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
Integrated pest management (IPM)/sustainable use:	
-	-

Environmental protection	
P273	Avoid release to the environment.
P391	Collect the spilage
P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
SPe3	To protect aquatic organisms respect a vegetated buffer zone of 10 m and an unsprayed buffer zone of 10 m to surface water bodies
SPe3	To protect non-target plants respect an unsprayed buffer zone of 10 m or an unsprayed buffer zone of 3 m in combination with 50% drift reducing nozzles or an unsprayed buffer zone of 1 m in combination with 90% drift reducing nozzles to non-agricultural land.
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

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

2.5.2 Specific restrictions linked to the intended uses

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

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

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1, date: 2020-12-07

PPP (product name/code):	GLOB1817H	Formulation type:	Emulsifiable concentrate (EC)
Active substance 1:	Prosulfocarb	Conc. of as 1:	667 g/L (c)
Active substance 2:	Diflufenican	Conc. of as 2:	14 g/L (c)
Active substance 3:	Halauxifen-methyl	Conc. of as 3:	1.33 g/L (c)
Safener:	Cloquintocet-mexyl	Conc. of safener:	1.33 g/L(c)
Synergist:	/	Conc. of synergist:	/ (c)
Applicant:	Globachem NV	Professional use:	☒
Zone(s):	Central(d)	Non professional use:	☐
Verified by MS:	yes/no		

Field of use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	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: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number/year	Min. interval between applications (days)	L product/ha max. rate per appl.	kg as/ha a) max. rate per appl.	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

1	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-14, (sept)oct-dec	a) 1 b) 1	/	a) 3 b) 3	a) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen-methyl: 0.00399 b) Prosulfocarb: 2.001 Diflufenican: 0.042 Halauxifen-methyl: 0.00399	200-300	/	Cloquintocet-mexyl: 0.00399 kg/ha

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 yellow liquid, with an aromatic odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a flash point of 69.0°C. In aqueous solution, it has a pH value around 4.80 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. ~~The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE-F*~~. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation.

Implications for labelling: none

Compliance with FAO specifications: The product GLOB1817H complies with the general FAO specifications.

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

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

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of GLOB1817H has been provided and is considered to be acceptable

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

GLOB1817H is an emulsifiable concentrate formulation (EC) containing the active ingredients prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L) for early post-emergence weed control in winter cereals, in combination with the safener cloquintocet-mexyl (1.33 g/L). All the active substances are known and already present on the market either alone or in mixture with other herbicides. The proposed label rate for GLOB1817H is 3 L/ha. From the presented results it can be clearly concluded that most of the weeds commonly populating cereal fields are susceptible or highly susceptible to GLOB1817H applied at the proposed rate of 3 L/ha.

Preliminary tests
The presented results, of three components in GLOB1817H prosulfocarb, diflufenican and halauxifen-methyl demonstrated activity against weed in cereals. GLOB1817H demonstrated at least comparable control and frequently superior control of weed compared to the standard product JURA. Therefore, the inclusion of proposed amount of prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L) in the formulation GLOB1817H are fully justified.

Minimum effective dose tests
North East EPPO zone
To determine the minimum effective dose for the control of weed in winter cereals by GLOB1817H, the applicant presented data from 10 field trials. GLOB1817H was tested at doses 1,8 L/ha, 2,4 L/ha (60%, 80% of the target dose rate) was compared with the full recommended rate of 3.0 L/ha of GLOB1817H, under EPPO standard PP 1/225 'Minimum effective dose'. No clear dose-response was observed for all tested weeds, all application rates provided similar very good control of tested weed.
Since limited results were available for *Brassica napus*, *Capsella bursa-pastoris*, *Lamium purpureum*, *Matricaria inodora* these weed results may not be representative.
The justification of the proposed application rate of 3,0 L/ha will be accepted.

Efficacy tests
North East EPPO zone
In these trials GLOB1817H at the recommended application rate of 3 L/ha provided good control (>85%) of the annual broadleaved weeds *Centaurea cyanus, Viola arvensis, Papaver rhoeas, Tripleurospermum inodorum, Galium aparine, Stellaria media, Veronica persica, Matricaria chamomilla, Myosotis arvensis, Thlaspi arvense* and grass *Apera spica-venti*.
Based on efficacy results from efficacy field trials with GLOB1817H applied post emergence for weed control in winter cereals the intended application rate of 3 L/ha can be justified for registration.

Phytotoxicity to host crop
North East EPPO zone
The crops that were used in these efficacy trials were Winter wheat (5), Winter barley (6), Winter rye (6) and Winter triticale (6). The results in this section show that GLOB1817H can be considered an herbicide with good crop safety when compared to a reference standard. As shown in the tables (Tables 3.4-6 to 3.4-12), the phytotoxicity observed at 2N only exceeded 15% in 1 trial. In all cases, the phytotoxicity symptoms caused by GLOB1817H were transient and did not affect the crop vigour, the growing and neither the grain yield. Additionally, comparable symptoms were observed following treatment with the reference product. Therefore, it is considered that the proposed use of GLOB1817H is unlikely to cause any unacceptable levels of phytotoxicity.

Information on the occurrence or possible occurrence of the development of resistance
The applicant addresses all points of the EPPO Standard PP 1/213 to evaluate the possible actual resistance risk of GLOB1817H and claims that the active substances prosulfocarb, diflufenican and halauxifen-methyl which are combined in the product GLOB1817H act by different modes of action. Based on HRAC assessment the applicant stated due to this mixture with different modes of action, the risk for development of resistance is considered to be low.
Therefore, the risk of resistance development against GLOB1817H is considered to be low if the product is used in adherence with the proposed management strategy.
Based on submitted information it can be concluded to accept the data provided by the applicant.

Impact on other plants including adjacent crops
From the results presented, it can be concluded that a buffer zone of 1 m in combination with 90% drift reducing techniques, a buffer zone of 3 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction is needed to protect non-target plants after application of GLOB1817H according to the intended use.

Impact on succeeding crops

From the results presented and current knowledge, it can be concluded that there is a risk of adverse effects of GLOB1817H herbicide on succeeding crops. There is a particular risk if cereal crops have to be liquidated. In case of crop failure, for any reason, before sowing winter cereals, peas and sunflower and maize, the soil previously treated with GLOB1817H should be ploughed (ensure complete inversion of the furrow patch) or cultivated to a depth of 20 cm. Beans should not be sown within 12 months of product application. The recommendations proposed by the applicant are acceptable and should be included on the national label.

PROPOSED FOR A NATIONAL LABEL

DZIAŁANIE NA CHWASTY

ELEDURA jest herbicydem zawierającym trzy substancje czynne. Substancja czynna prosulfokarb zaliczana jest do herbicydów blokujących syntezę kwasów tłuszczowych o długich łańcuchach. Działa aktywnie na chwasty w okresie ich kiełkowania co powoduje brak ich wschodów lub też wytwarzanie zdeformowanych kiełków czy młodych siewek, które szybko zamierają.
Substancja czynna diflufenikan należy do grupy fenoksynikotynoanilidów, które działają jak inhibitor biosyntezy karotenoidów w komórkach chwastów. Brak tych struktur powoduje zbielenie tkanek liści i rozpad komórek, co szczególnie jest widoczne w przypadku nowych tkanek. Po zastosowaniu diflufenikan pozostaje przez dłuższy czas na powierzchni gleby. Pobierany jest głównie przez pędy kiełkujących siewek, z ograniczoną translokacją. Diflufenikan najlepiej działa na młode, aktywnie rosnące chwasty. Diflufenikan zapewnia ochronę do 8 tygodni po zastosowaniu.
Halauksyfen metylu ma działanie podobne do auksyn i powoduje zniekształcenia liści. Ta substancja wpływa na równowagę hormonalna roślin i syntezę protein.
Po zastosowaniu chwasty wrażliwe przestają rosnąć, prędko pojawiają się deformacje liści i łodyg oraz chlorozy prowadzące do nekroz a w efekcie do zamierania chwastów. Najlepszy efekt chwastobójczy obserwuje się stosując środek na chwasty znajdujące się we wczesnych fazach rozwojowych, w trakcie intensywnego wzrostu.

Chwasty wrażliwe	chaber bławatek, fiołek polny, mak polny, maruna nadmorska, przytulia czepna, gwiazdnica pospolita, przetacznik perski, rumianek pospolity, niezapominajka polna, tobołki polne, miotła zbożowa

STOSOWANIE ŚRODKA

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

Pszenica ozima, jęczmień ozimy, żyto, pszenżyto ozime

Termin stosowania: środek stosować po wschodach zbóż, gdy z pochewki liściowej wydobywa się pierwszy liść do fazy 4 – go liścia (BBCH 10-14)
Maksymalna/zalecana dawka dla jednorazowego zastosowania:3 l/ha.

Zalecana ilość wody: 200 - 300 l/ha**.**
Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

1. Nasiona zbóż muszą być przykryte warstwą gleby o grubości 3 cm.
2. W przypadku stosowania środka przed wschodami zbóż mogą sporadycznie wystąpić spowolnienie wschodów roślin uprawnych. Jest to efekt przejściowy, nie mający negatywnego wpływu na plon.
3. W celu zwiększenia stopnia pokrycia cieczą użytkową opryskiwanej powierzchni, a co za tym

idzie – zwiększenia skuteczności zabiegu oraz w celu ograniczenia znoszenia i odparowywania cieczy w trakcie zabiegu, należy stosować się do poniższych uwag:

a) Środka nie stosować:
   - przy prędkości wiatru przekraczającej 4 m/s (zalecana do 2 m/s),
   - przy pełnym słońcu i niskiej wilgotności powietrza,
   - na glebach nadmiernie uwilgotnionych lub przesuszonych,

b) Zabiegi opryskiwania wykonywać w optymalnych warunkach, najlepiej:
   - z użyciem jedynie skalibrowanych opryskiwaczy oraz belek opryskiwacza ustawionych na wysokość nie większą niż 50 cm nad opryskiwaną powierzchnią gleby,
   - z wyłączonym wentylatorem w przypadku wykorzystywania opryskiwaczy z pomocniczym strumieniem powietrza,
   - przy prędkości opryskiwacza nie przekraczającej 8 km/h,
   - z użyciem rozpylaczy do oprysku średniokroplistego przy obniżonym ciśnieniu, celem uzyskania większej ilości frakcji kropel grubych,
   - wieczorem lub wcześnie rano, gdy temperatura powietrza nie przekracza 15^0C i stopień nasłonecznienia jest niski,
   - przy wysokiej wilgotności powietrza.

4. Środka nie stosować:
   - na rośliny mokre, zaatakowane przez choroby i szkodniki, znajdujące się pod wpływem stresu, uszkodzone przez mróz,
   - przy dużych wahaniach temperatury dobowej ze względu na możliwość wystąpienia przejściowych żółknięć roślin uprawnych.

5. Podczas stosowania środka nie dopuścić do:
   - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
   - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach

NASTĘPSTWO ROŚLIN

Środek nie stwarza zagrożenia dla roślin uprawianych następczo. W przypadku konieczności wcześniejszego zlikwidowania plantacji potraktowanej środkiem ELEDURA w wyniku uszkodzenia roślin przez mrozy, szkodniki lub choroby po zaoraniu plantacji jesienią można wysiać niezwłocznie pszenicę ozimą lub jęczmień ozimy.

W ciągu 12 miesięcy po zastosowaniu środka nie uprawiać bobiku i bobu. W przypadku innych roślin bobowatych zaleca się kontakt z posiadaczem zezwolenia lub jego pełnomocnikiem.

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

Resistance events have been reported in Europe for only 2 of the MoA groups to which active substances present in GLOB1817H belong and are mainly reported outside Europe. Cereal weeds typically produce only one generation per year and therefore development of resistance in general is a relatively slow process. In GLOB1817H, 3 active substances are applied in mixture, reducing even further the risk for development of resistance. Moreover, GLOB1817H is only applied once per year. Based on this information, it is considered that the risk of resistance development is negligible for all target weeds.

3.2.3 Adverse effects on treated crops

GLOB1817H is a formulated product based on active substances already used in straight formulations and/or in mixtures with other active substances and authorized in EU, with no negative effects known. Enough data to study the adverse effects on treated crops of GLOB1817H has been submitted and demonstrate the safe use of GLOB1817H at target rates on winter cereals, with the absence of negative effects on treated crops.

3.2.4 Observations on other undesirable or unintended side-effects

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

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of prosulfocarb, diflufenican, halauxifen-methyl and cloquintocet-mexyl in GLOB1817H were not evaluated as part of the EU review of these active substances. Therefore all relevant data are provided here and are considered adequate. An LC-QQQ method was submitted to analyse the active ingredient content in the formulation. The method was successfully validated.

3.3.2 Analytical methods for residues

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

zRMS:
In the context of the authorisation request the required methods are available.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Acute toxicity studies for GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl.
Studies to assess the acute oral, dermal and inhalation toxicity, skin/eye irritation and skin sensitisation properties of the plant protection product GLOB1817H were judged to be not necessary in the interest of animal welfare. The assessment has been conducted according to the calculation method outlined in Regulation EC 1272/2008. Full details on composition and classification of formulants are provided in part C of this registration report.
Based on all available data GLOB1817H should be classified as Acute Tox. 4; Eye Dam.1, Skin Sens 1 and STOT SE3.
According to Regulation (EC) 1272/2008 (CLP Regulation), GLOB1817H should be labelled as: *GHS05, GHS07; Danger; H302, H317, H318, H336.*

zRMS:
Based on all available data ELEDURA (GLOB1817H) should be classified as ~~Acute Tox. 4~~; Eye Dam.1, Skin Sens 1 and STOT SE3 and it should be labelled as: GHS05, GHS07; Danger; ~~H302,~~ H317, H318, H336 with corresponding precaution statements

3.4.2 Operator exposure

Operator exposure to GLOB1817H was not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl. Therefore all relevant data and risk assessments are provided here and are considered adequate.

Operator exposure was assessed against the AOEL agreed in the EU review of prosulfocarb (0.007 mg a.i./kg bw/d), diflufenican (0.11 mg/kg bw/d) and halauxifen-methyl (0.058 mg/kg bw/d). For dermal absorption of the concentrate 3% and for the spray solution 6.4% for prosulfocarb were used as determined in the dermal absorption study. Default values were used for the other active substances. Operator exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using GLOB1817H according to the intended use is acceptable with the use of gloves during mixing, loading and application.

zRMS:
The exposure to Prosulfocarb, an active substance of Eledura (GLOB1817H) of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H)) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (2.001 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 1491% of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Prosulfocarb is reduced to 75.34% of AOEL.

The exposure to Diflufenican an active substance of Eledura (GLOB1817H) of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H)) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (0.042 kg a.s./ha) using tractor-mounted/trailed boom sprayer, taking dermal absorption value of 58% calculated with the EFSA AOEM amounted to 79.87 % of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Diflufenican is reduced to 2.62 % of respective AOEL. In case the operator is using protective gloves during mixing/loading and application and dermal absorption is 70% the exposure to Diflufenican is 3.14 % of respective AOEL.

The exposure to Halauxifen-methyl an active substance of Eledura (GLOB1817H), of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (0.00399 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 29.27 % of AOEL. In case the operator is using protective gloves during mixing/loading and application the exposure to Halauxifen-methyl is reduced to 1.02 % of respective AOEL.

The exposure to Cloquintocet-mexyl, a safener in a product Eledura (GLOB1817H), of operator wearing a work clothing (long sleeved shirt, long trousers) but no PPE and applying Eledura (GLOB1817H) on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (0.00399 kg safener/ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 33.95 % of AOEL proposed by the applicant . In case the operator is using protective gloves during mixing/loading and application the exposure to Cloquintocet-mexyl is reduced to 1.19% of AOEL proposed by the applicant. Cloquintocet-mexyl, does not have AOEL set up in European Union, and in Poland the safeners are not considered as the active substances of the plant protection product , therefore the assessment of risk of operator to safeners is not required.

The sum of exposures of operator wearing work wear (arms, body and legs covered) and protective gloves during M/L and A to three active substances (Prosulfocarb, Diflufenican and Halauxifen-methyl) expressed as percentage of their AOELs (75.34% + 2.62 % (3.14 %) +1.02 %) is also below 100%, therefore the application of product Eledura (GLOB1817H) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator wearing protective

gloves during mixing/loading and application.

Since an hazard Index for operators is < 1, the combined exposure to all active substances in Eledura (GLOB1817H) is not expected to present a risk for operators when applied in accordance with GAP. No further refinement of the assessment is required.

Summing up the application of product Eledura (GLOB1817H) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs and protective gloves during mixing/loading and application. Since the product classified as Eye Dam. 1, Skin Sens. 1, STOT SE3 the operator should wear protective gloves, eye protection or face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

3.4.3 Worker exposure

Worker exposure to GLOB1817H was not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl. 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 GLOB1817H. As a standard rule, it could be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

zRMS:
The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (2.001 kg a.s./ha) as foreseen in GAP, to Prosulfocarb, an active substance of Eledura (GLOB1817H), calculated with the EFSA AOEM, assuming standard DFR and TC amounted 256.13% of respective AOEL. However when empirical DFR of 0.62 µg/cm^2/kg a.s./ha and TC of 601 cm^2/person/h were taken into account in calculation the worker exposure amounted to 22.72 % of AOEL for Prosulfocarb, thus not causing an unacceptable risk

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (0.042 kg a.s./ha) as foreseen in GAP, to Diflufenican, an active substance of Eledura (GLOB1817H), assuming dermal absorption of 58% calculated with the EFSA AOEM, assuming standard DFR and TC amounted 3.1 % of respective AOEL, thus not causing an unacceptable risk. In case a default value for dermal absorption has been 70 % in line with EU Dermal Absorption Guidance the worker exposure amounted to 3.74%.

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (0.00399 kg a.s./ha) as foreseen in GAP, to Halauxifen-methyl, an active substance of Eledura (GLOB1817H), calculated with the EFSA AOEM, assuming standard DFR and TC amounted 0.67 % of respective AOEL, thus not causing an unacceptable risk.

The exposure of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of cereals (BBCH10-14) treated with a product Eledura (GLOB1817H), at maximal dose of 3.0 L product/ha (0.00399 kg safener ./ha) as foreseen in GAP, to Cloquintocet-mexyl, a safener of Eledura (GLOB1817H), calculated with the EFSA AOEM, assuming standard DFR and TC amounted 0.78 % of AOEL proposed by the applicant. Cloquintocet-mexyl, does not have AOEL set up in European Union, and in Poland the safeners are not considered as the active substances of the plant protection product , therefore the assessment of risk of worker to safen-

ers is not required.

Since an hazard Index for workers is < 1, the combined exposure to all active substances in Eledura (GLOB1817H) is not expected to present a risk for workers when applied in accordance with GAP. No further refinement of the assessment is required.

Thus, it is concluded that the application of product Eledura (GLOB1817H) does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice.

3.4.4 Bystander and resident exposure

Bystander and resident exposure to GLOB1817H was not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl. Therefore, all relevant data and risk assessments have been provided and are considered adequate.
It is concluded that there is no undue risk to any bystander after accidental short-term exposure or to any resident after long-term exposure to GLOB1817H when using a 5 m no spray buffer zone and a 50% drift reducing technique.

zRMS:
The exposure estimation of resident (adult and child) to Prosulfocarb, an active substance of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14) at maximal dose of 3.0 L product/ha (2.001 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, , assuming standard DFR and TC, amounted 568.07 % to 205.40% of respective AOEL. However when empirical DFR of 0.62 µg/cm^2/kg a.s./ha and TC of 601 cm^2/person/h and drift reduction technology (50%) and 5 m buffer strip were taken into account in calculation the exposure amounted to 81.34 % of AOEL for child resident and 18.00 % of AOEL for adult resident, thus not causing an unacceptable risk

The exposure estimation of resident (adult and child) to Diflufenican, an active substance of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha (0.042 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%), assuming dermal absorption of 58% and 5 m buffer strip, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, , assuming standard DFR and TC, amounted respectively 1.98 % and 4.55% % of AOEL. In case the 70% dermal absorption was taken as a default value of EU Dermal Absorption Guidance the child resident exposure amounted to 6.02% of AOEL and adult resident exposure to 2.49% of AOEL. In both cases the exposure of residents was not causing an unacceptable risk.

The exposure estimation of resident (adult and child) to Halauxifen-methyl , an active substance of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha (0.00399 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, , assuming standard DFR and TC, amounted respectively 0.78 % and 2.62 % % of AOEL, thus not causing an unacceptable risk.

The exposure estimation of resident (adult and child) to Cloquintocet-mexyl, a safener of Eledura (GLOB1817H), applied on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha (0.00399 kg safnerha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident, assuming standard DFR and TC, amounted respectively 0.91 % and 3.04 %

of AOEL proposed by the applicant. Cloquintocet-mexyl, does not have AOEL set up in European Union, and in Poland the safeners are not considered as the active substances of the plant protection product , therefore the assessment of risk of worker to safeners is not required.

Since an Hazard Index for residents is < 1, the combined exposure to all active substances in Eledura (GLOB1817H) is not expected to present a risk for bystanders and residents when applied in accordance with GAP. No further refinement of the assessment is required.

Summing up application of a product Eledura (GLOB1817H), on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip in line with GAP does not pose an unacceptable health risk for residents and bystanders.
Additional calculations (presented in part B 6) using the TC values specific for residents calculated based on the data from the worker exposure study in the draft RAR of prosulfocarb (Volume 3 -B6 (CP)) demonstrated the exposure of adult and child residents due to application of a product Eledura (GLOB1817H), on a field of cereals (BBCH10-14), at maximal dose of 3.0 L product/ha, using tractor-mounted/trailed boom sprayer and drift reduction technology (50%) and 5 m buffer strip in line with GAP is below AOEL for Prosulfocarb and it does not pose an unacceptable risk for adult and child residents.

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

3.5.1 Residues

For the applied use of GLOB1817H in winter cereals, reference is made to the data that were submitted for the EU review of prosulfocarb, diflufenican and halauxifen-methyl. The evaluated GAP is covering the one intended for GLOB1817H.

Compliance with the EU MRLs of prosulfocarb, diflufenican and halauxifen-methyl is met for the intended uses of GLOB1817H.

3.5.2 Consumer exposure

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.005 mg/kg bw/day for prosulfocarb, 0.2 mg/kg bw/d for diflufenican and 0.058 mg/kg bw/d for halauxifen-methyl. It can therefore be concluded that acceptable margins of safety exist for consumers.

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

For prosulfocarb, the maximum calculated exposure values accounted for 47% of ADI (NL toddler). The calculation of the IEDI was not necessary since the calculation of the TMDI has shown that TMDIs were below the ADI. The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.1 mg/kg bw/day (max. 63% for carrots for UK infant).
For diflufenican, the maximum calculated exposure values accounted for 0.7% of ADI (NL toddler). The calculation of the IEDI was not necessary since the calculation of the TMDI has shown that TMDIs were below the ADI. IESTI calculations were not performed since no ARfD is set.
For halauxifen-methyl, the maximum calculated exposure values accounted for 4% of ADI (NL toddler). The calculation of the IEDI was not necessary since the calculation of the TMDI has shown that TMDIs

were below the ADI. The results of the IESTI calculations demonstrate that in no case the IESTI is above the acute reference dose (ARfD) of 0.058 mg/kg bw/day (max. 5% for potatoes for UK infant).

Based on the different calculations made to estimate consumer exposure, it can be concluded that the use of the product GLOB1817H does not lead to an unacceptable acute or chronic risk for consumers when applied according to the recommendations.

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

The cloquintocet-mexyl used as a safener was not be evaluated in this dossier (as a separate substance and in the mixture).

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

The PEC of prosulfocarb, diflufenican, halauxifen-methyl and their metabolites in soil have been assessed with the FOCUS model and the DT_{50} values established in the EU review. The maximum initial predicted environmental concentration in soil (PECs) of the active substances and the metabolites as well as for the formulation are provided in Section 8.

The PECsoil values were used for the ecotoxicological risk assessment.

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

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

The PECgw of the active substance and their metabolites did not exceed the threshold of 0.1 µg/L. Therefore, no unacceptable leaching to groundwater is anticipated for the intended use of GLOB1817H.

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

The PEC values (PEC_{sw} and PEC_{sed}) resulting from the FOCUS STEP 1 to 4 of prosulfocarb, diflufenican, halauxifen-methyl, and their metabolites were calculated for the intended use.
The PECsw and PECsed assessment was provided in Step 1 & 2 and Step 3 and Step 4 (SWAN model). The mitigation measures were proposed.

The relevant PECsw and PECsed were then used for the ecotoxicological risk assessment.

FOCUS profiles of diflufenican using EPAT were not evaluated.

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

The fate and behaviour in air of prosulfocarb, diflufenican and halauxifen-methyl was evaluated during the EU review of these active substances. No additional studies have been performed.
The active substance prosulfocarb is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance prosul-

focarb due to volatilization with subsequent deposition was considered.
The active substances diflufenican and halauxifen-methyl, and the safener cloquintocet-mexyl, are regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by diflufenican and halauxifen-methyl due to volatilization with subsequent deposition should not be considered.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds
Effects on birds for GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl. Therefore all relevant data and risk assessments are provided here and are considered adequate. The risk assessment for effects on birds is carried out according to the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009)[1].

The cloquintocet-mexyl used as a safener was not be evaluated in this dossier (as a separate substance and in the mixture).

The acute and long-term risks of GLOB1817H to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with prosulfocarb, diflufenican, halauxifen-methyl or cloquintocet-mexyl, and maximum residues occurring on food items following applications according to the proposed use pattern. Risk of secondary poisoning through contaminated drinking water has also been assessed. The risk of secondary poisoning through bioaccumulation has also been assessed, as all three active substances and the safener have a log P_{OW} > 3.0. Since GLOB1817H contains 3 active ingredients a combined risk assessment was also performed.

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

Terrestrial vertebrates (other than birds)
Effects on terrestrial vertebrates other than birds for GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl. Therefore all relevant data and risk assessments are provided here and are considered adequate.

The cloquintocet-mexyl used as a safener was not be evaluated in this dossier (as a separate substance and in the mixture).

The acute and long-term risks of GLOB1817H to wild mammals were assessed using the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009) by calculating the toxicity exposure ratios between toxicity endpoints, estimated from studies with prosulfocarb, diflufenican, halauxifen-methyl, and maximum residues occurring on food items following applications according to the use pattern.
For prosulfocarb, results of the first-tier assessment were not acceptable for the long-term risk. Refinement of DT_{50} for the reproductive assessment for herbivorous mammals was performed using residue decline trials on young cereal plants.

[1] EFSA (2009). Guidance of EFSA – Risk assessment for Birds and Mammals. EFSA Journal 2009; 7(12):1438.

Risk of secondary poisoning through contaminated drinking water has also been assessed. The risk of secondary poisoning through bioaccumulation has also been assessed, as all three active substances and the safener have a log P_{OW} > 3.0. Since GLOB1817H contains 3 active ingredients, a combined risk assessment was also performed.

In conclusion, the TER_A and TER_{LT} values are greater than the Annex VI trigger of 10 and 5 respectively, indicating low acute and long-term risks to mammals following application of GLOB1817H in winter cereals.

3.7.2 Effects on aquatic species

Effects on aquatic organisms for GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl. A new risk assessment was performed for the intended use using the toxicity data of GLOB1817H, the active substances as well as the metabolites.

The cloquintocet-mexyl used as a safener and was not be evaluated in this dossier (as a separate substance and in the mixture).

The risk to aquatic organisms for the metabolites of halauxifen-methyl and the metabolites of diflufenican was assessed as low at STEP 1 – 2 for the representative use in winter cereals.

The risk to aquatic organisms for prosulfocarb and prosulfocarb sulfoxide was assessed as low at STEP 3 for the representative use in winter cereals.

A high long-term risk to aquatic plants from the exposure to diflufenican and halauxifen-methyl was identified at in some scenarios of STEP 3.
For diflufenican, FOCUS profiles were analysed to check if they are covered by the peak exposure study in algae. The following scenarios were deemed acceptable in STEP 3: D4 pond, D5 pond and R1 pond. The following scenarios were deemed acceptable using a 5 m no spray buffer zone: D1 ditch, D1 stream, D2 stream, D3 ditch, D4 stream, D5 stream, D6 ditch, R1 stream and R3 stream. For the R4 stream scenario, the risk is acceptable using a 10 m no spray buffer zone including a 10 m vegetated buffer strip. For the D2 ditch scenario, the FOCUS profile does not change by increasing the mitigation measures and thus the risk remains unresolved.
For halauxifen-methyl, STEP 4 calculations were performed showing an acceptable risk in the R4 stream scenario using a 10 m no spray buffer zone including a 10 m vegetated filter strip. The risk in all other scenarios was already acceptable at STEP 3.

An acceptable risk for the formulation GLOB1817H following spray drift is concluded using a 5 m no spray buffer zone.

Taking into account the relevant scenarios for Poland (D3, D4, R1), a 10 m no spray buffer zone including a 10 m vegetated filter strip is sufficient to protect aquatic organisms when using GLOB1817H as recommended in winter cereals.

3.7.3 Effects on bees

Effects on bees for GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl.

The risk of GLOB1817H to honeybees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with the formulated product, and the single application rate of 3026 g a.i./ha. All the hazard quotients are considerably less than 50, indicating that GLOB1817H poses a low acute risk to honeybees.

The chronic risk to honeybees (adult and larvae) was assessed according to EPPO 2010.

The risk of GLOB1817H to bumble bees and chronic risk to honeybees (adult and larvae) was not assessed according to the "EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)" (EFSA Journal 2013;11(7):3295) as this guidance has not been agreed yet.

It was demonstrated that GLOB1817H poses a low chronic risk to honeybees.

No risk mitigation measure is necessary.

3.7.4 Effects on other arthropod species other than bees

Effects on non-target arthropods for GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl.

Extended laboratory studies were conducted on *Typhlodromus pyri, Aphidius rhopalosiphi, Aleaochara bilineata* and *Poecilus cupreus*. The in-field hazard quotients for *Aleaochara bilineata* and *Poecilus cupreus* and the off-field hazard quotients for all species are below the trigger values recommended by ESCORT 2. The in-field hazard quotients for *Typhlodromus pyri* and *Aphidius rhopalosiphi* were exceeding the trigger values, so an additional higher-tier risk assessment was needed. The ESCORT 2 guidance document recommends that any initial effects are acceptable if the potential for recovery within one year can be demonstrated. It is possible to model the dissipation of residues over time using simple first order kinetics and determine the time after the treatment application that the foliar residues would drop to a level that demonstrate an acceptable risk to non-target arthropods. Using the default foliar DT_{50} of 10 days (according to EFSA Guidance Document on the Risk Assessment of Birds and Mammals, 2009), it was demonstrated that potential recovery of in-field populations by arthropod immigration from the off-field habitat can occur well within 1 season and in less than 1 year. As evidenced by the off-field risk assessment, no adverse effects on off-field arthropods are likely and therefore rapid recolonization can take place.

The risk to non-target arthropods following application of GLOB1817H 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 GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl.

Earthworms

The long-term risk of GLOB1817H to earthworms was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the formulation and the maximum PECsoil.

The resulting TER values are greater than the Annex IV triggers of 5, indicating an acceptable risk to earthworms following application of GLOB1817H for the intended use.

No risk mitigation measure is necessary.

Effects on other soil non-target macro-organisms

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

The chronic TER value for GLOB1817H is greater than the Annex IV trigger of 5, indicating an acceptable risk to other soil non-target macro-organisms following application of GLOB1817H for the intended use.

Effects on soil non-target micro-organisms

Effects on soil microbial activity of GLOB1817H were not evaluated as part of the EU review for prosulfocarb, diflufenican or halauxifen-methyl. Therefore all relevant data and assessments were provided.
They show that GLOB1817H 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 GLOB1817H were not evaluated as part of the EU review of prosulfocarb, diflufenican or halauxifen-methyl.

The potential effect of GLOB1817H on vegetative vigour and seedling emergence has been tested through studies performed on non-target terrestrial plants. The most sensitive species in pre-emergence was *Daucus carota* with an ER_{50} of 335.65 mL/ha. In post-emergence, the most sensitive species was *Lycopersicon esculentum* with an ER_{50} of 75.93 mL/ha.

The risk was found to be acceptable using a buffer zone of 1 m in combination with 90% drift reducing techniques, a buffer zone of 3 m in combination with 50% drift reducing techniques or a buffer zone of 10 m without drift reduction.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.8 Relevance of metabolites (Part B, Section 10)

The metabolites prosulfocarb sulfoxide, AE 0542291, AE B107137, X11393729 (halauxifen), X11449757 and CGA 153433 are predicted to occur in groundwater at concentrations below 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

GLOB1817H contains diflufenican which is approved as a candidate for substitution because two of PBT.

As a conclusion of the comparative assessment, use 1 from GAP table in 2.6 is not suitable for substitution because there are not more than 4 alternative modes of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.
Some of the alternative active substances are CfS themselves or control only grasses or only broadleaved weeds, while GLOB1817H controls both.

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

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

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

Appendix 1 Copy of the product authorization

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

Appendix 2 Copy of the product label

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

Appendix 3 Letter of Access

A Letter of Access for a worker exposure study related to prosulfocarb from Syngenta was submitted.
Letters of Access related to halauxifen-methyl and cloquintocet-mexyl will be sent by Corteva Agriscience directly to the authorities.

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1-2.8, KCP 4.2	XXXX D.	2020	Determination of Storage Stability and Shelf Life Specification an Data for Emulsifiable Concentrate Formulation containing Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl, stored at 54ºC±2ºC for Two Weeks, in Compliance with Good Laboratory Practice. DNA5653 David XXXX Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 2.2.1 and 2.2.2 *Confidential – submitted in Part C.*	XXXX D.	2020	Theoretical certificate of explosive and oxidizing properties for an EC formulation containing 667 g/L prosulfocarb, 14g/L diflufenican, 1.33 g/L halauxi-fen-methyl and 1.33 g/L cloquintocet-mexyl. DNA5959 David XXXX Analytical Laboratories Ltd. Not GLP Unpublished	N	N	-	Globachem NV
KCP 2.7.2	XXXX D.	2023	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl, stored	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			at ambient temperature for 3 Years, in Compliance with Good Laboratory Practice. DNA5655 David XXXX Analytical Laboratories Ltd. GLP Unpublished				
KCP 2.7.5	XXXX D.	2022	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl, stored at ambient temperature for 2 Years, in Compliance with Good Laboratory Practice. DNA5654 David XXXX Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.1	XXXX D.	2020	Validation of the Methods of Determination of Prosulfocarb, Diflufenican, Halauxifen-methyl and Cloquintocet-Mexyl in an EC Formulation containing 667g/L Prosulfocarb, 14g/L Diflufenican, 1.33g/L Halauxifen-methyl and 1.33g/L Cloquintocet-Mexyl, in Compliance with Good Laboratory Practice DNA5656 David XXXX Analytical Laboratories Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.2.1*	XXXX D.	2021a	Acute toxicity of GLOB1817H to *Daphnia magna* in a 48-hour semi-static test 2 48 ADL 0015 Biochem Agrar GmbH GLP	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 5.1.2 *Submitted as KCP 10.2.1*	XXXX D.	2021b	Effects of GLOB1817H on *Pseudokirchneriella subcapitata* in an algal growth inhibition test 20 48 AAL 0019 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.2.1*	XXXX D.	2021c	Effects of GLOB1817H on Lemna gibba in a growth inhibition test under semi-static test conditions 20 48 ALE 0017 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.2.1*	XXXX D.	2021d	Effect of GLOB1817H on *Myriophyllum spicatum* in a semi-static water-sediment system 20 48 AMS 0010 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCA 8.2.6.1*	XXXX, D.	2012a	Effects of Prosulfocarb sulfoxide on *Chlamydomonas reinhardtii* in an algal growth inhibition test 12 10 48 057 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 *Submitted as KCA 8.2.6.1*	XXXX, D.	2012b	Effects of Prosulfocarb sulfoxide on *Chlorella vulgaris* in an algal growth inhibition test 12 10 48 059 W Biochem Agrar GmbH GLP	N	N	Data protection started with: R-31/2016	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 5.1.2 Submitted as KCA 8.2.6.2	XXXX, D.	2012c	Effects of Prosulfocarb sulfoxide on *Anabaena flos-aquae* in an algal growth inhibition test 12 10 48 058 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.2	XXXX, D.	2012d	Effects of Prosulfocarb sulfoxide on *Navicula pelliculosa* in an algal growth inhibition test 12 10 48 053 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 Submitted as KCA 8.2.6.2	XXXX, D.	2012e	Effects of Prosulfocarb sulfoxide on *Skeletonema costatum* in an algal growth inhibition test 12 10 48 060 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.3.1.1.1*	XXXX, K.	2021	Acute toxicity of GLOB1817H to the bumblebee *Bombus terrestris* L. under laboratory conditions 20 48 BBA 0029 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.3.1.2*	XXXX, S.	2021	Chronic toxicity of GLOB1817H to the honey bee *Apis mellifera* L. under laboratory conditions 20 48 BAC 0071 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2 *Submitted as KCP 10.3.1.3*	XXXX, K.	2021	GLOB1817H – Repeated exposure of the honey bee (Apis mellifera L.) larvae under laboratory conditions 20 48 BLC 0052 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.4.*1.2	XXXX, L.	2015	Effects of prosulfocarb 800 g/L EC on earthworms under field conditions. Biochem Agrar Report Number 14 10 48 008 F GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2 *Submitted as KCA 8.1.3*	XXXX, D.	2008	The bioaccumulation potential of prosulfocarb in earthworm (*Eisenia foetida foetida*). ENV8333/040822 Chemex Environmental International Ltd GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 5.1.2 *Submitted as KCP 10.6*	XXXX, M.	2021	GLOB1817H: terrestrial plant test: vegetative vigour test STC/20/E1409 Stockbridge Technology Center Ltd GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 5.1.2	XXXX F.	2010	Validation of the Analytical Method for the Determination of Prosulfocarb Residues in Potato Tubers, Sunflower Seeds and Winter Wheat Whole Plant + Amendment 1 to final report No. R A9085 (2014) Anadiag R A9085	N	N	Data protection started with: R-31/2016	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.2	XXXX G.	2008	Development and validation of a method for the determination of diflufenican and two metabolites in surface water and drinking water. PGD-307 Central Science Laboratory GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Sapec Group & Globachem NV & Punjab Chemicals and Crop Protection Ltd.
KCP 5.2	XXXX H.	2016	Validation of an analytical method for the determination of diflufenican in drinking water, ILV. VAL10/16 Laboratório de residuos Sapec Agro S.A. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Sapec Agro S.A. & Glo-bachem NV
KCP 6.2	XXXX R.	2021	Biological Assessment Dossier: GLOB1817H Globachem NV	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 7.2	XXXX A.	2016	Prosulfocarb: Measurement of Worker Exposure (Passive Dosimetery) during Typical Activities Associated with Re-entry Scouting following application of an EC formulation containing 800 g/L prosulfocarb) to Winter Wheat in Northern Europe RB424 Anadiag GLP Unpublished	N	N	-	Syngenta *Globachem access*
KCP 7.3	XXXX S.	2020	Prosulfocarb – In vitro percutaneous penetration of [14C]Prosulfocarb formulated as GLOB1817H through human skin membranes	N	Y	Data/study report never submitted before to PL.	Globachem NV

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			20200147 Innovative Environmental Services (IES) Ltd. GLP Unpublished				
KCA 6.10	XXXX F.	2010	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2009-2010. R A9051 Anadiag GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 6.10	XXXX A.	2010	Determination of Prosulfocarb Residues In Winter Wheat RAC Following Treatment with Prosulfocarb 800 g/l EC under Field Conditions in Northern Europe in 2011-2012. R B1234 Anadiag GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCP 9.2.4	XXXX, S	2021	Estimations of the PECgw of prosulfocarb, diflufenican, halauxifen-methyl, cloquintocet-mexyl and relevant metabolites GLOB1817HGW Globachem NV non GLP Unpublished	N	N	-	Globachem NV
KCP 9.2.5	XXXX, S	2021	Estimations of the PECsw of prosulfocarb, diflufenican, halauxifen-methyl, cloquintocet-mexyl and relevant metabolites GLOB1817HSW Globachem NV	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			non GLP Unpublished				
KCA 8.1.3	XXXX, D.	2008	The bioaccumulation potential of prosulfocarb in earthworm (*Eisenia foetida foetida*). ENV8333/040822 Chemex Environmental International Ltd GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.1	XXXX, D.	2012a	Effects of Prosulfocarb sulfoxide on *Chlamydomonas reinhardtii* in an algal growth inhibition test 12 10 48 057 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.1	XXXX, D.	2012b	Effects of Prosulfocarb sulfoxide on *Chlorella vulgaris* in an algal growth inhibition test 12 10 48 059 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.1	XXXX, D.	2012c	Effects of Prosulfocarb sulfoxide on *Anabaena flos-aquae* in an algal growth inhibition test 12 10 48 058 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
KCA 8.2.6.1	XXXX, D.	2012d	Effects of Prosulfocarb sulfoxide on *Navicula pelliculosa* in an algal growth inhibition test 12 10 48 053 W Biochem Agrar GmbH GLP	N	N	Data protection started with: R-31/2016	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 8.2.6.1	XXXX, D.	2012e	Effects of Prosulfocarb sulfoxide on *Skeletonema costatum* in an algal growth inhibition test 12 10 48 060 W Biochem Agrar GmbH GLP Unpublished	N	N	Data protection started with: R-31/2016	Globachem NV
~~KCA 8.3.1.2~~	~~XXXX, S.~~	~~2018a~~	~~XDE-729 Methyl - Assessment of Effects on the Adult Honey Bee, Apis mellifera L., in a 10-Day Chronic Feeding Test under Laboratory Conditions S17-00191~~ ~~Eurofins Agroscience Services Ecotox GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~N~~	-	~~Corteva Agriscience~~ ~~*Globachem access*~~
~~KCA 8.3.1.3~~	~~XXXX, S.~~	~~2018b~~	~~XDE-729 methyl - Honey Bee (Apis mellifera L.) 22 Day Larval Toxicity Test (Repeated Exposure) S17-00206~~ ~~Eurofins Agroscience Services Ecotox GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~N~~	-	~~Corteva Agriscience~~ ~~*Globachem access*~~
~~KCA 8.3.1.2~~	~~XXXX, T.~~	~~2016a~~	~~Chronic toxicity of Diflufenican technical on honeybees (*Apis mellifera* L.)~~ ~~TRC16-019BA~~ ~~Trialcamp~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~Y~~	~~Data/study report never submitted before to PL.~~	~~Globachem NV~~
~~KCA 8.3.1.3~~	~~XXXX, T.~~	~~2016b~~	~~Toxicity of Diflufenican technical on honey bee larvae (*Apis mellifera* L.) after repeated exposure under laboratory conditions~~ ~~TRC16-018BA~~ ~~Trialcamp~~	~~N~~	~~Y~~	~~Data/study report never submitted before to PL.~~	~~Globachem NV~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			~~GLP~~ ~~Unpublished~~				
KCP 10.2.1	XXXX, D.	2021a	Acute toxicity of GLOB1817H to *Daphnia magna* in a 48-hour semi-static test 2 48 ADL 0015 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	XXXX, D.	2021b	Effects of GLOB1817H on *Pseudokirchneriella subcapitata* in an algal growth inhibition test 20 48 AAL 0019 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	XXXX, D.	2021c	Effects of GLOB1817H on Lemna gibba in a growth inhibition test under semi-static test condi-tions 20 48 ALE 0017 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.2.1	XXXX, D.	2021d	Effect of GLOB1817H on *Myriophyllum spicatum* in a semi-static water-sediment system 20 48 AMS 0010 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.1	XXXX, M.	2020	Acute toxicity of GLOB1817H to the honeybee *Apis mellifera* L. under laboratory conditions. 20 48 BAA 0130 Biochem Agrar GmbH	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 10.3.1.1.1	XXXX, K.	2021	Acute toxicity of GLOB1817H to the bumblebee *Bombus terrestris* L. under laboratory conditions 20 48 BBA 0029 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.2	XXXX, S.	2021	Chronic toxicity of GLOB1817H to the honey bee *Apis mellifera* L. under laboratory conditions 20 48 BAC 0071 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.1.3	XXXX, K.	2021	GLOB1817H – Repeated exposure of the honey bee (Apis mellifera L.) larvae under laboratory conditions 20 48 BLC 0052 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	XXXX, U.	2020a	Effects of GLOB1817H on the parasitic wasp *Aphidius rhopalosiphi* (Destefani-Perez) in an extended laboratory test. 20 48 NAE 0018 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	XXXX, U.	2020b	Effects of GLOB1817H on the predatory mite *Typhlodromus Pyri* Scheuten in an extended laboratory test.	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			20 48 NTE 0013 Biochem Agrar GmbH GLP Unpublished				
KCP 10.3.2.2	XXXX, U.	2020c	Effects of GLOB1817H on the rove beetle *Aleochara bilineata* Gyll. in an extended laboratory test. 20 48 NKE 0010 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.3.2.2	XXXX, U.	2020d	Effects of GLOB1817H on the carabid beetle *Poecilus cupreus* L. in an extended laboratory test. 20 48 NLE 0007 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.1.1	XXXX, E.	2012	Earthworm reproduction test with prosulfocarb 800 g/L EC (OECD 222, April 2004). 12-99-012-ES Phytosafe s.a.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.1.1	XXXX, S.	2020	Effects of GLOB1817H on the reproduction of the earthworm *Eisenia fetida*. 20 48 TEC 0054 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.1.2	XXXX, L.	2015	Effects of prosulfocarb 800 g/L EC on earthworms under field conditions. Biochem Agrar	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report Number 14 10 48 008 F GLP Unpublished				
KCP 10.4.2.1	XXXX, S.	2016	A dose response study to assess the NOEC, $EC_{10\text{-}20\text{-}50}$ on reproduction and $LR_{10\text{-}20\text{-}50}$ on mortality of Prosulfocarb 800 EC of the predatory mite *Hypoapis aculeifer* on artificial soil in the laboratory. HA04/2016 Walloon Agricultural Research Centre GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2.1	XXXX, K.	2016	Diflufenican 500 g/L SC: Predatory mite (*Hypoaspis aculeifer*) reproduction test in soil. DF50GM Envigo CRS Limited GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV & Sapec Agro S.A.
KCP 10.4.2.1	XXXX, L.	2020	Effects of GLOB1817H on the reproduction of the predatory mite Hypoaspis aculeifer. 20 48 THC 0043 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.4.2.1	XXXX, S.	2020	Effects of GLOB1817H on the reproduction of the collembolan *Folsomia candida* 20 48 TCC 0059 Biochem Agrar GmbH GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.5	XXXX, L.	2020	Effect of GLOB1817H on the activity of soil micro-flora (Nitrogen transformation test)	N	Y	Data/study report never submitted before to PL.	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			20 48 SMN 0052 Biochem Agrar GmbH GLP Unpublished				
KCP 10.6	XXXX, A.	2021	GLOB1817H: terrestrial plant test: seedling emergence and seedling growth test STC/20/E1410 Stockbridge Technology Center Ltd GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV
KCP 10.6	XXXX, M.	2021	GLOB1817H: terrestrial plant test: vegetative vigour test STC/20/E1409 Stockbridge Technology Center Ltd GLP Unpublished	N	Y	Data/study report never submitted before to PL.	Globachem NV

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate 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	Verte-brate 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 au-thorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate 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 au-thorization>	Owner