REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

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

CORE ASSESSMENT

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	Corrected after evaluation at zonal level.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for a new product containing 667 g/L prosulfocarb, 14 g/L diflufenican, 1.33 g/L halauxifen-methyl and 1.33 g/L of the safener cloquintocet-mexyl formulated as a emulsifiable concentrate (EC).
This application 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.
The Annex II data for prosulfocarb and diflufenican are out of data protection. For the data regarding halauxifen-methyl and cloquintocet-mexyl the necessary letters of access have been submitted.
The Annex III data of GLOB1817H are owned by Globachem NV.
The intented sources of the active substances have been positively evaluated in the EU.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland, Eledura	Czech Republic, Eledura Germany, Eledura

0.1.3 Regulatory history of the active(s)

0.1.3.1 Prosulfocarb

Table 0.1-2: Summary of regulatory history of CAS No: 52888-80-9

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2007/76/EC Commission Implementing Regulation (EU) No 2019/1589 Commission Implementing Regulation (EU) No 540/2011
RMS	Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.04.2010

Status	
Date of final Commission (re-registration) deadline (Step 2)	31.10.2013
Current expiration of approval	~~31.10.2021~~ 31.10.2022
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,
- the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone,
- the protection of non-target plans and must ensure that the conditions of authorisation include, where appropriate, risk mitigations measures such as an in-field no spray buffer zone.

The SANCO report for prosulfocarb (SANCO/2824/07 rev. 3 – 10/09/2007) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 27 July 2007.

Table 0.1-3: Information on minimum purity of prosulfocarb

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
970 g/kg	970 g/kg (source 1) Equivalence report available: Y RMS: Sweden 980 g/kg (source 2) Equivalence report available: Y RMS: Sweden

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

0.1.3.2 Diflufenican

Table 0.1-4: Summary of regulatory history of CAS No: 83164-33-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/66/EC Commission Implementing Regulation (EU) No 2019/1589 Commission Implementing Regulation (EU) No 540/2011

Status	
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.05.2010
Date of final Commission (re-registration) deadline (Step 2)	31.12.2013
Current expiration of approval	~~31.12.2021~~ 31.12.2022
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate,
- the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones should be applied, where appropriate.

The SANCO report for diflufenican (SANCO/3782/08 rev. 1 – 14/03/2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 17 December 2007.

Table 0.1-5: Information on minimum purity of diflufenican

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
≥ 970 g/kg	990 g/kg (source 1 and source 2) Equivalence report available: Y RMS: UK/Germany 975 g/kg (source 3) Equivalence report available: Y RMS: UK

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.3.3 Halauxifen-methyl

Table 0.1-6: Summary of regulatory history of CAS No: 943831-98-9

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2015/1165 Commission Implementing Regulation (EU) No 540/2011
RMS	UK

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	05.08.2015
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	04.01.2016
Date of final Commission (re-registration) deadline (Step 2)	04.08.2019
Current expiration of approval	05.08.2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- The risk to aquatic and non-target terrestrial plants. Conditions of authorisation shall include risk mitigation measures, where appropriate.

The SANCO report for halauxifen-methyl (SANTE/10406/2015 rev. 1 – 26/01/2018) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 17 November 2014.

Table 0.1-7: Information on minimum purity of halauxifen-methyl

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
≥ 930 g/kg	930 g/kg Equivalence report available: Y/N RMS: UK

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

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

The three-year storage stability study is ongoing. It has to be assessed in the post-registration.
Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy:

This document summarises the information related to the efficacy assessment of the plant protection product GLOB1817H, an emulsifiable concentrate formulation (EC) containing the active ingredients prosulfocarb (667 g/L), diflufenican (14 g/L) and halauxifen-methyl (1.33 g/L), they belong to different groups of HRAC and act by different modes of action. The target of GLOB1817H is early post-emergence weed control in winter wheat (TRZAW), winter barley (HORVW), winter rye (SECCW) and triticale (TTLWI), in combination with the safener cloquintocet-mexyl (1.33 g/L). The proposed use rate is 3,0 L/ha with a maximum of one application at growth stages ranging from BBCH 10-14. To support

the proposed use of GLOB1817H data is presented from trials conducted between 2018 and 2019 in European countries of the maritime EPPO zone, and northeast EPPO zone.

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

Maritime EPPO zone

To determine the minimum effective dose for the control of weed in winter cereals by GLOB1817H, the applicant presented data from 23 field trials. GLOB1817H was tested at doses 1,8 L/ha (60% 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'. A clear dose-response was observed for almost all tested weeds, except *Geranium sp. Veronica sp, Thlaspi arvense and, Viola arvensis* where the weeds were controlled above 90% with two application rates, the full application rate 3.0 L/ha and reduced application rate 1,8 L/ha.

A very marked dosage-response was observed for grasses *Apera spica-venti, Poa annua* and broad-leaved *Centaurea cyanus, Galium aparine, Matricaria chamomilla, Matricaria inodora, Myosotis arvensis, Papaver rhoeas, Stellaria media*. For these weeds, the lower dose (1.8 l/ha) gave inferior but still good control, while increasing the dose to the full 3.0 l/ha led to very good control. The justification of the proposed application rate of 3,0 L/ha will be accepted.

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

Maritime EPPO zone

Data are presented from 23 efficacy trials with GLOB1817H. The trials were conducted in the Maritime, EPPO zone between 2018 and 2019 by GEP certified research institutions in the Czech Republic, France, Germany, and the Netherlands. The crops that were used in these efficacy trials were winter wheat (19), winter rye (1), winter barley (1) and winter triticale (2).

The data show that a single application of 3 L/ha GLOB1817H in winter cereals gives very good (>85%) control of the majority of presented in the trials of annual broadleaved *weeds Galium aparine, Centaurea cyanus, Papaver rhoeas, Viola arvensis, Stellaria media, Matricaria inodora, Veronica persica, Geranium dissectum, Matricaria chamomilla, Thlaspi arvense, Myosotis arvensis, Descurainia Sophia, Fumaria officinalis* and annual grasses *Apera spica-venti* and *Poa annua*. The only weed partially controlled was *Senecio vulgaris*, where the average control was around 77,5%. 'GLOB1817H' demonstrated either comparable or higher control than the reference products

North East EPPO zone

A total of 10 trials were carried out in the North-East EPPO Zone to evaluate the efficacy of GLOB1817H for the control of weeds on winter wheat (5), winter barley (1), winter triticale (4). Those

trials have been conducted between 2018 and 2019 in Poland. Additionally, those trials were combined with the results of the German and Czech trials of winter wheat (18), winter barley (1) and winter rye (1).

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

Maritime EPPO zone

The crops that were used in these efficacy trials were winter wheat (8), winter barley (7), winter rye (8) and winter triticale (8). As shown in the tables (Tables 3.4-6 to 3.4-12), the phytotoxicity observed at N and 2N only exceeded 15% in one trial. Overall, whilst there were some phytotoxicity symptoms, the majority were transient and disappeared over time and they did not appear to have a negative impact on the 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.

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 a 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.

Yield and quality parameters

Maritime EPPO Zone

In the Maritime EPPO Zone, statistically lower yield was observed in two cases. In one trial on winter wheat, a lower yield was observed, but in the same trial with the 2N dose this effect was not observed. The second case was observed on winter barley at N and 2 N rates. A similar yield reduction was observed for the reference product, despite even lower levels of phytotoxicity effect.

Overall, the yield following treatments with ‘GLOB1817H’ and the reference products at both N and 2N were comparable to the untreated. The data indicate that at the proposed dose 3 l/ha of ‘GLOB1817H’ is unlikely to have a significant negative effect on the yield of winter cereals.

North east EPPO zone

In the North East EPPO zone, statistically lower yield was observed in two cases. Overall, the yield following treatments with ‘GLOB1817H’ and the reference products at both N and 2N were comparable to the untreated. The data indicate that at the proposed dose 3 l/ha of ‘GLOB1817H’ is unlikely to have a significant negative effect on the yield of winter cereals.

Overall, the data have shown that neither the proposed dose of GLOB1817H nor 2N are likely to have a significant negative impact on the TGW, hectolitre weight of winter cereals. Therefore, it is considered that the proposed uses of GLOB1817H are unlikely to have a significant negative impact on quality of claimed crops.

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 halauxi-

fen-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 crop

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.

Section 6. Toxicology and health risk:

Based on all available data the product 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.

The product Eledura (GLOB1817H) applied in accordance with on cereals (BBCH10-14) at maximal dose of 3.0 L product/ha using tractor-mounted/trailed boom sprayer 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.

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

The 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 adult and child residents and bystanders.

Section 7. Metabolism and Residues:

The evaluation of the application for Eledura resulted in the decision to grant the authorization for the intended GAP.

Section 8. Fate and behaviour:

In accordance with intended use, an exposure assessment for the all active substances and GLOB1817H formulation was submitted.

The mitigation measures were proposed, and final decision will be made in ecotoxicological section.

Section 9. Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of GLOB1817H as a herbicide on: winter wheat, winter barley, winter rye and triticale poses acceptable risk

to non-target organisms, if applied according to the recommended use pattern.

To protect the aquatic organisms, it is necessary to apply following mitigation measures: 10 m no spray buffer zone including a 10 m vegetated buffer strip.

To protect the non-target terrestrial plants the following mitigation measures should be applied: 10 m or 3 m with use of 50% DRN or 1 m with use of 90% DRN.

Uses to be considered safe on the basis of EU methodology:

use no. 1

Uses to be considered non-safe on the basis of EU methodology:

none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

N/A

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP rev. 1, date: 2020-09-11

PPP (product name/code):	Eledura/GLOB1817H	Formulation type:	Emulsifiable concentrate (EC) [a, b]
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: herbicide

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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL, DE, CZ	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