

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GLOB1912H

Product name: **Jura Max**

Chemical active substances:

Prosulfocarb, 667 g/L

Diflufenican, 14 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: November 2021

Evaluation date: August 2022

MS Finalisation date: December 2022

Version history

When	What
November 2021	Initial dossier submission by the applicant for approval of new product.
August 2022	Version evaluated by zRMS PL
December 2022	Updated after zonal evaluation

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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 and 14 g/L diflufenican formulated as an 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. The Annex III data used for GLOB1912H are owned by Globachem NV.

The intended 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, Jura Max	Czech Republic, Jura Max Germany, Jura Max Belgium, Jura Max Hungary, Jura Max

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	31.10.2022 31.10.23
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 plants 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	Source 1 970 g/kg Equivalence report available: Y RMS: Sweden Source 2 - 980 g/kg Equivalence report available: Y RMS: Sweden Source 3 - 980 g/kg Equivalence report available: Y RMS: Poland

* 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

Status	
	Commission Implementing Regulation (EU) No 540/2011
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)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2012
Current expiration of approval	31.12.2022 31.12.23
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	Source 1 - 990 g/kg Equivalence report available: Y RMS: UK/ Germany Source 2 - 990 g/kg Equivalence report available: Y RMS: Germany Source 3 - 975 g/kg 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.

0.1.4 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 two-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:

GLOB1912H is recommended as a pre-emergence or early post-emergence treatment for the control of some annual grasses and broadleaved weeds in winter cereals and as a pre-emergence application in potatoes and sunflowers. The majority of the efficacy data were produced in the Maritime and North-East EPPO zones, with a limited number of trials in the South-East zone. Therefore, CMS based on national experience should consider whether presented data there are appropriate to support the registration of GLOB1912H.

Section 6. Toxicology and health risk:

The product JURA MAX (GLOB1912H) used on low crops according with GAP at maximal dose of 3.2 L product/ha does not pose an unacceptable risk to the health of operator providing that operator is wearing work wear covering arms, body and legs and protective gloves during mixing/loading and application. Since the product is classified as Eye Dam. 1 and Skin Sens. 1 the operator should wear protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

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

There is no unacceptable risk for residents and bystanders when the product is used as intended , providing that risk mitigation measures are used, either buffer zone of 5 m or drift reduction technology – 50%.

Section 7. Metabolism and Residues:

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for prosulfocarb and diflufenican as laid down in Reg. (EU) 396/2005 is not expected. The chronic and the short-term intakes of prosulfocarb and diflufenican residues are unlikely to present a public health concern. As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

Section 8. Fate and behaviour:

The results of leaching simulation run with FOCUS PELMO, FOCUS PEARL and FOCUS MACRO demonstrate that GLOB1912H can be applied safely according to the recommended use patterns without risk of prosulfocarb, diflufenican and their metabolites exceeding acceptable levels in groundwater. The exposure of adjacent surface waters and terrestrial ecosystems by prosulfocarb and diflufenican due to volatilization with subsequent deposition is considered to be low.

Section 9. Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed uses of GLOB1912H poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from GLOB1912H applications are required for aquatic organisms and non-target terrestrial plants.

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

Uses No. 1-8

Ecotoxicology: Uses No. 2, 4, 6 and 8

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:

Ecotoxicology: Uses No. 1, 3, 5, and 7 – For collembola exposed to prosulfocarb (endpoint derived from product study - GLOB1817H), earthworms and collembola exposed to formulation, the risk is unresolvable based on standard assessment. In zRMS opinion, the acceptable risk for soil organisms can be concluded based on WoE approach. As is not standard assessment, the acceptability of this statement should be taken at MSs level.

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: 2021-07-15

PPP (product name/code): Jura Max/GLOB1912H
Active substance 1: Prosulfocarb
Active substance 2: Diflufenican
Safener: /
Synergist: /
Applicant: Globachem NV
Zone(s): central ^(d)
Verified by MS: **yes/no**

Formulation type: Emulsifiable concentrate (EC) ^(a, b)
Conc. of as 1: 667 g/L ^(c)
Conc. of as 2: 14 g/L ^(c)
Conc. of safener: / ^(c)
Conc. of synergist: / ^(c)
Professional use:
Non professional use:

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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL, DE, CZ, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW), Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	
2	PL, DE, CZ, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW) , Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/
3	PL, DE, CZ, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW) , Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-13	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300	/	
4	PL, DE, CZ, BE, HU	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI), Winter durum wheat (TRZDW) , Spelt (TRZSP)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH10-13	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/
5	PL, DE, CZ, BE, HU	Potato (SOLTU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a)Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300		

6	PL, DE, CZ, BE, HU	Potato (SOLTU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/
7	PL, DE, CZ, HU	Sunflower (HELAN)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.2 b) 3.2	a) Prosulfocarb: 2.134 Diflufenican: 0.0448 b)Prosulfocarb: 2.134 Diflufenican: 0.0448	160-300		
8	PL, DE, CZ, HU	Sunflower (HELAN)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 3.0 b) 3.0	a)Prosulfocarb: 2.001 Diflufenican: 0.042 b)Prosulfocarb: 2.001 Diflufenican: 0.042	160-300	/	/

Remarks table heading:

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

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

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