

# REGISTRATION REPORT

## Part B

### Section 0

Product Background, Regulatory Context and  
GAP information

Product code: GLOB1913H

Product name: Roxy XL

Chemical active substances:

Prosulfocarb, 900 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

Applicant: Globachem NV

Submission date: September 2022

MS Finalisation date: 10/09/2023

After commenting period: 15/11/2023

## Version history

When	What
September 2022	Initial dossier submission by the applicant for product approval.
September 2023	zRMS assessment
November 2023	After commenting period.

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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 900 g/L prosulfocarb 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 are out of data protection. The Annex III data of GLOB1913H are owned by Globachem NV.

The intended sources of the active substance 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, Roxy XL	Ireland, Roxy XL Belgium, Roxy XL Hungary, Roxy XL Slovakia, Roxy XL

#### 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 Extension of the approval period - 31/01/2027 (Commission Implementing Regulation (EU) 2023/1757).
RMS	Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2009

<b>Status</b>	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.04.2010
Date of final Commission (re-registration) deadline (Step 2)	31.10.2013
Current expiration of approval	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 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**

<b>EU agreed minimum purity from Inclusion Directive or Implementing regulation</b>	<b>(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **</b>
970 g/kg	970 g/kg 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.

#### **0.1.4 Regulatory history of the product**

Not relevant as the product has not yet been authorised

#### **0.2 zRMS conclusion**

Authorization can be recommended for proposed use.

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

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

See Appendix 1.

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

See Appendix 1

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:

See Appendix 1

All uses are covered by established MRLs.

## Appendix 1 ALL intended uses

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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			

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, CAPBP, FUMOF, MYOAR, STEME, THLAR, VERPE.	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 4.4 b) 4.4	a) Prosulfocarb: 3.96 b) Prosulfocarb: 3.96	155-300	/	/	
2	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	c) 4.0 d) 4.0	a)Prosulfocarb: 3.6 b)Prosulfocarb: 3.6	155-300	/	/	
3	IE, BE, HU, SK	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	e) 4.0 f) 4.0	c)Prosulfocarb: 3.6 d)Prosulfocarb: 3.6	155-300	/	/	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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			
4	IE, BE, HU, SK	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	FUMOF, STEME, GALAP.	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	g) 4.4 h) 4.4	a) Prosulfocarb: 3.96 b) Prosulfocarb: 3.96	155- 300	/	/	
5	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, FUMOF, GERPU, MATCH, STEME, VERHE	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	a) 3.5 b) 3.5	a) Prosulfocarb: 3.15 b) Prosulfocarb: 3.15	155- 300	/	/	
6	IE, BE, HU, SK	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, FUMOF, STEME, GERPU, MATCH)	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	c) 3.5 d) 3.5	c) Prosulfocarb: 3.15 d) Prosulfocarb: 3.15	155- 300	/	/	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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			
7	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, CAPBP, FUMOF, MYOAR, STEME, THLAR, VERPE.	Downward spraying	BBCH 10-29	a) 1 b) 1	/	a) 4.4 b) 4.4	a) Prosulfocarb: 3.96 b) Prosulfocarb: 3.96	155- 300	/	/	
8	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH 10-29	a) 1 b) 1	/	c) 4.0 d) 4.0	c) Prosulfocarb: 3.6 d) Prosulfocarb: 3.6	155- 300	/	/	
9	IE, BE, HU, SK	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	BBCH 10-29	a) 1 b) 1	/	e) 4.0 f) 4.0	e) Prosulfocarb: 3.6 f) Prosulfocarb: 3.6	155- 300	/	/	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					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			
10	IE, BE, HU, SK	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, POAAN, THLAR, FUMOF, MYOAR.	Downward spraying	BBCH 10-29	a) 1 b) 1	/	g) 4.4 h) 4.4	g)Prosulfocarb: 3.96 h)Prosulfocarb: 3.96	155- 300	/	/	
11	PL	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, POAAN, FUMOF, GERPU, LAMPUR, MYOAR, STEME, THLAR, VERHE, VERPE.	Downward spraying	BBCH 10-29	a) 1 b) 1	/	a) 3.5 b) 3.5	a)Prosulfocarb: 3.15 b)Prosulfocarb: 3.15	155- 300	/	/	
12	IE, BE, HU, SK	Winter wheat (TRZAW), Winter barley (HORVW), Winter rye (SECCW), Triticale (TTLWI)	F	APESV, VERPE, GERPU, THLAR, LAMPUR, FUMOF	Downward spraying	BBCH 10-29	a) 1 b) 1	/	c) 3.5 d) 3.5	c)Prosulfocarb: 3.15 d)Prosulfocarb: 3.15	155- 300	/	/	
13	PL	Potato (SOL-TU)	F	AMARE, CHEAL GASPA, GERPU, MATIN, POLPE, STEME, THLAR and VIOAR.	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	a) 4.4 b) 4.4	a)Prosulfocarb: 3.96 b)Prosulfocarb: 3.96	155- 300	/	/	
14	IE, BE, HU, SK	Potato (SOL-TU)	F	THLAR, CHEAL	Downward spraying	Pre-emergence (BBCH 0-09)	a) 1 b) 1	/	c) 4.4 d) 4.4	c)Prosulfocarb: 3.96 d)Prosulfocarb: 3.96	155- 300	/	/	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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			
15	PL	Potato (SOL- TU)	F	CAPBP	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	a) 3.5 b) 3.5	a)Prosulfocarb: 3.15 b)Prosulfocarb: 3.15	155- 300	/	/	
16	IE, BE, HU, SK	Potato (SOL- TU)	F	Annual broad leaved weeds (BBBAN) & grasses (GGGAN)	Downward spraying	Pre- emergence (BBCH 0- 09)	a) 1 b) 1	/	c) 3.5 d) 3.5	c)Prosulfocarb: 3.15 d)Prosulfocarb: 3.15	155- 300	/	/	
17	PL	Winter durum wheat (TRZDW)	F	APESV, POAAN, GERPU, VERPE, VERHE)	Downward spraying	Pre- emergence	a) 1 b) 1	/	a) 2.6 b) 2.6	a)Prosulfocarb: 2.34 e)Prosulfocarb: 2.34	155- 300	/	/	
18	IE, BE, HU, SK	Winter durum wheat (TRZDW)	F	APESV, FUMOF, STEME	Downward spraying	Pre- emergence	a) 1 b) 1	/	c) 2.6 d) 2.6	b)Prosulfocarb: 2.34 f) Prosulfocarb: 2.34	155- 300	/	/	
19	PL	Winter durum wheat (TRZDW)	F	APESV, POAAN, FUMOF, GERPU, LAMP, MYOAR, THLAR, VERHE, VERPE	Downward spraying	BBCH10-29	a) 1 b) 1	/	a) 2.6 b) 2.6	a)Prosulfocarb: 2.34 g)Prosulfocarb: 2.34	155- 300	/	/	
20	IE, BE, HU, SK	Winter durum wheat (TRZDW)	F	APESV, VERPE, GERPU, THLAR, FUMOF	Downward spraying	BBCH10-29	a) 1 b) 1	/	c) 2.6 d) 2.6	b)Prosulfocarb: 2.34 h)Prosulfocarb: 2.34	155- 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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	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.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions