

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: CHR/H/DIK 480 SL

Product name(s): Macamba 480 SL, Dikambin 480 SL

Chemical active substance:

Dicamba, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 08/2022

MS Finalisation date: 12/01/2024

Version history

When	What
01/2023	Dossier sent for evaluation
04/2023	zRMS evaluation of dRR
06/2023	Final version prepared by zRMS after Commenting period
01/2024	zRMS update

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

In the following documents, data for active substances - dicamba - was described during its inclusion on Annex 1 process in respectively 2009. Where reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.

0.1 Introduction

This document describes the acceptable use conditions required for authorization of CHR/H/DIK 480 SL (Macamba 480 SL, Dikambin 480 SL) containing dicamba in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part A and C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/H/DIK 480 SL where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/H/DIK 480 SL have been made using endpoints agreed in the EU review of dicamba.

This document describes the specific conditions of use and labelling required for the registration of Macamba 480 SL, Dikambin 480 SL), product code CHR/H/DIK 480 SL.

0.1.1 Reason for application

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.

In addition to the submission of studies as listed in section(s) B0-B10 exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

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)
Northern zone	-	-
Central zone	CHR/H/DIK 480 SL Macamba 480 SL/Dikambin 480 SL	-
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Dicamba

Table 0.1-2: Summary of regulatory history of CAS No: 1918-00-9

Status	
Approved in EU	Y
Original Inclusion Directive or	COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011

Status	
Commission Implementing Regulation	of 25 May 2011
RMS	DK
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)	31.12.202 2 3
Date of final Commission (re-registration) deadline (Step 2)	31.12.202 2 3
Current expiration of approval	31.12.202 2 3
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:

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate.

The SANCO report for dicmaba (SANCO/829/08 – final rev. 2- 12 July 2016) 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 14 January 2011.

Table 0.1-3: Information on minimum purity of dicmaba

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalence report *, **
850 g/kg	Please refer to Part C.

* 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

Based on physicochemical properties the PPP is not classified.

The two years storage stability study is ongoing. It has to be evaluated in the post-registration at national level.

Section 3. Efficacy

The evaluation of the application of Dikambin 480 SL/Macamba 480 SL resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical methods

The analytical method used for analysing active substance in in the plant protection product meets the SANCO/3030/99 rev. 5.

Section 6. Mammalian Toxicology

Classification of CHR/H/DIK 480 SL: Acute Tox. 4 (H302), Skin Corr. 1B (H314), Eye Dam. 1 (H318), STOT SE 3 (H335)

Operator: None PPE according to the exposure assessment. Due to the hazard characterisation – protective clothes, protective gloves and face/eye protection at the mixing/loading step.

Worker: None (workwear)

Residents and Bystanders: None

Section 7. Metabolism and Residues

All the studies on which this dossier was based were evaluated during inclusion of dicamba to Annex I. The Applicant did not provide any new studies.

Comparison of EU critical GAPs with the proposed use of CHR/H/DIK 480 SL on maize is presented below:

Source of GAP	Member State or Country	Formulation	Growth stage at application	Number of applications	Application rate per treatment (kg as/ha)	PHI
SANCO/829/08-final rev.2, 12 July 2016 EFSA Journal 2011;9(1):1965	EU (N&S)	SL	Post-emergence until BBCH 16	1	0.360	- Period between treatment and harvest is > 100 days, no PHI is applicable
Intended GAP	PL (N)	SL	12-16	1	0.288	-

The EU GAP covers GAP proposed for CHR/H/DIK 480 SL.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.5 mg/kg for maize as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of dicamba 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 use on maize.

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

Analytical methods for the determination of residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- A primary and confirmatory method for the determination of dicamba in body fluids.

The identified data gap also applies to the active substance and should be supplemented at the stage of on-going re-evaluation of the substance. Dicamba is not classified as toxic or very toxic.

Section 8. Environmental Fate

In accordance with proposed pattern use of CHR/H/DIK 480 SL, all relevant information was submitted.

Section 9. Ecotoxicology

In accordance with proposed pattern use, risk assessment to non-target organisms for the formulation CHR/H/DIK 480 SL of was sufficient.

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of CHR/H/DIK 480 SL as herbicide in maize poses an acceptable risk to non-target organisms in application rate 0.6 L/ha zRMS.

Particular precautions to reduce the environmental concentrations resulting from CHR/H/DIK 480 SL applications are required for:

- non-target terrestrial plants

Section 10. Assessment of the relevance of metabolites in groundwater

No metabolites exceeded trigger value 0.1 µg/L, therefore the relevance assessment of the metabolites is not required.

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

1

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

None

Appendix 1 ALL intended uses

PPP (product name/code):	CHR/H/DIK 480 SL	Formulation type:	SL ^(a, b)
Active substance 1:	dicamba	Conc. of as 1:	480 g/L ^(c)
Active substance 2:	-	Conc. of as 2:	- ^(c)
Active substance 3:	-	Conc. of as 3:	- ^(c)
Safener:	-	Conc. of safener:	- ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	Innvigo Sp. z o.o.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	No		

Field of use: herbicide

[illegible]

[illegible]

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 I
- (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 ap-
plication
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