

# **REGISTRATION REPORT**

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: RBN 072 A

Product name(s): **MATLAM**

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

### **CORE ASSESSMENT**

(authorization)

Applicant: XXXX

Submission date: June 2024

Evaluation date: February 2025

MS Finalisation date: October 2025

## Version history

When	What
June 2024	Version submitted by the applicant
February 2025	Version evaluated by zRMS PL
October 2025	The amendment introduced by the evaluator, at the request of the MRiRW included in the email of Fri, 24 Oct 2025, of the submitted for the evaluation GAP, because in accordance with the Regulation of MRiRW of 18 September 2023 (JoL 2023, 2008) winter oats are not recognized as a minor crop in Poland.

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

This application is submitted by XXXX.

This application pursues the registration (Art. 33+34) of the herbicide Florasulam 50 g/L SC (MATLAM), which is a suspension concentrate containing 50 g/L of florasulam for use in winter and spring cereals.

~~The composition of the product is comparable to plant protection product Kantor 050 SC Dow AgroSciences.~~

#### **RMS conclusion on the composition equivalence to the Kantor 050 SC and Floras 50 SC.**

From physicochemical perspective MATLAM is not considered equivalent/ comparable to already registered Kantor 050 SC in Poland under Composition's comparison in accordance with Article 34 of Regulation 1107/2009. So, unprotected physicochemical data taken from Kantor 050 SC cannot be used to support Matlam registration in Poland.

From physicochemical perspective MATLAM is considered equivalent/ comparable to already registered Floras 50 SC in Poland under Composition's comparison. Applicant has provided the letter of access to the Floras 50 SC data .So, physicochemical data taken from Floras 50 SC can be used to support Matlam registration in Poland.

#### 0.1.1 Reason for application

This is an application for approval of Florasulam 50 SC (MATLAM) under Regulation (EC) No. 1107/2009.

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.

#### 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	

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Florasulam

**Table 0.1-2: Summary of regulatory history of CAS No: 145701-23-1**

Status	
Approved in EU	Y

<b>Status</b>	
Original Inclusion Directive or Commission Implementing Regulation	OMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011  COMMISSION IMPLEMENTING REGULATION (EU) 2015/1397 of 14 August 2015
RMS	CZ
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2016
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01.01.2016
Date of final Commission (re-registration) deadline (Step 2)	01.01.2016
Current expiration of approval	31.12.2030
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), the following 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 risk to aquatic organisms and non-target terrestrial plants.

The SANTE report for florasulam (SANTE/10542/2015 Rev 1 14.07.2015) 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 13 January 2015.

**Table 0.1-3: Information on minimum purity of florasulam**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equiv- alency report *, **
970 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

Identity, physical and chemical properties:

The two-year shelf life is accepted for the PPP.

#### Efficacy:

The evaluation of the application of Matlam (RNB 072 A) (florasulam – 50 g/L), resulted in a decision to grant the authorization for weed control in cereal crops. The authorization covers the post-emergence application of herbicide at the rate of 0.1 L/ha, at crop growth stages BBCH 13-32, for weeds control in winter and spring wheat, winter wheat spelt, winter and spring barley, winter and spring triticale, winter rye, spring oat. The tested product was selective for all tested crops, did not cause phytotoxicity, and had no impact on the yield and its quality, succeeding and adjacent crops. The unprotected data of Kantor 050 EC herbicide were used to support Matlam registration.

#### Toxicology and health risk:

The application of product MATLAM (formulation RNB 072 A) does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice even when operator is not wearing work wear covering arms, body and legs during mixing/loading and application.

The application of product MATLAM (formulation RNB 072 A) does not pose an unacceptable risk to the health of worker for its intended use within good agricultural practice even if the worker is not wearing a work clothing (long sleeved shirt, long trousers) during 2 hrs inspection. No unacceptable risk for residents and bystanders is identified when the product is used as intended.

#### Residues:

The data available are considered sufficient for risk assessment. An exceedance of the current MRL regarding intended uses for active substance as laid down in Reg. (EU) 2022/1363 is not expected. The chronic and the short-term intakes of active substances residues are unlikely to present a public health concern. The approval for the intended Matlam GAP can be granted.

#### Fate and behaviour:

The PEC<sub>GW</sub> values are below the trigger value of 0.1 µg/L for florasulam, 5-OH florasulam and DFP-ASTCA, for the proposed use pattern. Metabolites ASTCA and TSA are above the trigger value of 0.1 µg/L, but below the trigger value of 0.75 µg/L. The metabolites are not toxicologically relevant (please refer to dRR Part B10).

#### Ecotoxicology:

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

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

Uses: 1, 2, 5, 6, 7.

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:

None

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. 1.0, date: 2023-08

PPP (product name/code): MALTAM  
Active substance 1: Florasulam  
Safener: -  
Synergist: -  
Applicant: XXXX  
Zone(s): CEU  
Verified by MS: yes/no

Formulation type: SC <sup>(a, b)</sup>  
Conc. of as 1: 50 g/L <sup>(c)</sup>  
Conc. of safener: - <sup>(c)</sup>  
Conc. of synergist: - <sup>(c)</sup>  
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. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (i)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or 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 Winter spelt, Winter barley, Winter triticale, Winter rye	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring applica- tion)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200- 400	60	
2.	PL	Spring barley Spring wheat Spring triticale, Spring oat	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring applica- tion)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200- 400	55	



Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5	PL	Winter wheat durum	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60	
6	PL	Winter oat	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	60	
7	PL	Spring wheat durum	F	dicotyledonous weeds (TTTDS)	Broadcast spray	BBCH 12-33 (spring application)	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) 5.0 b) 5.0	200-400	55	
Minor uses according to Article 51 (interzonal uses)													
8													
9													

**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