

REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: FLORAS 50 SC

Product name(s): Floras 50 SC, HerbiFlo 50 SC

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Elvita Sp. z o.o.

Submission date: November 2023

MS Finalisation date: April 2024 (initial Core Assessment)

June 2024 (final Core Assessment)

Version history

When	What
November 2023	Initial dRR – Elvita Sp. z o.o.
April 2024	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck-through and shaded for transparency.
June 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the 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 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.

This dossier has been submitted in order to register new product. Data protection period for active substance Florasulam has been terminated therefore applicant shall be exempted from supplying the test and study in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Not relevant as the product has not yet been authorised in any zone.

Table 0.1-1: Overview of zRMS and cMS

Not relevant as the product has not yet been authorised.

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
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No. 540/2011
RMS	PL
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)	-
Date of final Commission (re-registration) deadline (Step 2)	-
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 shall pay particular attention to the risk to aquatic organisms and non-target terrestrial plants.

The SANCO report for Florasulam (SANTE/10542/2015) 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 14 July 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 equivalency report *, **
970 g/kg	970 g/kg Equivalence report available: Y RMS: BE

* 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

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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 column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

PPP (product name/code): Floras 50 SC
Active substance: Florasulam
Safener: No
Synergist: No
Applicant: Elvita Sp. z o.o.
Zone(s): Central
Verified by MS: no
Field of use: herbicide

Formulation type: SC
Conc. of as 1: 50 g/l
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

GAP rev. 21, date: April 2024 ~~2023-10-31~~

herbicide																					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. <small>※</small>	Member state(s)	Crop and/ or situa- tion (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I <small>※※</small>	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Re- marks: e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	Poland	Winter wheat	F	<i>Anthemis arvensis</i> , <i>Brachiaria nana</i> , <i>Bras- sica napus</i> , <i>Capsella bursa-pastoris</i> , <i>Des- curainia sophia</i> , <i>Fallo- pia convolvulus</i> , <i>Galium aparine</i> , <i>Tripleurosper- mum inodorum</i> , <i>Myoso- tis arvensis</i> , <i>Papaver rhoeas</i> , <i>Fallopia con- volvulus</i> , <i>Sinapis arven- sis</i> , <i>Stellaria media</i> , <i>Thlaspi arvense</i> , <i>Veron- ica persica</i> .	Foliar spraying; small drops	BBCH 12 20-32	1	-	a) 0.1	Florasulam: 5.0 500	200 -400	-	Herbi- cide for use with field sprayers	A	A	A	A	A	R NTTP, Aquatic: (R1, R3* scenarios)	A	A
																			A Remained species		

2	Poland	Spring barley	F	<i>Anthemis arvensis</i> , <i>Amaranthus retroflexus</i> , <i>Brassica napus</i> , <i>Capsella bursa-pastoris</i> , <i>Chenopodium album</i> , <i>Descurainia sophia</i> , <i>Fallopia convolvulus</i> , <i>Galeopsis tetrahit</i> , <i>Galium aparine</i> , <i>Ga- linsoga parviflora</i> , <i>Tripleurospermum inodorum</i> , <i>Silene latifo- lia subsp. Alba</i> , <i>Myoso- tis arvensis</i> , <i>Polygonum aviculare</i> , <i>Fallopia convolvulus</i> , <i>Persicaria maeulosa</i> , <i>Sinapis arvensis</i> , <i>Stellaria media</i> , <i>Thlaspi arvense</i> , <i>Veronica persica</i> .	Foliar spraying; small drops	BBCH 12-32	1	-	a) 0.1	Florasulam: 5.0	200 -400	-	Herbi- cide for use with field sprayers	A	A	A	A	A	R NTTP, Aquatic: (R1, R3* scenarios)	A	A
																		A Remained species			

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

* not relevant scenario for PL

**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.

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

- 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
- 15 Overall conclusions - explanation for the column 15 is below *