

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: **MEZOFLOR 103 SC**

Product names: **MEZOFLOR 103 SC / FLOCORN 103 SC**

Chemical active substances:

Mesotrione, 100 g/L

Florasulam, 3 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o. o.**

Submission date: 07/2023

MS Finalisation date: 10/2024, 12/2024

Version history

When	What
07/2023	Initial dRR
10/2024	zRMS assessment of dRR
12/2024	The final Registration Report

Table of Contents

0	Product background, regulatory context and GAP information	4
0.1	Introduction.....	4
0.1.1	Reason for application	4
0.1.2	Details of zRMS(s) and concerned MS	4
0.1.3	Regulatory history of the active(s).....	4
0.1.3.1	Mesotrione	4
0.1.3.2	Florasulam.....	5
0.1.4	Regulatory history of the product	6
0.2	zRMS conclusion	6
Appendix 1	ALL intended uses	8

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.

On 13 June 2020 data protection period for existing active substance **Florasulam** has been terminated. On 01 June 2017 **Mesotrione** has been renewed. Relevant letter of access to protected data is enclosed to the dossier. For data which have already been assessed during previous approval and are still valid exemption in accordance with Article 34 of Regulation (EC) No. 1107/2009 shall be used.

0.1.2 Details of zRMS(s) and concerned MS

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

0.1.3 Regulatory history of the active(s)

0.1.3.1 Mesotrione

Table 0.1-1: Summary of regulatory history of CAS No: 104206- 82-8

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Directive 2003/68/EC of 16.07.2003
RMS	BE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2017
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	31.05.2032
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:
Not relevant.

The SANTE report for mesotrione (SANTE/11654/2016 23 March 2017) 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 07 March 2016.

Table 0.1-2: Information on minimum purity of mesotrione

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 *, **
920 g/kg	For minimum purity of active substance see part C For details regarding specification of the active substance see also in 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.

0.1.3.2 Florasulam

Table 0.1-3: Summary of regulatory history of CAS No: 145701- 23-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Directive 2002/64/EC of 18 July 2002
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 must pay particular attention to:

should pay particular attention to the potential for ground water contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.

The SANTE report for florasulam (SANTE/10542/2015 14 July 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 0.1-4: 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	For minimum purity of active substance see part C For details regarding specification of the active substance see also in 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

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

Mammalian toxicology: 1
Residues section: 1
Environmental fate and behavior section:
Ecotoxicology section: 1 for PL
Efficacy section: 1

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

Mammalian toxicology: none
Residues section: none
Environmental fate and behavior section: none
Ecotoxicology section: none for PL
Efficacy section: none

Conclusions:

Physical and chemical properties:

No data gaps. The phrases “Mix well before use” and “Store below 30°C” should be included in the label.

Mammalian toxicology:

Classification of the product: Repr. 2 – H361d

PPE / Risk mitigation measures:

Operator: protective gloves, protective clothing during mixing/loading and application.

Worker: protective gloves and work wear.

Bystander/resident: warning boards preventing from resident/bystander entry into treated area are installed and re-main till the end of cultivation, min. 5-meter buffer zone is kept during spraying, drift-

reduction nozzles are used.

Metabolism and residues: uses are accepted.

Environmental fate and behaviour: No data gaps.

Efficacy section: All uses were accepted. Only list of accepted weed species was modified for recommended dose 1.0 L/ha and 1.25 l/ha.

Ecotoxicology section:

Use is accepted for PL. The refinement risk assessment for mammals should be considered by MSs level.

MEZOFLOR 103 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone:

-4 m buffer non-spray zone with 4 meter vegetated filter strip.

To protect non-target plants respect an unsprayed buffer zone of 5 m buffer zone and 75 % drift reduction nozzle to non-agricultural land or 10 m buffer zone and 50 % drift reduction nozzle or 15 m buffer zone to non-agricultural land.

The studies for formulation of **MEZOFLOR 103 SC** for earthworms and *Folsomia candida* and *Hyposaspis aculeifer* with risk assessment was accepted by zRMS only provisionally. The Applicant should complete the calculation the toxicity endpoints based on geometric mean measured concentration with risk assessment.

The risk assessment for soil organisms should be considered by MSs level.

Identity section: The evaluators also verified whether the co-formulants contained in plant protection product MEZOFLOR 103 SC are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by the applicant or manufacturer of the co-formulant, the product MEZOFLOR 103 SC does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information, none of the co-formulants in the plant protection product MEZOFLOR 103 SC meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C and annex to Part C of this submission (section 1.2.2).

Appendix 1 ALL intended uses

GAP rev., date: 07/2023

PPP (product name/code): MEZOFLO103 SC, FLOCO 103 SC/ MEZOFLO 103 SC
Active substance 1: Mesotrion
Active substance 2: Florasulam
Applicant: Synthos Agro Sp. z o.o.
Zone: central ^(d)
Verified by MS: -
Field of use: Herbicide

Formulation type: SC
Conc. of as 1: 100 g/l
Conc. of as 2: 3 g/l
Professional use: yes ☒
Non professional use: no ☐

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, 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 ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		

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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergis- t per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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	Maize	F	susceptible weeds: <i>Capsella bursa-pastoris</i> <i>Galinsoga parviflora</i> <i>Thlaspi arense</i> <i>Matricaria chamomilla</i> <i>Matricaria maritima</i> <i>Anthemis arvensis</i> <i>Viola arvensis</i> <i>Centaurea cyanus</i> <i>Stellaria media</i> <i>Geranium pusillum</i> <i>Polygonum convolvulus</i> <i>Brassica napus</i> <i>Persicaria maculosa</i> moderate susceptible weeds: <i>Chenopodium album</i> <i>Echinochloa crus-galli</i> <i>Galium aparine</i> <i>Solanum nigrum</i> <i>Capsella bursa-pastoris</i> <i>Galinsoga parviflora</i> <i>Thlaspi arense</i> <i>Matricaria chamomilla</i> <i>Matricaria maritima</i> <i>Anthemis arvensis</i> <i>Viola arvensis</i> <i>Centaurea cyanus</i> <i>Stellaria media</i> <i>Geranium pusillum</i>	Foliar spraying	BBCH 12-18	1	N/A	1.0 L/ha	Mesotrione 100 g as/ha Florasulam 3.00 g as/ha	200- 300 L/ha	Not relevant	

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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergis- per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
				<i>Polygonum convolvulus</i> <i>Brassica napus</i> <i>Persicaria maculosa</i> <i>Amaranthus retroflexus</i> <i>Anchusa arvensis</i> Medium resistance: <i>Echinochloa crus-galli</i>									
				susceptible weeds: <i>Chenopodium album</i> , <i>Galium aparine</i> <i>Solanum nigrum</i> <i>Capsella bursa-pastoris</i> <i>Galinsoga parviflora</i> <i>Thlaspi arense</i> <i>Matricaria chamomilla</i> <i>Matricaria martima</i> <i>Anthemis arvensis</i> <i>Viola arvensis</i> <i>Stellaria media</i> <i>Geranium pusillum</i> <i>Polygonum convolvulus</i> <i>Brassica napus</i> <i>Persicaria maculosa</i> <i>Amaranthus retroflexus</i> <i>Anchusa arvensis</i> moderate susceptible weeds: <i>Echinochloa crus-galli</i> <i>Galium aparine</i> <i>Solanum nigrum</i>	Foliar spraying	BBCH 12-18	1	-	1.25 L/ha Mesotrione 125 g as/ha Florasulam 3.75 g as/ha	200- 300 L/ha	Not relevant		

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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (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		
				Capsella bursa-pastoris Galinsoga parviflora Thlaspi areense Matricaria chamomilla Matricaria maritima Anthemis arvensis Viola arvensis Centaurea cyanus Stellaria media Geranium pusillum Polygonum convolvulus Brassica napus									

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