

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: **ORKAN 350 SL**

Product names: **ORKAN 350 SL, SPRINTER 350 SL**

Chemical active substance(s):

MCPA, 90 g/L

Glyphosate, 260 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(renewal of authorisation)

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

Submission date: **04.2020**

Finalisation date: 09.2020; 11.2021

Version history

When	What
04/2020	Submission date
09/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

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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 renew an authorisation according to article 43 of Regulation (EC) No. 1107/2009.

On 16 December 2017 **Glyphosate** 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.

On 1 May 2011 data protection period for existing active substance **MCPA** has been terminated. Taking into account above applicant shall be exempted from supplying the test and study for MCPA in accordance with Article 34 of Regulation (EC) No. 1107/2009.

0.1.2 Details of zRMS(s) and concerned MS

Product has been authorized only in Poland.

Table 0.1-1: Overview of zRMS and cMS

Product has been authorized only in Poland.

0.1.3 Regulatory history of the active(s)

0.1.3.1 Glyphosate

Table 0.1-2: Summary of regulatory history of CAS No: 1071-83-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	DE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	16/12/2017
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)	-

Status	
Current expiration of approval	15.12.2022
Low risk substance or Candidate for Substitution?	No

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 protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses.

The SANTE report for Glyphosate (SANTE/10441/2017 Rev 2; 9 November 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 12 November 2015.

Table 0.1-3: Information on minimum purity of Glyphosate

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 *, **
950 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 MCPA

Table 0.1-4: Summary of regulatory history of CAS No: 94-74-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011
RMS	IT
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.05.2006
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	31.10.2020
Low risk substance or Candidate for Substitution?	No

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:

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

- to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.

The SANCO report for MCPA (SANCO/4062/2001-finl/10441; 11 July 2011) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-5: Information on minimum purity of MCPA

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 *, **
930 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

Product has been authorised in Poland under three commercial names:

Orkan 350 SL Authorisation number R- 88/2012 from 26 June 2012 with further amendments

Sprinter 350 SL R -142/2017 from 19 July 2017

Rayder 350 SL R - 79/2018 from 13 April 2018

0.2 zRMS conclusion

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

Section Residues: 1,2,4

Efficacy section: 1,2,4 with some restrictions presented in the GAP table

Fate & behaviour: 1-5

Ecotoxicology: 2, 4 and 1,3, 5 - at application rates 5-7 L/ha

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

Section Residues: 3, 5

Efficacy section: 3 (only pear could be accepted on the basis on previous registration with some restrictions presented in B3 dRR), 5

Ecotoxicology: Uses 1, 3, 5 at the application rate 8 L/ha are considered non-safe on the basis of EU methodology.

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:

Residue section: Uses on apples and cherries are covered by established MRLs.

Effects on terrestrial vertebrates other than birds – higher tier risk assessment need to be confirmed

Phys-chem section:

The Applicant provided data on the physico-chemical properties and validation of the analytical method for the analysis of the content of relevant impurities. The data and validation has been accepted.

Efficacy section:

Re-registered product should be similar to previous registration. If Applicant wish to change uses, he should submit a request for extension and the evaluation of the report should take place in accordance with Article 45. The Evaluator seen some discrepancies between the presented GAP table and the label design. The difference concerns cherries, which in the GAP are classified as small area crops and treated in accordance with the ART. 51 (no tests required). Considering the fact that during the first registration, cherries were included for the application of plant protection product in minor crops and applications, now are included in the proposed GAP table as minor uses according to Article 51, they should be classified in accordance with earlier registered label (R-133/2016d, dated: 01.03.2016) and the GAP table accepted. Hazelnuts, walnuts, nectarine, quince, medlar cannot be accepted according to Article 43. Those minor crops were not included in the label after first registration. If the applicant wishes to expand the label, a request to the Ministry of Agriculture and Rural Development for extend the use of the product should be made.

In the expert's opinion, on the basis of Article 43, no significant changes can be made to the label and GAP table in comparison with the earlier registration. Therefore, the classification of weed sensitivity should not be changed with a division into 3 doses: 5 l/ha, 7 l/ha and 8/ha instead of 2 doses: 5 l/ha and 7-8 l/ha (in line with the previous registration) Such changes should be made in the re-expansion mode of the registration, especially with the addition of two new weed species to the label.

Toxicology section:

ORKAN 350 SL is classified as Eye Irrit.2/H319. No risk for operator and worker (with PPE) and bystander/resident.

Residues section:

Uses on apples and cherries are accepted. Uses on pear, quince, medlar, peaches, nectarines, plums, apricot and nuts are not accepted.

Noticed data gaps are:

MCPA

One additional trial on apple is required.

Fate & behaviour:

In accordance with proposed pattern use, an exposure assessment for the formulation of ORKAN 350 SL was submitted and sufficient.

Ecotoxicology: In accordance with proposed pattern use, risk assessment to non-target organisms for the formulation of ORKAN 350 SL was sufficient.

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of ORKAN 350 SL as herbicide in orchards poses an acceptable risk to non-target organisms (uses 1-5) with the exception of use 1,3,5 in application rate 8 L/ha.

Precautions to reduce the environmental concentrations resulting from ORKAN 350 SL applications are required for:

- aquatic organisms
- non-target terrestrial plants.

Appendix 1 ALL intended uses

GAP rev.2, date: 11.2021

PPP (product name/code): ORKAN 350 SL, SPRINTER 350 SL,/ ORKAN 350 SL
Active substance 1: glyphosate
Active substance 2: MCPA
Applicant: Synthos Agro sp. z o.o.
Zone(s): central

Formulation type: Soluble (liquid) concentrate (SL)
Conc. of as 1: 260 g/l
Conc. of as 2: 90 g/l
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. ^(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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Poland	Apple	F	susceptible weeds in dose 5,0 l/ha: <i>Senecio vulgaris</i> <i>Stellaria media</i> <i>Capsella-bursa-pastoris</i> <i>Galium aparine</i> <i>Poa annua</i> <i>Echinochloa crus-galli</i> <i>Chenopodium album</i> susceptible weeds in dose 7,0 – 8 l/ha l/ha: <i>Chenopodium album</i> <i>Geranium pusillum</i>	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7,0 8,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8L/ha: 0,63- 0,72 kg/ha (MCPA) 1,82- 2,08 kg/ha (glyphosate)	300 L/ha	n.a 7 days	At first registration was: 7-8 l/ha, not separately the weed classification for 7 and 8 l/ha. We can't take into account weeds that were not taken into account during the first registration (<i>Galium aparine</i> , <i>Lamium purpureum</i>)

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		
				<i>Convolvulus arvensis</i> Po- lygonum aviculare Malva neglecta susceptible weeds in dose 8,0 l/ha: Taraxacum officinale Epilobium ciliatum Lamium purpureum Elymus repens Equisetum arvense									Use for 8L/ha can not be granted on the basis of the evaluation in the section B9
Minor uses according to Article 51 (zonal uses)													
2	Poland	Cherry	F	susceptible weeds in dose 5,0 l/ha: Senecio vulgaris Stellaria media Poa annua Vicia cracca Chenopodium album susceptible weeds in dose 7,0 8,0 l/ha: Taraxacum officinale Epilobium ciliatum	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 8,0 7,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8 L/ha: 0,63 0,72 kg/ha (MCPA) 1,82 2,08 kg/ha (glyphosate)	300 L/ha	n.a. 7 days.	Acceptable with further restrictions. At first registration dose 5-8 l/ha was registered, not 5-7 l/ha.
3	Poland	Pear, quince, medlar	F	susceptible weeds in dose 5,0 l/ha: Senecio vulgaris Stellaria media Capsella bursa-pastoris Galium aparine Poa annua Echinochloa crus-galli susceptible weeds in dose 7,0 l/ha: Chenopodium album Geranium pusillum Convolvulus arvensis Po- lygonum aviculare	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0-8,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8L/ha: 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	300 L/ha	n.a.	Not accepted

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		
				<i>Malva neglecta</i> susceptible weeds in dose 8,0 l/ha: <i>Taraxacum officinale</i> <i>Epilobium ciliatum</i> <i>Lamium purpureum</i> <i>Elymus repens</i> <i>Equisetum arvense</i>									
4	Poland	Sweet cherry, plum, peach, apricot, nectarine	F	susceptible weeds in dose 5,0 l/ha: <i>Senecio vulgaris</i> <i>Stellaria media</i> <i>Poa annua</i> <i>Vicia cracca</i> <i>Chenopodium album</i> susceptible weeds in dose 7,0 8,0 l/ha: <i>Taraxacum officinale</i> <i>Epilobium ciliatum</i>	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 8,0 7,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7 8,0 L/ha: 0,63 0,72 kg/ha (MCPA) 1,82 2,08 kg/ha (glyphosate)	300 L/ha	a 7 days.	Plum, peach, apricot, nectarine: not accepted Dose 5-8 l/ha was previous registered, not 5-7 l/ha.
5	Poland	Hazelnuts, Walnuts	F	susceptible weeds in dose 5,0 l/ha: <i>Senecio vulgaris</i> <i>Stellaria media</i> <i>Capsella bursa-pastoris</i> <i>Galium aparine</i> <i>Poa annua</i> <i>Echinochloa crus-galli</i> susceptible weeds in dose 7,0 l/ha: <i>Chenopodium album</i> <i>Geranium pusillum</i> <i>Convolvulus arvensis</i> <i>Polygonum aviculare</i> <i>Malva neglecta</i> susceptible weeds in dose	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 8,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8L/ha: 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	300 L/ha	n.a.	Not accepted

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		
				8,0 L/ha: <i>Taraxacum officinale</i> <i>Epilobium ciliatum</i> <i>Lamium purpureum</i> <i>Elymus repens</i> <i>Equisetum arvense</i>									

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