

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: MIEDZIAN EXTRA 350 SC

Product names: **MIEDZIAN EXTRA 350 SC,**
~~COBRESAL EXTRA 350 SC, KARES 350 SC~~

Chemical active substance:

Copper as a copper oxychloride, 350 g/l

Central

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(re-authorization according art. 43 and art. 51, Reg. 1107/2009)

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

Submission date: **07/2020**

MS Finalisation date: **02/2022, 08/2022 03/2023**

Version history

When	What
02/2022	GAP revision submitted by the applicant
02/2022	ZRMs evaluated version of dRR submitted by Applicant.
08/2022	The Final RR
03/2023	Eff. section made correction in GAP according to comments from MRiRW

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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 and article 51 of Regulation (EC) No. 1107/2009.

On 01 January 2019 **Copper compounds including copper oxychloride** have 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

Product has been authorized only in Poland.

0.1.3 Regulatory history of the active(s)

0.1.3.1 Copper oxychloride

Table 0.1-1: Summary of regulatory history of CAS No: 1332-65-6 or 1332-40-7

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018
RMS	FR
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2019
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	31.12.2025
Low risk substance or Candidate for Substitution?	CfS

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 operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate;
- the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate;
- the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, do not exceed the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment taking into account background levels of copper at the application site, and, where the information is available, copper input from other sources. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of copper.

The SANCO report for copper compounds (SANTE/10506/2018 Rev. 5 –27/11/2008) 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 16 January 2018.

Table 0.1-2: Information on minimum purity of copper oxychloride

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 *, **
550 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

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-3: Summary of regulatory history of the product Miedzian ~~50 WP~~ Extra 350 SC

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
Miedzian Extra 350 SC	Miedzian Extra 350 SC	PL	MRiRW nr R-135/2015 from 03.09.2015 Last changed by MRiRW nr R - 727/2019d from 07.10.2019	03.09.2015	-
Miedzian Extra 350 SC	Cobresal Extra 350 SC	PL	MRiRW nr R-185/2015 from 28.10.2015	28.10.2015	-
Miedzian Extra 350 SC	Kares 350 SC	PL	MRiRW nr R-20/2018 from 02.02.2018	10.10.2017	-

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology: 1-3, 5-23, 25-24

Uses to be considered non-safe on the basis of EU methodology: 4, 24 25

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: The risk mitigation measures for aquatic organism and bees.

All accepted uses / GAPs are covered by established MRLs

zRMS main conclusions:

Physical and chemical properties section:

No data gaps.

In the Commission Implementing Regulation (EU) 2018/1981, 8 metals appear as relevant impurities for all copper compounds. However, in the Final Renewal report for the a.s. copper compounds (SAN-TE/10506/2018), only 3 metals (Cd, As, Pb) appear as relevant impurities for copper oxychloride. This implies an inconsistency in the conclusions of the evaluation of the active substance and should be noticed. This implies an inconsistency in the conclusions of the evaluation of the active substance and should be noticed. Zonal RMS assessment has been made considering only As, Cd and Pb.

Analytical methods section

No data gaps.

Efficacy section:

The data presented in this dossier fully support the renewal under Article 43 of Miedzian Extra 350 SC for the control of fungicide diseases in apple, pear, cherry and sweet cherry in Poland. Tomato (outdoor), cucumber (outdoor), and French bean could also be registered in the main part of label (according to previous registration of product). Peach can be accepted as minor crop according to Article 51 (dose was changed by Applicant compared to previous registration, which is not accepted in the case of lack efficacy trials). Many minor uses according to Article 51 (grapevine, black-currant, walnut, hazelnut, quince, apricot, plum, peach, protected tomato, aubergine (indoor and open field), cucumber (indoor), gherkin, zucchini, melon (indoor), pumpkin (indoor), watermelon (indoor), and pea and pod beans) can be accepted.

Toxicology section:

Classification of MIEDZIAN EXTRA 350 SC: Acute Tox. 4/ H302; Acute Tox. 4/ H332; Skin Sens. 1/ H317; Eye Irrit. 2/ H319.

No unacceptable risks have been identified for professional operators and workers when the product is used as intended and provided that personal protective equipment / risk mitigation measures as specified in Part B6 are applied. No unacceptable risk for amateur operators, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk was found for the resident / bystander at the 2-3 m buffer.

Metabolism and residues section:

Use No 24 is not accepted

Appendix 1 ALL intended uses - re-authorization according art. 43, Reg. 1107/2009

2.6.2. Intended uses (only NATIONAL GAP) - re-authorization according art. 43, Reg. 1107/2009

GAP rev.3, date: 02.2022

PPP (product name/code): MIEDZIAN EXTRA 350 SC
Active substance 1: Copper oxychloride
Applicant: Synthos Agro Sp. z.o.o.
Zone(s): Central
Field of use: fungicide

Formulation type: Suspension Concentrate (SC)
Conc. of as 1: 23,77% (350 g Cu/l)
Professional use: ☒
Non professional use: ☒

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/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	PL	Apple	Fpn	Venturia inaequalis	spraying	BBCH 00-07	a)1 b)2	7-10	a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	n.a.	
2	PL	Pear	Fpn	Venturia inaequalis Erwinia amylovora	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	7-14	B7
3	PL	Cherry, sweet cherry	Fpn	Pseudomonas syringae	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	14	
4	PL	Peach	Fpn	Taphrina deformans	Spraying	BBCH 00-03	1	-	3,0	1,05 kg Cu/ha	700	n.a.	Efficacy section: only as minor crop according to Article 51 can be accepted.
Minor uses according to Article 51 (zonal uses)													
5	PL	Quince	Fpn	Venturia inaequalis Erwinia amylovora	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	7- 14	B7: Accepted PHI: 14
6	PL	Medlar	Fpn	Venturia inaequalis Erwinia amylovora	spraying	BBCH 00-07 BBCH 60-71	a)1 b)2 a)1 b)2	7-10 7-10	a)1,5 b)3,0 a)1,5 b)3,0	a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	7- 14	B7 Accepted PHI: 14
5	PL	Cherry, sweet cherry	Fpn	Pseudomonas syringae	Spraying	BBCH 51	1	7-10	a) 3	a) 1,05 kg Cu/ha	500	14	

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/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		
						BBCH 60	2		b)3 a)1,5 b)3	b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	750		
7	PL	Apricot	Fpn	<i>Pseudomonas syringae</i>	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	14	
8	PL	Plum	Fpn	<i>Pseudomonas syringae</i>	Spraying	BBCH 51 BBCH 60	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,05 kg Cu/ha b)1,05 kg Cu/ha a) 0,525 kg Cu/ha b) 1,05 kg Cu/ha	500- 750	14	
8-9	PL	Peach	Fpn	<i>Taphrina deformans</i>	Spraying	BBCH 00-03	1	1	3,0	1,05 kg Cu/ha	700	n.a.	
9 10	PL	Walnut	Fpn	<i>Gnomonia leptostyla</i> , <i>Xantomonas campestris</i> pv. <i>Juglandis</i> ,	Spraying	Before flower- ing	2 1	10-14	a)3 b)6	a)1,05kg Cu/ha b)2,10 kg Cu/ha	800- 1000	n.a.	B7: Accepted: 1 application
10 11	PL	Hazelnut	Fpn	<i>Gnomonia leptostyla</i> , <i>Xanthomonas arboricola</i> pv. <i>corylina</i>	Spraying	Before flower- ing	2 1	10-14	a)3 b)6	a)1,05kg Cu/ha b)2,10 kg Cu/ha	800- 1000	n.a.	B7 Accepted: 1 application

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/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		
11-12	PL	Tomato (outdoor)	Fpn	<i>Pseudomonas syringae</i> pv. <i>Tomato</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 51-85	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	B7 only in Poland as minor use Efficacy section: Tomato (outdoor) should be accept- ed as zonal use, not according to Article 51
12-13	PL	Tomato (indoor)	I	<i>Pseudomonas syringae</i> pv. <i>Tomato</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 56-88	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200- 1000	3	
13-14	PL	Aubergines (out- door)	Fpn	<i>Pseudomonas syringae</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 51-85	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	B7 only in Poland as minor use
14-15	PL	Aubergines (indoor)	I	<i>Pseudomonas syringae</i> pv. <i>Tomato</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 56-88	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200- 1000	3	
15-16	PL	Cucumber (outdoor)	Fpn	<i>Pseudomonas syringae</i> pv. <i>Lachrymans</i> , <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 62-78	3	7-10	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	3	Efficacy section: Cucumber (out- door should be accepted as zonal use, not accord- ing to Article 51
16-17	PL	Cucumber (indoor)	I	<i>Pseudomonas syringae</i> pv. <i>Lachrymans</i> , <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 10-89	4	7	a) 2.3 b) 9.2	a) 0.800kg Cu/ha b)3,20 kg Cu/ha	200- 1500	3	B7 only in Poland as minor use
17-18	PL	Gherkins	Fpn	<i>Pseudomonas syringae</i> pv.	Spraying	BBCH 62-78	3	7-10	a)2,5	a)0,875kg Cu/ha	700	7	

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/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>Lachrymans,</i> <i>Pseudoperonospora cubensis</i>					b)7,5	b)2,625 kg Cu/ha			
18 19	PL	Courgette	Fpn	<i>Pseudomonas syringae</i> pv. <i>Lachrymans,</i> <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 62-78	3	7-10	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	
19 20	PL	Melon (indoor)	I	<i>Pseudoperonospora cubensis</i> <i>Alternaria spp Colletotrichum</i> <i>orbiculare</i> <i>Bacterial diseases</i>	Spraying	BBCH 10-89	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200- 1500	7	B7 only in Poland as minor use
20 21	PL	Pumpkins (indoor)	I	<i>Pseudoperonospora cubensis</i> <i>Alternaria spp Colletotrichum</i> <i>orbiculare</i> <i>Bacterial diseases</i>	Spraying	BBCH 10-89	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200- 1500	7	B7 only in Poland as minor use
24 22	PL	Watermelon (indoor)	I	<i>Pseudoperonospora cubensis</i> <i>Alternaria spp Colletotrichum</i> <i>orbiculare</i> <i>Bacterial diseases</i>	Spraying	BBCH 10-89	3	7	a)3.6 b)10.8	a)1.25 kg Cu/ha b)3.75 kg Cu/ha	200- 1500	7	B7 only in Poland as minor use
22 23	PL	French bean, bean with pods	Fpn	<i>Pseudomonas syringae</i> pv. <i>Phaseolicola,</i> <i>Colletotrichum lindemuthi-</i> <i>anum,</i> <i>Botritis cinerea</i>	Spraying	BBCH 65-69	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	Efficacy section: French bean should be accept- ed as zonal use, not according to Article 51
23 24	PL	Peas with pods	Fpn	<i>Pseudomonas syringae</i> pv. <i>Phaseolicola,</i> <i>Colletotrichum lindemuthi-</i> <i>anum,</i> <i>Botritis cinerea</i>	Spraying	BBCH 65-69	3	7	a)2,5 b)7,5	a)0,875kg Cu/ha b)2,625 kg Cu/ha	700	7	
24 25	PL	Grape (table, wine)	Fpn	<i>Plasmopara viticola</i>	Spraying	BBCH 13-17, 71-73, 73-77	3	10	a)3,0 b)9,0	a)1,05kg Cu/ha b)3,15 kg Cu/ha	500- 900	21	Metabolism and residues section:

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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/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		
													Use No 24 is not accepted
25 26	PL	Currant	Fpn	<i>Drepanopeziza ribis</i> , <i>Mycosphaerella ribis</i> <i>Cronartium ribicola</i> ,	Spraying	BBCH 59-65 BBCH 65–81	2	10	a)3,0 b)6,0	a)1,05kg Cu/ha b)2,1kg Cu/ha	700	7	B7: Accepted BBCH: 59-65

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

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.

(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.

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