

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: MIEDZIAN 50 WP

Product names: **MIEDZIAN 50 WP,**

~~COBRESAL 50 WP, DALION 50 WP, SPATOR 50 WP~~

Chemical active substance:

Copper as a copper oxychloride, 500 g/kg

Central Zone

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
12/2021	Addition of information about new studies in Section B1, 2-4 and B7.
02/2022	GAP revision.
02/2022	Assessment by the experts
08/2022	The Final RR
03/2023	Final RR after correction in GAP

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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

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
Miedzian 50 WP	Miedzian 50 WP	PL	MRiRW nr R-134/2015 from 03.09.2015 Last changed by MRiRW nr R - 621/2019d from 29.08.2019	03.09.2015	-
Miedzian 50 WP	Cobresal 50 WP	PL	MRiRW nr R-186/2015 from 28.10.2015	28.10.2015	-
Miedzian 50 WP	Dalion 50 WP	PL	MRiRW nr R-200/2017 from 10.10.2017	10.10.2017	-
Miedzian 50 WP	Spator 50 WP	PL	MRiRW nr R-	10.10.2017	-

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
			201/2017 from 10.10.2017		

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology: 1, 2, 4-22, 23, ~~24-25~~

Uses to be considered non-safe on the basis of EU methodology: 3, ~~23~~ 24

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 may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Efficacy section:

The following crops were approved in the main part of the label: apple, pear, cherry, sweet cherry, tomato in field, cucumber in field and green bean, and in the part dedicated to minor crops (registration without studies under Art. 51): grapevine, blackcurrant, walnut, hazelnut, cherry, quince, common cherry, 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. For professional use on apple, pear and cherry and sweet cherry trees, the LWA rate was proposed

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.

Metabolism and Residues section:

See remarks in GAP table

Toxicology section:

Classcation MIEDZIAN 50 WP: Acute Tox.4/H302.

In the case of professional use, it can be concluded that the risk for the operator using COPPER 50 WP is acceptable when using personal protective equipment. When using a hand-held knapsack sprayer, operator exposure is acceptable when personal protective gloves, work clothes (covered arms, body and legs), head and respiratory protection equipment (FP1, P1 and similar) are used during mixing / loading and application. For non-professional use with a home garden sprayer, it can be concluded that the risk for the operator using COPPER 50 WP is acceptable even in the absence of personal protective equipment.

It can be concluded that the risk for the worker is acceptable when using personal protective equipment

(gloves). Estimating the exposure of bystanders / residents indicates an acceptable risk of exposure for this population group when using a 2-3 m buffer zone.

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

PPP (product name/code): MIEDZIAN 50 WP Formulation type: Wettable powder (WP)
 Active substance 1: copper oxychloride Conc. of as 1: 50% (500g Cu/kg)
 Applicant: Synthos Agro Sp. z o.o. Professional use: ☒
 Zone(s): central Non professional use: ☒
 Field of use: fungicide

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 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	PL	Apple, pear	Fpn	<i>Venturia inaequalis</i> <i>Erwinia amylovora</i>	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	14	
2	PL	Cherry, sweet cherry	Fpn	<i>Pseudomonas syringae</i>	Spraying	BBCH 51-61 BBCH 65-73	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,5 kg Cu/ha b)1,5 kg Cu/ha a)0,75kg Cu/ha, b) 1,5 kg Cu/ha	500-750	14	
3	PL	Peach	Fpn	<i>Taphrina deformans</i>	Spraying	BBCH 00-03	1	-	3,0	1,5 kg Cu/ha	700	n.a.	Efficacy section: only according to Article 51 as a minor crop can be accepted.
Minor uses according to Article 51 (zonal uses)													
4	PL	Quince	Fpn	<i>Venturia inaequalis</i> <i>Erwinia amylovora</i>	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	14	
5	PL	Medlar	Fpn	<i>Venturia inaequalis</i> <i>Erwinia amylovora</i>	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10	a)1,5 b)6,0	a) 0,75kg Cu/ha b) 3kg Cu/ha	500-750	14	
4	PL	Cherry, sweet cherry	Fpn	<i>Pseudomonas syringae</i>	Spraying	BBCH 51-61 BBCH 65-73	1 2	7-10	a) 3 b)3 a)1,5 b)3	a) 1,5 kg Cu/ha b)1,5 kg Cu/ha a)0,75kg Cu/ha, b) 1,5 kg Cu/ha	500-750	14	
6	PL	Apricot	Fpn	<i>Pseudomonas syringae</i>	Spraying	BBCH 51-61	1	-	a) 3 b)3	a)1,5 kg Cu/ha b)1,5 kg Cu/ha	500-750	n.a. 14	Metabolism and residues: accepted 14 PHI
7	PL	Plum	Fpn	<i>Pseudomonas syringae</i>	Spraying	BBCH 51-61	1	-	a) 3 b)3	a)1,5 kg Cu/ha b)1,5 kg Cu/ha	500-750	n.a. 14	Metabolism and residues: accepted 14 PHI
7 8	PL	Peach	Fpn	<i>Taphrina deformans</i>	Spraying	BBCH 00-03	1	-	6,0	3,0 kg Cu/ha	700	14	Eff. Peach is accepted only as a minor crop
8 9	PL	Walnut	Fpn	<i>Gnomonia leptostyla</i> , <i>Xantomonas campestris</i> pv. <i>Juglandis</i> ,	Spraying	Before flowering	2 1	10-14	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	800-1000	14	Metabolism and residues: 1 application is accepted
9 10	PL	Hazelnut	Fpn	<i>Gnomonia leptostyla</i> , <i>Xanthomonas arboricola</i> pv. <i>corylina</i>	Spraying	Before flowering	2 1	10-14	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	800-1000	14	B7: 1 application is accepted

10 11	PL	Tomato (outdoor)	Fpn	<i>Pseudomonas syringae</i> pv. <i>Tomato</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 51-85	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7	B7: Accepted only as minor use. Central Zone 4 additional trials on tomato are required Efficacy section: Tomato (outdoor) should be accepted as zonal use, not according to Article 51
11 12	PL	Tomato (indoor)	I	<i>Pseudomonas syringae</i> pv. <i>Tomato</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 56-88	3	7-10	a)3 b)9	a)1,5kg Cu/ha b)4,5 kg Cu/ha	1500-2000	3	
12 13	PL	Aubergines (outdoor)	Fpn	<i>Pseudomonas syringae</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 51-85	3	7-10	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7	B7:Accepted only as minor use. Central Zone 4 additional trials are required
13 14	PL	Aubergines (indoor)	I	<i>Pseudomonas syringae</i> pv. <i>Tomato</i> , <i>Phytophthora infestans</i>	Spraying	BBCH 56-88	3	7-10	a)3 b)9	a)1,5kg Cu/ha b)4,5 kg Cu/ha	1500-2000	3	
14 15	PL	Cucumber (outdoor)	Fpn	<i>Pseudomonas syringae</i> pv. <i>Lachrymans</i> , <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	700	7	B7:Accepted only as minor use. Central Zone 4 additional trials are required Efficacy section: Cucumber (out-door) should be accepted as zonal use, not according to Article 51
15 16	PL	Cucumber (indoor)	I	<i>Pseudomonas syringae</i> pv. <i>Lachrymans</i> , <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 10-89	4	7	a)1,6 b)6,4	a)0,8 kg Cu/ha b) 3,2 kg Cu/ha	500-1500	3	B7:Accepted only as minor use. Central Zone 1 additional trials is required
16 17	PL	Gherkins	Fpn	<i>Pseudomonas syringae</i> pv. <i>Lachrymans</i> , <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	700	7	B7:Accepted only as minor use. Central Zone 4 additional trials are

													required
17 18	PL	Courgette	Fpn	<i>Pseudomonas syringae</i> pv. <i>Lachrymans</i> , <i>Pseudoperonospora cubensis</i>	Spraying	BBCH 62-78	3	7	a)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	700	7	B7:Accepted only as minor use. Central Zone 4 additional trials are required
18 19	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)2,5 b)7,5	a) 1,25kg Cu/ha b) 3,75 kg Cu/ha	500- 1500	7	B7:Accepted only as minor use. Central Zone 2 additional trials are required
19 20	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)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	500- 1500	7	B7:Accepted only as minor use. Central Zone 2 additional trials are required
20 21	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)2,5 b)7,5	a) 1,25kg Cu/ha b)3,75 kg Cu/ha	500- 1500	7	B7:Accepted only as minor use. Central Zone 2 additional trials are required
21 22	PL	French bean, beans 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	2	7	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	600- 800	7	B7:Accepted only as minor use. Central Zone 4 additional trials are required Efficacy section: French bean should be accepted as zonal use, not according to Article 51
22 23	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	2	7	a)3 b)6	a)1,5kg Cu/ha b)3 kg Cu/ha	600- 800	7	B7:Accepted only as minor use. Central Zone 4 additional trials are required
23 24	PL	Grape (table, wine)	Fpn	<i>Plasmopara viticola</i>	Spraying	BBCH 13-17, 17-73, 73-77	3	10-14	a)2,5 b)7,5	a)1,25kg Cu/ha b)3,75 kg Cu/ha	500- 900	21	Metabolism and resi- dues Not accepted
24 25	PL	Currant	Fpn	<i>Drepanopeziza ribis</i> , <i>Mycosphaerella ribis</i> <i>Cronartium ribicola</i> ,	Spraying	BBCH 59-65 BBCH 59-81	2	10	a)2.4 b)4.8	a)1,2kg Cu/ha b)2.4kg Cu/ha	700	7	Metabolism and resi- dues 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	(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/m ³ 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