

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

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: **12/2021; 08/2022**

Version history

When	What
07/2020	Renewal of registration of plant protection product according art. 43, Reg. 1107/2009
12/2021	Assessment by expert
08/2022	The Final RR

Table of Contents

1	Section 1: Identity of the plant protection product.....	5
1.1	Applicant (KCP 1.1)	5
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	5
1.2.1	Producer(s) of the preparation	5
1.2.2	Producer(s) of the active substance(s)	5
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s).....	5
1.2.3.1	Copper Oxychloride	5
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3).....	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)	6
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	6
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	6
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	6
1.5	Type and code of the plant protection product (KCP 1.5).....	7
1.6	Function (KCP 1.6)	7
2	Section 2: Physical, chemical and technical properties of the plant protection product	8
3	Section 3 is presented as a separate document	21
4	Section 4: Further information on the plant protection product	22
4.1	Packaging and Compatibility with the Preparation (KCP 4.4)	22
Appendix 1	Lists of data considered in support of the evaluation.....	26
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance.....	29
A 2.1	Copper oxychloride.....	29

Version history

When	What
09/2020	Additional information about packaging
12/2020	Addition of a new study (Section 2)
05/2021	Correction of information about packaging
12/2021	Addition of information about new studies
12/2021	zRMS finalised the assessment

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Synthos Agro Sp. z o.o
Address: ul. Chemików 1
32-600 Oświęcim

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Copper Oxychloride

Copper Oxychloride	min. 550 g/kg
Lead	max. 0.5 mg/g of copper content
Cadmium	max. 0.1 mg/g of copper content
Arsenic	max. 0.1 mg/g of copper content

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Trade names: Miedzian 50 WP
~~Cobresal 50 WP~~
~~Dalion 50 WP~~
~~Spator 50 WP~~

Company code number: Miedzian 50 WP

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)
Copper oxychloride	50 g/kg	47.5 – 52,5 g/kg	86.4 – 95.5

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

Table 1.4-2: Safener and synergists

Neither safener nor synergists were used in the formulation.

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Lead	max. 0.5 mg/g of copper content 250 mg/kg of product contains containing 500 g of copper
Cadmium	max. 0.1 mg/g 50 mg/kg of product contains containing 500 g of copper
Arsenic	max. 0.1 mg/g 50 mg/kg of product contains containing 500 g of copper

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on Copper Oxychloride

Type	Name/Code Number
ISO common name	Copper Oxychloride
CAS No.	1332-65-6 or 1332-40-7
EC No.	215-572-9
CIPAC No.	44.602

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Wettable Powder

[Code: WP]

1.6 Function (KCP 1.6)

Fungicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of light green crystalline powder, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature above 400 °C. In aqueous solution, it has a pH value around 8.88 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *PELD foil sacks*. Its technical characteristics are acceptable for a *wettable powders* formulation.

The intended concentration of use is ~~0.1% (0.75 kg of product/ 750 l of water)~~ 0.11% (1.6 kg of product/1500 l of water) to ~~1% (7 kg of product/ 700 l of water)~~ 0.6% (3 kg of product/500 l of water).

Justified Proposals for Classification and Labelling (KCP 12) for physical-chemical part only

Classification

~~Acute Tox. 4 – Acute toxicity (oral), Hazard Category 4~~

~~Aquatic Chronic 1 – Hazardous to the aquatic environment – Chronic Hazard, Category 1~~

Labelling

~~Pictograms: – Exclamation mark~~

~~– Environmental hazard~~

~~Signal words: – Warning~~

Notifier Proposals for Risk and Safety Phrases (KCP 12)

~~Hazard Statements:~~

~~H302 – Harmful if swallowed.~~

~~H410 – Very toxic to aquatic life with long-lasting effects.~~

~~EUH 401 – To avoid risks to human health and the environment, comply with the instructions for use.~~

~~Precautionary statements:~~

~~Prevention:~~

~~P264 – Wash hands thoroughly after handling.~~

~~P270 – Do not eat, drink or smoke when using this product.~~

~~P273 – Avoid release to the environment.~~

~~Response:~~

~~P301 + P312 – IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.~~

~~P330 – Rinse mouth.~~

~~P391 – Collect spillage.~~

~~Disposal:~~

~~P501 – Dispose of contents/ container to an approved waste disposal plant~~

Compliance with FAO specifications:

The product Miedzian 50 WP complies with FAO Specification 44.2oxch/WP/S (1989)

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Polish Pharmacopoeia VI Edition (2002) and EPA Product Properties Test Guidelines OPPTS 830.6302 to 04.	Miedzian 50 WP Batch no.: 4/W/01.2011	Light green crystalline powder of characteristic odour	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011	The study was assessed during first authorisation.
Explosive properties (KCP 2.2.1)			Not applicable. Considering the composition of the formulation and the individuals components, the product is not expected to have explosives properties.			The study was assessed during first authorisation.
Oxidizing properties (KCP 2.2.2)	Method A.17	Miedzian 50 WP Batch no.: 4/W/01.2011	Test item has no oxidizing properties	Y	Michał Frączak, MSc.; Institute of Industrial Organic Chemistry; BC-10/A/11; Warsaw; June 2011	The study was assessed during first authorisation.
Flash point (KCP 2.3.1)			Not applicable. It is not a plant protection product in the liquid form.			
Flammability (KCP 2.3.2)	EEC A.10	Miedzian 50 WP Batch no.: 4/W/01.2011	Test item is not highly flammable	Y	Michał Frączak, MSc.; Institute of Industrial Organic Chemistry; BC-10/A/11; Warsaw; June 2011	The study was assessed during first authorisation.
Self-heating (KCP 2.3.3)	EEC A.16	Miedzian 50 WP Batch no.: 4/W/	The product has not got the auto-ignition temperature up to 400 °C	Y	Michał Frączak, MSc.; Institute of Industrial Organic Chemistry; BC-10/11; Warsaw; June 2011	The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		01.2011				
Acidity or alkalinity and pH (KCP 2.4.1)			Not applicable. It is not a plant protection product which is acidic (pH < 4) or alkaline (pH > 10).			The study was assessed during first authorisation.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC Method MT 75.2	Miedzian 50 WP Batch no.: 4/W/ 01.2011	8.88	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011	The study was assessed during first authorisation.
Viscosity (KCP 2.5.1)			Not applicable. It is not a plant protection product in the liquid form.			
Surface tension (KCP 2.5.2)			Not applicable. It is not a plant protection product in the liquid form.			
Relative density (KCP 2.6.1)			Not applicable. It is not a plant protection product in the liquid form.			
Bulk density (KCP 2.6.2)	CIPAC Method MT 33	Miedzian 50 WP Batch no.: 4/W/ 01.2011	The average tapped density is 1.177 g/ml.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011	The study was assessed during first authorisation.
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Miedzian 50 WP Batch no.: 1/WR/ 06.2012	Storage Stability after 14 days at 54° C	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-32/12; Warsaw; July 2012	These studies were assessed during first authorisation.
	Visual inspection, nasal inhalation		Light green small crystalline powder of characteristic odor			
	CIPAC MT 75		pH 1 % suspension: 9.34 units			
	CIPAC MT 15		Determination of suspension stability: 78.29 %			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 59.3		Wet sieve test: Residue in 45 µm sieve – 0.00 %			
	Potentiometric titration		Active ingredient content: Copper oxychloride 84.403 % (844.03 g/kg) Copper 50.22 % (502.20 g/kg)			
	CIPAC MT 53.3	Miedzian 50 WP Batch no.: 287385/04	Wettability: The average wetting time is 25 seconds.	Y	Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019	The storage temperature varied between 53.5 and 54.1°C. During the wettability test, small amount of a water-soluble bag made of PVOH was added.
	ICP – OES	Miedzian 50 WP Batch no.: 287385/04	Relevant impurities: Initial: Arsenic 1.2 mg/kg Cadmium 2.1 mg/kg Lead 32.49 mg/kg After accelerated storage: Arsenic 1.21 mg/kg Cadmium 2.08 mg/kg Lead 32.34 mg/kg	Y	Magdalena Bielak-Łakomska, Selvita Services sp. z o.o. Life Science Park, K410/MB/01 Krakow, July 2020	See comments in KCP 2.7.5 regarding the relevant impurities. Accepted.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			Not applicable. The product is chemically and physically stable after storage for 14 days at 54° C.			
Minimum content after heat stability testing (KCP 2.7.3)	Potentiometric titration	Miedzian 50 WP Batch no.: 1/WR/06.2012	Active ingredient content: Copper oxychloride 84.403 % (844.03 g/kg) Copper 50.22 % (502.20 g/kg)	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-32/12; Warsaw; July 2012	The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Effect of low temperatures on stability (KCP 2.7.4)			Not applicable. It is not a plant protection product in the liquid form.			
Ambient temperature shelf life (KCP 2.7.5)	Organoleptic	Miedzian 50 WP Batch no.: 4/W/01.2011	Physical state colour and odour <u>After the first year</u> Light green small crystalline powder of characteristic odour <u>After the second year</u> Light green small crystalline powder of characteristic odour	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; April 2013	The study was assessed during first authorisation.
	CIPAC MT 75		pH of 1% water suspension <u>After the first year</u> 8.52 <u>After the second year</u> 8.68			The study was assessed during first authorisation.
	CIPAC MT 53.3		Wettability determination <u>After the first year</u> 16 s <u>After the second year</u> 13 s			The study was assessed during first authorisation.
	CIPAC MT 15		Suspensibility stability <u>After the first year</u> 75.33 % <u>After the second year</u> 77.15%			The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 185		Wet sieve test <u>After the first year</u> Residue in 75 µm sieve 0.08 % <u>After the second year</u> Residue in 75 µm sieve 0.10 %			The study was assessed during first authorisation.
	CIPAC MT 187		Particle size distribution <u>After the first year</u> · 31.52 % particles < 2 µm, · 68.48 % particles in the range 2 µm - 200 µm, · 0 % particles > 200 µm, · d43 = 3.40 µm, SD = 0.025 µm, RSD = 0.74 % <u>After the second year</u> · 33.44 % particles < 2 µm, · 66.56 % particles in the range 2 µm - 200 µm, · 0 % particles > 200 µm, · d43 = 3.46 µm, SD = 0.045 µm, RSD = 1.30 %			The study was assessed during first authorisation.
	GEFAP No. 17		Package stability <u>After the first year</u> Without any change Colourless foil sack <u>After the second year</u> Without any change			The study was assessed during first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Colourless foil sack			
	Titration		Active ingredients content <u>After the first year</u> Copper in the form of copper oxychloride was 51.20 % (512.0 g/kg) <u>After the second year</u> Copper in the form of copper oxychloride was 50.83 % (508.3 g/kg)			The study was assessed during first authorisation.
	ICP - OES	Miedzian 50 WP Batch no.: 287385/04	Relevant impurities: Initial: Arsenic 1.2 mg/kg Cadmium 2.1 mg/kg Lead 32.49 mg/kg After one year of storage: Arsenic 1.24 mg/kg Cadmium 2.23 mg/kg Lead 32.22 34.22 mg/kg	Y	Magdalena Bielak-Łakomska, Selvita Services sp. z o.o. Life Science Park, K410/MB/01 Kraków, June 2021	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 (SANTE/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. Zonal RMS assessment has been made considering only As,

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Cd and Pb. The content of 3 relevant impurities was determined after 1 year of storage and was within specified limits. Accepted.
	CIPAC MT 184	Miedzian 50 WP Batch no.: 287385/04	Suspension stability: <u>After the first year</u> Concentration 0.1%: 77.70% Concentration 1%: 79.54% <u>After the second year</u> Concentration 0.1%: 82.71% Concentration 1%: 85.09%	Y	Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; December November 2020 Enzo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; September 2021	The storage temperature varied from 18.1°C to 21.8°C. The material was stored in cardboard packages with the watersoluble plastic bags made of PVOH containing the item inside. See comments in KCP 2.8.1 regarding the wettability, KCP 2.8.3.1 regarding the suspensibility, and KCP 2.8.5.1.2 regarding wet sieve tests results. Accepted.
	CIPAC MT 53.3		Wettability determination <u>After the first year</u> 26 29 s <u>After the second year</u> 30 s			
	CIPAC MT 185		Wet sieve test <u>After the first year</u> Residue in 75 µm sieve 0.10 0.20 % <u>After the second year</u> 0.00 %			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable. Proposed shelf life is not less than 2 years.			
Wettability (KCP 2.8.1)	CIPAC Method MT 53.3	Miedzian 50 WP Batch no.: 287385/04	The average wetting time is 26 seconds.	Y	Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019	During the test, a small amount of a water-soluble bag made of PVOH was added. Accepted.
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Miedzian 50 WP Batch no.: 287385/04	The persistent of foaming: Concentration 0.1%: – 6 ml after 1 min., – 0 ml after 12 min. Concentration 1% 7%: – 33 ml after 1 min., – 21 ml after 12 min.	Y	Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019	The test was performed with standard water D. The test was performed in the presence of dissolved water soluble bag material made of PVOH. The suspension concentrations tested were lower (0.1% w/v) and much higher (7% w/v) than the minimum and maximum concentrations recommended for use (0.11% w/v and 0.6% w/v). Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Miedzian 50 WP Batch no.: 287385/04	Suspensibility: Concentration 0.1%: 86.92%	Y	Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic	The test was performed with standard water D at 30°C. The suspensibility test was performed in the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Concentration 1%: 90.02%		Chemistry; BF-26/19; Warsaw; October 2019	presence of dissolved water soluble bag material made of PVOH. The suspension concentrations tested were lower (0.1% w/v) and higher (1% w/v) than the minimum and maximum concentrations recommended for use (0.11% w/v and 0.6% w/v). As the lowest recommended concentration is lower than 0.2%, according to method MT 184 the concentration 0.2% should be used. As the results are within limits it is deemed acceptable. Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)			Not applicable. It is not a water dispersible plant protection product.			
Dispersion stability (KCP 2.8.3.3)			Not applicable. It is not a water dispersible plant protection product.			
Degree of dissolution and dilution stability (KCP 2.8.4)			Not applicable. It is not a plant protection product diluted in water.			
Particle size distribution	CIPAC MT 187	Miedzian	Determined particle size:	Y	Idris Al Amin, Ph.D.;	The study was assessed

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
/ nominal size range of granules (KCP 2.8.5.1.1)		50 WP Batch no.: 4/W/01.2011	25.2% of particles diameter was less than 2 µm; 74.8% of particles diameter was between 2 µm and 200 µm; 0% particles diameter is above 200 µm. d43 – 4.8 µm, Standard deviation - 0.029 µm; Confidence interval - 0.036 µm.		Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011	during first authorisation.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Miedzian 50 WP Batch no.: 287385/04	0.10% was retained on a 75 µm sieve	Y	Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019	The procedure of the method used in the study was different from the CIPAC MT 185: - the amount of water used to dilute the material was 20 ml instead of 100 ml - the amount of water used to rinse the beaker and sieve was 150 ml instead of a jet of tap water (4-5 litres/min.). However, as the procedure used in the study would lead to the higher residue and the result is within the limit specified in the FAO specification it is acceptable. Accepted.
Dust content (KCP 2.8.5.2.1)			Not applicable. It is not a granular plant protection product.			
Particle size of dust			Not applicable.			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.2.2)			It is not a granular plant protection product.			
Attrition (KCP 2.8.5.3)			Not applicable. It is not a plant protection product in the form of granules or tablets which are loose packed.			
Hardness and integrity (KCP 2.8.5.4)			Not applicable. It is not a plant protection product in the form of tablets.			
Emulsifiability (KCP 2.8.6.1)			Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.			
Emulsion stability (KCP 2.8.6.2)			Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.			
Re-emulsifiability (KCP 2.8.6.3)			Not applicable. It is not a plant protection product, which exist as emulsion in the spray tank.			
Flowability (KCP 2.8.7.1)			Not applicable. It is not a granular plant protection product.			
Pourability (KCP 2.8.7.2)			Not applicable. It is not a plant protection product in the form of suspension.			
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable. It is not a granular plant protection product.			
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable. No tank mixtures with this product are recommended.			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable. No tank mixtures with this product are recommended.			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (KCP 2.10.1)			Not applicable. It is not a plant protection product for seed treatment.			
Distribution to seed (KCP 2.10.2)			Not applicable. It is not a plant protection product for seed treatment.			
Other/special studies (KCP 2.11)	CIPAC MT 176	Miedzian 50 WP Batch no.: 1/WR/06.2012	The sacks used as inner package are soluble in water	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-32/12; Warsaw; July 2012	The study was assessed during first authorisation.
Other/special studies (KCP 2.11)	According to brochure “Dobra praktyka postępowania przy stosowaniu środków ochrony roślin” issued by Research Institute of Horticulture (Instytut Ogrodnictwa, Skierniewice 2014, ISBN 978-83-89800-63-3)	Miedzian 50 WP Batch No.: A1991005	Residues of copper in the tank after the cleaning procedure corresponded to <0.15% of the initial concentration in spray liquid. Considering the results, cleaning of the spray equipment with water is considered adequate and no adverse effect would be expected.	N	Piotr Paleń; Synthos Agro Sp. z o.o.; AGRO/14/20; Oświęcim; June 2020	Accepted.

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	<p>In the shelf-life study conducted in 2013 (<i>Miedzian 50 WP. Stage III: Determination of physicochemical properties after second year of storage</i>, Study code no. BF-14/11), the formulation was stored in the commercial packaging made of water-soluble PELD sacks in a cardboard package and in the commercial packaging made of PELD bags in a cardboard package and the packaging remained stable during the storage.</p> <p>In the shelf-life study conducted in 2019 (<i>Miedzian 50 WP. Stage II: Determination of physicochemical properties of the preparation after one year of storage</i>, Study code no. BF-26/19) and in 2021 (<i>Miedzian 50 WP Stage III: Determination of physicochemical properties of the preparation after two years of storage</i>, Study code no BF-26/19), the formulation was stored in its proposed commercial packaging made of water-soluble PVOH bags and the packaging was stable during the storage.</p> <p>Therefore, the proposed commercial packs are considered acceptable.</p>
-------------------	---

Non-Professional users:

PE:

10 g, 15 g, 20 g, 50 g, 100 g, 250 g, 500 g

PVOH (water soluble):

10 g, 15 g, 20 g, 50 g, 100 g, 250 g, 500 g, 1 kg

PAPER/PE/ALU/PE:

15 g, 100 g.

Professional users:

PE:

250 g, 500 g, 1.5 kg, 3 kg, 10 kg, 20 kg

PVOH (water soluble):

250 g, 500 g, 1 kg, 1.5 kg, 2 x 1.5 kg (3 kg), 10 x 1 kg (10 kg), 20 x 1 kg (20 kg), 30 x 1.5 kg (45 kg)

Table 4.1-1: Packaging information for 250 g, 500 g, 1.5 kg, 3 kg, 10 kg, 20 kg bags – professional users; 10 g, 15 g, 20 g, 50 g, 100 g, 250 g, 500 g – non-professional users

Type	Description
Name:	Nr 18/PP/2017
Material:	PE-LD
Shape/size:	<p>Foil sachets:</p> <p>10 g: 90 mm x 100 mm 84 mm x 140 mm 90 mm x 150 mm</p> <p>15 g: 100 mm x 140 mm 80 mm x 140 mm</p> <p>20 g: 84 mm x 140 mm 97 mm x 150 mm</p> <p>50 g: 130 mm x 100 mm</p>

Type	Description
	<p>97 mm x 150 mm 130 mm x 150 mm 120 mm x 150 mm 100 g: 190 mm x 100 mm 138 mm x 220 mm 155 mm x 205 mm 130 mm x 180 mm 150 mm x 180 mm</p> <p>Foil: Width 465 ± 5 mm; Thickness 0.08 mm</p> <p>Bags made of foil: 250 g: 220 mm x 140-180 mm 500 g: 220 mm x 170-210 mm 1.5 kg: 220 mm x 340-390 mm 3 kg: 220 mm x 370-420 mm 10 kg: 370 mm x 800 mm 20 kg: 510 mm x 1050 mm</p>
Closure:	Thermal sealing

**Table 4.1-2: Packaging information for 10 g, 15 g, 20 g, 50 g, 100 g, 250 g, 500 g, 1 kg - non-professional users
 250 g, 500 g, 1 kg, 1.5 kg, 3 kg, 10 kg, 20 kg, 45 kg. – professional users**

Type	Description
Name:	Hydrofolia typ LTF Nr 4/ŚP/2011
Material:	PVOH – water soluble
Shape/size:	<p>Foil: Width 479 - 485 mm; Thickness 0.04 mm</p> <p>Bags made of foil:</p> <p>10 g: 84 mm x 140 mm 90 mm x 150 mm</p> <p>15 g: 100 mm x 140 mm 80 mm x 140 mm x 5 mm</p> <p>20 g: 84 mm x 140 mm 97 mm x 150 mm</p> <p>50 g-20 g: 97 mm x 150 mm 130 mm x 150 mm x 5 mm 120 mm x 150 mm</p> <p>100 g: 138 mm x 220 mm 155 mm x 205 mm 130 mm x 180 mm x 10 mm 150 mm x 180 mm</p> <p>250 g: 220 mm x 140-180 mm</p> <p>500 g: 240 mm x 170-210 mm</p> <p>1 kg:</p>

Type	Description
	240 mm x 320-360 mm 1.5 kg: 240 mm x 350-390 mm Packaging sets 2 x 1.5 kg 30 x 1.5 kg 10 x 1 kg 20 x 1 kg
Closure:	Thermal sealing

Table 4.1-3: 10 g, 15 g, 20 g, 50 g, 100 g, 250 g, 500 g, 1 kg - non-professional users
 250 g, 500 g, 1 kg, 1.5 kg, 3 kg, 10 kg, 20 kg, 45 kg. – professional users

Type	Description
Name:	Folia typ L330 Taśma Bezbarwna z firmy MonoSol Nr 26/SP/2012
Material:	PVOH – water soluble
Shape/size:	Foil: Width 479 - 485 mm; Thickness 0.04 mm Bags made of foil: 10 g: 84 mm x 140 mm 90 mm x 150 mm 15 g: 100 mm x 140 mm 80 mm x 140 mm x 5 mm 20 g: 84 mm x 140 mm 97 mm x 150 mm 50 g – 20 g: 97 mm x 150 mm 130 mm x 150 mm x 5 mm 120 mm x 150 mm 100 g: 138 mm x 220 mm 155 mm x 205 mm 130 mm x 180 mm x 10 mm 150 mm x 180 mm 250 g: 220 mm x 140-180 mm 500 g: 240 mm x 170-210 mm 1 kg: 240 mm x 320-360 mm 1.5 kg: 240 mm x 350-390 mm Packaging sets 2 x 1.5 kg 30 x 1.5 kg 10 x 1 kg 20 x 1 kg

Type	Description
Closure:	Thermal sealing

Table 4.1-4: Packaging information for 15 g, 100 g bags – non-professional users

Type	Description
Name:	SACHETS MATERIAL: PE/ALU/PE/ PAPER
Material:	PAPER/PE/ALU/PE
Shape/size:	<p>Bags 15 g: Weight of bags 3 g. PAPER – 50 g/m³ PE – 12 g/m³ ALU – 7 µm PE – 25 g/m³ – inner lyer Size: 100 mm x 140 mm, weld: 10 mm</p> <p>Bags 100 g: Weight of bags 7 g. PAPER – 50 g/m³ PE – 12 g/m³ ALU – 7 µm PE – 25 g/m³ – inner lyer Size: 155 mm x 205 mm, weld: 10 mm</p>
Closure:	Thermal sealing

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1	Idris Al Amin, Ph.D.	2011	Miedzian 50 WP Stage I: Physicochemical properties evaluation of initial preparation. Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.2.2	Michał Frączak, MSc.	2011	Miedzian 50 WP: Determination flammability and oxidizing properties (solids). Michał Frączak, MSc.; Institute of Industrial Organic Chemistry; BC-10/A/11; Warsaw; June 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.3.2	Michał Frączak, MSc.	2011	Miedzian 50 WP: Determination flammability and oxidizing properties (solids). Michał Frączak, MSc.; Institute of Industrial Organic Chemistry; BC-10/A/11; Warsaw; June 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.3.3	Michał Frączak, MSc.	2011	Michał Frączak, MSc.; Institute of Industrial Organic Chemistry; BC-10/11; Warsaw; June 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.4.2	Idris Al Amin, Ph.D.	2011	Miedzian 50 WP Stage I: Physicochemical properties evaluation of initial preparation. Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.6.2	Idris Al Amin, Ph.D.	2011	Miedzian 50 WP Stage I: Physicochemical properties evaluation of initial preparation. Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.1	Idris Al	2012	Miedzian 50 WP Stage I: Determination of water soluble	N	Synthos

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Amin, Ph.D.		sacks dissolution rate and evaluation of the physicochemical properties of the preparation after accelerated storage Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-32/12; Warsaw; July 2012 GLP Unpublished		Agro Sp. z o.o.
KCP 2.7.1	Enzo Arévalo Arévalo, Ph.D.	2019	Miedzian 50 WP Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.1	Magdalena Bielak-Łakomska	2020	Determination of arsenic, cadmium and lead content in the Miedzian 50 WP – 2 years stability studies. Selvita Services sp. z o.o. Life Science Park, K410/MB/01 Krakow, July 2020 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.3	Idris Al Amin, Ph.D.	2012	Miedzian 50 WP Stage I: Determination of water soluble sacks dissolution rate and evaluation of the physicochemical properties of the preparation after accelerated storage Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-32/12; Warsaw; July 2012 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.5	Idris Al Amin, Ph.D.	2013	Miedzian 50 WP Stage III: Determination of physicochemical properties after the second year of storage. Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; April 2013 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.5	Enzo Arévalo Arévalo, Ph.D.	2020	Miedzian 50 WP Stage II: Determination of physicochemical properties of the preparation after one year of storage Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry;	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			BF-26/19; Warsaw; December November 2020 GLP		
KCP 2.7.5	Enzo Arévalo	2021	Miedzian 50 WP Stage III: Determination of physicochemical properties of the preparation after two years of storage BF-26/19 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Warsaw; September 2021 GLP	N	Synthos Agro Sp. z o.o.
KCP 2.7.5	Magdalena Bielak-Łakomska	2021	Determination of arsenic, cadmium and lead content in the Miedzian 50 WP – 2 years stability studies (Partial report no.2) Selvita Services Sp. z o.o. Life Science Park, K410/MB/01 Kraków, June 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.1	Enzo Arévalo Arévalo, Ph.D.	2019	Miedzian 50 WP Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.2	Enzo Arévalo Arévalo, Ph.D.	2019	Miedzian 50 WP Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.3.1	Enzo Arévalo Arévalo, Ph.D.	2019	Miedzian 50 WP Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.5.1.1	Idris Al Amin,	2011	Miedzian 50 WP Stage I: Physicochemical properties evaluation of initial preparation.	N	Synthos

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Ph.D.		Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-14/11; Warsaw; May 2011 GLP Unpublished		Agro Sp. z o.o.
KCP 2.8.5.1.2	Enzo Arévalo Arévalo, Ph.D.	2019	Miedzian 50 WP Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage Enzo Arévalo Arévalo, Ph.D., Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-26/19; Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.11	Idris Al Amin, Ph.D.	2012	Miedzian 50 WP Stage I: Determination of water soluble sacks dissolution rate and evaluation of the physicochemical properties of the preparation after accelerated storage Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-32/12; Warsaw; July 2012 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.11	Piotr Paleń, MSc.	2020	Miedzian 50 WP Effectiveness of the equipment cleaning procedure. Study Code: AGRO/14/20; Synthos Agro Sp. z o.o.; Oświęcim; Non GLP Unpublished	N	Synthos Agro Sp. z o.o.

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Copper oxychloride

No new and additional data.