

# **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 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: **01/2022; 08/2022**

## Version history

When	What
07.2020	Submission date
12.2021	Update
01.2022	zRMS finalised the dRR assessment
08/2022	The Final RR

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## Version history

When	What
21.01.2019	Extension of packaging types
07.2020	Renewal of registration of plant protection product according art. 43, Reg. 1107/2009
10.2020	Additional information about packaging
12.2020	Addition of a new study (KCP 2.7.5)
12.2021	Addition of a new study (KCP 2.7.5)
01.2022	zRMS finalised the dRR 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. purity 550 g/kg of pure copper.
Relevant impurities:	
Lead	max. 0.5 mg/g of copper
Cadmium	max. 0.1 mg/g of copper
Arsenic	max. 0.1 mg/g of copper

### 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 name: Miedzian Extra 350 SC  
Kares 350 SC  
Cobresal Extra 350 SC  
Company code number: Miedzian Extra 350 SC

## 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)	Technical content** (%w/w)
Copper oxychloride	350 g/L	N/A 332.5 – 367.5 g/L	636,4 g/L	43.2 %w/w

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

\*\* Based on the density of the formulation = 1,472 g/ml, (Note: only applies if a liquid formulation – delete this comment if not needed)

**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 175 mg/kg mg/L of product containing 500 350 g of copper/L
Cadmium	max. 0.1 mg/g 35 mg/kg mg/L of product containing 350 g of copper/L
Arsenic	max. 0.1 mg/g 35 mg/kg mg/L of product containing 350 g of copper/L

### 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: Suspension concentrate

[Code: SC]

## **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 green colour, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 6.70 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 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 HDPE. Its technical characteristics are acceptable for a *suspension concentrate* formulation.

The intended concentration of use is 0.1% 0.15% to 1% 1.8%.

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

#### Classification

Accute Tox.4 – H302: Harmful if swallowed  
Accute Tox.4 – H332: Harmful if inhaled  
Skin Sens. 1 – H317: May cause an allergic skin reaction  
Eye Irrit. 2 – H319: Causes serious eye irritation  
Aquatic Chronic 1 – H410: Very toxic to aquatic life with long lasting effects

#### Labelling

##### Pictograms:

GHS 07 – Exclamation mark  
GHS 09 – Environment

##### Signal words:

Warning

### Notifier Proposals for Risk and Safety Phrases (KCP 12)

#### Hazard Statements:

H302: Harmful if swallowed  
H332: Harmful if inhaled  
H317: May cause an allergic skin reaction  
H319: Causes serious eye irritation  
H410: Very toxic to aquatic life with long lasting effects

#### Precautionary Statements:

##### Prevention:

P261 – Avoid breathing dust/fume/gas/mist/vapours/ spray  
P264 – Wash hands thoroughly after handling.  
P270 – Do not eat, drink or smoke when using this product.  
P271 – Use only outdoors or in a well ventilated area.  
P272 – Contaminated work clothing should not be allowed out of the workplace.  
P273 – Avoid release to the environment.  
P280 – Wear protective gloves/protective clothing/eye protection/face protection.

#### Response:



~~P302 + P352 IF ON SKIN: Wash with plenty of water with soap~~  
~~P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.~~  
~~P301 + P312 SWALLOWED: Call a POISON CENTER/doctor/.../if you feel unwell.~~  
~~P330 Rinse mouth.~~  
~~P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.~~  
~~P312 Call a POISON CENTER/ doctor/.../if you feel unwell.~~  
~~P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.~~  
~~P321 Specific treatment (see on this label).~~  
~~P362 + P364 Take off contaminated clothing and wash it before reuse.~~  
~~P337 + P313 If eye irritation persists: Get medical advice/attention.~~  
~~P391 Collect spillage.~~

**Disposal:**

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

**Compliance with FAO specifications:**

No FAO specification exist for Copper oxychloride in the formulation of SC.

**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 Extra 350 SC  Batch No.: 5/04.2007	Miedzian Extra 350 SC is a green and homogenous concentrate suspension of slight characteristic odour.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
Explosive properties (KCP 2.2.1)	EEC A.14	Miedzian Extra 350 SC  Batch No.: 3/02.2012	Miedzian Extra 350 SC does not have explosive properties.	Y	Tomasz Sałaciński, M. Sc. Eng.; Institute of Industrial Organic Chemistry; BW-02/12 Warsaw; March 2012	This study was assessed during the first authorisation.
Oxidizing properties (KCP 2.2.2)			Not applicable. Considering the composition of the formulation and the individuals components, the product is not expected to have oxidizing properties.			This study was assessed during the first authorisation.
Flash point (KCP 2.3.1)			Not applicable. The product doesn't contains flammable solvents.			
Flammability (KCP 2.3.2)			Not applicable. It is not a solid or gas plant protection product.			
Self-heating (KCP 2.3.3)			Not applicable. The product doesn't contains flammable solvents.			
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).			
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC Method MT 75.3	Miedzian Extra 350 SC	6.70		Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry;	This study was assessed during the first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.4.2)		Batch No.: 5/04.2007			BF-C/09/07; Warsaw; June 2006	
Viscosity (KCP 2.5.1)	OECD 114	Miedzian Extra 350 SC  Batch No.: A1991051	Dynamic viscosity at 20°C at shear rate of 5 s <sup>-1</sup> 2506 mPa*s at shear rate of 10 s <sup>-1</sup> 1642 mPa*s at shear rate of 25 s <sup>-1</sup> 977 mPa*s at shear rate of 50 s <sup>-1</sup> 673 mPa*s  Dynamic viscosity at 40°C at shear rate of 5 s <sup>-1</sup> 2017 mPa*s at shear rate of 10 s <sup>-1</sup> 1280 mPa*s at shear rate of 25 s <sup>-1</sup> 739 mPa*s at shear rate of 50 s <sup>-1</sup> 494 mPa*s	Y	Enzo Arévalo Arévalo, Ph.D Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019	The test was performed with a Brookfield rotational viscometer. The formulation is non-Newtonian liquid. Accepted.
Surface tension (KCP 2.5.2)	EEC A. 5	Miedzian Extra 350 SC  Batch No.: A1991051	Surface tension of 1% concentration: 41.67 mN/m	Y	Enzo Arévalo Arévalo, Ph.D Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019	The test was performed at the concentration 1% v/v which is lower than the highest recommended concentration (1.8% v/v). According to the guidelines, the surface tension of a liquid preparation should be determined at the highest in-use spray concentration. However, as the EEC A.5 method recommends the conc. of 1% it is proposed to accept the result. The formulation is surface-active. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Relative density (KCP 2.6.1)	CIPAC MT 3	Miedzian Extra 350 SC  Batch No.: 5/04.2007	At 20°C: Absolute 1.472 g/ml and relative at 4°C: 1.472 g/ml	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
Bulk density (KCP 2.6.2)			Not applicable. It is not a plant protection product in the form of powder or granules.			
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46		-			
	Polish Pharmacopoeia VI Edition (2002) and EPA Product Properties Test Guidelines OPPTS 830.6302 to 04.	Miedzian Extra 350 SC  Batch No.: 5/04.2007	After accelerated storage a 3% suspension appeared (solution of surfactans), but without hard precipitate. Odour was slight and characteristic.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
	Potentiometric titration	Miedzian Extra 350 SC  Batch No.: 5/04.2007	After accelerated storage, calculated as copper 24.14% (355,34 g/l).  Before storage the content was 24.73% (364.03 g/l).	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	
	CIPAC MT 75.3	Miedzian Extra 350 SC  Batch No.: 5/04.2007	pH 6.59	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	
	CIPAC MT 185	Miedzian Extra 350 SC	0.00% product was retained on a 75 µm sieve.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07;	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No.: 5/04.2007			Warsaw; June 2006	
	CIPAC MT 160	Miedzian Extra 350 SC  Batch No.: 4/02.2013	Spontaneity of dispersion: 91.86%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/13-2; Warsaw; April 2013	This study was assessed during the first authorisation.
	CIPAC MT 148	Miedzian Extra 350 SC  Batch No.: 4/02.2013	Pourability: R = 5.14% R' = 0.28%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/13-2; Warsaw; April 2013	
	CIPAC MT 184	Miedzian Extra 350 SC  Batch No.: A1991051	Suspension stability (1% v/v): 95.53 %	Y	Enzo Arévalo Arévalo, Ph.D Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019	The tested material was stored in the glass container. During the storage, the temperature ranged from 53.3 to 54.1°C. See KCP 2.8.3.1 regarding suspensibility results. The change of a.s content was 3%. The content of relevant impurities after accelerated storage was below the limit values (see comment in KCP 2.7.5). Accepted.
	Potentiometric titration	Miedzian Extra 350 SC  Batch No.: A1991051	Initial formulation Active ingredient was 24.18% ± 0.72% (348.20 g/L) After the accelerated storage: Active ingredient was 23.45% ± 0.07% (337.73 g/L)	Y	Enzo Arévalo, Ph.D Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019	
	ICP – OES	Miedzian Extra 350 SC	Relevant impurities: Initial: Arsenic 0.61 mg/kg mg/L Cadmium 1.08 mg/kg mg/L	Y	Magdalena Bielak-Łakomska, Selvita Services sp. z o.o.	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No.: A1991025	Lead 36.59 mg/kg mg/L After accelerated storage: Arsenic 0.58 mg/kg mg/L Cadmium 1.03 mg/kg mg/L Lead 34.75 mg/kg mg/L		Life Science Park, K411/MB/01 Krakow, July 2020	
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 Extra 350 SC  Batch No.: 5/04.2007	After accelerated storage, calculated as copper 24.14% (355,34 g/l).	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.1	Miedzian Extra 350 SC  Batch No.: 1/03.2011	-	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-07/13-1; Warsaw; April 2013	This study was assessed during the first authorisation.
	CIPAC MT 185		Wet sieve test 0.00% product was retained on a 75 µm sieve.			
	CIPAC MT 161		Suspension stability: 88.06%			
	CIPAC MT 160		Spontaneity of dispersion: 92.13%			
Ambient temperature shelf life (KCP 2.7.5)	Polish Pharmacopoeia VI Edition (2002) and EPA Product Properties Test Guidelines OPPTS 830.6302 to 04.	Miedzian Extra 350 SC  Batch No.: 5/04.2007	After two years of storage, 18 to 25% suspension on the top were appeared without caking. But after the preparation was shaken, it became homogenous green suspension of slight characteristic odour.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; July 2009	These studies were assessed during the first authorisation.
	Potentiometric titration		Active ingredient after the first and second years of storage were 24.98% (367.71 g/l) and 24.83%			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			(365.50 g/l) respectively.			
	CIPAC MT 75.3		pH: The average measured pH value of 1% water suspension was 6.48 units after the first year and 6.40 units after the second year of storage.			
	CIPAC MT 185		Wet sieve test: About 0.01% of solid was retained in a 75 µm sieve of samples after one and two years of storage.			
	CIPAC MT 160		Spontaneity of dispersion based in cupper after the first and second years of storage were 89.0% and 94.2% respectively.			
	CIPAC MT 161		Suspension stability based on cupper after the first and second years of storage were 87.7% and 86.4% respectively.			
	Package evaluation – GIFAP17		The packages of Miedzian Extra 350 SC are stable during two years of storage at 20°C temperature.			
	CIPAC MT 148	Miedzian Extra 350 SC  Batch No.: 1/02.2010	Pourability: R = 3.15% R' = 0.21%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-13/12; Warsaw; March 2012	The storage temperature varied in the range 18.1°C to 21.8°C. The preparation was stored in HDPE packages. The change in the active substance content after 1 <sup>st</sup> year of storage was 1% and after 2 <sup>nd</sup> year was 3.3%.
	CIPAC MT 184	Miedzian Extra 350 SC  Batch No.: A1991051	Suspension stability: After the first year of storage: 94.47% After the second year of storage: 96.04% Study is ongoing	Y	Enzo Arévalo Arévalo, Ph.D. Lukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; December 2020 Enzo Arévalo, Ph.D	
	Potentiometric titration		Initial formulation Active ingredient was 24.18% ± 0.72% (348.20 g/L) After the first year of storage:			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Active ingredient was 24.42% $\pm$ 0.07% (351.71 g/l) After the second year of storage: <u>Study is ongoing</u> Active ingredient was 23.39% $\pm$ 0.35% (336.82 g/l)		Lukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19, part III Warsaw; September 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 oxochloride. 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. The content of 3 relevant impurities was determined after 1 year of storage and was within specified limits. Accepted. See KCP 2.8.3.1 comments regarding suspensibility result. Accepted.
	ICP – OES	Miedzian Extra 350 SC  Batch No.: A1991025	Relevant impurities: <u>Initial:</u> Arsenic 0.61 mg/L Cadmium 1.08 mg/L Lead 36.59 mg/L <u>After 1 year of storage:</u> Arsenic 0.49 mg/L Cadmium 1.09 mg/L Lead 28.31 mg/L <u>After 2 years of storage:</u> <u>Study is ongoing</u>	Y	Magdalena Bielak-Lakomska, Selvita Services sp. z o.o. Life Science Park, K411/MB/01 Krakow, June 2021	



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)			Not applicable. It is not a solid plant protection product, which is diluted for use.			
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47	Miedzian Extra 350 SC  Batch No.: 5/04.2007	1% concentration - 40 ml foam after 10 seconds of stopping mixing the solution; - 30 ml foam after 1 min of stopping mixing the solution.; - 20 ml foam after 3 min. of stopping mixing the solution; - 14 ml foam after 12 min. of stopping mixing the solution.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Miedzian Extra 350 SC  Batch No.: A1991051	Suspensibility of 1% concentration: 95.64 %	Y	Enzo <del>Arévalo</del> Arévalo, Ph.D Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019	CIPAC water D was used. The test was performed at 30°C. The test was performed at the concentration 1% v/v which is between lowest and highest recommended concentrations (0.15-1.8% v/v). According to the method, the test should be performed at the lowest (or if the lowest conc. is less then 0.2%, than at 0.2%) and highest recommended concentrations. During first registration,

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						the suspensibility was tested at the 2% v/v conc. (according to CIPAC MT 161 and with water C) and the result was acceptable. As the results are well within the limit values it is proposed to accept the result. Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Miedzian Extra 350 SC  Batch No.: 5/04.2007	83.7%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
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 water soluble plant protection product.			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187 ISO 13320-1	Miedzian Extra 350 SC  Batch No.: 5/04.2007	d10 = 0.176 µm, d50 = 1.839 µm, d90 = 5.678 µm d4,3= 2.428 µm SD = 0.024 µm, RSD = 0.988%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Miedzian Extra 350 SC  Batch No.:	0.01% product was retained on a 75 µm sieve.	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		5/04.2007				
Dust content (KCP 2.8.5.2.1)			Not applicable. It is not a granular plant protection product.			
Particle size of dust (KCP 2.8.5.2.2)			Not applicable. 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)	CIPAC MT 148	Miedzian Extra 350 SC  Batch No.: 5/04.2007	R = 4.63% R' = 0.23%	Y	Idris Al Amin, Ph.D.; Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006	This study was assessed during the first authorisation.
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable. It is not a plant protection product in the form of dustable powder.			
Physical compatibility			Not applicable.			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
of tank mixes (KCP 2.9.1)			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.			
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)	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 Extra 350 SC Batch No.: A2091005	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/15/20; 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:	In the shelf-life study the formulation was stored in the packaging made of HDPE and the packaging remained stable during the storage. For SC formulation it is possible to extrapolate results to other plastic packaging, therefore, the proposed commercial packs are considered acceptable.
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Miedzian Extra 350 SC is packaging in the following way:

HDPE (5 ml, 10 ml, 15 ml, 20 ml, 30 ml, 50 ml, 60 ml, 100 ml, 250 ml, 500 ml, 1L, 5L, 10L, 20L)

**Table 4.1-1: Packaging information for 5 ml container No.1**

Type	Description
Name:	5 ml container
Material:	PET/ Glue/APET/ PE/ PA/ EVOH/ PA/ PE
Shape/size:	20.5 x 105 mm
Opening:	Tear-off opening

**Table 4.1-2: Packaging information for 5 ml container No.2**

Type	Description
Name:	5 ml container
Material:	PET/ PE
Shape/size:	20.5 x 105 mm
Opening:	Tear-off opening

**Table 4.1-3: Packaging information for 10 ml bottle**

Type	Description
Name:	10 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	12 mm
Closure:	Cap

**Table 4.1-3: Packaging information for 15 ml bottle**

Type	Description
Name:	15 ml bottle
Material:	HDPE

Type	Description
Shape/size:	Bottle
Opening:	12 mm
Closure:	Cap

**Table 4.1-4: Packaging information for 20 ml bottle**

Type	Description
Name:	20 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	12 mm
Closure:	Cap

**Table 4.1-5: Packaging information for 30 ml bottle**

Type	Description
Name:	30 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	14,1 mm
Closure:	Cap

**Table 4.1-6: Packaging information for 50 ml bottle**

Type	Description
Name:	50 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	12 mm 14,1 mm 38 ml
Closure:	Cap

**Table 4.1-7: Packaging information for 60 ml bottle**

Type	Description
Name:	60 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	30,6 mm
Closure:	Cap

**Table 4.1-8: Packaging information for 100 ml bottle**

Type	Description
Name:	100 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	12 mm 30,6 mm 34 mm
Closure:	Cap

**Table 4.1-9: Packaging information for 250 ml bottle**

Type	Description
Name:	250 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	40 mm
Closure:	Cap

**Table 4.1-10: Packaging information for 500 ml bottle**

Type	Description
Name:	500 ml bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	40 mm
Closure:	Cap

**Table 4.1-11: Packaging information for 1 l bottle**

Type	Description
Name:	1 l bottle
Material:	HDPE
Shape/size:	Bottle
Opening:	40 mm
Closure:	Cap

**Table 4.1-12: Packaging information for 5 l canister**

Type	Description
Name:	5 l canister

Type	Description
Material:	HDPE
Shape/size:	Canister
Opening:	40 mm
Closure:	Cap

**Table 4.1-13: Packaging information for 10 l canister**

Type	Description
Name:	10 l canister
Material:	HDPE
Shape/size:	Canister
Opening:	40 mm 52 mm
Closure:	Cap

**Table 4.1-14: Packaging information for 20 l canister**

Type	Description
Name:	20 l canister
Material:	HDPE
Shape/size:	Canister
Opening:	40 mm
Closure:	Cap



## 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.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.2.1	Tomasz Sałaciński, M.Sc. Eng.;	2012	Miedzian Extra 350 SC – Determination of Explosive Properties. Institute of Industrial Organic Chemistry; BW-02/12 Warsaw; March 2012 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.4.2	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.5.1	Enzo Arévalo Arévalo, Ph.D	2019	Miedzian Extra 350 SC Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019	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
			GLP Unpublished		
KCP 2.5.2	Enzo Arévalo Arévalo, Ph.D	2019	Miedzian Extra 350 SC Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.6.1	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.1	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.1	Idris Al Amin, Ph.D.	2013	Miedzian Extra 350 SC Determination of physicochemical properties after accelerated storage Institute of Industrial Organic Chemistry; BF-07/13-2; Warsaw; April 2013 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.1	Enzo Arévalo	2019	Miedzian Extra 350 SC Stage I: Determination of physicochemical properties of the initial	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
	Arévalo, Ph.D		preparation and after accelerated storage. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019 GLP Unpublished		Agro Sp z o.o.
KCP 2.7.1	Magdalena Bielak-Łakomska	2020	Determination of arsenic, cadmium and lead content in the Miedzian Extra 350 SC – 2 years stability studies. Selvita Services sp. z o.o. Life Science Park, K411/MB/01 Krakow, July 2020 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.3	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.4	Idris Al Amin, Ph.D.	2013	Miedzian Extra 350 SC Determination of physicochemical properties after accelerated storage Institute of Industrial Organic Chemistry; BF-07/13-2; Warsaw; April 2013 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.5	Idris Al Amin, Ph.D.	2009	Miedzian Extra 350 SC Stage II : Physicochemical properties evaluation after the first and second years of storage Institute of Industrial Organic Chemistry; BF-C/09/07;	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
			Warsaw; July 2009 GLP Unpublished		
KCP 2.7.5	Idris Al Amin, Ph.D.	2012	Miedzian Extra 350 SC Stage II : Physicochemical properties evaluation after the first and second years of storage Institute of Industrial Organic Chemistry; BF-13/12; Warsaw; March 2012 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.5	Enzo Arévalo Arévalo, Ph.D	2020	Miedzian Extra 350 SC Stage II: Determination of physicochemical properties of the preparation after one year of storage. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; December 2020 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.5	Enzo Arévalo, Ph.D	2021	Miedzian Extra 350 SC Stage III: Determination of physicochemical properties of the preparation after two years of storage. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; September 2021 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.7.1	Magdalena Bielak-Łakomska	2021	Determination of arsenic, cadmium and lead content in the Miedzian Extra 350 SC – 2 years stability studies. Selvita Services sp. z o.o. Life Science Park, K411/MB/01 Krakow, June 2021 GLP	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
			Unpublished		
KCP 2.8.2	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.8.3.1	Enzo Arévalo Arévalo, Ph.D	2019	Miedzian Extra 350 SC Stage I: Determination of physicochemical properties of the initial preparation and after accelerated storage. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF – 27/19 Warsaw; October 2019 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.8.3.2	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.8.5.1.1	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.8.5.1.2	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years	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
			Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished		Agro Sp z o.o.
KCP 2.8.7.2	Idris Al Amin, Ph.D.	2006	Miedzian Extra 350 SC Storage Stability test at normal temperature for two years Stage I: Physicochemical properties evaluation of initial tested material. Institute of Industrial Organic Chemistry; BF-C/09/07; Warsaw; June 2006 GLP Unpublished	N	Synthos Agro Sp z o.o.
KCP 2.11	Piotr Paleń, MSc.	2020	Miedzian Extra 350 SC Effectiveness of the equipment cleaning procedure. Study Code: AGRO/15/20; 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.