

# 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: **MEZOFLOR 103 SC**

Product names: **MEZOFLOR 103 SC / FLOCORN 103 SC**

Chemical active substances:

Mesotrione, 100 g/L

Florasulam, 3 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

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

Submission date: 07/2023

MS Finalisation date: 12/2023, 12/2024

## Version history

When	What
07/2023	Initial dRR
12/2023	zRMS assessment of dRR
12/2024	The final Registration Report

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## **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 Poland

### **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 Mesotrione**

Mesotrione	min. 920 g/kg
R287431	max. 2 mg/kg
R287432	max. 2 g/kg
1,2 - dichloroethane	max. 1 g/kg

##### **1.2.3.2 Florasulam**

Florasulam	min. 970 g/kg
2,6-DFA	max. 2 mg/kg

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

Trade name: MEZOFLOR 103 SC, FLOCORN 103 SC  
Company code number: MEZOFLOR 103 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 substances and variants of the active substances**

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Mesotrione	100 g/L	90 g/L – 110 g/L	107.5 108.7	10.1 10.23
Florasulam	3 g/L	2.55 g/L – 3.45 g/L	3.2	0.3

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (920 g/kg for mesotrione and 970 g/kg for florasulam)

\*\* Based on the density of the formulation = 1.062 g/ml

**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)
R287431	max. 2 mg/kg in the active substance as manufactured (mg/kg) max. 0.2 mg/kg of MEZOFLO 103 SC
R287432	max. 2 g/kg in the active substance as manufactured (g/kg) max. 0.2 g/kg of MEZOFLO 103 SC
1,2 - dichloroethane	max. 1 g/kg in the active substance as manufactured (g/kg) max. 0.1 g/kg of MEZOFLO 103 SC
2,6-DFA	max. 2 mg/kg in the active substance as manufactured (g/kg) max. 0.006 mg/kg of MEZOFLO 103 SC

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

**Table 1.4-4: Information on Mesotrione**

Type	Name/Code Number
ISO common name	Mesotrione

Type	Name/Code Number
CAS No.	104206-82-8
EC No.	600-533-4
CIPAC No.	625

**Table 1.4-5: Information on Florasulam**

Type	Name/Code Number
ISO common name	Florasulam
CAS No.	145701-23-1
EC No.	604-488-1
CIPAC No.	616

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

**Table 1.4-5: Information on safeners/ synergists / co-formulant**

CONFIDENTIAL information is provided separately (Part C).

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

Type: SC (Suspension concentrate)

[Code: MEZOFLO 103 SC]

### **1.6 Function (KCP 1.6)**

Herbicide

## **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 homogenous whitish liquid with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable/hasn't got the flash point up to the boiling point. It has a self ignition temperature of 585°C. In aqueous solution, it has a pH value around 3.48 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 SC formulation. The intended concentration of use is ~~0.5%~~ 0.33% to 0.66%.

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

No classification or labelling is proposed for physical chemical part.

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

No proposals for risk and safety phrases for physical chemical part.

### **Compliance with FAO specifications:**

No FAO specification exist for mesotrione and florasulam both 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)	Visual inspection, nasal inhalation	MEZOFLO 103 SC, batch no. SNS-H-05-18	Homogenous whitish liquid of characteristic odour.	Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	MEZOFLO 103 SC, batch no. SNS-H-05-18	MEZOFLO 103 SC does not have explosive properties. In the impact sensitivity test, no explosion occurred. In the thermal sensitivity test, no explosion occurred.	Y	Daniel Buczkowski, PhD Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BW-14/21; Warsaw; June 2021	In the thermal sensitivity (Koenen) test no explosion occurred. In the impact sensitivity test no explosion occurred. The formulation does not have explosive properties. Accepted.
Oxidizing properties (KCP 2.2.2)	EC A.21	MEZOFLO 103 SC, batch no. SNS-H-05-18	MEZOFLO 103 SC has not got the oxidizing properties. During the test no spontaneous ignition was noted; the pressure did not reach the critical value of 2070 kPa. The formulation is not oxidising.	Y	Paulina Flasińska, MSc., Łukasiewicz Research Network – Institute of Industrial Organic Chemistry; BC-21/21; Warsaw, June 2021	The formulation is not oxidising. Accepted.
Flash point (KCP 2.3.1)	EC A.9	MEZOFLO 103 SC, batch no. SNS-H-05-18	MEZOFLO 103 SC hasn't got the flash point up to the boiling point. The test was performed with the Pensky-Martens closed-cup apparatus. No flash point up to the boiling point of 99°C. The formulation is not flammable.	Y	Paulina Flasińska, MSc., Łukasiewicz Research Network – Institute of Industrial Organic Chemistry; BC-04/22; Warsaw, January 2022	The formulation is not flammable. Accepted.
Flammability (KCP 2.3.2)	Not applicable. It is not a solid or gas plant protection product.					
Self-heating	EC A.15	MEZOFLO 103 SC,	MEZOFLO 103 SC has got not the auto-	Y	Paulina Flasińska, MSc.,	Accepted.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.3)		batch no. SNS-H-05-18	ignition temperature up to 585°C.		Łukasiewicz Research Network – Institute of Industrial Organic Chemistry; BC-21/21; Warsaw, June 2021	
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 CIPAC MT 191	MEZOFLOR 103 SC, batch no. SNS-H-05-18	Undiluted: 3.65  Acidity: 1.50%	Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3		1 % aqueous dilution: 3.48			Accepted.
Viscosity (KCP 2.5.1)	OECD 114		Non-Newtonian liquid: <div>Temperature</div> <div>shear rate:    20°C            40°C</div> <div>5.0 s<sup>-1</sup>        410 mPa ·s    289 mPa ·s</div> <div>10.0 s<sup>-1</sup>       261 mPa ·s    194 mPa ·s</div> <div>25.0 s<sup>-1</sup>       144 mPa ·s    112 mPa ·s</div> <div>50.0 s<sup>-1</sup>       93 mPa ·s     74 mPa ·s</div> <div>The viscosity was determined by using of Brookfield Test Method.</div> <div>The formulation is a non-Newtonian liquid.</div> <div>The formulation does not pose an aspiration hazard</div>			The product is a non-Newtonian liquid. The product does not pose an aspiration hazard. Accepted.
Surface tension (KCP 2.5.2)	OECD 115		29.68 mN/m (at 20°C) The surface tension of the formulation was tested using the ring method. The product is surface active.			The product is surface active. Accepted.
Relative density (KCP 2.6.1)	CIPAC MT 3.2.1		1.062 (at 20°C)			Accepted.
Bulk density	Not applicable.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																					
(KCP 2.6.2)	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 46.3	MEZOFLOR 103 SC, batch no. SNS-H-05-18	Physical state, color and odour: Homogenous whitish liquid of characteristic odour.	Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	The temperature varied between 53.1°C and 54.4°C. The product was stored in the original 1-litre HDPE bottles. The content of active substances and relevant impurities was determined with methods validated according to SANCO/3030/99 rev.5; (see Part B5 of the dRR). The change of a.s. content after storage: - mesotrione: 1.2% - florasulam: 7.4% The content of a.s. florasulam after storage decreased by more than 5%. As in the ambient temperature storage, it only decreased by 3.9% after 2 years and the phrase “Store below 30°” is already included in the proposed label it can be accepted. The contents of the relevant impurities determined before and after storage were below the levels of Reg. 2015/1397 and Reg. 2017/725. During storage, the packaging material proved to																					
	CIPAC MT 75.3		pH undiluted: 3.58 pH 1 % solution: 3.51																								
	CIPAC MT 191		Acidity: 1.52 %																								
	OECD 114		Non-Newtonian liquid: <table><tr><td></td><td colspan="2">Temperature</td></tr><tr><td>shear rate:</td><td>20°C</td><td>40°C</td></tr><tr><td>5.0 s<sup>-1</sup></td><td>350 mPa ·s</td><td>214 mPa ·s</td></tr><tr><td>10.0 s<sup>-1</sup></td><td>232 mPa ·s</td><td>153 mPa ·s</td></tr><tr><td>25.0 s<sup>-1</sup></td><td>132 mPa ·s</td><td>94 mPa ·s</td></tr><tr><td>50.0 s<sup>-1</sup></td><td>87 mPa ·s</td><td>64 mPa ·s</td></tr><tr><td>5.0 s<sup>-1</sup></td><td>350 mPa ·s</td><td>214 mPa ·s</td></tr></table>					Temperature		shear rate:	20°C	40°C	5.0 s <sup>-1</sup>	350 mPa ·s	214 mPa ·s	10.0 s <sup>-1</sup>	232 mPa ·s	153 mPa ·s	25.0 s <sup>-1</sup>	132 mPa ·s	94 mPa ·s	50.0 s <sup>-1</sup>	87 mPa ·s	64 mPa ·s	5.0 s <sup>-1</sup>	350 mPa ·s	214 mPa ·s
			Temperature																								
	shear rate:		20°C				40°C																				
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5.0 s <sup>-1</sup>	350 mPa ·s	214 mPa ·s																									
CIPAC MT 47.3	Persistent foam: 0.66% : 0 ml after 1 min. and 12 min.																										
CIPAC MT 184.1	Suspension stability: <table><tr><td></td><td>mesotrione</td><td>florasulam</td></tr><tr><td>0.4%</td><td>99.25%</td><td>99.11%</td></tr><tr><td>0.66%</td><td>100.34%</td><td>99.90%</td></tr></table>		mesotrione	florasulam	0.4%	99.25%	99.11%	0.66%	100.34%	99.90%																	
	mesotrione	florasulam																									
0.4%	99.25%	99.11%																									
0.66%	100.34%	99.90%																									
CIPAC MT 160	Dispersion spontaneity: mesotrione    florasulam 99.22%        98.90%																										
CIPAC MT 185	Wet sieve test: Residue in 75 µm sieve: 0.00%																										
CIPAC MT 148.1	Pourability: R= 1.44%, R'=0.18%																										

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CropLife International Technical Monograph no. 17		Package stability: The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.			be resistant to its content. No significant changes in other properties were noted (appearance, colour or odour, pH, acidity, wet sieve, persistent foaming, pourability, suspensibility, and spontaneity of dispersion). Accepted.
	HPLC		Mesotrione content: initial 9.99%, after storage 9.87% Florasulam content: initial 0.297%, after storage 0.275%			
	UHPLC		Impurities content: 1-cyano-6-(methylsulfonyl)-7-nitro-9Hxanthen-9-one (R287431) standard solution: initial <LOQ, after storage < LOQ 6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile (R287432): initial 0.000055% (0.00058 g/L), after storage 0.000074 % 0.000073% (0.00078 g/L) 2.6- DFA: initial <LOQ, after storage < LOQ			
	HS-GC-FID		Impurities content: 1.2-dichloroethane: initial <LOQ, after storage < LOQ			
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)	CIPAC MT 46.3 (HPLC)	MEZOFLOR 103 SC, batch no. SNS-H-05-18	Mesotrione content: 9.87% Florasulam content: 0.275%	Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	Accepted.
Effect of low	Visual		Homogenous whitish liquid of characteristic			The storage temperature

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
temperatures on stability (KCP 2.7.4)	inspection, nasal inhalation		odour.			varied between –0.7°C and 1.0°C. The visual inspection was carried out immediately after storage, at room temperature, and after 24 hours at room temperature and one inversion. Accepted.
	CIPAC MT 184.1		Suspension stability:  <div> <div>mesotrione</div> <div>florasulam</div> </div> <div> <div>0.4%</div> <div>99.79%</div> <div>99.32%</div> </div> <div> <div>0.66%</div> <div>99.75%</div> <div>99.06%</div> </div>			
	CIPAC MT 185		Wet sieve test: Residue in 75 µm sieve: 0.00%			
Ambient temperature shelf life (KCP 2.7.5)	Visual inspection, nasal inhalation		Physical state color and odour: <b>Initial:</b> Homogenous whitish liquid of characteristic odour <b>After 1 year:</b> Before mixing - at the top ~ 25% v/v surfactants solution, after mixing - homogenous whitish liquid of characteristic odour. <b>After 2 years:</b> Before mixing - at the top ~ 50% v/v surfactants solution, after mixing - homogenous whitish liquid of characteristic odour.		Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021  Jarosław Kupiec, M.Sc. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; <del>July</del> August 2022	The temperature varied between 18.2°C and 21.2°C. The formulation was stored in the original 1-litre HDPE bottles and the packaging was stable. The content of active substances and relevant impurities was determined with methods validated according to SANCO/3030/99 rev.5; (see Part B5 of the dRR). The change of a.s. content after 1 year of storage: - mesotrione: 0.2% - florasulam: 3.9% after 2 years: - mesotrione: 3.9% - florasulam: 3.9% The contents of the relevant impurities determined before and after storage were below the levels of Reg. 2015/1397 and Reg. 2017/725.
	CIPAC MT 75.3		<b>Initial:</b> pH undiluted: 3.65 pH 1 % solution: 3.48 <b>After 1 year:</b> pH undiluted: 3.89 pH 1 % solution: 3.54 <b>After 2 years:</b> pH undiluted: 3.76 pH 1 % solution: 3.41		Jarosław Kupiec, M.Sc. Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; June 2023	
	CIPAC MT 191		Acidity determination: <b>Initial:</b>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			1.50% <b>After 1 year:</b> 1.54% <b>After 2 years:</b> 1.59%			No significant changes in other properties were noted (appearance, colour or odour, pH, acidity, wet sieve, pourability, suspensibility, and spontaneity of dispersion). After storage, the surfactant solution was separated at the top, therefore the phrase “Mix well before use” should be included in the label. Accepted.
	CIPAC MT 184.1		Suspension stability: <b>Initial:</b> mesotrione florasulam 0.4% 103.86% 103.21% 0.66% 103.07% 102.56% <b>After 1 year:</b> mesotrione florasulam 0.4% 99.70% 99.90% 0.66% 98.89% 101.82% <b>After 2 years:</b> mesotrione florasulam 0.4% 99.13% 99.52% 0.66% 98.52% 98.29%			
	CIPAC MT 160		Dispersion spontaneity: <b>Initial:</b> mesotrione florasulam 103.89% 103.77% <b>After 1 year:</b> mesotrione florasulam 98.51% 99.57% <b>After 2 years:</b> mesotrione florasulam 98.38% 98.00%			
	CIPAC MT 185		Wet sieve test: <b>Initial:</b> Residue in 75 µm sieve: 0.00% <b>After 1 year:</b>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Residue in 75 µm sieve: 0.00% <b>After 2 years:</b> Residue in 75 µm sieve: 0.00%			
	CIPAC MT 148.1		Pourability: <b>Initial:</b> R= 1.26%, R'=0.19% <b>After 1 year:</b> R= 1.14%, R'=0.18% <b>After 2 years:</b> R= 1.19%, R'=0.14%			
	CropLife International Technical Monograph no. 17		Package stability: <b>After 1 year:</b> The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package, negligible mass change. <b>After 2 years:</b> The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package, negligible mass change.			
	HPLC		<b>Initial:</b> Mesotrione content: 9.99% Florasulam content: 0.279% <b>After 1 year:</b> Mesotrione content: 9.97% Florasulam content: 0.29% <b>After 2 years:</b> Mesotrione content: 9.60% Florasulam content: 0.29%			
	UHPLC		Impurities content: <b>Initial:</b> 1-cyano-6-(methylsulfonyl)-7-nitro-9Hxanthen-9-one standard solution (R287431): < LOQ			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile (R287432): 0.000055% 2.6- DFA: < LOQ <b>After 1 year:</b> 1-cyano-6-(methylsulfonyl)-7-nitro-9Hxanthen-9-one standard solution (R287431): < LOQ 6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile (R287432): 0.000084% 2.6- DFA: < LOQ <b>After 2 years:</b> 1-cyano-6-(methylsulfonyl)-7-nitro-9Hxanthen-9-one standard solution (R287431): < LOQ 6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile (R287432): 0.00000039% 2.6- DFA: < LOQ			
	HS-GC-FID		Impurities content: <b>Initial:</b> 1.2-dichloroethane: < LOQ <b>After 1 year:</b> 1.2-dichloroethane: < LOQ <b>After 2 years:</b> 1.2-dichloroethane: < LOQ			
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 47.3	MEZOFLOR 103 SC, batch no. SNS-H-05-18	Persistent foam: 0.66% w/v: 0 ml after 1 min. and 12 min.	Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry;	The test was performed with the highest recommended concentration. Accepted.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1		0.4%	mesotrione 103.86%	florasulam 103.21%		BF-20/21; Warsaw; July 2021	The test was performed with the highest recommended concentration (0.66% w/v=0.63% v/v) and the concentration slightly higher than the lowest recommended conc. (0.4% w/v=0.38% v/v). Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160		0.66%	103.07%	102.56%			mesotrione: 103.89% florasulam: 103.77%
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)	Not applicable. It is not a solid plant protection product.							According to SANCO/10473/2003 –rev.5, particle size distribution could be required for SC formulation. However, according to the FAO Manual (2022), the determination of particle size range by laser diffraction is not an ideal criterion to ensure the suitability of liquid formulations. This should be evaluated by wet sieve test (MT 185) and suspensibility (MT 184.1) or



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						dispersion stability (MT 180). As wet sieve test and suspensibility were tested and the results are acceptable the lack of this study can be accepted. Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	MEZOFLOR 103 SC, batch no. SNS-H-05-18	Residue in 75 µm sieve: 0.00%	Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	Accepted.
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.					

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	MEZOFLO 103 SC, batch no. SNS-H-05-18	R= 1.26 % R’= 0.19 %			Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	Accepted.
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 of tank mixes (KCP 2.9.1)	Not applicable. Tank mixes are not recommended.							
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable. Tank mixes are not 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)	“Dobra praktyka postępowania przy stosowaniu środków ochrony roślin” issued by Research Institute of Horticulture (ISBN 978-83-	MEZOFLO 103 SC, batch no. SNS-H-05-18	Effectiveness of the equipment cleaning procedure			N	Renata Buczek, Piotr Paleń, Synthos Agro Sp. z o.o. Agro/1/21 Oświęcim, June 2021	According to the brochure „Dobra praktyka postępowania przy stosowaniu środków ochrony roślin" (‘Good practice in the use of plant protection products’) issued by Research Institute of Horticulture (ISBN 978-83-89800-63-3), the effective method of washing is the
			Recommended concentration: 0.75 L with 200 L of water					
			Tested item	Concentration of mesotrione	Concentration of florasulam			
			Spray liquid	356 ppm	11 ppm			
			1 <sup>st</sup> washing liquid	15 ppm	1 ppm			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments															
	89800-63-3)		<table><tr><td>2<sup>nd</sup> washing liquid</td><td>5 ppm</td><td>&lt; LOQ</td></tr></table> <p>Recommended concentration: 1.25 L with 200 L of water</p> <table><tr><td>Tested item</td><td>Concentration of mesotrione</td><td>Concentration of florasulam</td></tr><tr><td>Spray liquid</td><td>598 ppm</td><td>18 ppm</td></tr><tr><td>1<sup>st</sup> washing liquid</td><td>25 ppm</td><td>0.5 ppm</td></tr><tr><td>2<sup>nd</sup> washing liquid</td><td>7 ppm</td><td>&lt; LOQ</td></tr></table> <p>LOQ = 0.1 ppm for mesotrione and florasulam</p>	2 <sup>nd</sup> washing liquid	5 ppm	< LOQ	Tested item	Concentration of mesotrione	Concentration of florasulam	Spray liquid	598 ppm	18 ppm	1 <sup>st</sup> washing liquid	25 ppm	0.5 ppm	2 <sup>nd</sup> washing liquid	7 ppm	< LOQ				method that allows the volume of water corresponding to 10% of tank capacity to dilute residues of the a.s. to below 2% of the initial concentration in spray liquid. Considering the results, the effectiveness of the equipment cleaning procedure is acceptable. Accepted.
2 <sup>nd</sup> washing liquid	5 ppm	< LOQ																				
Tested item	Concentration of mesotrione	Concentration of florasulam																				
Spray liquid	598 ppm	18 ppm																				
1 <sup>st</sup> washing liquid	25 ppm	0.5 ppm																				
2 <sup>nd</sup> washing liquid	7 ppm	< LOQ																				
Other/special studies (KCP 2.11)	CropLife International Technical Monograph no. 17	MEZOFLOR 103 SC, batch no. SNS-H-05-18	Package stability: The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.		Y	Enzo Arévalo, Ph.D.; Łukasiewicz Research Network - Institute of Industrial Organic Chemistry; BF-20/21; Warsaw; July 2021	The packaging is stable during ambient storage for 2 years. Accepted.															
							The formulation need not be classified according to Reg. (EC) 1272/2008 under physicochemical assessment.  The product is not explosive, not flammable, not oxidising, and hasn't got the auto-ignition temperature up															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>to 585°C - none of these end-points meets the criteria for physical-chemical classification according to CLP.</p> <p>The product is a water-based SC formulation, so it is not pyrophoric and does not emit flammable gases when in contact with water.</p> <p>The formulation is not an organic peroxide.</p> <p>The formulation does not contain any mutually reactive groups, sulphonyl halides/cyanides/hydrazides, phosphites, strained rings, olefins or cyanates so it is not a self-reactive substance.</p> <p>One of the co-formulants is classified as H290 – May be corrosive to metals, but with its very low content in the formulation it is unlikely to expect the product to be corrosive to metals.</p>

### 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 accelerated storage and 2-year shelf-life stability study, the formulation was stored in commercial packaging (1 L bottles made of HDPE) and the packaging remained stable during the storage, therefore, the proposed commercial packs are considered acceptable. Since the formulation is SC formulation, it is possible, according to the guideline of the Ministry of Agriculture and Rural Development (Wytuczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin), to extrapolate the results to another plastic packaging, therefore, also the other proposed commercial packs made of PE/PA are considered acceptable.
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Packagings proposed for MEZOFLOR 103 SC are as follows:

**0.25 l, 0.5 l, 1 l** HDPE bottle  
**0.5 l** PE/PA bottle  
**5 l, 10 l, 20 l** HDPE canister  
**220 l** HDPE drum  
**1000 l** HDPE container

**Table 4.1-1: Packaging information for 0.25 litre bottle**

Type	Description
Material:	HDPE
Shape/size:	Bottle / 60 - 65 mm x 125 – 135 mm
Opening and closure:	polyethylene screw cap, 40 – 50 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 0.5 litre bottle**

Type	Description
Material:	HDPE
Shape/size:	Bottle / 65 - 75 mm x 170 – 190 mm
Opening and closure:	polyethylene screw cap, 40 – 60 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information for 0.5 litre bottle**

Type	Description
Material:	PE/PA

Type	Description
Shape/size:	cylindrical / approx. 60 - 80 mm diameter x 180 - 200 mm
Opening:	40 - 60 mm diameter
Closure:	screw cap

**Table 4.1-4: Packaging information for 1 litre bottle**

Type	Description
Material:	HDPE
Shape/size:	Bottle / 85 - 95 mm x 230 – 250 mm
Opening and closure:	polyethylene screw cap, 40 – 60 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information for 5 litre canister**

Type	Description
Material:	HDPE
Shape/size:	125 - 145 mm x 190 – 200 mm x 295 – 320 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 10 litre canister**

Type	Description
Material:	HDPE
Shape/size:	160 - 185 mm x 220 – 250 mm x 370 – 390 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm
Seal:	With liner or induction sealing
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-7: Packaging information for 20 litre canister**

Type	Description
Material:	HDPE
Shape/size:	230 - 265 mm x 280 – 300 mm x 365 – 405 mm
Opening and closure:	polyethylene screw cap, 50 – 65 mm
Seal:	With liner or induction sealing

Type	Description
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-8: Packaging information for 220 litre drum with cork**

Type	Description
Material:	HDPE
Shape/size:	Cylindrical / approx. 581 mm x 935 mm

**Table 4.1-9: Packaging information for 1000 litre container**

Type	Description
Material:	HDPE
Shape/size:	1000-1100 mm x 1150-1250 mm x 950 -1050 mm

## 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	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.2.1	Daniel Buczkowski	2021	MEZOFLOR 103 SC Determination of explosive properties Study code number: BW – 14/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.2.2	Paulina Flasińska	2021	MEZOFLOR 103 SC Determination of flash point, auto – ignition temperature and oxidising properties Study code number: BC – 21/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.3.1	Paulina Flasińska	2022	MEZOFLOR 103 SC Determination of flash point,	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
			Study code number: BC – 04/22 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished		
KCP 2.3.3	Paulina Flasińska	2021	MEZOFLOR 103 SC Determination of flash point, auto – ignition temperature and oxidising properties Study code number: BC – 21/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.4.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.4.2	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.5.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low	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
			temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished		
KCP 2.5.2	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.6.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	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
KCP 2.7.3	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.4	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.5	Jarosław Kupiec	2022	MEZOFLOR 103 SC Part II: Determination of physicochemical properties of the preparation after one year of storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.7.5	Jarosław Kupiec	2023	MEZOFLOR 103 SC Determination of physicochemical properties. Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Synthos Agro Sp. z o.o.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 2.8.2	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.3	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.5	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCP 2.8.7	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP	N	Synthos Agro Sp. z o.o.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Unpublished		
KCP 2.11	Renata Buczek, Piotr Paleń	2021	MEZOFLOR 103 SC Effectiveness of the equipment cleaning procedure Study code number: AGRO/1/21 Synthos Agro Sp.z o.o. Oświęcim, 2021 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                    Mesotrione**

No new or additional data.

### **A 2.2                    Florasulam**

No new or additional data.