

# **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: RNB 072 A

Product name: **MATLAM**

Chemical active substance:

Florasulam, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## **CORE ASSESSMENT**

(authorization)

Applicant: XXXX

Submission date: June 2024

Evaluation date: February 2025

MS Finalisation date: May 2025

## Version history

When	What
February 2025	Version evaluated by zRMS PL

## Table of Contents

<b>1</b>	<b>Section 1: Identity of the plant protection product.....</b>	<b>4</b>
1.1	Applicant (KCP 1.1) .....	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2) .....	4
1.2.1	Producer(s) of the preparation .....	4
1.2.2	Producer(s) of the active substance(s) .....	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s) .....	4
1.2.3.1	Florasulam.....	4
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) .....	5
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	5
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	5
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	5
1.5	Type and code of the plant protection product (KCP 1.5).....	6
1.6	Function (KCP 1.6) .....	6
<b>2</b>	<b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>	<b>7</b>
<b>3</b>	<b>Section 3 is presented as a separate document .....</b>	<b>16</b>
<b>4</b>	<b>Section 4: Further information on the plant protection product .....</b>	<b>17</b>
4.1	Packaging and Compatibility with the Preparation (KCP 4.4) .....	17
4.2	Packaging and Compatibility with the Preparation (KCP 4.4) .....	17
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>27</b>
<b>Appendix 2</b>	<b>Additional data on the physical, chemical and technical properties of the active substance.....</b>	<b>29</b>
A 2.1	Florasulam.....	29

State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

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: XXXX.  
Address: XXXX

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

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

#### **1.2.1 Producer(s) of the preparation**

Name: XXXX.  
Address: XXXX

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

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

Name: XXXX.  
Address: XXXX

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 Florasulam**

Florasulam	min. 970 g/kg (SANTE/10542/2015 Rev 1)
Florasulam	min. 980 g/kg (Rainbow source)
2,6-DFA	max. 2.0 g/kg (SANTE/10542/2015 Rev 1)

### 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: MATLAM  
Company code number: RNB 072 A

### 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)
Florasulam	50.00 g/L	45.00 – 55.00 g/L (± 10%)	51.02 g/L	4.91

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

\*\* Based on the density of the formulation = 1.040 g/mL

**Table 1.4-2: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
2,6-DFA	0.102 g/L

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

**Table 1.4-3: 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)

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)**

The product is intended to be used as 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 white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 495 °C. In aqueous solution, it has a pH value around 4.84 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 commercial packaging*. Its technical characteristics are acceptable for a *Suspension concentrate* formulation.

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

Neither classification or labelling are relevant for this section.

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

No risk and safety phrases are relevant for this section.

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

The product RNB 072 A complies with FAO specifications.

### **Formulation used for tests**

The formulation used for tests is the one cited in dRR Part C.

### **RMS conclusion on the PPP composition equivalence to the Kantor 050 SC and Floras 50 SC:**

From physicochemical perspective **MATLAM is not considered equivalent/ comparable to already registered Kantor 050 SC in Poland under Composition's comparison in accordance with Article 34 of Regulation 1107/2009.** So, unprotected physicochemical data taken from Kantor 050 SC cannot be used to support Matlam registration in Poland.

From physicochemical perspective **MATLAM is considered equivalent/ comparable to already registered Floras 50 SC in Poland** under Composition's comparison. Applicant has provided the letter of access to the Floras 50 SC data .So, physicochemical data taken from Floras 50 SC can be used to support Matlam registration in Poland.

**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)	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Floras 50 SC (Batch No. RFEAR0501)	Homogeneous, white liquid with characteristic odor	Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
Explosive properties (KCP 2.2.1)	Theoretical	-	The composition does not contain any co-formulants with oxidizing/explosive properties, therefore it is assumed that test item does not exhibit such properties as well.	N	-	Accepted Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
Oxidizing properties (KCP 2.2.2)	Theoretical	-	The composition does not contain any co-formulants with oxidizing/explosive properties, therefore it is assumed that test item does not exhibit such properties as well.	N	-	Accepted Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
Flash point (KCP 2.3.1)	EEC A.9	Floras 50 SC (Batch No. RFEAR0501)	The test item has no flash point until the boiling point.	Y	P. Flasińska, 2022 Report No. BC-28/22	Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
Flammability (KCP 2.3.2)	-	-	Not relevant	-	-	
Self-heating (KCP 2.3.3)	EEC A.15	Floras 50 SC (Batch No. RFEAR0501)	Auto-ignition temperature: 495°C	Y	P. Flasińska, 2022 Report No. BC-28/22	Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required as the pH is in the range of 4-10.	-	-	
pH of a 1% aqueous	CIPAC MT 75.3	Floras 50 SC	pH neat = 6.00	Y	J. Kupiec, 2022	Accepted



Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
dilution, emulsion or dispersion (KCP 2.4.2)		(Batch No. RFEAR0501)	pH 1% suspension = 4.84				Report No. BF-21/22	Data for Floras 50 SC are acceptable for the Matlam in Poland
Viscosity (KCP 2.5.1)	CIPAC MT 192	Floras 50 SC (Batch No. RFEAR0501)	Shear rate/Temp.	20°C	40°C	Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
			5.0 s <sup>-1</sup>	620 mPa·s	556 mPa·s			
			10.0 s <sup>-1</sup>	361 mPa·s	324 mPa·s			
			25.0 s <sup>-1</sup>	181 mPa·s	161 mPa·s			
			50.0 s <sup>-1</sup>	110 mPa·s	97 mPa·s			
Surface tension (KCP 2.5.2)	OECD 115	Floras 50 SC (Batch No. RFEAR0501)	56.18 mN/m			Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland  No classification can be assign
Relative density (KCP 2.6.1)	OECD 109	Floras 50 SC (Batch No. RFEAR0501)	Relative denesity = 1.040 g/mL			Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted Data for Floras 50 SC are acceptable for the Matlam in Poland
Bulk density (KCP 2.6.2)	-	-	Not relevant			-	-	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 148 CIPAC MT 184.1 CIPAC MT 160 CIPAC MT 185 CIPAC MT 187 Appropriated validated	Floras 50 SC (Batch No. RFEAR0501)	Test	Initial	After accelerated storage		J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
			Florasulam content	4.86% w/v	4.80% w/v			
			2,6-DFA content	<LOQ	<LOQ			
			Appearance	Homogeneous, white liquid with	Homogeneous, white liquid with			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
	method according to SANCO/3030/99 rev. 5			characteristic odor	characteristic odor			
			pH neat	6.0	6.10			
			pH 1% suspension	4.84	5.15			
			Pourability	R = 1.46%	R = 1.51%			
			Suspensibility	0.65 g/L in Standard Water D: 80.72%	0.65 g/L in Standard Water D: 77.30%			
			Wet sieve test	0.0% remained on 75µm sieve	0.0% remained on 75µm sieve			
			Spontaneity of dispersion	95.72%	96.38%			
			Particle size distribution	D <sub>10</sub> = 0.538 D <sub>50</sub> = 2.021 D <sub>90</sub> = 5.679	D <sub>10</sub> = 0.553 D <sub>50</sub> = 2.184 D <sub>90</sub> = 5.953			
			Stability of packaging	-	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant			-	-	
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not relevant			-	-	

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 184.1 CIPAC MT 185 CIPAC MT 187	Floras 50 SC (Batch No. RFEAR0501)	Test	Initial	After 7 days at 0°C		J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
			Pourability	R = 1.46%	R = 1.51%			
			Suspensibility	0.65 g/L in Standard Water D: 80.72%	0.65 g/L in Standard Water D: 85.83%			
			Wet sieve test	0.0% remained on 75µm sieve	0.0% remained on 75µm sieve			
			Particle size distribution	D <sub>10</sub> = 0.538 D <sub>50</sub> = 2.021 D <sub>90</sub> = 5.679	D <sub>10</sub> = 0.603 D <sub>50</sub> = 2.592 D <sub>90</sub> = 3.490			
			Stability of packaging	-	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.			
Ambient temperature shelf life (KCP 2.7.5)	CropLife Technical Monograph No. 17 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 148 CIPAC MT 184.1 CIPAC MT 160 CIPAC MT 185 CIPAC MT 187 Appropriated validated method according to SANCO/3030/99 rev. 5	Floras 50 SC (Batch No. RFEAR0501)	For more detailed information on the storage please refer to the Table 2-2 below.			-	A. Łysik, 2024 Report No. BF-21/22	Accepted  All the physicochemical parameters were accepted for the PPP. A HDPE packaging remained intact after storage. <u>In summary, the shelf life of tho years can be granted for the PPP.</u>  Data for Floras 50 SC

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
								are acceptable for the Matlam in Poland
Shelf life in months (if less than 2 years) (KCP 2.7.6)	CropLife Technical Monograph No. 17 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 148 CIPAC MT 184.1 CIPAC MT 160 CIPAC MT 185 CIPAC MT 187 Appropriated validated method according to SANCO/3030/99 rev. 5	Floras 50 SC (Batch No. RFEAR0501)	Test	Initial	After 12 months		A. Łysik, 2023 Report No. BF-21/22	Not required. Please refer to the point above.  Data for Floras 50 SC are acceptable for the Matlam in Poland
			Florasulam content	4.86% w/w	4.80% w/w 51.10 g/L			
			2,6-DFA content	<LOQ	<LOQ			
			Appearance	Homogeneous, white liquid with characteristic odor	Homogeneous, white liquid with characteristic odor			
			pH neat	6.0	5.73			
			pH 1% suspension	4.84	4.84			
			Pourability	R = 1.46%	R = 1.51%			
			Suspensibility	0.65 g/L in Standard Water D: 80.72%	0.65 g/L in Standard Water D: 71.72%			
			Wet sieve test	0.0% remained on 75µm sieve	0.0% remained on 75µm sieve			
			Spontaneity of dispersion	95.72%	92.55%			
			Particle size distribution	D <sub>10</sub> = 0.538 D <sub>50</sub> = 2.021 D <sub>90</sub> = 5.679	D <sub>10</sub> = 0.603 D <sub>50</sub> = 2.592 D <sub>90</sub> = 3.490			
			Stability of packaging	-	The shape and colour of the 1 litre HDPE package were stable. No			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					visible leaking in the package. Negligible mass change.			
Wettability (KCP 2.8.1)	-	-	Not relevant			-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Floras 50 SC (Batch No. RFEAR0501)	0.4 g/L in Standard Water D			Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	Floras 50 SC (Batch No. RFEAR0501)	0.65 g/L in Standard Water D: 80.72%			Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Floras 50 SC (Batch No. RFEAR0501)	95.72%			Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant			-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant			-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant			-	-	
Wet sieve test	CIPAC MT 185	Floras 50 SC	0.0% remained on 75µm sieve			Y	J. Kupiec, 2022	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.1.2)		(Batch No. RFEAR0501)			Report No. BF-21/22	Data for Floras 50 SC are acceptable for the Matlam in Poland
Dust content (KCP 2.8.5.2.1)	CIPAC MT 187	Floras 50 SC (Batch No. RFEAR0501)	D <sub>10</sub> = 0.538 D <sub>50</sub> = 2.021 D <sub>90</sub> = 5.679	Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not relevant	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not relevant	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148	Floras 50 SC (Batch No. RFEAR0501)	R = 1.46%	Y	J. Kupiec, 2022 Report No. BF-21/22	Accepted  Data for Floras 50 SC are acceptable for the Matlam in Poland
Dustability following accelerated storage	-	-	Not relevant	-	-	

Annex point	Method used / deviations	Test materi- al	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant	-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not relevant	-	-	
Other/special studies (KCP 2.11)	-	-	Not relevant	-	-	

**Table 2-2: Summary of the two-year ambient storage stability study**

Initial preparation, after accelerated storage, low temperature storage and after 1 and 2 years of storage						
Test type	Methods	Findings				
		Initial preparation (5.11)	After accelerated storage (5.11)	After low temperature storage (5.11)	After 1 year (5.12)	After 2 years
Appearance	OPPTS 830.6302-04	homogenous, white liquid of characteristic odour	homogenous, white liquid of characteristic odour	-	homogenous, white, concentrated suspension, of characteristic odour	homogenous, white, concentrated suspension, of characteristic odour
pH of 1% undiluted 1%	CIPAC MT 75.3	6.00	6.10	-	5.73	5.68
		4.84	5.15	-	4.84	4.81
Density	OECD 109	Absolute 1.040 g/ml Relative 1.040 20°C 40°C	-	-	-	-
Viscosity	CIPAC MT 192	5.0 s <sup>-1</sup> : 620 mPa-s; 556 mPa-s; 10.0 s <sup>-1</sup> : 361 mPa-s; 324 mPa-s; 25.0 s <sup>-1</sup> : 181 mPa-s; 161 mPa-s; 50.0 s <sup>-1</sup> : 110 mPa-s; 97 mPa-s.	-	-	-	-
Persistent foam	CIPAC MT 47.3	4 ml after 1 min 1 ml after 12 min	-	-	-	-
Pourability	CIPAC MT 148	R = 1.46%	R = 1.51%	-	R = 1.37%	R = 1.59%
Surface tension	OECD 115	56.18 mN/m	-	-	-	-
Suspension stability	CIPAC MT 184.1	80.72%	77.30%	85.83%	71.72%	67.31%
Dispersion spontaneity	CIPAC MT 160	95.72%	96.38%	-	92.55%	95.11%
Wet sieve test	CIPAC MT 185	Residue in 75 µm sieve 0.00%	Residue in 75 µm sieve 0.00%	Residue in 75 µm sieve 0.00%	Residue in 75 µm sieve 0.00%	Residue in 75 µm sieve 0.00%
Particle size distribution	CIPAC MT 187	Average d <sub>10</sub> = 0.538 µm Average d <sub>50</sub> = 2.021 µm Average d <sub>90</sub> = 5.679 µm Average d <sub>4,3</sub> = 2.627 µm SD = 0.008 µm RSD = 0.305 %	Average d <sub>10</sub> = 0.553 µm Average d <sub>50</sub> = 2.184 µm Average d <sub>90</sub> = 5.953 µm Average d <sub>4,3</sub> = 2.780 µm SD = 0.115 µm RSD = 4.137 %	Average d <sub>10</sub> = 0.530 µm Average d <sub>50</sub> = 2.021 µm Average d <sub>90</sub> = 5.672 µm Average d <sub>4,3</sub> = 2.622 µm SD = 0.050 µm RSD = 1.907 %	Average d <sub>10</sub> = 0.603 µm Average d <sub>50</sub> = 2.592 µm Average d <sub>90</sub> = 7.228 µm Average d <sub>4,3</sub> = 3.490 µm SD = 0.051 µm RSD = 1.941 %	Average d <sub>10</sub> = 0.881 µm Average d <sub>50</sub> = 4.011 µm Average d <sub>90</sub> = 18.03 µm Average d <sub>4,3</sub> = 6.887 µm SD = 0.232 µm RSD = 3.369 %
Package stability	CropLife International Technical Monograph No. 17.	1 litre HDPE	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.	-	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.	The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change.
Florasulam content	HPLC, MT/BA-37/22	4.86%	4.80%	-	4.91%	4.98%
Impurities content: 2.6-DFA	UHPLC – MS/MS	< LOQ	< LOQ	-	< LOQ	< LOQ

### 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)

### 4.2 Packaging and Compatibility with the Preparation (KCP 4.4)

#### RMS comment

All the packaging accepted for the Floras 50 SC is acceptable for the Matlam as well.

**Table 4.2-1: Packaging information for 100 ml bottle**

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 45.0 mm diameter x 115.0 mm
Opening:	26.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-2: Packaging information for 250 ml bottle**

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 58.0 mm diameter x 149.0 mm
Opening:	31.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-3: Packaging information for 500 ml bottle**

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 72.0 mm diameter x 192.0 mm
Opening:	38.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-4: Packaging information for 1.0 L bottle**

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 88.5 mm diameter x 250.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-5: Packaging information for 4.0 L square barrel**

Type	Description
Material:	HDPE
Shape/size:	Square barrel / approx. 190.0 mm x 250.0 mm x 282.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-6: Packaging information for 5.0 L square barrel**

Type	Description
Material:	HDPE
Shape/size:	Square barrel / approx. 183.0 mm x 133.0 mm x 300.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-7: Packaging information for 10.0 L square barrel**

Type	Description
Material:	HDPE
Shape/size:	Square barrel / approx. 260.0 mm x 185.0 mm x 305.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-8: Packaging information for 20.0 L square barrel**

Type	Description
Material:	HDPE
Shape/size:	Square barrel / approx. 285.00 mm x 225.0 mm x 474.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-9: Packaging information for 200.0 L drum**

Type	Description
Material:	HDPE
Shape/size:	Drum / approx. 585.0 mm diameter x 940.0 mm
Opening:	64 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-10: Packaging information for 100 ml bottle**

Type	Description
Material:	HDPE/PA
Shape/size:	Round bottle / approx. 45.0 mm diameter x 115.0 mm
Opening:	26.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-11: Packaging information for 250 ml bottle**

Type	Description
Material:	HDPE/PA
Shape/size:	Round bottle / approx. 58.0 mm diameter x 149.0 mm

Type	Description
Opening:	31.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-12: Packaging information for 500 ml bottle**

Type	Description
Material:	HDPE/PA
Shape/size:	Round bottle / approx. 72.0 mm diameter x 192.0 mm
Opening:	38.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-13: Packaging information for 1.0 L bottle**

Type	Description
Material:	HDPE/PA
Shape/size:	Round bottle / approx. 88.5 mm diameter x 250.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-14: Packaging information for 4.0 L square barrel**

Type	Description
Material:	HDPE/PA
Shape/size:	Square barrel / approx. 190.0 mm x 250.0 mm x 282.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-15: Packaging information for 5.0 L square barrel**

Type	Description
Material:	HDPE/PA
Shape/size:	Square barrel / approx. 183.0 mm x 133.0 mm x 300.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-16: Packaging information for 10.0 L square barrel**

Type	Description
Material:	HDPE/PA
Shape/size:	Square barrel / approx. 260.0 mm x 185.0 mm x 305.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-17: Packaging information for 20.0 L square barrel**

Type	Description
Material:	HDPE/PA
Shape/size:	Square barrel / approx. 285.00 mm x 225.0 mm x 474.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-18: Packaging information for 200.0 L drum**

Type	Description
Material:	HDPE/PA
Shape/size:	Drum / approx. 585.0 mm diameter x 940.0 mm
Opening:	64 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

**Table 4.2-19: Packaging information for 100 ml bottle**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Round bottle / approx. 45.0 mm diameter x 115.0 mm
Opening:	26.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-20: Packaging information for 250 ml bottle**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Round bottle / approx. 58.0 mm diameter x 149.0 mm
Opening:	31.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-21: Packaging information for 500 ml bottle**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Round bottle / approx. 72.0 mm diameter x 192.0 mm
Opening:	38.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-22: Packaging information for 1.0 L bottle**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Round bottle / approx. 88.5 mm diameter x 250.0 mm
Opening:	50 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-23: Packaging information for 4.0 L square barrel**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Square barrel / approx. 190.0 mm x 250.0 mm x 282.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-24: Packaging information for 5.0 L square barrel**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Square barrel / approx. 183.0 mm x 133.0 mm x 300.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-25: Packaging information for 10.0 L square barrel**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Square barrel / approx. 260.0 mm x 185.0 mm x 305.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-26: Packaging information for 20.0 L square barrel**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Square barrel / approx. 285.00 mm x 225.0 mm x 474.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-27: Packaging information for 200.0 L drum**

Type	Description
Material:	HDPE/EVOH
Shape/size:	Drum / approx. 585.0 mm diameter x 940.0 mm
Opening:	64 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-28: Packaging information for 100 ml bottle**

Type	Description
Material:	HDPE/F
Shape/size:	Round bottle / approx. 45.0 mm diameter x 115.0 mm
Opening:	26.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-29: Packaging information for 250 ml bottle**

Type	Description
Material:	HDPE/F
Shape/size:	Round bottle / approx. 58.0 mm diameter x 149.0 mm
Opening:	31.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded



Type	Description
UN/ADR	compliant

**Table 4.2-30: Packaging information for 500 ml bottle**

Type	Description
Material:	HDPE/F
Shape/size:	Round bottle / approx. 72.0 mm diameter x 192.0 mm
Opening:	38.5 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-31: Packaging information for 1.0 L bottle**

Type	Description
Material:	HDPE/F
Shape/size:	Round bottle / approx. 88.5 mm diameter x 250.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-32: Packaging information for 4.0 L square barrel**

Type	Description
Material:	HDPE/F
Shape/size:	Square barrel / approx. 190.0 mm x 250.0 mm x 282.0 mm
Opening:	50 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-33: Packaging information for 5.0 L square barrel**

Type	Description
Material:	HDPE/F
Shape/size:	Square barrel / approx. 183.0 mm x 133.0 mm x 300.0 mm
Opening:	63 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-34: Packaging information for 10.0 L square barrel**

Type	Description
Material:	HDPE/F
Shape/size:	Square barrel / approx. 260.0 mm x 185.0 mm x 305.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-35: Packaging information for 20.0 L square barrel**

Type	Description
Material:	HDPE/F
Shape/size:	Square barrel / approx. 285.00 mm x 225.0 mm x 474.0 mm
Opening:	63 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.2-36: Packaging information for 200.0 L drum**

Type	Description
Material:	HDPE/F
Shape/size:	Drum / approx. 585.0 mm diameter x 940.0 mm
Opening:	64 mm inner diameter
Closure:	HDPE screw cap with PE gasket
Seal:	Pressure seal
Manner of construction	extruded
UN/ADR	compliant

## 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 2.1-2.11	J. Kupiec	2022	Floras 50 SC Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Instytut Przemysłu Organicznego Report No. BF-21/22 GLP Unpublished	N	Elvita
KCP 2.3.1 KCP 2.3.3	P. Flasińska	2022	Floras 50 SC Determination of flash point and auto-ignition temperature Instytut Przemysłu Organicznego Report No. BC-28/22 GLP Unpublished.	N	Elvita
KCP 2.7.6	A. Łysik	2023	Floras 50 SC Stage I: Determination of physicochemical properties of the preparation after one year of storage. Instytut Przemysłu Organicznego Report No. BF-21/22 GLP Unpublished	N	Elvita
KCP 2.7.5	A. Łysik	2024	Floras 50 SC Final report Determination of physicochemical properties. Instytut Przemysłu Organicznego Report No. BF-21/22 GLP Unpublished	N	Elvita

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

**List of data relied on and not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

### **A 2.1            Florasulam**

No new data submitted