

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: FLORAS 50 SC

Product name(s): Floras 50 SC

Chemical active substance:

Florasulam, 50 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 30/11/2023

MS Finalisation date: April 2024 (initial Core Assessment)

June 2024 (final Core Assessment)

Version history

When	What
November 2023	Original version from applicant for submission to zRMS: Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009.
April 2024	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
June 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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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:

- The results of the stability test of the plant protection product stored in HDPE packaging at ambient temperature after 2 years of storage should be provided.
- Suspensibility results should be given for the highest and lowest recommended concentrations.
- Persistence of foaming results should be given for the highest and lowest recommended concentrations.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)



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 Florasulam



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: Floras 50 SC

Company code number: Floras 50 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)

The formulation of the product wasn't the representative formulation.

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	None	51,55	4,96

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

** Based on the density of the formulation = 1,04 g/L

Table 1.4-2: Safener and synergists

Neither safener nor synergists were used in the formulation.

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

Table 1.4-3: Information on the active substance(s)

Type	Name/Code Number
ISO common name	Florasulam
CAS No.	145701-23-1
EC No.	-
CIPAC No.	616
Salt, ester anion or cation present	-

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: SC (Suspension Concentrate)

[Code: (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 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 495 °C. In aqueous solution, it has a pH value around 6,0 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 two-year stability study at ambient temperature is ongoing. The product showed no significant physical changes after one years of storage. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging material. Its technical characteristics are acceptable for a *Suspension Concentrate* formulation.

The intended concentration of use is 0.025% to 0.05%.

The product is not intended to be mixed in the tank together with other products.

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

None.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None.

Compliance with FAO specifications:

At the time of evaluation no FAO specification was allocated.

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	Floras 50 SC Batch No.: RFEAR0501	Homogenous white liquid of characteristic odour.	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.																																		
Explosive properties (KCP 2.2.1)	Not applicable. Considering the composition of the formulation and the individuals components, the product is not expected to have explosive and oxidizing properties.					Accepted.																																		
Oxidizing properties (KCP 2.2.2)						The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.																																		
Flash point (KCP 2.3.1)	EEC A.9	Floras 50 SC Batch No.: RFEAR0501	<div>Product not got the flash point up to the boiling point according to A.9 method.</div> <div>Floras 50 SC has no flash point up to the boiling point according to criteria of EC A.9 method.</div> <table><tr><td colspan="2">t_{ambient} = 27 °C</td><td colspan="2">p_{ambient} = 1006 hPa</td></tr><tr><td rowspan="3">Preliminary test</td><td>from 25 °C to 49 °C</td><td colspan="2">no flash point</td></tr><tr><td>from 52 °C to 100 °C</td><td colspan="2">the vapors extinguish the flame</td></tr><tr><td>103 °C</td><td colspan="2">the beginning of the boil</td></tr><tr><td rowspan="3">Test no. 1</td><td>from 32 °C to 48 °C</td><td colspan="2">no flash point</td></tr><tr><td>from 49 °C to 99 °C</td><td colspan="2">the vapors extinguish the flame</td></tr><tr><td>100 °C</td><td colspan="2">the beginning of the boil</td></tr><tr><td rowspan="3">Test no. 2</td><td>from 32 °C to 48 °C</td><td colspan="2">no flash point</td></tr><tr><td>from 49 °C to 99 °C</td><td colspan="2">the vapors extinguish the flame</td></tr><tr><td>100 °C</td><td colspan="2">the beginning of the boil</td></tr></table>	t _{ambient} = 27 °C		p _{ambient} = 1006 hPa		Preliminary test	from 25 °C to 49 °C	no flash point		from 52 °C to 100 °C	the vapors extinguish the flame		103 °C	the beginning of the boil		Test no. 1	from 32 °C to 48 °C	no flash point		from 49 °C to 99 °C	the vapors extinguish the flame		100 °C	the beginning of the boil		Test no. 2	from 32 °C to 48 °C	no flash point		from 49 °C to 99 °C	the vapors extinguish the flame		100 °C	the beginning of the boil		Y	Paulina Flasińska, M.Sc.; Institute of Industrial Organic Chemistry; BC-28/22; Warsaw; 2022	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
t _{ambient} = 27 °C		p _{ambient} = 1006 hPa																																						
Preliminary test	from 25 °C to 49 °C	no flash point																																						
	from 52 °C to 100 °C	the vapors extinguish the flame																																						
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	100 °C	the beginning of the boil																																						
Test no. 2	from 32 °C to 48 °C	no flash point																																						
	from 49 °C to 99 °C	the vapors extinguish the flame																																						
	100 °C	the beginning of the boil																																						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
Flammability (KCP 2.3.2)	Not applicable. It is not a solid or gas plant protection product.					-
Self-heating (KCP 2.3.3)	EEC A.15	Floras 50 SC Batch No.: RFEAR0501	Product not got the auto ignition temperature of 495 °C according to A.15 method. The autoignition temperature is higher than 495 °C.	Y	Paulina Flasińska, M.Sc.; Institute of Industrial Organic Chemistry; BC-28/22; Warsaw; 2022	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
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 (KCP 2.4.2)	CIPAC MT 75.3	Floras 50 SC Batch No.: RFEAR0501	pH = 4,84 at 20 °C. (undiluted pH= 6,00 at 20 °C)	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	Floras 50 SC Batch No.: RFEAR0501	20°C 40°C 5.0 s-1: 620 mPa·s; 556 mPa·s; 10.0 s-1: 361 mPa·s; 324 mPa·s; 25.0 s-1: 181 mPa·s; 161 mPa·s; 50.0 s-1: 110 mPa·s; 97 mPa·s.	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.
Surface tension (KCP 2.5.2)	EEC A.5	Floras 50 SC Batch No.: RFEAR0501	56.18 mN/m at 20.0°C	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.

Annex point		Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
Relative density (KCP 2.6.1)		CIPAC MT 3.2	Floras 50 SC Batch No.: RFEAR0501	1,04 g/ml at 20 °C	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.
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)	Physical state colour and odour	CIPAC MT 46.3	Floras 50 SC Batch No.: RFEAR0501	Homogenous white liquid of characteristic odour	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted. The product showed no significant physical changes after accelerated storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material. Suspensibility results should be given for the highest and lowest recommended concentrations. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial
	pH of 1% aqueous dispersion			5,15			
	Suspension stability			77.30%			
	Pourability			R = 1.51%			
	Dispersion spontaneity			96.38%			
	Wet sieve test			Residue in 75 µm 0.00%			
	Particle size distribution			Average d10 = 0.553 µm Average d50 = 2.184 µm Average d90 = 5.953 µm Average d4,3 = 2.780 µm SD = 0.115 µm RSD = 4.137 %			
	Package stability			The shape and colour of the 1 L HDPE package were stable. No visible leaking in the package. Negligible mass change.			
	Florasulam			4.80%			

Annex point		Method used / deviations		Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
	content				The content of active substance Florasulam in the examined samples was determined in accordance with the method (MT/BA-37/22) in accordance to EU requirements described in SANCO/3030/99 rev. 5 (22/03/19) guideline and according to the Standard Operating Procedure SPO/BA/090/b. The method is based on determination of Florasulam using reversed phase high performance liquid chromatography (RP-HPLC) with UV-VIS detection at wavelength 260 nm.			packaging (HDPE).
	Impurities content: 2.6-DFA	UHPLC – MS/MS	< LOQ					
	Summary of results:							

Annex point		Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / Comments
		Test type		Methods	Findings			
					Initial preparation	After accelerated storage		
		Appearance		OPPTS 830.6302-04	homogenous, white liquid of characteristic odour	homogenous, white liquid of characteristic odour		
		pH	undiluted	CIPAC MT 75.3	6.00	6.10		
			1%		4.84	5.15		
		Density		OECD 109	Absolute 1.040 g/ml Relative 1.040	-		
		Viscosity		CIPAC MT 192	20°C 40°C 5.0 s ⁻¹ : 620 mPa·s; 556 mPa·s; 10.0 s ⁻¹ : 361 mPa·s; 324 mPa·s; 25.0 s ⁻¹ : 181 mPa·s; 161 mPa·s; 50.0 s ⁻¹ : 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%		
		Surface tension		OECD 115	56.18 mN/m	-		
		Suspension stability		CIPAC MT 184.1	80.72%	77.30%		
		Dispersion spontaneity		CIPAC MT 160	95.72%	96.38%		
		Wet sieve test		CPAC MT 185	Residue in 75 µm sieve 0.00%	Residue in 75 µm 0.00%		
		Particle size distribution		CIPAC MT 187	Average d ₁₀ = 0.538 µm Average d ₅₀ = 2.021 µm Average d ₉₀ = 5.679 µm Average d _{4,3} = 2.627 µm SD = 0.008 µm RSD = 0.305 %	Average d ₁₀ = 0.553 µm Average d ₅₀ = 2.184 µm Average d ₉₀ = 5.953 µm Average d _{4,3} = 2.780 µm SD = 0.115 µm RSD = 4.137 %		
		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.		
		Florasulam content		HPLC	4.86%	4.80%		
		Impurities content: 2.6-DFA		UHPLC – MS/MS	< LOQ	< LOQ		

Annex point	Method used / deviations		Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
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)	HPLC		Floras 50 SC Batch No.: RFEAR0501	4,80 %	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3		Floras 50 SC Batch No.: RFEAR0501	Temperatures were between -1,0 °C to 0,2 °C. Observations: - immediately after storage - at room temperature - after 24 h at room temp. and one inversion. Result: Homogenous liquid.	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.
	Suspension stability	CIPAC MT 184.1		85.83%			
	Wet sieve test	CIPAC MT 185		Residue in 75 µm 0.00%			
	Particle size distribution	CIPAC MT 187		Average d10 = 0.530 µm Average d50 = 2.021 µm Average d90 = 5.672 µm Average d4,3 = 2.622 µm SD = 0.050 µm RSD = 1.907 %			
Ambient temperature shelf life (KCP 2.7.5)	Studies are done for Floras 50 SC; Batch No.: RFEAR0501.						The two-year stability study at ambient temperature is ongoing. The product showed no significant physical changes after one years of storage.
	Results of studies after first year of storage at ambient temperature:						
	Physical state colour and odour	Organoleptic	Floras 50 SC Batch No.: RFEAR0501	Homogenous white liquid of characteristic odour	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2023	
	pH of 1% aqueous dispersion	CIPAC MT 75.3		4.84			

Annex point	Method used / deviations		Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
	Pourability	CIPAC MT 148		R = 1.37%			No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material.
	Suspension stability	CIPAC MT 184.1		71.72%			No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.
	Dispersion spontaneity	CIPAC MT 160		92.55%			The stability data indicate a shelf life of 2 years at ambient temperature when stored in commercial packaging (HDPE).
	Wet sieve test	CIPAC MT 185		Residue in 75 µm sieve 0.00%			
	Particle size distribution	CIPAC MT 187		Average d ₁₀ = 0.603 µm Average d ₅₀ = 2.592 µm Average d ₉₀ = 7.228 µm Average d _{4,3} = 3.490 µm SD = 0.051 µm RSD = 1.941 %			
	Package stability	Technical Monograph No. 17		The shape and colour of the 1L HDPE package were stable. No visible leaking in the package. Negligible mass change.			
	Florasulam content	HPLC		4.91 % (51.1 g/l) The content of active substance Florasulam in the examined samples was determined in accordance with the method (MT/BA-37/22) in accordance to EU requirements described in SANCO/3030/99 rev. 5 (22/03/19) guideline and according to the Standard Operating Procedure SPO/BA/090/b. The method is based on determination of Florasulam using reversed phase high performance liquid chromatography (RP-HPLC) with UV-VIS detection at wavelength 260 nm.			
	Impurities content: 2.6-DFA	UHPLC – MS/MS		< LOQ			
Summary of the results:							

Annex point	Method used / deviations		Test material	Findings		GLP Y/N	Reference	Acceptability / Comments
	TABLE 1: SUMMARY OF RESULTS							
	Test type		Methods	Findings				
				Initial preparation	After one year of storage			
	Appearance		OPPTS 830.6302-04	homogenous, white liquid of characteristic odour	homogenous, white, concentrated suspension, of characteristic odour			
	pH	undiluted	CIPAC MT 75.3	6.00	5.73			
		1%		4.84	4.84			
	Density		OECD 109	Absolute 1.040 g/ml Relative 1.040	-			
	Viscosity		CIPAC MT 192	20°C 40°C 5.0 s ⁻¹ : 620 mPa·s; 556 mPa·s; 10.0 s ⁻¹ : 361 mPa·s; 324 mPa·s; 25.0 s ⁻¹ : 181 mPa·s; 161 mPa·s; 50.0 s ⁻¹ : 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 = 1.37%			
	Surface tension		OECD 115	56.18 mN/m	-			
	Suspension stability		CIPAC MT 184.1	80.72%	71.72%			
	Dispersion spontaneity		CIPAC MT 160	95.72%	92.55%			
	Wet sieve test		CPAC MT 185	Residue in 75 µm sieve 0.00%	Residue in 75 µm sieve 0.00%			
	Particle size distribution		CIPAC MT 187	Average d ₁₀ = 0.538 µm Average d ₅₀ = 2.021 µm Average d ₉₀ = 5.679 µm Average d _{4,3} = 2.627 µm SD = 0.008 µm RSD = 0.305 %	Average d ₁₀ = 0.603 µm Average d ₅₀ = 2.592 µm Average d ₉₀ = 7.228 µm Average d _{4,3} = 3.490 µm SD = 0.051 µm RSD = 1.941 %			
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				
Florasulam content		HPLC	4.86 %	4.91 % (51.1 g/l)				
Impurities content: 2,6-DFA		UHPLC – MS/MS	< LOQ	< LOQ				

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 isn't 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	Floras 50 SC Batch No.: RFEAR0501	(0.1 L of the preparation in 200 L of water - highest recommended concentration) 4 ml after 1 min 1 ml after 12 min	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	The test results are acceptable, but since the anti-foaming agent is contained in the formulation, the lowest recommended use should also be tested.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	Floras 50 SC Batch No.: RFEAR0501	(0.1 L of the preparation in 200 L of water - highest recommended concentration) 80.72%	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	The test results are acceptable, but for SC formulations, the results should be given for the highest and lowest recommended concentrations.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Floras 50 SC Batch No.: RFEAR0501	95.72%	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.
Dispersion stability (KCP 2.8.3.3)	Not applicable.					-
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable.					-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Floras 50 SC Batch No.: RFEAR0501	Average d10 = 0.538 µm Average d50 = 2.021 µm Average d90 = 5.679 µm Average d4,3 = 2.627 µm SD = 0.008 µm RSD = 0.305 %	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Floras 50 SC Batch No.: RFEAR0501	Residue in 75 µm sieve 0.00%	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	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.					-
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. Product is not an EC (emulsifiable concentrate) formulation.					-
Emulsion stability (KCP 2.8.6.2)	Not applicable. Product is not an EC (emulsifiable concentrate) formulation.					-
Re-emulsifiability (KCP 2.8.6.3)	Not applicable. Product is not an EC (emulsifiable concentrate) formulation.					-
Flowability (KCP 2.8.7.1)	Not applicable. It is not a plant protection product in the form of granules.					-
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Floras 50 SC Batch No.: RFEAR0501	R = 1.46%	Y	Jarosław Kupiec, M.Sc.; Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022	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. No tank mixtures with this product are recommended.					No tank mixtures are recommended.
Chemical compatibility of tank mixes	Not applicable. No tank mixtures with this product are recommended.					No tank mixtures are recommended.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / Comments
(KCP 2.9.2)						
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)	No additional data.					-

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:	The two-year stability study at ambient temperature is ongoing. The product showed no significant physical changes after one years of storage. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).
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The containers was used for technical properties determinations and the accelerate storage stability study and no problems have been reported. Such packaging and closures are used as standard and their suitability is known from experience.

The materials proposed for use are known from experience to be compatible with solvent based formulations and are resistant to the influences of chemicals. The resistance of packaging material to its contents has been tested in the accelerate storage stability studies and the results show that no detrimental effects were noted thus demonstrating the acceptability of the packaging material.

Table 4.1-1: Packaging information for 1 liter bottle

Type	Description
Trade name:	Romak – Butelka D7 z wlewem Φ 40
Material:	HDPE
Shape/size:	cylindrical / approx. 88.5 ± 1 mm diameter x 231 ± 2 mm; weight 78 ± 2 g
Opening:	40 ± 1 mm inner diameter

Table 4.1-2: Packaging information for 1 liter bottle

Type	Description
Trade name:	Suway – Butelka BO-1
Material:	HDPE
Shape/size:	cylindrical / approx. 84 ± 1.5 mm diameter x 230.1 ± 3 mm
Opening:	38 mm outer diameter

Table 4.1-3: Packaging information for 1 liter bottle

Type	Description
Trade name:	Romak – Butelka D7 z wlewem Φ 55
Material:	HDPE
Shape/size:	cylindrical / approx. 88.5 mm diameter x 227 mm; weight 80 ± 2 g
Opening:	55 mm inner diameter

Table 4.1-4: Packaging information for 5 liter canister

Type	Description
Trade name:	Romak - Kanister “AGRO”
Material:	HDPE
Shape/size:	canister / approx. 195 mm x 139 mm x 305 mm; weight 230 g
Opening:	39 mm inner diameter

Table 4.1-5: Packaging information for 10 liter canister

Type	Description
Trade name:	Suway – Kanister K-10N
Material:	HDPE
Shape/size:	canister / approx. 228 ± 7 mm x 192 ± 3 mm x 313 ± 7 mm
Opening:	52 mm outer diameter

Table 4.1-6: Packaging information for 20 liter canister

Type	Description
Trade name:	Suway – K-20N
Material:	HDPE
Shape/size:	canister / approx. 292 ± 8 mm x 257.5 ± 6 mm x 376 ± 8 mm
Opening:	52 mm inner diameter

Table 4.1-7: Packaging information for 120 ml bottle

Type	Description
Trade name:	Turnaire – 0L120 C40 Obturateur
Material:	HDPE
Shape/size:	bottle / 50 ± 1 mm x 93 ± 1 mm
Opening:	28.4 ± 0.3 mm inner diameter

Table 4.1-8: Packaging information for 250 ml bottle

Type	Description
Trade name:	Chempak – Pojemnik P250/38
Material:	HDPE
Shape/size:	bottle / 110.7 ± 1 mm x 63 ± 1 mm
Opening:	30.5 ± 0.2 mm inner diameter

Table 4.1-9: Packaging information for 500 ml bottle

Type	Description
Trade name:	Inter Chempak – Butelka B-28
Material:	HDPE
Shape/size:	bottle / 221 ± 0.5 % x 65 ± 1.5 %
Opening:	38 mm inner diameter

Table 4.1-10: Packaging information for 220 liter drum

Type	Description
Trade name:	Schutz – 220l F1 tight drum / blue
Material:	HDPE
Shape/size:	drum / 935 ± 5 mm x 581 ± 3 mm
Opening:	Two closures with inner diameter 57,3 and 52,9 mm

Table 4.1-11: Packaging information for 1000 liter container

Type	Description
Trade name:	Schutz – Ecobulk LX
Material:	HDPE
Shape/size:	IBC container / 1200 x 1000 x 1160 mm

Type	Description
Trade name:	Schutz – Ecobulk LX
Opening:	DN 150/225 with screw cap DN 50 – outlet valve

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	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.3.1	Paulina Flasińska, MSc.	2022	Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry; BC-28/22; Warsaw; 2022 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.3.3	Paulina Flasińska, MSc.	2022	Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry; BC-28/22; Warsaw; 2022 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.4.2	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.5.1	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry;	N	Elvita Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			BF-21/22; Warsaw; 2022, 2023 GLP Unpublished		
KCP 2.5.2	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.6.1	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.7.1	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.7.3	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP	N	Elvita 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 2.7.4	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.7.5	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.2	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.3.1	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.3.2	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage.	N	Elvita 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
			Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished		
KCP 2.8.5.1.1	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.5.1.2	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.
KCP 2.8.7.2	Jarosław Kupiec	2022 2023	Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Part II: Determination of physicochemical properties after the first year of storage. Institute of Industrial Organic Chemistry; BF-21/22; Warsaw; 2022, 2023 GLP Unpublished	N	Elvita Sp. z o.o.

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

A 2.1 Florasulam.

No additional data.