

# 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: FLD-HER 306 SE

Product name(s): -

Chemical active substances:

2,4-D 300 g/L

florasulam 6.25 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: January 2021

MS Finalisation date: 08.2021; 11.2021

## Version history

When	What
08.2021	RMS Assessment
11.2021	Final Registration Report

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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).

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: Pestila Spółka z ograniczoną odpowiedzialnością  
Address: Studzianki 24a  
97-320 Wolbórz  
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**

Name: Pestila Spółka z ograniczoną odpowiedzialnością  
Address: Studzianki 24a  
97-320 Wolbórz  
Poland.

#### **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**

Florasulam min 970 g/kg

Relevant impurity	Maximum content (g/L or g/kg)
2,6-DFA	max. 2 g/kg (according to Regulation 2015/1397)

##### **1.2.3.2 2,4-D**

2,4-D  $\geq 960$  g/kg  
2,4-D (expressed as 2,4-D 2EHE) min. 960 g/kg

Relevant impurities	Maximum content (g/L or g/kg)
Free phenols (expressed as 2,4-DCP)	max. 3 g/kg (according to Regulation 2015/2033)

Sum of dioxins and furans	max. 0,01 mg/kg (according to Regulation 2015/2033)
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### 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 and/or cover letter

Company code number: FLD-HER 306 SE

### 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	6.25 g/L	5.31 g/L – 7.19 g/L	5.47 g/L – 7.41 g/L	0.51 – 0.70
2,4-D (expressed as 2,4-D acid)	300 g/L	285 g/L – 315 g/L	296.9 g/L – 328.1 g/L	27.9 – 30.8
2,4-D (expressed as 2,4-D 2EHE)	452.3 g/L	429.7 g/L – 474.9 g/L	447.6 g/L – 494.7 g/L	42,1 – 46.5

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

\*\* Based on the density of the formulation = 1.0641 g/mL

**Table 1.4-2: Safener and synergists**

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
NA	NA	NA	NA	NA

\* Based on the minimum purity of the safener/synergist declared for registration

\*\* Based on the density of the formulation = X.XX (Note: only applies if a liquid formulation – delete this comment if not needed)

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
2,6-difluoroaniline (2,6-DFA)	0,00279 g/kg
Free phenols (calculated as 2,4-D)	0,033 g/kg
Sum of dioxins and furans	$2.7 \times 10^{-8}$

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

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

Type	Name/Code Number	
ISO common name	florasulam	Variant
CAS No.	145701-23-1	not relevant
EC No.	Not available	not relevant
CIPAC No.	616	not relevant

**Table 1.4-5: Information on 2,4-D/2,4-D 2EHE**

Type	Name/Code Number	
ISO common name	2,4-D	acid
	2,4-D 2EHE (ethlyxyl ester)	ester
CAS No.	94-75-7	acid
	1928-43-4	ester
EC No.	202-361-1	acid
	217-673-3	ester
CIPAC No.	1	acid
	1.3	ester

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

Not relevant. Product does not contain safeners and synergists.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Suspo-emulsion

[Code: SE]

## 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 white to beige liquid, with a specific odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 440 °C. In aqueous solution, it has a pH value around 3,7 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 **1 year** at ambient temperature when stored in HDPE/PA (COEX).

Its technical characteristics are acceptable for a SE formulation.

The intended concentration of use is 0,1% to 0,3%.

### RMS Comments:

Based on 1-year storage stability study shelf life in Poland is: 1 year

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

Study	Result	Classification acc. to Reg. 1272/2008	Labelling acc. to Reg. 1272/2008
Explosive properties (A.14)	Product does not have explosive properties.	Not classified.	None.
Oxidizing properties (A.21)	Product does not have oxidizing properties.	Not classified.	None.
Flammability – not relevant for liquids.	Product is not flammable.	Not classified.	None.
Flash point – not relevant, product does not have flammable solvents.	Product is not flammable.	Not classified.	None.

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

Not relevant.

Because pH is under 4, H290 - May be corrosive to metals is recommended

### Compliance with FAO specifications:

The product FLD-HER 306 SE complies with FAO specifications.

### Formulation used for tests

Product used in the test has the same composition as the one cited in Part C.

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Polish Pharmacopoeia VI Edition (2002) & EPA Product Properties Test Guidelines OPPTS 830.6302 to 04	FLD-HER 306 SE  Batch No. FLD/01/2 019	FLD-HER 306 SE is a homogenous, white to beige liquid of typical odour.	Y	0008/DPL / 2019 stage 1	Accepted
Explosive properties (KCP 2.2.1)	A.14	FLD-HER 306 SE  Batch No. FLD/01/2 019	FLD-HER 306 SE does not have explosive properties.	Y	BW-02/19	Accepted
Oxidizing properties (KCP 2.2.2)	A.21	FLD-HER 306 SE  Batch No. FLD/01/2 019	FLD-HER 306 SE does not have oxidizing properties.	Y	BC-09/19	Accepted
Flash point (KCP 2.3.1)	A.9	FLD-HER 306 SE  Batch No. FLD/01/2 019	FLD-HER 306 SE has not got the flash point up to the boiling point.	Y	BC-09/19	Accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flammability (KCP 2.3.2)	-	-	Not relevant. FLD-HER 306 SE is liquid form.	-	-	Statement accepted
Self-heating (KCP 2.3.3)	DIN 51794:2003-05	FLD-HER 306 SE  Batch No. FLD/01/2 019	Auto-ignition temperature of FLD-HER 306 SE is 440°C.	Y	BC-09/19	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	FLD-HER 306 SE  Batch No. FLD/01/2 019	<u>Before storage:</u> pH = 3.7 <u>After accelerated storage:</u> pH = 3.5  According to CIPAC MT191 Free acidity at 20°C 0.15%	Y	0008/DPL / 2019 stage 1&3	Accepted  RMS Comments: Because pH is under 4, H290 ( May be corrosive to metals) is recommended
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	FLD-HER 306 SE  Batch No. FLD/01/2 019	<u>Before storage:</u> pH = 4.0 <u>After accelerated storage:</u> pH = 3.6	Y	0008/DPL / 2019 stage 1&3	Accepted
Viscosity (KCP 2.5.1)	OECD 114	FLD-HER 306 SE  Batch No. FLD/01/2 019	<u>At 20 °C:</u> - at shear rate of 2.5 s <sup>-1</sup> 2611 mPa·s, - at shear rate of 5 s <sup>-1</sup> 1552 mPa·s, - at shear rate of 10 s <sup>-1</sup> 940 mPa·s, - at shear rate of 25 s <sup>-1</sup> 502 mPa·s, <u>At 40 °C:</u> - at shear rate of 2.5 s <sup>-1</sup> 2150 mPa·s, - at shear rate of 5 s <sup>-1</sup> 1307 mPa·s, - at shear rate of 10 s <sup>-1</sup> 800 mPa·s, - at shear rate of 25 s <sup>-1</sup> 427 mPa·s,	Y	BF-17/19-02	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
Surface tension (KCP 2.5.2)	A.5	FLD-HER 306 SE  Batch No. FLD/01/2019	<u>Concentrate</u> : 35,83 mN/m at 20.2 °C <u>Highest concentration of usable liquid</u> : 33.0 mN/m at 20.2 °C	Y	BF-17/19-03	Accepted		
Relative density (KCP 2.6.1)	CIPAC MT 3 A.3	FLD-HER 306 SE  Batch No. FLD/01/2019	1.0641 g/ml at 20 °C	Y	0008/DPL / 2019 stage 1&3	Accepted		
Bulk density (KCP 2.6.2)	-	-	Not relevant. FLD-HER 306 SE is liquid form.	-	-	Statement accepted		
Storage Stability after 14 days at 54° C (KCP 2.7.1)	IA/L/016 CIPAC MT 75.3, EEC A.3., CIPAC MT 47.3, CIPAC MT 180, CIPAC MT 185, CIPAC MT 187, CIPAC MT 148, CIPAC MT 184,	FLD-HER 306 SE  Batch No. FLD/01/2019	Storage stability after 14 days at 54 °C.		Y	0007/DPL / 2019 stage 1&3 0008/DPL / 2019 stage 1&3 BA-09/20 K458/KG	Accepted  RMS Comments: Active substance content and stability of packaging were tested. All physical and chemical properties remained stable after the test and accepted.  Test carried out in HDPE/PA coex bottles	
			Parameter	Initial				After storage for 14 days at 54 °C
			Florasulam content	6.7 g/L				6.6 g/L
			2,4-D acid content	306.5 g/L				301,2 g/L
			Physical state, colour and odour	Homogenous, white to beige liquid of typical odour				Homogenous, beige liquid of typical odour
			pH directly	3.7				3.5
			pH of 1% suspension	4.0				3.6
			Acidity, calculated as H <sub>2</sub> SO <sub>4</sub>	0.15% m/m				0.30% m/m

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments			
	CIPAC MT 160, CIPAC MT 36.3, CIPAC MT 191, CIPAC MT 3, SOP/L-014, CIPAC MT 46.3		Dispersion stability of suspoemulsion	0.1% (w/v)		0.1% (w/v)				Because pH is under 4, H290 ( May be corrosive to metals) is recommended		
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C					
				0 h	<b>Initial dispersion complete</b> Cream: <b>0 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	0 h				<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>
				0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0.5 h				Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>
				24 h	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	24 h				<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>
				24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	24.5 h				Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>
				0.3% (w/v)		0.3% (w/v)						
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C					
				0 h	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	0 h				<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>
				0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0.5 h				Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>
				24 h	<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	24 h				<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>
				24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	24.5 h				Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>
				2% (w/v)		2% (w/v)						
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C					
				0 h	<b>Initial dispersion complete</b> Cream: <b>0.05 ml</b>	<b>Initial dispersion complete</b> Cream: <b>0.10 ml</b>	0 h				<b>Initial dispersion complete</b> Cream: <b>0.05 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>
				0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0.5 h				Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>
				24 h	<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Re-dispersion complete</b> Cream: <b>0.10 ml</b>	24 h				<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Re-dispersion complete</b> Cream: <b>0.05 ml</b>
				24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	24.5 h				Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>
				Particle size analysis by	<b>Dx 10 (µm) = 0.507</b>		<b>Dx 10 (µm) = 0.503</b>					
					<b>Dx 50 (µm) = 0.875</b>		<b>Dx 50 (µm) = 0.874</b>					

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			laser diffraction	Dx 90 (µm) = 1.56		Dx 90 (µm) = 1.57			
				Dx 99 (µm) = 18.2		Dx 99 (µm) = 33.2			
				D [3;2] = 0.819		D [3;2] = 0.818			
				D [4;3] = 1.47		D [4;3] = 1.85			
			Wet sieve test	0.0%		0.0%			
			Emulsion characteristics and re-emulsification properties	0.1% (v/v)		0.1% (v/v)			
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		
				0 h	Initial emulsification complete	0 h	Initial emulsification complete		
				0.5 h	Cream: 0 ml Free oil: 0 ml	0.5 h	Cream: 0 ml Free oil: 0 ml		
				2 h	Cream: 0 ml Free oil: 0 ml	2 h	Cream: 0 ml Free oil: 0 ml		
				24 h	Cream: 0 ml Free oil: 0 ml	24 h	Cream: traces Free oil: 0 ml		
				24 h	Re-emulsification complete	24 h	Re-emulsification complete		
				24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml		
				0.3% (v/v)		0.3% (v/v)			
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		
				0 h	Initial emulsification complete	0 h	Initial emulsification complete		
				0.5 h	Cream: 0 ml Free oil: 0 ml	0.5 h	Cream: traces Free oil: 0 ml		
				2 h	Cream: traces Free oil: 0 ml	2 h	Cream: traces Free oil: 0 ml		
				24 h	Cream: traces Free oil: 0 ml	24 h	Cream: traces Free oil: 0 ml		
				24 h	Re-emulsification complete	24 h	Re-emulsification complete		
				24.5 h	Cream: traces Free oil: 0 ml Sediment: 0 ml	24.5 h	Cream: traces Free oil: 0 ml Sediment: 0 ml		
			Pourability of suspension concentrates	R = 3.34%		R = 3.82%			
				R' = 0.40%		R' = 0.36%			
			Suspensibility	CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments					
			of formulation forming suspension on dilution with water	florasulam		florasulam								
				0.1% (w/v)		0.1% (w/v)								
				100%		100%					94%		98%	
				0.3% (w/v)		0.3% (w/v)								
				99%		99%					88%		90%	
				2,4-D		2,4-D								
				0.1% (w/v)		0.1% (w/v)								
				100%		100%					100%		100%	
				0.3% (w/v)		0.3% (w/v)								
				100%		100%					100%		100%	
			Spontaneity of dispersion of suspension concentrate	CIPAC Water A		CIPAC Water C					CIPAC Water A		CIPAC Water C	
				florasulam		florasulam								
				0.1% (w/v)		0.1% (w/v)								
				89%		92%					83%		85%	
				0.3% (w/v)		0.3% (w/v)								
				92%		92%					83%		83%	
				2,4-D		2,4-D								
				0.1% (w/v)		0.1% (w/v)								
				96%		96%					98%		96%	
				0.3% (w/v)		0.3% (w/v)								
			98%		95%		95%				92%			
			Persistent foam	0.1 % (v/v)		0.1 % (v/v)								
				after 1 min.		13 ml					after 1 min.		10 ml	
				after 12 min.		9 ml					after 12 min.		4 ml	
				0.3% (v/v)		0.3% (v/v)								
				after 1 min.		15 ml					after 1 min.		12 ml	
				after 12 min.		8 ml					after 12 min.		7 ml	
			Loss of bottle weight (HDPE/PA) after 54°C storage stability test	-		inhomogeneous liquid with separated layer (10 ml – upper, water phase) and traces of oil on this water phase (bottle weigh loss: 0.27 g)								
			2,6-difluoroaniline (2,6-DFA)	0,00279 g/kg		<LOQ								

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments	
			Free phenols (calculated as 2,4-D)	0,033 g/kg	0,031 g/kg					
			Sum of diox-ins and furans	2.7 x10 <sup>-8</sup> mg/kg	2.0 x10 <sup>-8</sup> mg/kg					
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant. The product was stable after 14 days at 54°C.				-	-	Statement accepted	
Minimum content after heat stability testing (KCP 2.7.3)	IA/L/053 IA/L/058 CIPAC 46.3	FLD-HER 306 SE  Batch No. FLD/01/2019	Florasulam – 6.6 g/L (0.62 %). 2,4-D (expressed as acid) – 301.2 g/L (28.31 %).				Y	0007/DPL / 2019 stage 3	Accepted	
Effect of low temperatures on stability (KCP 2.7.4)	IA/L/016, CIPAC MT 75.3, EEC A.3., CIPAC MT 47.3, CIPAC MT 180, CIPAC MT 185, CIPAC MT 187, CIPAC MT 148, CIPAC MT 184, CIPAC MT	FLD-HER 306 SE  Batch No. FLD/01/2019	Storage stability after 7 days at 0°C.				Y	0007/DPL / 2019 stage 1&2 0008/DPL / 2019 stage 1&2 BA-21/19	Accepted  RMS Comments:  Active substance content and stability of packaging were tested.  All physical and chemical properties remained stable after the test and accepted.  Test carried out in HDPE/PA coex bottles	
			Parameter	Initial	After storage for 7 days at 0 °C					
			Florasulam content	6.7 g/L	6.7 g/L					
			2,4-D acid content	306.5 g/L	301.6 g/L					
			Physical state, colour and odour	Homogenous, white to beige liquid of typical odour	Homogenous, white to beige liquid of typical odour					
			pH directly	3.7	after 1 min.	3.6				
					after 2 min.	3.7				
			pH of 1% suspension	4.0	after 1 min.	4.0				
					after 2 min.	3.9				
			Acidity, calculated as H <sub>2</sub> SO <sub>4</sub>	0.15% m/m	0.15% m/m					
			Dispersion stability of suspoemulsion	0.1% (w/v)		0.1% (w/v)				
				CIPAC Water A	CIPAC Water C	CIPAC Water A				CIPAC Water C

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
	160, CIPAC MT 36.3, CIPAC MT 191, CIPAC MT 3, IA/L/053, IA/L/058, CIPAC MT 39.3, CIPAC MT 59, SOP/L-014			0 h <b>Initial dispersion complete</b> Cream: <b>0 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24 h <b>Re-dispersion complete</b> Cream: <b>0 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24.5 h Cream: <b>0 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> <b>Re-dispersion complete</b> Cream: <b>0 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0 h <b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24 h <b>Re-dispersion complete</b> Cream: <b>0 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24.5 h Cream: <b>0 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>			Because pH is under 4, H290 ( May be corrosive to metals) is recommended
				0.3% (w/v)		0.3% (w/v)			
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		
				0 h <b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24 h <b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24.5 h Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> <b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0 h <b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24 h <b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24.5 h Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>			
				2% (w/v)		2% (w/v)			
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		
				0 h <b>Initial dispersion complete</b> Cream: <b>0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24 h <b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24.5 h Cream: <b>&lt;0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	<b>Initial dispersion complete</b> Cream: <b>0.10 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> <b>Re-dispersion complete</b> Cream: <b>0.10 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0 h <b>Initial dispersion complete</b> Cream: <b>0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24 h <b>Re-dispersion complete</b> Cream: <b>0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b> 24.5 h Cream: <b>0.05 ml</b> Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments	
				ml						
			Particle size analysis by laser diffraction	Dx 10 (µm) = 0.507		Dx 10 (µm) = 0.508				
				Dx 50 (µm) = 0.875		Dx 50 (µm) = 0.869				
				Dx 90 (µm) = 1.56		Dx 90 (µm) = 1.51				
				Dx 99 (µm) = 18.2		Dx 99 (µm) = 21.2				
				D [3;2] = 0.819		D [3;2] = 0.812				
				D [4;3] = 1.47		D [4;3] = 1.51				
			Wet sieve test	0.0%		0.0%				
			Emulsion characteristics and re-emulsification properties	0.1% (v/v)		0.1% (v/v)				
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C			
				0 h	Initial emulsification complete	0 h	Initial emulsification complete			
				0.5 h	Cream: 0 ml Free oil: 0 ml	0.5 h	Cream: 0 ml Free oil: 0 ml			
					Cream: 0 ml		Cream: 0 ml			
				2 h	Free oil: 0 ml	2 h	Free oil: 0 ml			
					Cream: 0 ml		Cream: 0 ml			
				24 h	Free oil: 0 ml	24 h	Free oil: 0 ml			
				24 h	Re-emulsification complete	24 h	Re-emulsification complete			
				24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
0.3% (v/v)		0.3% (v/v)								
CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C							



Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
				0 h	Initial emulsification complete	Initial emulsification complete	0 h	Initial emulsification complete	Initial emulsification complete			
				0.5 h	Cream: 0 ml	Cream: 0 ml	0.5 h	Cream: traces	Cream: traces			
				h	Free oil: 0 ml	Free oil: 0 ml	h	Free oil: 0 ml	Free oil: 0 ml			
				2 h	Cream: traces	Cream: traces	2 h	Cream: traces	Cream: traces			
				2 h	Free oil: 0 ml	Free oil: 0 ml	2 h	Free oil: 0 ml	Free oil: 0 ml			
				24 h	Cream: traces	Cream: traces	24 h	Cream: traces	Cream: traces			
				24 h	Free oil: 0 ml	Free oil: 0 ml	24 h	Free oil: 0 ml	Free oil: 0 ml			
				24 h	Re-emulsification complete	Re-emulsification complete	24 h	Re-emulsification complete	Re-emulsification complete			
			24.5 h	Cream: traces	Cream: traces	24.5 h	Cream: traces	Cream: traces				
			h	Free oil: 0 ml	Free oil: 0 ml	h	Free oil: 0 ml	Free oil: 0 ml				
				Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml				
			Pourability of suspension concentrates	R = 3.34%			R = 4.32%					
				R' = 0.40%			R' = 0.44%					
			Suspensibility of formulation forming suspension on dilution with water	CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C			
				florasulam		florasulam		florasulam				
				0.1% (w/v)		0.1% (w/v)		0.1% (w/v)				
				100%	100%	100%	100%	100%	100%			
				0.3% (w/v)		0.3% (w/v)		0.3% (w/v)				
				99%	99%	99%	99%	99%	99%			
				2,4-D		2,4-D		2,4-D				
				0.1% (w/v)		0.1% (w/v)		0.1% (w/v)				
				100%	100%	100%	100%	100%	100%			
				0.3% (w/v)		0.3% (w/v)		0.3% (w/v)				
			100%	100%	100%	100%	100%	100%				
			Spontaneity of dispersion of suspension concentrate	CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C			
				florasulam		florasulam		florasulam				
				0.1% (w/v)		0.1% (w/v)		0.1% (w/v)				
				89%	92%	86%	85%	86%	85%			
				0.3% (w/v)		0.3% (w/v)		0.3% (w/v)				
				92%	92%	91%	83%	91%	83%			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				<b>2,4-D</b>	<b>2,4-D</b>			
				0.1% (w/v)	0.1% (w/v)			
				<b>96%</b>	<b>92%</b>			
				0.3% (w/v)	0.3% (w/v)			
				<b>98%</b>	<b>99%</b>			
			Persistent foam	0.1 % (v/v)	0.1 % (v/v)			
				after 1 min. <b>13 ml</b>	after 1 min. <b>12 ml</b>			
				after 12 min. <b>9 ml</b>	after 12 min. <b>5 ml</b>			
				0.3% (v/v)	0.3% (v/v)			
				after 1 min. <b>15 ml</b>	after 1 min. <b>14 ml</b>			
				after 12 min. <b>8 ml</b>	after 12 min. <b>6 ml</b>			
			Loss of bottle weight (HDPE/PA) after 54°C storage stability test	-	after 7 days (0±2°C): inhomogeneous liquid with separated layer (3 ml – upper phase (water phase)) and traces of cream at the bottom of the centrifuge tube (0.05 ml). after 7 days (0±2°C) and one turn after 24h (23±2°C): homogeneous liquid without separated layers (wet sieving test: 0.00%; bottle weigh loss: 0.00g).			
Ambient temperature shelf life (KCP 2.7.5)	-	-	Study on-going. Expected date of completing the study June 2021.			-	-	Statement accepted  RMS Comments: Based on 1-year storage stability study shelf life in Poland is: 1 year.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	IA/L/016 CIPAC MT 75.3, EEC A.3., CIPAC MT 47.3, CIPAC MT 180, CIPAC MT	FLD-HER 306 SE  Batch No. FLD/01/2019	Storage stability after 12 months at ambient temperature.			Y	0007/DPL / 2019 stage 1&4 0008/DPL / 2019 stage 1&4	Accepted  RMS Comments: Active substance content and stability of packaging were tested. All physical and chemical properties remained stable after
			Parameter	Initial	After storage for 1 year at ambient temperature			
			Florasulam content	6.7 g/L	6.81 g/L			
			2,4-D acid content	306.5 g/L	299.9 g/L			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
	185, CIPAC MT 187, CIPAC MT 148, CIPAC MT 184, CIPAC MT 160, CIPAC MT 36.3, CIPAC MT 191, CIPAC MT 3, SOP/L-014, GIFAP 17		Physical state, colour and odour	Homogenous, white to beige liquid of typical odour	Homogenous, white to beige liquid of typical odour				the test and accepted. Test carried out in HDPE/PA coex bottles  Based on 1-year storage stability study shelf life in Poland is: 1 year  Because pH is under 4, H290 ( May be corrosive to metals) is recommended
			pH directly	3.7	3.0				
			pH of 1% suspension	4.0	3.7				
			Acidity, calculated as H <sub>2</sub> SO <sub>4</sub>	0.15% m/m	0.2% m/m				
			Dispersion stability of suspoemulsion	0.1% (w/v)		0.1% (w/v)			
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		
				0 h	<b>Initial dispersion complete</b> Cream: <b>0 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	0 h	<b>Initial dispersion complete</b> Cream: <b>0 ml</b>	
				0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	
				24 h	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	24 h	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	
				24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	
				0.3% (w/v)		0.3% (w/v)			
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C		
				0 h	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	0 h	<b>Initial dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	
				0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	0.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	
				24 h	<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	<b>Re-dispersion complete</b> Cream: <b>&lt;0.05 ml</b>	24 h	<b>Re-dispersion complete</b> Cream: <b>0 ml</b>	
				24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	24.5 h	Free oil: <b>0 ml</b> Sediment: <b>0 ml</b>	

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
				2% (w/v)			2% (w/v)					
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C					
				0 h	Initial dispersion complete Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Initial dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml	0 h	Initial dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml	Initial dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml			
				0.5 h	Free oil: 0 ml Sediment: 0 ml	Free oil: 0 ml Sediment: 0 ml	0.5 h	Free oil: 0 ml Sediment: 0 ml	Free oil: 0 ml Sediment: 0 ml			
				24 h	Re-dispersion complete Cream: <0.05 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml	24 h	Re-dispersion complete Cream: 0.05 ml Free oil: 0 ml Sediment: 0 ml	Re-dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml			
				24.5 h	Free oil: 0 ml Sediment: 0 ml	Free oil: 0 ml Sediment: 0 ml	24.5 h	Free oil: 0 ml Sediment: 0 ml	Free oil: 0 ml Sediment: 0 ml			
				Particle size analysis by laser diffraction	Dx 10 (µm) = 0.507			Dx 10 (µm) = 0.509				
			Dx 50 (µm) = 0.875			Dx 50 (µm) = 0.863						
			Dx 90 (µm) = 1.56			Dx 90 (µm) = 1.47						
			Dx 99 (µm) = 18.2			Dx 99 (µm) = 26.6						
			D [3;2] = 0.819			D [3;2] = 0.809						
			Wet sieve test	D [4;3] = 1.47			D [4;3] = 1.63					
				0.0%			0.0%					
			Emulsion characteristics and re-emulsification properties	0.1% (v/v)			0.1% (v/v)					
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C					
				0 h	Initial emulsification complete Cream: 0 ml Free oil: 0 ml	Initial emulsification complete Cream: 0 ml Free oil: 0 ml	0 h	Initial emulsification complete Cream: 0 ml Free oil: 0 ml	Initial emulsification complete Cream: 0 ml Free oil: 0 ml			
				0.5 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml	0.5 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml			
				2 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml	2 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml			
				24 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml	24 h	Cream: traces Free oil: 0 ml	Cream: traces Free oil: 0 ml			
				24 h	Re-emulsification complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-emulsification complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	24 h	Re-emulsification complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Re-emulsification complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	24.5 h	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Cream: 0 ml Free oil: 0 ml Sediment: 0 ml			
				0.3% (v/v)			0.3% (v/v)					
				CIPAC Water A	CIPAC Water C	CIPAC Water A	CIPAC Water C					

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments	
				0 h	Initial emulsification complete	Initial emulsification complete	0 h	Initial emulsification complete	Initial emulsification complete			
				0.5 h	Cream: 0 ml	Cream: 0 ml	0.5 h	Cream: 0 ml	Cream: 0 ml			
					Free oil: 0 ml	Free oil: 0 ml		Free oil: 0 ml	Free oil: 0 ml			
					Cream: traces	Cream: traces		Cream: 0 ml	Cream: 0 ml			
				2 h	Free oil: 0 ml	Free oil: 0 ml	2 h	Free oil: 0 ml	Free oil: 0 ml			
					Cream: traces	Cream: traces		Cream: 0.5 ml	Cream: 0.5 ml			
				24 h	Free oil: 0 ml	Free oil: 0 ml	24 h	Free oil: 0 ml	Free oil: 0 ml			
					Re-emulsification complete	Re-emulsification complete		Re-emulsification complete	Re-emulsification complete			
				24 h	Cream: traces	Cream: traces	24 h	Cream: 0 ml	Cream: 0 ml			
				24.5 h	Free oil: 0 ml	Free oil: 0 ml	24.5 h	Free oil: 0 ml	Free oil: 0 ml			
					Sediment: 0 ml	Sediment: 0 ml		Sediment: 0 ml	Sediment: 0 ml			
			Pourability of suspension concentrates	R = 3.34%			R = 2.38%					
				R' = 0.40%			R' = 0.35%					
			Suspensibility of formulation forming suspension on dilution with water	CIPAC Water A		CIPAC Water C	CIPAC Water A		CIPAC Water C			
				florasulam			florasulam					
				0.1% (w/v)			0.1% (w/v)					
				100%		100%	99%		101%			
				0.3% (w/v)			0.3% (w/v)					
				99%		99%	94%		99%			
				2,4-D			2,4-D					
				0.1% (w/v)			0.1% (w/v)					
				100%		100%	100%		100%			
				0.3% (w/v)			0.3% (w/v)					
					100%		100%	100%				
			Spontaneity of dispersion of suspension concentrate	CIPAC Water A		CIPAC Water C	CIPAC Water A		CIPAC Water C			
				florasulam			florasulam					
				0.1% (w/v)			0.1% (w/v)					
				89%		92%	87%		91%			
				0.3% (w/v)			0.3% (w/v)					
				92%		87%	87%		88%			
				2,4-D			2,4-D					

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments													
				0.1% (w/v)	0.1% (w/v)															
				96%96%	97%92%															
				0.3% (w/v)	0.3% (w/v)															
				98%95%	95%92%															
			Persistent foam	0.1 % (v/v)	0.1 % (v/v)															
				after 1 min. after 1 min.	after 1 min. traces															
				after 12 min. after 12 min.	after 12 min. traces															
				0.3% (v/v)	0.3% (v/v)															
				after 1 min. 15 ml	after 1 min. 6 ml															
				after 12 min. 8 ml	after 12 min. 4 ml															
		Loss of bottle weight (HDPE/PA) after 54°C storage stability test	-		bottle weigh loss: 0.11 g															
Wettability (KCP 2.8.1)	-	-	Not relevant. FLD-HER 306 SE is liquid form.					Statement accepted												
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	FLD-HER 306 SE  Batch No. FLD/01/2019	At concentration 0.1%: after 1 min. 13 ml At concentration 0.3%: after 1 min. 15 ml			Y	008/DPL/2019 stage 1	Accepted												
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	FLD-HER 306 SE  Batch No. FLD/01/2019	<table><tr><td colspan="2">CIPAC Water C</td></tr><tr><td>florasulam</td><td>2,4-D</td></tr><tr><td colspan="2">0.1% (w/v)</td></tr><tr><td>100%</td><td>100%</td></tr><tr><td colspan="2">0.3% (w/v)</td></tr><tr><td>99%</td><td>100%</td></tr></table>			CIPAC Water C		florasulam	2,4-D	0.1% (w/v)		100%	100%	0.3% (w/v)		99%	100%	Y	008/DPL/2019 stage 1	Accepted
CIPAC Water C																				
florasulam	2,4-D																			
0.1% (w/v)																				
100%	100%																			
0.3% (w/v)																				
99%	100%																			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	FLD-HER 306 SE	<table><tr><td colspan="2">CIPAC Water C</td></tr><tr><td>florasulam</td><td>2,4-D</td></tr><tr><td colspan="2">0.1% (w/v)</td></tr></table>			CIPAC Water C		florasulam	2,4-D	0.1% (w/v)		Y	008/DPL/2019 stage 1	Accepted						
CIPAC Water C																				
florasulam	2,4-D																			
0.1% (w/v)																				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		Batch No. FLD/01/2019						
			92%	96%				
			0.3% (w/v)					
			92%	95%				
Dispersion stability (KCP 2.8.3.3)	CIPAC MT 180	FLD-HER 306 SE				Y	008/DPL/2019 stage 1	Accepted
		Batch No. FLD/01/2019						
			CIPAC Water C					
			Initial dispersion complete Cream: <0.05 ml Free oil: 0 ml Sediment: 0 ml Re-dispersion complete Cream: 0 ml Free oil: 0 ml Sediment: 0 ml	Initial dispersion complete Cream: <0.05 ml Free oil: 0 ml Sediment: 0 ml Re-dispersion complete Cream: <0.05 ml Free oil: 0 ml Sediment: 0 ml	Initial dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml Re-dispersion complete Cream: 0.10 ml Free oil: 0 ml Sediment: 0 ml			RMS Comments: The test has been done in water A andC
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant. FLD-HER 306 SE is liquid form.			-	-	Statement accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	FLD-HER 306 SE	Dx 10 (µm) = 0.507 Dx 50 (µm) = 0.875 Dx 90 (µm) = 1.56 Dx 99 (µm) = 18.2 D [3;2] = 0.819 D [4;3] = 1.47			Y	008/DPL/2019 stage 1	Accepted
		Batch No. FLD/01/2019						
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	FLD-HER 306 SE	Residue on 75 µm sieve 0%.			Y	008/DPL/2019 stage 1	Accepted
		Batch No. FLD/01/2019						
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant. FLD-HER 306 SE is liquid form.			-	-	Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant. FLD-HER 306 SE is liquid form.	-	-	Statement accepted		
Attrition (KCP 2.8.5.3)	-	-	Not relevant. FLD-HER 306 SE is liquid form.	-	-	Statement accepted		
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant. FLD-HER 306 SE is liquid form.	-	-	Statement accepted		
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SE formulation.	-	-	Statement accepted		
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	FLD-HER 306 SE  Batch No. FLD/01/2019		0.1% (v/v)		Y	008/DPL/2019 stage 1	Accepted
				CIPAC Water A	CIPAC Water C			
			0 h	Initial emulsification complete Cream: 0 ml Free oil: 0 ml	Initial emulsification complete Cream: 0 ml Free oil: 0 ml			
			0.5 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml			
			2 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml			
			24 h	Cream: 0 ml Free oil: 0 ml	Cream: 0 ml Free oil: 0 ml			
			24 h	Re-emulsification complete Cream: 0 ml Free oil: 0 ml	Re-emulsification complete Cream: 0 ml Free oil: 0 ml			
			24.5 h	Sediment: 0 ml	Sediment: 0 ml			
				0.3% (v/v)				
				CIPAC Water A	CIPAC Water C			
			0 h	Initial emulsification complete Cream: 0 ml Free oil: 0 ml	Initial emulsification complete Cream: 0 ml Free oil: 0 ml			
			0.5 h	Cream: traces Free oil: 0 ml	Cream: traces Free oil: 0 ml			
			2 h	Cream: traces Free oil: 0 ml	Cream: traces Free oil: 0 ml			
			24 h	Cream: traces Free oil: 0 ml	Cream: traces Free oil: 0 ml			
			24 h	Re-emulsification complete Cream: traces Free oil: 0 ml	Re-emulsification complete Cream: traces Free oil: 0 ml			
24.5 h	Sediment: 0 ml	Sediment: 0 ml						



Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	FLD-HER 306 SE  Batch No. FLD/01/2019		0.1% (v/v)				
				CIPAC Water A	CIPAC Water C			
			0 h	Initial emulsification complete Cream: 0 ml	Initial emulsification complete Cream: 0 ml			
			0.5 h	Free oil: 0 ml Cream: 0 ml	Free oil: 0 ml Cream: 0 ml			
			2 h	Free oil: 0 ml Cream: 0 ml	Free oil: 0 ml Cream: 0 ml			
			24 h	Free oil: 0 ml	Free oil: 0 ml			
			24 h	Re-emulsification complete Cream: 0 ml Free oil: 0 ml	Re-emulsification complete Cream: 0 ml Free oil: 0 ml			
			24.5 h	Sediment: 0 ml	Sediment: 0 ml			
				0.3% (v/v)				
				CIPAC Water A	CIPAC Water C			
			0 h	Initial emulsification complete Cream: 0 ml	Initial emulsification complete Cream: 0 ml			
			0.5 h	Free oil: 0 ml Cream: traces	Free oil: 0 ml Cream: traces			
			2 h	Free oil: 0 ml Cream: traces	Free oil: 0 ml Cream: traces			
			24 h	Free oil: 0 ml Re-emulsification complete	Free oil: 0 ml Re-emulsification complete			
			24 h	Cream: traces Free oil: 0 ml	Cream: traces Free oil: 0 ml			
			24.5 h	Sediment: 0 ml	Sediment: 0 ml			
Flowability (KCP 2.8.7.1)	-	-	Not required for SE formulation.			-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148	FLD-HER 306 SE  Batch No. FLD/01/2019	R = 3.34% R' = 0.40%			Y	008/DPL/2019 stage 1	Accepted
Dustability following accelerated	-	-	Not relevant. FLD-HER 306 SE is liquid form.			-	-	Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments						
storage (KCP 2.8.7.3)												
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. FLD-HER 306 SE is not recommended for tank-mixes usage.	-	-	Statement accepted						
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant. FLD-HER 306 SE is not recommended for tank-mixes usage.	-	-	Statement accepted						
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant. FLD-HER 306 SE is not a seedtreatment.	-	-	Statement accepted						
Distribution to seed (KCP 2.10.2)	-	-	Not relevant. FLD-HER 306 SE is not a seedtreatment.	-	-	Statement accepted						
Other/special studies (KCP 2.11)	Efficacy Guideline 305: 2004	FLD-HER 306 SE  Batch No. FLD/01/2019	Application equipment cleaning effectiveness. <table><tr><th>Substance</th><th>Cleaning effectiveness [%]</th></tr><tr><td>2,4-D</td><td>97.75</td></tr><tr><td>Florasulam</td><td>98.95</td></tr></table>	Substance	Cleaning effectiveness [%]	2,4-D	97.75	Florasulam	98.95	Y	BF-17/19-01	Accepted
Substance	Cleaning effectiveness [%]											
2,4-D	97.75											
Florasulam	98.95											

### 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

Taking into account extrapolation rules of *Polish guideline on the general principles for approval of packaging of plant protection products* (actualization 17.10.2019), we are applying for additional packaging made of fHDPE (fluorinated HDPE) for professional users. According to this guideline extrapolation from HDPE/PA (COEX) to fHDPE (fluorinated HDPE) is possible for SE formulations.

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

**Table 4.1-1: Packaging information for 0,5L bottle**

Type	Description	
<b>Material:</b>	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cylindrical / approx. 77,6 mm diameter x 160,6 mm	cylindrical / approx. 69 mm diameter x 186,2 mm
<b>Opening:</b>	31,3 mm inner diameter	45 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	31,3 mm inner diameter
<b>Seal:</b>	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	not relevant	UN certified

**Table 4.1-2: Packaging information for 1L bottle**

Type	Description	
<b>Material:</b>	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cylindrical / approx. 88 mm diameter x 236,5 mm	cylindrical / approx. 88,5 mm diameter x 233,2 mm
<b>Opening:</b>	48 mm inner diameter	45 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	not relevant	UN certified

**Table 4.1-3: Packaging information for 5L canister**

Type	Description	
<b>Material:</b>	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cuboid / approx. 187 x 135 mm, H <sub>max</sub> =305 mm	cuboid / approx. 193 x 142 mm, H <sub>max</sub> =305 mm
<b>Opening:</b>	53 mm inner diameter	54 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)

Type	Description	
<b>Seal:</b>	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	not relevant	UN certified

**Table 4.1-4: Packaging information for 10L canister**

Type	Description	
<b>Material:</b>	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cuboid / approx. 230 x 166 mm, H <sub>max</sub> =375 mm	cuboid / approx. 240 x 179 mm, H <sub>max</sub> =377,5 mm
<b>Opening:</b>	53 mm inner diameter	54 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	compliant	UN certified

**Table 4.1-5: Packaging information for 20 L**

Type	Description	
<b>Material:</b>	HDPE/PA (COEX)	fHDPE
<b>Shape/size:</b>	cuboid / approx. 294 x 245 mm, H <sub>max</sub> =400 mm	cuboid / approx. 293 x 245 mm, H <sub>max</sub> =400 mm
<b>Opening:</b>	53 mm inner diameter	48,5 mm inner diameter
<b>Closure:</b>	high-density polyethylene cap (screw-on type)	high-density polyethylene cap (screw-on type)
<b>Seal:</b>	HF-seal	HF-seal
<b>Manner of construction</b>	blowing extrusion	blowing extrusion
<b>UN/ADR</b>	compliant	UN certified

RMS Comments:  
All recommended packaging are accepted

## 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 KCP 2.4.1 KCP 2.4.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.8.7.2	Zajac S.	2019	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Pestila*
KCP 2.2.1	Śliwa P.	2019	FLD-HER 306 SE Determination of explosive properties Report No BW-02/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*
KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P.	2019	FLD-HER 306 SE Determination of flash point, auto-ignition temperature and oxidizing properties. Report No BC-09/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*

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 2.4.1 KCP 2.4.2 KCP 2.6.1 KCP 2.7.1	Zajac S.	2019	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 3: Determination of physicochemical properties of preparation stored at temperature 54±2°C for 14 days. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Pestila*
KCP 2.5.1	Arévalo E.	2019	FLD-HER 306 SE Determination of viscosity. Report No BF-17/19-02 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*
KCP 2.5.2	Łysik A.	2019	FLD-HER 306 SE Determination of surface tension. Report No BF-17/19-03 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*
KCP 2.7.1/01	Zajac S.	2019	FLD-HER 306 SE. Determination of active substances content of preparation in COEX bottle. Stage 1: Determination of active substances content of initial preparation. Stage 3: Determination of active substances content of preparation stored at temperature 54±2°C for 14 days. Report No 007/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Pestila*

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 2.7.1/02	Gutowska I.	2019	FLD-HER 306 SE (2,4-D 300 g/L + florasulam 6.25 g/L) Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation. Report No BA-21/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*
KCP 2.7.1/03	Gutowska I.	2020	Determination of the content of the relevant impurities of 2,4-D (free phenols) and florasulam (2,6-difluoroaniline) in the preparation after the accelerated storage Report No BA-09/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished.	N	Pestila*
KCP 2.7.1/04	Grodowska K.	2020	Analysis of FLD-HER 306 SE before and after ageing tests to determine content of dioxins and furans Report No K458/KG Selvita Services Sp. z o.o. GLP Yes Unpublished.	N	Pestila*
KCP 2.7.6	Zajac S.	2020	FLD-HER 306 SE. Determination of physicochemical properties of preparation in COEX bottle. Stage 1: Determination of physicochemical properties of initial preparation. Stage 4: Determination of physicochemical properties of preparation stored at temperature 20±2°C for 1 year. Report No 008/DPL/2019 Pestila II Spółka z ograniczoną odpowiedzialnością Sp.k. GLP Yes Unpublished	N	Pestila*

<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>
KCP 2.11	Arévalo E.	2019	FLD-HER 306 SE Application equipment cleaning effectiveness. Report No BF-17/19-01 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Yes Unpublished	N	Pestila*

\* Pestila Spółka z ograniczoną odpowiedzialnością.