

# 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: SHA 2619 A

Product name(s): KONARK

Chemical active substances:

Pendimethalin, 30 g/L

Flufenacet, 60 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

Update date: September 2021

MS Finalisation date: September 2021, May 2023

## Version history

When	What
September 2021	Updated by the Applicant
September 2021	zRMS evaluation
May 2023	zRMS revision after commenting phase – final version of the RR

## 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).....	5
1.2.3.1	Pendimethalin .....	5
1.2.3.2	Flufenacet.....	5
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).....	6
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	6
1.5	Type and code of the plant protection product (KCP 1.5).....	6
1.6	Function (KCP 1.6).....	7
<b>2</b>	<b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>	<b>8</b>
<b>3</b>	<b>Section 3 is presented as a separate document .....</b>	<b>24</b>
<b>4</b>	<b>Section 4: Further information on the plant protection product .....</b>	<b>25</b>
4.1	Packaging and Compatibility with the Preparation (KCP 4.4) .....	25
<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>31</b>
A 2.1	Pendimethalin .....	31
A 2.2	Flufenacet.....	31

**zRMS comment:**

Submitted data are sufficient for evaluation

Data gap: The shelf-life study is on-going, study report shall be submitted when finished. Based on the composition of the formulation and results of the accelerated storage study, one-year conditional registration of the product is proposed.

Packaging: Based on the stability tests, proposed packaging: COEX (HDPE/PA) **and HDPE are is** appropriate and accepted.

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

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

Name: Sharda Cropchem España S.L.  
Address: Edificio Atalayas Business Center,  
Carril Condomina nº 3, 12<sup>th</sup> Floor,  
30006 Murcia, Spain  
Phone: +34868127589  
FAX: +34868127588

### **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: Sharda Cropchem Ltd.  
Address: Prime Business Park  
Dashrathlal Joshi Road  
Vile Parle (West)  
Mumbai – 400 056  
India  
Phone number: + 91 22 6678 2800  
Fax number: + 91 22 6678 2828/ 2808  
Email: [shardaint@vsnl.com](mailto:shardaint@vsnl.com)  
[regn@shardaintl.com](mailto:regn@shardaintl.com)

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

Name: Sharda Cropchem Ltd.  
Address: Prime Business Park  
Dashrathlal Joshi Road  
Vile Parle (West)  
Mumbai – 400 056  
India  
Phone number: + 91 22 6678 2800  
Fax number: + 91 22 6678 2828/ 2808  
Email: [shardaint@vsnl.com](mailto:shardaint@vsnl.com)

[regn@shardaintl.com](mailto:regn@shardaintl.com)

### 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

#### 1.2.3.1 Pendimethalin

Pendimethalin	min. 900 g/kg (SANTE/11656/2016 rev 2, 18 May 2017)
Pendimethalin	min. 980 g/kg (Sharda Source)
1,2-dichloroethane	max. 1 g/kg (SANTE/11656/2016 rev 2, 18 May 2017)
Total N-Nitroso compounds	max. 100 mg/kg of which N-Nitroso-Pendimethalin < 45 mg/kg (SANTE/11656/2016 rev 2, 18 May 2017)

#### 1.2.3.2 Flufenacet

Flufenacet	min. 950 g/kg (7469/VI/98-Final)
Flufenacet	min. 980 g/kg (Sharda Source)

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

Trade name: KONARK  
 Company code number: SHA 2619 A  
 Flufenacet 6% + Pendimethalin 30% EC

### 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)
Flufenacet	60 g/L	54 – 66 g/L (± 10%)	61.22 g/L	6.19%
Pendimethalin	300 g/L	285 – 315 g/L (± 5%)	306.12 g/L	30.97%

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

\*\* Based on the density of the formulation = 0.9886 g/mL

**Table 1.4-2: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
1,2-dichloroethane	1 g/kg
	0.306 g/kg *
Total N-Nitroso-compounds	100 mg/kg of which N-Nitroso-pendimethalin < 45 mg/kg
	30.6 mg/kg of total N-Nitroso compounds where N-Nitroso-pendimethalin < 13.8 mg/kg *

\* max content based on the nominal content of pendimethalin in the formulation

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

**Table 1.4-3: Information on Pendimethalin**

Type	Name/Code Number
ISO common name	Pendimethalin
CAS No.	40487-42-1
EC No.	254-938-2
CIPAC No.	357

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

Type	Name/Code Number
ISO common name	Flufenacet
CAS No.	142459-58-3
EC No.	604-290-5
CIPAC No.	588

### 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: Emulsifiable Concentrate

[Code: EC]

## **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 ambient liquid, with a mild pungent odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 109.5°C. It has a self-ignition temperature above 350°C. In aqueous solution, it has a pH value around 4.83 at 25 °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 study on the stability for 2-years storage period is on-going and will be provided as soon as possible. Its technical characteristics are acceptable for an *Emulsifiable concentrate* formulation.

The intended concentration of use is 1% to 2%.

The products is not intended to be tank mixed.

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

Neither classification or labelling is relevant for this section.

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

No risk and safety phrases are relevant for this section.

~~P280 Wear protective gloves/protective clothing/eye protection/face protection~~

### Compliance with FAO specifications:

The product Flufenacet 6% + Pendimethalin 30% EC (code: SHA 2619 A) complies with general FAO specification guidelines for *Emulsifiable Concentrate*. At the time of the valuation, there is no FAO specification for a of pendimethalin and flufenacet mixture.

### Formulation used for tests

The formulation used for tests is the one cited in dRR 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)	OCSPP 830.6302 OCSPP 830.6303 OCSPP 830.6304	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	Amber liquid with mild pungent odour.	Y	B. Rajasekhar, 2020 Report No. 7713/2020	<b>Accepted</b>
Explosive properties (KCP 2.2.1)	EEC A.14	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	The test item has no explosive properties.	Y	B. Rajasekhar, 2020 Report No. 7704/2020	<b>Accepted</b>  No implications for labelling
Oxidizing properties (KCP 2.2.2)	EEC A.21	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	The test item has no oxidizing properties.	Y	B. Rajasekhar, 2020 Report No. 7707/2020	<b>Accepted</b>  No implications for labelling
Flash point (KCP 2.3.1)	EEC A.9	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	The flash point of the formulation is 109.5°C at 1083.8 mm/Hg atmospheric pressure.	Y	B. Rajasekhar, 2020 Report No. 7703/2020	<b>Accepted</b>  No implications for labelling
Flammability (KCP 2.3.2)	-	-	Not relevant. Product is a liquid.	-	-	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments	
Self-heating (KCP 2.3.3)	ASTM E 659-78	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	>350°C	Y	B. Rajasekhar, 2020 Report No. 7710/2020	<b>Accepted</b>	
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	pH = 4.84 (neat) temp. 25°C Since the pH was in a range 4-10, acidity/alkalinity test was not performed.	Y	B. Rajasekhar, 2020 Report No. 7713/2020	<b>Accepted</b>  Acidity/alkalinity test was not required	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	pH = 4.83 temp. 25°C	Y	B. Rajasekhar, 2020 Report No. 7713/2020	<b>Accepted</b>	
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	Temperature = 20°C		Y	B. Rajasekhar, 2020 Report No. 7708/2020	<b>Accepted</b>  Formulation is a Newtonian liquid. No implications for labelling
			Speed (RPM)	Mean viscosity (cP)			
			50	22.3			
			100	22.7			
			Temperature = 40°C				
			50	22.1			
100	22.5						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments	
Surface tension (KCP 2.5.2)	EEC A.5 OECD 115	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	45.142/mN/m 20 mL/L solution: 40.352 mN/m	Y	B. Rajasekhar, 2020 Report No. 7706/2020	<b>Accepted</b>  The formulation is surface active	
Relative density (KCP 2.6.1)	EEC A.3	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	<b>Relative Density of the formulation = 0.9886 g/mL at 20°C</b> <b>Relative Density = 0.9903 at 20°C</b>	Y	B. Rajasekhar, 2020 Report No. 7705/2020	<b>Accepted</b>	
Bulk density (KCP 2.6.2)	-	-	Not relevant for EC formulation.	-	-	Not required	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 OCSPP 830.6302 OCSPP 830.6303 OCSPP 830.6304 CIPAC MT 75.3 CIPAC MT 18 CIPAC MT 36.3 HPLC LC-MS/GC	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855 and SCL- 44652)	Test	0 day	After 14 days at 54°C	Y  B. Rajasekhar, 2020 Report No. 7713/2020  <b>S. D. Revankar, 2021 Report No. G21362</b>	No significant changes of physical-chemical properties after storage. A.s. and impurity contents within the limits.  Commercial packaging used - <b>COEX (HDPE/PA)</b>  <b>Accepted</b>
			Appearance	Amber liquid with mild pungent odour	Amber liquid with mild pungent odour		
			Pendimethalin content (% w/v)	30.68 <b>29.54</b>	30.23 <b>29.35</b>		
			Flufenacet content (% w/v)	6.03 <b>5.60</b>	5.93 <b>5.47</b>		
			<b>N-Nitroso Pendimethalin relevant impurity content</b>	<b>3.817 µg/g</b>	<b>3.840 µg/g</b>		

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			N-Nitrosodimethylamine relevant impurity content	<LOD (0.092 µg/g)	<LOD (0.092 µg/g)			
			N-Nitrosomethylethylamine relevant impurity content	<LOD (0.015 µg/g)	<LOD (0.015 µg/g)			
			N-Nitrosopyrrolidine relevant impurity content	<LOD (0.009 µg/g)	<LOD (0.009 µg/g)			
			N-Nitrosodiethylamine relevant impurity content	<LOD (0.004 µg/g)	<LOD (0.004 µg/g)			
			N-Nitrosopiperidine relevant impurity content	<LOD (0.011 µg/g)	<LOD (0.011 µg/g)			
			N-Nitrosodipropylamine relevant impurity content	<LOD (0.005 µg/g)	<LOD (0.005 µg/g)			
			N-Nitrosodibutylamine relevant impurity content	<LOD (0.216 µg/g)	<LOD (0.216 µg/g)			
			1,2-Dichloroethane relevant impurity content	<LOQ (10.40 µg/g)	<LOQ (10.40 µg/g)			
			pH at 25°C	4.84	4.84			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			pH of 1% aqueous dilution at 25°C	4.83	4.82			
			Emulsion stability	0.625% v/v in Standard Water A Initial emulsification: No oil, no solid matter nor cream were observed. 30min: No oil, no solid matter nor cream were observed. 2hours: No oil, no solid matter nor cream were observed. 24 hours: No oil, no solid matter nor cream were observed. 24.5 hours: No oil, no solid matter nor cream were observed.	0.625% v/v in Standard Water A Initial emulsification: No oil, no solid matter nor cream were observed. 30min: No oil, no solid matter nor cream were observed. 2hours: No oil, no solid matter nor cream were observed. 24 hours: No oil, no solid matter nor cream were observed. 24.5 hours: No oil, no solid matter nor cream were observed.			
				2.0% v/v in	2.0% v/v in			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
				<p>Standard Water A Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>0.625% v/v in Standard Water D Initial emulsification:</p>			
				<p>Standard Water A Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>0.625% v/v in Standard Water D Initial emulsification:</p>			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
				<p>No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water D Initial emulsification: No oil, no solid matter nor cream were</p>			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			<p>observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p>	<p>observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p>			
			Packaging compability	-			No physical damages with no cracking, no change in shape, no leakages and no weight changes. COEX bottle
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant.		-	-	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	GC-FID validated method	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	Pendimethalin: 30.23% w/v Flufenacet: 5.93% w/v	Y	B. Rajasekhar, 2020 Report No. 7713/2020	
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	No layer separation was observed after storage for 7 days at 0°C.  <u>Emulsion characteristics</u> <b>Before storage:</b> 0.625% v/v in Standard Water A Initial emulsification: No oil, no solid matter nor cream were observed. 30min: No oil, no solid matter nor cream were observed. 2hours: No oil, no solid matter nor cream were observed. 24 hours: No oil, no solid matter nor cream were observed. 24.5 hours: No oil, no solid matter nor cream were observed.  2.0% v/v in Standard Water A Initial emulsification: No oil, no solid matter nor cream were observed. 30min: No oil, no solid matter nor cream were observed. 2hours: No oil, no solid matter nor cream were observed. 24 hours: No oil, no solid matter nor cream were observed. 24.5 hours: No oil, no solid matter nor cream were observed.  0.625% v/v in Standard Water D Initial emulsification: No oil, no solid matter nor cream were observed. 30min: No oil, no solid matter nor cream were observed. 2hours: No oil, no solid matter nor cream were observed. 24 hours: No oil, no solid matter nor cream were observed. 24.5 hours: No oil, no solid matter nor cream were observed.	Y	B. Rajasekhar, 2020 Report No. 7709/2020	<b>Accepted</b>  The formulation was not affected by low temperature

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>2.0% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p><b>After storage for 7 days at 0°C:</b>                      0.625% v/v in Standard Water A                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water A                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>0.625% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			observed. 30min: No oil, no solid matter nor cream were observed. 2hours: No oil, no solid matter nor cream were observed. 24 hours: No oil, no solid matter nor cream were observed. 24.5 hours: No oil, no solid matter nor cream were observed.			
Ambient temperature shelf life (KCP 2.7.5)	-	-	Study on-going.	-	-	The shelf-life study report shall be submitted when finished.  Based on the composition of the formulation and results of the accelerated storage study, one-year conditional registration of the product is proposed. Final registration will be possible after submission of the 2-year shelf-life study
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.	-	-	See point KCP 2.7.5
Wettability (KCP 2.8.1)	-	-	Not relevant for EC formulation.	-	-	Not required
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3 CIPAC MT 18	Flufenacet 6% + Pendimethalin 30% EC (Batch No.	0.625% v/v After 1 minute: 0 mL After 12 minutes: 0 mL  2.0% v/v	Y	B. Rajasekhar, 2020 Report No. 7711/2020	<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		SCL-39855)	After 1 minute: 0 mL After 12 minutes: 0 mL			
Suspensibility (KCP 2.8.3.1)	-	-	Not relevant for EC formulation.	-	-	Not required
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not relevant for EC formulation.	-	-	Not required
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for EC formulation.	-	-	Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for EC formulation.	-	-	Not required
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant for EC formulation.	-	-	Not required
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not relevant for EC formulation.	-	-	Not required
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant for EC formulation.	-	-	Not required
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for EC formulation.	-	-	Not required
Attrition (KCP 2.8.5.3)	-	-	Not relevant for EC formulation.	-	-	Not required
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for EC formulation.	-	-	Not required
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	Flufenacet 6% +	0.625% v/v in Standard Water A Initial emulsification: No oil, no solid matter nor cream were	<b>Y</b>	B. Rajasekhar, 2020 Report No.	<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Pendimethalin 30% EC (Batch No. SCL-39855)	<p>observed.</p> <p>30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water A                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>0.625% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p>		7713/2020	
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Flufenacet 6% + Pendimethalin 30% EC (Batch No.	<p>0.625% v/v in Standard Water A                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.</p>	Y	B. Rajasekhar, 2020 Report No. 7713/2020	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		SCL-39855)	<p>24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water A                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>0.625% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p>			
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	<p>0.625% v/v in Standard Water A                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water A</p>	Y	B. Rajasekhar, 2020 Report No. 7713/2020	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>0.625% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p> <p>2.0% v/v in Standard Water D                      Initial emulsification: No oil, no solid matter nor cream were observed.                      30min: No oil, no solid matter nor cream were observed.                      2hours: No oil, no solid matter nor cream were observed.                      24 hours: No oil, no solid matter nor cream were observed.                      24.5 hours: No oil, no solid matter nor cream were observed.</p>			
Flowability (KCP 2.8.7.1)	-	-	Not relevant for EC formulation.	-	-	Not required
Pourability (KCP 2.8.7.2)	-	-	Not relevant for EC formulation.	-	-	Not required
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for EC formulation.	-	-	Not required
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	The products is not intended to be tank mixed.	-	-	Not applicable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	The products is not intended to be tank mixed.	-	-	Not applicable
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant.	-	-	Not required
Distribution to seed (KCP 2.10.2)	-	-	Not relevant.	-	-	Not required
Other/special studies (KCP 2.11)	<del>OECD 204/2014</del> PSD 302, 305	Flufenacet 6% + Pendimethalin 30% EC (Batch No. SCL-39855)	The percentage of the test substance removed by water washing was 100%	Y	B. Rajasekhar, 2020 Report No. 7712/2020	<b>Accepted</b>

### 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)

**Table 4.1-1: Packaging information for 0.250 liter bottle**

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	Round bottle / approx. 61 mm diameter x 138.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 0.500 liter bottle**

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	Round bottle / approx. 69 mm diameter x 199.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information for 1 liter bottle**

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	Round bottle / approx. 88.5 mm diameter x 239.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-4: Packaging information for 5 liter bottle**

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	jerrycan / approx. 136 mm x 192 mm x 285 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap

Type	Description
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information for 10 liter bottle**

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	jerrycan / approx. 174 mm x 226 mm x 368 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 20 liter bottle**

Type	Description
Material:	Fluorinated
Shape/size:	jerrycan / approx. 245 mm x 294 mm x 400 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 20 liter bottle**

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 245 mm x 294 mm x 400 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

<b>zRMS comment:</b>	No data supporting the acceptance of the HDPE packaging type were submitted until the end of the commenting phase, therefore HDPE packaging was crossed out
----------------------	---

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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 2.7.1 KCP 2.7.3 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3	B. Rajasekhar	2020	Accelerated Storage Stability Study of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7713/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.2.1	B. Rajasekhar	2020	Determination of Explosive Properties of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7704/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.2.2	B. Rajasekhar	2020	Determination of Chemical Oxidizing properties of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7707/2020 GLP Unpublished	N	Sharda Cropchem Limited

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 2.3.1	B. Rajasekhar	2020	Determination of Flash Point of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7703/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.3.3	B. Rajasekhar	2020	Determination of Auto-ignition temperature of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7710/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.5.1	B. Rajasekhar	2020	Determination of Viscosity of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7708/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.5.2	B. Rajasekhar	2020	Determination of Surface Tension of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7706/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.6.1	B. Rajasekhar	2020	Determination of Density of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7705/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.1	S. D. Revankar	2021	Accelerated storage stability test by heating at elevated temperature of Flufenacet 6% + Pendimethalin 30% SC. Eurofins Advinus Report No. G21362 GLP	N	Sharda Cropchem Limited

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
			<b>Unpublished</b>		
KCP 2.7.4	B. Rajasekhar	2020	Low Temperature Stability (0°C) of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7709/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.8.2	B. Rajasekhar	2020	Determination of Persistent Foaming of Flufenacet 6% + Pendimethalin 30% EC. Bioscience research foundation Report No. 7711/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.11	B. Rajasekhar	2020	Washing efficiency of Flufenacet 6% + Pendimethalin 30% EC after application. Bioscience research foundation Report No. 7712/2020 GLP Unpublished	N	Sharda Cropchem Limited

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

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
-	-	-	-	-	-

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

**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 Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

### **A 2.1 Pendimethalin**

No new data submitted in the framework of this application.

### **A 2.2 Flufenacet**

No new data submitted in the framework of this application.