

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 5400 A

Product name: FASHION

Chemical active substances:

Fluroxypyr, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: SHARDA Cropchem Limited

Submission date: January 2022

MS Finalisation date: September 2023; January 2025

Version history

When	What
January 2022	Application to Ministry of Agriculture and Rural Development as zRMS, as a "no-data" application based on article 33 and 34 of Regulation (EU) No 1107/2009 using data from the existing reference product Starane 250 EC (Reg. No. R-52/2013 and previously No. 634/99).
September 2023	ZRMs evaluated dRR submitted by Applicant
January 2025	The final Registration Report

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zRMS comments:

Submitted data are sufficient for evaluation. Based on the accelerated storage stability results, expiration date of 2 years is acceptable and proposed.

Tank mixes: Based on the comment of the Applicant, information on tank-mixing with Tribenuron methyl 750 g/Kg has been crossed out from the GAP tables.

Packaging: Based on the accelerated storage results, COEX HDPE/PA packaging is appropriate and acceptable packaging type for FASHION.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

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
regn@shardaintl.com

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
regn@shardaintl.com

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

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
regn@shardaintl.com

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 Fluroxypyr

Fluroxypyr min. ~~980~~ 985 g/kg Sharda source
Fluroxypyr min. 950 g/kg (SANCO/11019/2011 rev. 5, 23 March 2017)

N-methyl-2-pyrrolidone ~~max.~~ ≤ 3 g/kg (SANCO/11019/2011 rev. 5, 23 March 2017)

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: FASHION
Company code number: SHA 5400 A

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Fluroxypyr	250 g/L	± 6% (235 – 265)	253.81 g/L	25.15 % w/w
<i>Fluroxypyr-meptyl</i>	360.1 g/L	± 5% (342.1 – 378.1)	365.58 g/L	36.22 %w/w

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

** Based on the density of the formulation = 1.0093 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
N-methyl-2-pyrrolidone	1.08 g/L

1.4.2 Information on the active substances (KCP 1.4.2)

Table 1.4-4: Information on Fluroxypyr

Type	Name/Code Number	
ISO common name	Fluroxypyr	Fluroxypyr-meptyl
CAS No.	69377-81-7	81406-37-3
EC No.	614-957-2	279-752-9
CIPAC No.	431	431.214

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: Emulsion concentrate [Code: EC]

1.6 Function (KCP 1.6)

The product FASHION is intended to be used as an 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 yellowish brown liquid with an aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 64.5 °C. It has self-ignition temperature above 350°C. In aqueous solution, it has a pH value around 5.88 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. Its technical characteristics are acceptable for an *Emulsion concentrate* formulation.

The intended concentration of use is ~~0.1~~ 0.2 % to 0.4 % (v/v).

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

Neither classification nor labelling are relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

~~The product FASHION complies with FAO specifications.~~

At the time of the evaluation, there is no FAO specification for the formulation with fluroxypyr.

Formulation used for tests

The product used to determinate the physical, chemical and technical properties is 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 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	Yellowish brown (4/30 AS-12) liquid with aromatic odour.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted
Explosive properties (KCP 2.2.1)	EEC A. 14	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	The product has no explosive properties.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Thermal and mechanical sensitivity – negative. Non-explosive
Oxidizing properties (KCP 2.2.2)	OCSP 830.6314 EEC A. 21	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	The test item has no oxidizing properties.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Non-oxidizing
Flash point (KCP 2.3.1)	EC A.9	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	64.5°C	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Performed with the Pensky-Martens tester cup. Non-flammable
Flammability (KCP 2.3.2)	-	-	Please refer to KCP 2.3.1.	-	-	Not required
Self-heating (KCP 2.3.3)	ASTM E 659 78 EEC A. 15	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	No ignition was observed up to 350°C.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Not auto-flammable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																			
Acidity or alkalinity and pH (KCP 2.4.1)	ASTM G 31-12	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	Since the pH value ranged from 4 to 10 (see below), the acidity or alkalinity test was not performed Corrosion rate (mm/y): <table border="1"> <tr> <td rowspan="3">Aluminium</td> <td>Fully immersed</td> <td>0.00071</td> </tr> <tr> <td>Half immersed</td> <td>0.00036</td> </tr> <tr> <td>Air</td> <td>0.00024</td> </tr> <tr> <td rowspan="3">Brass</td> <td>Fully immersed</td> <td>0.00064</td> </tr> <tr> <td>Half immersed</td> <td>0.00030</td> </tr> <tr> <td>Air</td> <td>0.00019</td> </tr> <tr> <td rowspan="3">Copper</td> <td>Fully immersed</td> <td>0.00062</td> </tr> <tr> <td>Half immersed</td> <td>0.00033</td> </tr> <tr> <td>Air</td> <td>0.00022</td> </tr> <tr> <td rowspan="3">Iron</td> <td>Fully immersed</td> <td>0.00081</td> </tr> <tr> <td>Half immersed</td> <td>0.00047</td> </tr> <tr> <td>Air</td> <td>0.00028</td> </tr> <tr> <td rowspan="3">Steel</td> <td>Fully immersed</td> <td>0.00080</td> </tr> <tr> <td>Half immersed</td> <td>0.00040</td> </tr> <tr> <td>Air</td> <td>0.00026</td> </tr> </table>	Aluminium	Fully immersed	0.00071	Half immersed	0.00036	Air	0.00024	Brass	Fully immersed	0.00064	Half immersed	0.00030	Air	0.00019	Copper	Fully immersed	0.00062	Half immersed	0.00033	Air	0.00022	Iron	Fully immersed	0.00081	Half immersed	0.00047	Air	0.00028	Steel	Fully immersed	0.00080	Half immersed	0.00040	Air	0.00026	Y	G. B. Azeema, 2021 Report No. 9307/2021	Accepted Insignificant rate of corrosion.
Aluminium	Fully immersed	0.00071																																							
	Half immersed	0.00036																																							
	Air	0.00024																																							
Brass	Fully immersed	0.00064																																							
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	Half immersed	0.00040																																							
	Air	0.00026																																							
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	pH of 1% w/v aqueous emulsion pH = 5.88 at 25°C Neat sample: 3.36 at 25°C	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted																																			
Viscosity (KCP 2.5.1)	CIPAC MT 192 OECD 114	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	<table border="1"> <thead> <tr> <th>Shear rate (sec⁻¹)</th> <th>Dynamic viscosity at 20°C (cP)</th> <th>Dynamic viscosity at 40°C (cP)</th> </tr> </thead> <tbody> <tr> <td>24.5</td> <td>30.4</td> <td>28.4</td> </tr> <tr> <td>36.7</td> <td>34.5</td> <td>31.4</td> </tr> <tr> <td>61.2</td> <td>36.4</td> <td>33.5</td> </tr> <tr> <td>73.4</td> <td>38.7</td> <td>35.5</td> </tr> </tbody> </table>	Shear rate (sec ⁻¹)	Dynamic viscosity at 20°C (cP)	Dynamic viscosity at 40°C (cP)	24.5	30.4	28.4	36.7	34.5	31.4	61.2	36.4	33.5	73.4	38.7	35.5	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Considered non-Newtonian liquid. Conclusion based on results - does not pose an aspiration hazard.																				
Shear rate (sec ⁻¹)	Dynamic viscosity at 20°C (cP)	Dynamic viscosity at 40°C (cP)																																							
24.5	30.4	28.4																																							
36.7	34.5	31.4																																							
61.2	36.4	33.5																																							
73.4	38.7	35.5																																							
Surface tension (KCP 2.5.2)	OECD No. 115 EC A.5	Fluroxypyr (as Meptyl ester) 250 g	Test item undiluted = 60.649 mN/m at 20°C Test item aqueous solutions at 0.1% v/v = 58.650	Y	G. B. Azeema, 2021 Report No. 9307/2020	Accepted																																			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments		
		a.e./L EC SCL-36455	mN/m at 20°C		9307/2021	Should be performed at the highest conc. recommended (0.4 %). Formulation is considered surface-active		
Relative density (KCP 2.6.1)	EEC A. 3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	Density = 1.0093 g/mL at 20°C Relative density: 1.0097	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted		
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 Validated analytical methods CIPAC MT 30.5 CIPAC MT 36.3 CIPAC MT 47.3 CIPAC MT 75.3 CIPAC MT 148 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 OPPTS 830.7000 SANCO/3030/99 rev.5	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	Test	Initial	After 14 days at 54°C	Y	G. B. Azeema, 2021 Report No. 9308/2020 9308/2021	Accepted Temp. recorded: 54 ± 2°C. Stored in the commercial packaging (COEX HDPE/PA). Following storage, no significant changes in the physical, chemical, or technical properties of the formulation and the packaging remained stable, with 0.02% weight loss.
			Appearance	Yellowish brown (4/30 AS-12) liquid with aromatic odour.	Yellowish brown (4/30 AS-12) liquid with aromatic odour.			
			Fluoxypyr-1-methyl heptyl ester content (%w/w)	35.6648	35.6642			
			Fluroxypyr content (g/L)	250.005	250.001			
			Relevant impurity: (1-methyl-2-pyrrolidone)	0.0993 % w/w 1.003 g/L	0.0993 % w/w 1.002 g/L			
			pH of 1% aqueous	5.88	5.85			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments	
			emulsion pH neat	3.36	3.33			
			Pourability	R = 0.8086 % R' = 0.1952%	R = 0.7531% R' = 0.1673%			
			Emulsion characteristics	0.1% v/v and 5% v/v in Standard Water D Initial: Uniform emulsion was observed 30 min: No free oil/cream were observed at top/bottom of the emulsion. 2 hours: No free oil/cream were observed at top/bottom of the emulsion. 24 hours: No free oil, no solid matter nor cream were observed. Re-emulsification complete 24.5: No fre	0.1% v/v and 5% v/v in Standard Water D Initial: Uniform emulsion was observed 30 min: No free oil/cream were observed at top/bottom of the emulsion. 2 hours: No free oil/cream were observed at top/bottom of the emulsion. 24 hours: No free oil, no solid matter nor cream were observed. Re-emulsification complete 24.5: No fre			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
				oil, no solid matter nor cream were observed.	oil, no solid matter nor cream were observed.		
			Stability of packaging	No perforations, no darkening, no leakage and no rutiness	No perforations, no darkening, no leakage and no rutiness		
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required, please refer to KCP 2.7.1.		-	-	Not required
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please refer to KCP 2.7.1.		-	-	See KCP 2.7.1.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	After 7 days at 0 ± 2 °C: the test substance was homogeneous in nature and no crystal formation was observed after 24 h. After low temperature stability at 0 °C for 7 days, emulsion characteristics were determined and the results are comparable to the initial results: Emulsion Characteristics: Standard Water A and D Complete initial emulsification (0h) and re-emulsification (24h) for both application rates (0.1% v/v and 5% v/v). No free oil and cream were observed at the top or bottom of the emulsion after 30 minutes, 2h and 24h for both application rates (0.1% v/v and 5% v/v).		Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Not affected by low temperature

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)	-	-	Not relevant for a EC formulation.	-	-	Based on the composition of the product and the results of accelerated storage tests, 2-years expiration date is acceptable and proposed
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Study on going.	-	-	Not required
Wettability (KCP 2.8.1)	-	-	Not relevant for EC formulation.	-	-	Not required
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	5 g/L in Standard Water D After 1 min.: 3 mL After 12 min: 1 mL 10 g/L in Standard Water D After 1 min.: 6 mL After 12 min: 2 mL	Y	G. B. Azeema, 2021 Report No. 9307/2020 <u>9307/2021</u>	Accepted Conc. tested covers conc. recommended (0.2-0.4%)
Suspensibility (KCP 2.8.3.1)	-	-	Not relevant for a EC formulation.	-	-	Not required
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not relevant for a EC formulation.	-	-	Not required
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for a EC formulation.	-	-	Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for a EC formulation.	-	-	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant for a EC formulation.	-	-	Not required
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not relevant for a EC formulation.	-	-	Not required
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant for a EC formulation.	-	-	Not required
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for a EC formulation.	-	-	Not required
Attrition (KCP 2.8.5.3)	-	-	Not relevant for a EC formulation.	-	-	Not required
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for a EC formulation.	-	-	Not required
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	0.1% v/v and 5% v/v in Standard Water D Initial: Uniform emulsion was observed 30 min: No free oil/cream were observed at top/bottom of the emulsion. 2 hours: No free oil/cream were observed at top/bottom of the emulsion. 24 hours: No free oil, no solid matter nor cream were observed. Re-emulsification complete 24.5: No free oil, no solid matter nor cream were observed.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Conc. tested covers conc. recommended (0.2-0.4%)
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	0.1% v/v and 5% v/v in Standard Water D Initial: Uniform emulsion was observed 30 min: No free oil/cream were observed at top/bottom of the emulsion. 2 hours: No free oil/cream were observed at top/bottom of the emulsion.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Conc. tested covers conc. recommended (0.2-0.4%)

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			24 hours: No free oil, no solid matter nor cream were observed. Re-emulsification complete 24.5: No free oil, no solid matter nor cream were observed.			
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	0.1% v/v and 5% v/v in Standard Water D Initial: Uniform emulsion was observed 30 min: No free oil/cream were observed at top/bottom of the emulsion. 2 hours: No free oil/cream were observed at top/bottom of the emulsion. 24 hours: No free oil, no solid matter nor cream were observed. Re-emulsification complete 24.5: No free oil, no solid matter nor cream were observed.	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Conc. tested covers conc. recommended (0.2-0.4%)
Flowability (KCP 2.8.7.1)	-	-	Not relevant for a EC formulation.	-	-	Not required
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	R = 0.8086% R' = 0.1952%	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Acceptable Additional study, not required for an EC formulation
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for a EC formulation.	-	-	Not required
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant. The product is not intended to be tank mixed.	-	-	Not required
Chemical compatibility of tank	-	-	Not relevant. The product is not intended to be tank mixed.	-	-	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
mixes (KCP 2.9.2)						
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant, not used for seed treatment.	-	-	Not required
Distribution to seed (KCP 2.10.2)	-	-	Not relevant, not used for seed treatment.	-	-	Not required
Other/special studies (KCP 2.11)	PSD Efficacy Guideline 305 CIPAC MT 30.5	Fluroxypyr (as Meptyl ester) 250 g a.e./L EC SCL-36455	% Removed = 99.5% Moisture content = 1.3646 %	Y	G. B. Azeema, 2021 Report No. 9307/2020 9307/2021	Accepted Additional studies

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

zRMS comment: Based on the accelerated storage results, COEX HDPE/PA packaging is appropriate and acceptable packaging type for FASHION.

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

Table 4.1-5: Packaging information for 10 litter 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 litter bottle

Type	Description
Material:	COEX HDPE/PA
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

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 2.2.1 KCP 2.2.2 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.6.1 KCP 2.8.2 KCP 2.7.3 KCP 2.8.2 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3 KCP 2.8.7.2 KCP 2.11	G. B. Azeema	2021	Physico-chemical studies of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC Bioscience Research Foundation Report No.: 9307/2021 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.1	G. B. Azeema	2021	Accelerated Storage Stability Study of Fluroxypyr (as Meptyl ester) 250 g a.e./L EC Bioscience Research Foundation Report No.: 9308/2021 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

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

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

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

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

A 2.1 Fluroxypyr

Not relevant, there is no additional data on the active substance.