

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 4100 A

Product name: HIFEN

Chemical active substance:

Thifensulfuron-methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem Ltd

Submission date: September 2023

MS Finalisation date: 02.2024; 02.2025

Version history

When	What
09.2023	Submission date
02.2024	zRMS evaluation
02.2025	The final Registration Report.

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zRMS comments:

Submitted data are sufficient for evaluation. Data gaps: none.

Shelf-life: 2 years

Packaging: The accelerated storage was performed in the COEX (HDPE-EVOH) bottle and the 2-years study was performed in the HDPE bottle. Both types of packaging remained unaltered and are acceptable packaging types for the formulation SHA 4100 A (HIFEN). See Section 4 for details.

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

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

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

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

1.2.3.1 Thifensulfuron-methyl

Thifensulfuron-methyl min. 960 g/kg (SANTE/10150/2016 rev. 2 12 July 2016)
min. 980 g/kg (Sharda source) (UK, 2016)

There are no relevant impurities

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

Trade name: HIFEN
Company code number: SHA 4100 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)
Thifensulfuron-methyl	750 g/kg	± 25 g/kg (725 – 775 g/kg)	765.31 g/kgs	76.53%

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

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

Table 1.4-2: Information on Thifensulfuron-methyl

Type	Name/Code Number
ISO common name	Thifensulfuron-methyl
CAS No.	79277-27-3
EC No.	616-673-4
CIPAC No.	452

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: Water dispersible granules

[Code: WG]

1.6 Function (KCP 1.6)

The product HIFEN (SHA 4100 A) 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 beige solid granules with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 5.49 at 21 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE commercial packaging*. Its technical characteristics are acceptable for *water dispersible granules* formulation.

The intended concentration of use is 0.01% to 0.02% of (PPP).

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

Neither classification or labelling are relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

The product SHA 4100 A complies with FAO specifications.

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	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Beige solid granules with characteristic odour.	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	The test item has no explosive properties.	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted No explosion occurred in thermal and mechanical sensitivity tests
Oxidizing properties (KCP 2.2.2)	EEC A.17	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	The test item has no oxidizing properties.	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted No oxidizing properties.
Flash point (KCP 2.3.1)	-	-	Please refer to KCP 2.3.2	-	-	Not required
Flammability (KCP 2.3.2)	EEC A.10	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	The product is not flammable.	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted Not flammable
Self-heating	EEC A.16	THIFENSULFURON	The product is not self-igniting, the substance melts down.	Y	Escudero,	Accepted

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments									
(KCP 2.3.3)		METHYL 75% WG (Batch No. SWEPL-13205)					2017, Laboratorios Munuera Report No. 15-4150-19										
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 31.2	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	%w/w as H ₂ SO ₄ = 1.0288 ± 0.0007%			Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Based on the pH result the test was not obligatory Accepted									
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	pH = 5.49 ± 0.03			Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted									
Viscosity (KCP 2.5.1)	-	-	Not relevant for WG formulation.			-	-	Not required									
Surface tension (KCP 2.5.2)	-	-	Not relevant for WG formulation.			-	-	Not required									
Relative density (KCP 2.6.1)	-	-	Not relevant for WG formulation			-	-	Not required									
Bulk density (KCP 2.6.2)	CIPAC MT 186	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Pour density: 0.76 ± 0.01 g/mL Tap density: 0.78 ± 0.02 g/mL			Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted									
Storage Stability after 14 days at 54° C	OPPTS 830.6320 Visual CIPAC MT 172	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-	<table><tr><th>Parameter</th><th>room T°</th><th>14 d at 54°C</th></tr><tr><td>a. s. content</td><td>74.8 ± 0.5</td><td>74.1 ± 0.4 (- 0.94%)</td></tr><tr><td>Corrosive</td><td>-</td><td>Unaltered container</td></tr></table>			Parameter	room T°	14 d at 54°C	a. s. content	74.8 ± 0.5	74.1 ± 0.4 (- 0.94%)	Corrosive	-	Unaltered container	Y	Escudero, 2017, Laboratorios	Commercial packaging (COEX
Parameter	room T°	14 d at 54°C															
a. s. content	74.8 ± 0.5	74.1 ± 0.4 (- 0.94%)															
Corrosive	-	Unaltered container															

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.1)	CIPAC MT 31.2 CIPAC MT 75.3 CIPAC MT 53.3 CIPAC MT 58.2 CIPAC MT 178.2 CIPAC MT 171 CIPAC MT 184 CIPAC MT 174 CIPAC MT 167 HPLC - UV	13205)	properties				Munuera Report No. 15-4150-19	HDPE/EVOH) remained stable and unaltered. The content of a.s. was determined using HPLC-UV, validated according to SANCO/3030/99 rev. 5 (see dRR Part B5). No significant changes in the a.s. content and in the physical, chemical, or technical properties of the formulation after storage. Accepted
			Physical state	Solid granules	Solid granules			
			Colour	Beige	Beige			
			Odour	Characteristic	Characteristic			
			Flowability after storage under pressure	-	The simple drops through the sieve spontaneously			
			Free acidity	1.0288 ± 0.0007%	0.8485 ± 0.0007%			
			pH	5.49 ± 0.03	5.37 ± 0.03			
			Wettability	complete wetting of the powder after 6 s	complete wetting of the powder after 1 s			
			Particle size distribution	Test sieve/%residue 150µm 0.3 250µm 2.3 355µm 1.6 400µm 9.7 500µm 29.4 710µm 18.6 850µm 38.0	Test sieve/%residue 150µm 0.1 250µm 1.4 355µm 1.3 400µm 8.6 500µm 26.9 710µm 19.7 850µm 41.9			
			Attrition resistance	99.93 ± 0.01%	99.79 ± 0.01%			
			Dust content	Nearly dust - free	Nearly dust - free			
			% suspensibility (0.2%)	100 ± 0%	100 ± 0%			
			Degree of dispersion	100 ± 1%	99 ± 1%			
			Wet sieve test	<0.1%	<0.1%			
			Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-			
Minimum content after heat stability	HPLC – UV	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-	Thifensulfuron (%w/w) At room temperature: 74.8 ± 0.5% After 14 days at 54°C: 74.1 ± 0.4%			Y	Escudero, 2017, Laboratorios	

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
testing (KCP 2.7.3)		13205)							Munuera Report No. 15-4150-19	
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not required for WG formulation.					-	-	Not required
Ambient temperature shelf life (KCP 2.7.5)	OPPTS 830.6320 Visual/organoleptic CIPAC MT 31 CIPAC MT 75.3 CIPAC MT 184 CIPAC MT 167 CIPAC MT 53.3 CIPAC MT 58 CIPAC MT 174 CIPAC MT 178.2 CIPAC MT 171 HPLC – UV GIFAP No 17	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Test	Room temp.	6 months at 25°C	12 months at 25°C	24 months at 25°C	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-20	Temp. recorded: between 23.5 – 26.5°C Packaging (HDPE bottle) remained stable and unaltered. The content of a.s. was determined using HPLC-UV, validated according to SANCO/3030/99 rev. 5 (see dRR Part B5). No significant changes in the a.s. content and in the physical, chemical, or technical properties of the formulation after
			Corrosive properities	-	Unaltered container	Unaltered container	Unaltered container			
			Appearance	Beige solid granules with characteristic odour	Beige solid granules with characteristic odour	Beige solid granules with characteristic odour	Beige solid granules with characteristic odour			
			Free acidity (as H ₂ SO ₄)	1.0288 ± 0.0007%	0.9819 ± 0.0026%	1.2281 ± 0.0434%	1.0083 ± 0.0380%			
			pH (1% dilution)	5.49 ± 0.03	5.41 ± 0.05	5.48 ± 0.04	5.39 ± 0.04			
			% Suspensibility (0.2%)	100 ± 0%	100 ± 0%	98 ± 0%	98 ± 0%			
			Wet sieve test	<0.1%	<0.1%	<0.1%	<0.1%			
			Wettability	Complete wetting of the powder after 6s	Complete wetting of the powder after 1s	Complete wetting of the powder after 1s	Complete wetting of the powder after 1s			
			Particle size distribution	150 µm 0.3 250 µm 2.3 335 µm 1.6 400 µm 9.7 500 µm 29.4 710 µm 18.6	150 µm 0.4 250 µm 2.1 335 µm 1.6 400 µm 10.1 500 µm 28.0 710 µm 18.4	150 µm 0.1 250 µm 1.3 335 µm 1.3 400 µm 8.1 500 µm 26.8 710 µm 20.2	150 µm 0.1 250 µm 1.2 335 µm 1.2 400 µm 8.0 500 µm 27.4 710 µm 19.9			

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
				850 µm 38.0	850 µm 39.2	850 µm 42.0	850 µm 42.0			storage. Accepted
			Degree of dispersion	100 ± 1%	101 ± 0%	99 ± 1%	97 ± 1%			
			Attrition resistance	99.93 ± 0.01%	99.91 ± 0.01%	99.90 ± 0.00%	99.85 ± 0.07%			
			Dust content	Nearly dust-free	Nearly dust-free	Nearly dust-free	Nearly dust-free			
			a.s. content	74.8 ± 0.5%	75.6 ± 0.2% (+ 1.07%)	75.5 ± 0.9% (+ 0.94%)	74.6 ± 0.6% (- 0.27%)			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.					-	-	Not required
Wettability (KCP 2.8.1)	CIPAC MT 53.3	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Complete wetting of the powder after 6 second.					Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	0.1 g/L in Standard water D After 12 min: 8 mL 0.2 g/L in Standard water D After 12 min: 22 mL					Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted Tested at the min-max concentrations recommended for use
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	0.2% w/v = 100%					Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	100 ± 1%	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for WG formulation.	-	-	Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for WG formulation.	-	-	Not required
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 58.2	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Test sieve	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted Additional study
			150 µm			
			250 µm			
			355 µm			
			400 µm			
			500 µm			
			710 µm			
			850 µm			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 167	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	% retained in 75 µm sieve: <0.1%	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Product categories, nearly dust - free	Y	Escudero, 2017, Laboratorios Munuera Report No.	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					15-4150-19	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for WG formulation.	-	-	Not required
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	Attrition resistance: 99.93 ± 0.01%	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for WG formulation.	-	-	Not required
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for WG formulation.	-	-	Not required
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for WG formulation.	-	-	Not required
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for WG formulation.	-	-	Not required
Flowability (KCP 2.8.7.1)	CIPAC MT 172	THIFENSULFURON METHYL 75% WG (Batch No. SWEPL-13205)	The sample drops through the sieve spontaneously	Y	Escudero, 2017, Laboratorios Munuera Report No. 15-4150-19	Accepted
Pourability (KCP 2.8.7.2)	-	-	Not relevant for WG formulation.	-	-	Not required
Dustability following	-	-	Not relevant.	-	-	Not required

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
accelerated storage (KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant.	-	-	Not required
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant.	-	-	Not required
Adhesion to seeds (KCP 2.10.1)	-	-	Not required. The product is not intended to be applied to seeds.	-	-	Not required
Distribution to seed (KCP 2.10.2)	-	-	Not required. The product is not intended to be applied to seeds.	-	-	Not required
Other/special studies (KCP 2.11)	Efficacy guideline 302 and 305	Thifensulfuron 75% WG (batch No. SWELP-13205)	The average of three replicate of removed was 99.99 ± 0% removed test item.	Y	Escudero, 2019, Laboratorios manuera Report No. 16-4150-14	Accepted

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:

The accelerated storage was performed in the COEX (HDPE-EVOH) bottle and the 2-years study was performed in the HDPE bottle. Both types of packaging remained unaltered and are acceptable packaging types for the formulation SHA 4100 A (HIFEN).

According to the current guidelines of the Polish Ministry of Agriculture and Rural Development of 5 September 2023, extrapolation from rigid to elastic packaging is not acceptable for solid preparations and therefore all bags have been crossed out (Tables 4.1-8 – 4.1-16).

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information for 50 g (0.100 liter bottle)

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 56.50 mm diameter x 69.50 mm
Opening:	42 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 100 g (0.200 liter bottle)

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 62.0 mm diameter x 141.0 mm
Opening:	39.0 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 200 g (0.500 liter bottle)

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 73.0 mm diameter x 180.0 mm
Opening:	39.0 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1-4: Packaging information for 250 g (0.750 liter bottle)

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 89.0 mm diameter x 240.0 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 500 g (1 liter bottle)

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	Round bottle / approx. 89 mm diameter x 240 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 750 g (2 liter bottle)

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 241.0 mm x 68.0 mm x 159.7 mm
Opening:	33.80 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 1000 g (5 liter bottle)

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	jerrycan / approx. 307 mm x 193 mm x 142 mm

Type	Description
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

The bags used for packaging 50, 100, 200, 250, 500, 750 and 1000 grams are obtained from a coil, and the material of these bags consists in PE* multifilm with the next layers:

Material 1:	PET (Polyethylene terephthalate)	Thickness: 12.0 mc	Outside layer
Material 2:	ALU (Aluminium)	Thickness: 9.0 mc	Middle layer
Material 3:	PEBD TR (Thermoplastic low density polyethylene)	Thickness: 65.0 mc	Inside layer (in contact with the product)

The specifications of size for these bags are in the next tables:

Table 4.1 8: Packaging information for 50 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 105 mm x 70 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1 9: Packaging information for 100 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 195 mm x 130 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 200 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 170 mm
Seal:	Heat seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1 11: Packaging information for 250 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 170 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1 12: Packaging information for 500 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 210 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information for 750 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 260 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1 14: Packaging information for 1 kg

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 260 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1 15: Packaging information for 5 kg and 10 kg

Type	Description
Material:	PE
Shape/size:	Sac / approx. 380 mm (width) x 570 mm (length) x 100 mm (bottom) Layers of sac, the three layers are of paper: 1. Semi-stretchable white (70 g/m²) (Outside layer) 2. Straight (70 g/m²) (Middle layer) 3. Straight (70 g/m²) (Inside layer) Inner bag (Low density polyethylene): approx. 390 mm (width) x 680 mm (length) [thickness:45 µm] (Layer in contact with the product)
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1 16: Packaging information for 20 kg and 25 kg

Type	Description
Material:	PE
Shape/size:	Sac / approx. 550 mm (width) x 810 mm (length) x 130 mm (bottom) Layers of sac, the three layers are of paper: 1. Semi-stretchable white (70 g/m²) (Outside layer) 2. Semi-stretchable (70 g/m²) (Middle layer) 3. Semi-stretchable (70 g/m²) (Inside layer) Inner bag (Low density polyethylene): approx. 560 mm (width) x 910 mm (length) [thickness:37 µm] (Layer in contact with the product)
Seal:	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 2.3.2 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.7.3 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP	J. A. Escudero	2017	Physico-Chemical Characterization of THIFENSULFURON MEHYL 75% WG. Laboratorios Munuera Report No. 15-4150-19 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
2.8.5.2.1 KCP 2.8.5.3 KCP 2.8.7.1					
KCP 2.7.5	J. A. Escudero	2019	Storage stability for two years at $25 \pm 2^{\circ}\text{C}$ of THIFENSULFURON METHYL 75% WG. Laboratorios Munuera Report No. 15-4150-20 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.11	J. A. Escudero	2019	Cleaning application equipment – Small scale jar test protocol for THIFENSULFURON MEHYL 75% WG. Laboratorios Munuera Report No. 16-4150-14 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 Thifensulfuron-methyl

No new data were submitted in the framework of this application.