

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 1100 D

Product name(s): CANDELA

Chemical active substance(s):

Glyphosate 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: February 2018

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MS Finalisation date: 18/10/2022

Version history

When	What
10/2018	Dossier sent for evaluation to Merit Mark (PL)
October 2018	Updated by the applicant.
August 2020	Applicant update
10/2021	zRMS finalised evaluation
10/2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- There are no data on levels of glyphosate's relevant impurities in the PPP in the two-year study. Nevertheless, it may be completed and assessed in post-registration at national level.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sharda Cropchem España S.L.
Address: Carril Condomina, nº3, 30006 Murcia, Spain

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

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

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

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

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

Glyphosate	min. 950 g/kg
Formaldehyde	max. 1.3 g/kg
N-Nitroso-glyphosate	max. 1.0 g/kg

RMS comment:

The source's minimum purity is 955 g/kg. For full details please refer to the parc C.

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: CANDELA
Company code number: SHA 1100 D

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)
Glyphosate	540 g/l	515-565 g/l	568.4 g/L	46.05% 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 = 1.2373 (Note: only applies if a liquid formulation – delete this comment if not)

needed)

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

Table 1.4-2: Information on Glyphosate

Type	Glyphosate
ISO common name	N-(phosphonomethyl)glycine
CAS No.	1071-83-6
EC No.	213-997-4
CIPAC No.	284

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: Soluble concentrate

[Code: SL]

1.6 Function (KCP 1.6)

The product Glyphosate 54% SL is 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 pale yellow liquid, with a non characteristic odour. It is not explosive. The product has a flash point > 100°C. It has a self-ignition temperature of 510°C. In aqueous solution, it has a pH value around 4.52 at 20.5°C. There is no effect of low temperature on the stability of the formulation.

The intended concentration of use is ~~0.35% to 1.75%~~ 0.2% to 1%. v/v.

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

Not relevant.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant.

Compliance with FAO specifications:

The product Glyphosate 54% SL complies with FAO specifications.

Formulation used for tests

The product used to determine 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)	OCSPP 830.6302, 830.6303, 830.6304 No deviation	Glyphosate 54% SL	The Munsell notation for the colour of Gyphosate 54% SL was 7.5Y 8.5/12 (pale yellow) in natural daylight. The Glyphosate 54% SL was liquid having non characteritic odour at 20 ± 1°C.	Y	Hetal K, Desai, 2017 Report 201-2-11-15985	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Glyphosate 54% SL	Negative results	Y	H.S. Anand, 2017 Report G14423	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.21	Glyphosate 54% SL	Non-oxidizing.	Y	Hetal K. Desai, 2018, Report 230-2-11-18940	Accepted
Flash point (KCP 2.3.1)	EC A.9 No deviation	Glyphosate 54% SL	> 110 °C	Y	Hetal K. Desai, 2017, Report 221-2-11-15982	Accepted
Flammability (KCP 2.3.2)	Not relevant for SL formulation					
Self-heating (KCP 2.3.3)	EC A.15 No deviation	Glyphosate 54% SL	At 510°C with a yelloww flame after a mean time-lag of 4 seconds at 760 mm Hg atmospheric pressure.	Y	Hetal K. Desai, 2017 Report 2.41-2-11-15989	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 No deviation	Glyphosate 54% SL	The mean pH of undiluted Glyphosate 54% SL was 4.66 ± 0.01 at 20.6°C	Y	Hetal K. Desai, 2017 Report 210-2-11-15986	Accepte
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3 No deviation	Glyphosate 54% SL	The mean pH of 1% (w/w) aqueous solution of Glyphosate 54% SL was 4.52 ± 0.00 at 20.5°C	Y	Hetal K. Desai, 2017 Report 210-2-11-15986	Accepted
Viscosity (KCP 2.5.1)	OECD 114 No deviation	Glphosate 54% SL	Mean viscosity at 20 ± 0.2°C = 264.3 cP (mPa s). Mean viscosity at 40 ± 0.2°C = 78.8 cP (mPa s). Mean kinematic viscosity at 20 ± 0.2°C = 214.1 (m²/s). Mean kinematic viscosity at 40 ± 0.2°C = 63.8 (m²/s).	Y	Hetal K. Desai, 2017 Report 214-2-11-15987	Accepted
Surface tension	EEC A.5	Glphosate	50.97 mN/m (at 20 °C) (at 1 g/L)	Y	Hetal K. Desai, 2018	Accepted

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
(KCP 2.5.2)		54% SL				Report 234-2-11-18053	A surface active
Relative density (KCP 2.6.1)	OCSPP 830.7300 /CIPAC MT 3.2.1 No deviation	Glyphosate 54% SL	Specific gravity: 1.2372 ± 0.0017 at 20 ± 0.5°C Mean density: 1.2342 ± 0.0018 at 20 ± 0.5°C		Y	Hetal K. Desai, 2017 Report 236-2-11-15992	Accepted
	EC A.3 No deviation	Glyphosate 54% SL	Mean relative density: 1.2373 ± 0.0031g/mL at 20°C		Y	Hetal K. Desai, 2017 Report 260-2-11-16583	
Bulk density (KCP 2.6.2)	Not relevant for SL formulation						
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3.1	Glphosate 54% SL	Before Storage	After Storage at 54°C ± 2°C for 14 days	Y	Hetal K. Desai, 2018 Report 234-2-11-18053	Accepted HDPE pack remained intact after storage. All pchysicochemical parameters required for SL formulation before and after storage are acceptable. Since levels of relevant impurities in the PPP data are covered by Report No. 0484/2020 the study can accepted.
			Packaging inspection				
			No perforation No rusting/ leaking at the seam No distortion	No perforation No rusting/ leaking at the seam No distortion			
			Appearance of the HDPE container (visual)				
			Cylindrical shape White colour No crack	Cylindrical shape White colour No crack			
			Appearance				
			Pale yellow (Munsell Notation: 7.5Y 8.5/12) Liquid having non-characteristic odour	Reddish yellow (Munsell Notation: 7.5YR 6/14) Liquid having non-characteristic odour			
			pH				
			1% w/v dilution: 4.34 Undiluted: 4.61	1% w/v dilution: 4.39 Undiluted: 4.64			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
		Batch No. 201912001	Active ingredient content			Y	Mercedes Pardo Martinez, 2020 Report No. 0484/2020		
			Glyphosate: 543.85 g/L (44.07% w/w) Glyphosate IPA salt: 733.92 g/L (59.47% w/w)		Glyphosate: 543.79 g/L (44.06% w/w) Glyphosate IPA salt: 733.86 g/L (59.46% w/w)				
			Dilution stability						
			No separation of material observed at the top or at the bottom of the cylinder for minimum and maximum doses after 30 minutes and after 24 hours.		No separation of material observed at the top or at the bottom of the cylinder for minimum and maximum doses after 30 minutes and after 24 hours.				
			The product is stable in HDPE bottle after 14 days storage at 54 °C.						
			Test	Initial characterisation	After 14 days of storage at 54°C				
			Packaging	HDPE bottle with a screw cap	HDPE bottle with a screw caps “A” and “B”				
			Weight variation (%)	-	“A”: - 0.06 % “B”: - 0.07 %				
			N-NO-	0.31 ± 0.01	0.32 ± 0.01				

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
			Glyphosate impurity	µg/g	µg/g			
			Formaldehyde impurity	n.d.	n.d.			
			Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	-	The container didn't present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not relevant.							
Minimum content after heat stability testing (KCP 2.7.3)	Not relevant.							
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 No deviation	Glyphosate 54% SL	After 7 days at 0 ± 2°C, less than 0.15 ml of separated layer was observed at the bottom of the centrifuge tubes. After stirage of centrifuge tubes at 23 ± 2°C for 24 hours, a very negligible vomuleless than 0.05 ml of separated layer was observed at the bottom of the centrifuge tubes.			Y	Hetal K. Desai, 2017 Report 252-2-11-15991	Accepted
Ambient temperature shelf life			Before Storage	After 24 months				DATA GAP

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.5)			Packaging inspection				HDPE pack remained intact after storage. Concentrations of the a.s. before and after storage were into FAO/WHO tolerance. Presented results meet the SL formulation requirements. However, there are some data still missing. In case of Glyphosate, levels of its relevant impurities shall be analyzed in the PPP as well (especially NNG). Applicant has confirmed that adequate data should be available in 2022 (the additional two-year study is ongoing). Summarizing. this study may be accepted Yet. missing data on relevant impurities tested in the two-year study shall be evaluated in post-registration at national level when available.
			No perforation No rusting/ leaking at the seam No distortion	No perforation No rusting/ leaking at the seam No distortion			
			Appearance of the HDPE container (visual)				
			Cylindrical shape White colour No crack	Cylindrical shape White colour No crack			
			Appearance				
			Pale yellow (Munsell Notation: 7.5Y 8.5/12) Liquid having non-characteristic odour	Reddish yellow (Munsell Notation: 7.5YR 6/14) Liquid having non-characteristic odour			
			pH				
			1% w/v dilution: 4.34 Undiluted: 4.61	1% w/v dilution: 4.48 Undiluted: 4.53			
			Active ingredient content				
			Glyphosate: 543.85 g/L (44.07% w/w) Glyphosate IPA salt: 733.92 g/L (59.47% w/w)	Glyphosate: 541.01 g/L (43.84% w/w) Glyphosate IPA salt: 730.09 g/L (59.16% w/w)			
			Dilution stability				
			No separation of material observed at the top or at the bottom of	No separation of material observed at the top or at the bottom of			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<div>the cylinder for minimum and maximum doses after 30 minutes and after 24 hours.</div> <div>the cylinder for minimum and maximum doses after 30 minutes and after 24 hours.</div> <div>The product is stable in HDPE bottle after two years at ambient temperature,.</div>			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not relevant.					
Wettability (KCP 2.8.1)	Not relevant for SL formulation					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2 No deviation	Glyphosate 54% SL	<u>Minimum dose (0.35 %):</u> Initial: 31.1 ± 0.3 ml 10 ± 1 s: 22.2 ± 0.4 ml 1 min ± 10 s: 6.4 ± 0.4 ml 3 min ± 10 s: 0 ml 12 min ± 10 s: NA <u>Maximum dose (1.75 %):</u> Initial: 45.2 ± 0.5 ml 10 ± 1 s: 29.6 ± 0.7 ml 1 min ± 10 s: 14.1 ± 0.4 ml 3 min ± 10 s: 0 ml 12 min ± 10 s: NA	Y	Hetal K. Desai, 2017 Report 248-2-11-15990	Accepted There is no data on the 0.2% concentration. However, based on presented results it is not expected to trigger 60 ml of foam after 1 min for the 0.2% tank mix concentration as well.
Suspensibility (KCP 2.8.3.1)	Not relevant for SL formulation					
Spontaneity of dispersion (KCP 2.8.3.2)	Not relevant for SL formulation					
Dispersion stability (KCP 2.8.3.3)	Not relevant for SL formulation					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41.1 No deviation	Glyphosate 54% SL	No separation of material observed at the top or at the bottom of the measuring cylinder at minimum and maximum recommended doses in three replication when left undisturbed at $30 \pm 2^{\circ}\text{C}$ for 30 minutes and 24 hours	Y	Report Hetal K. Desai, 2017, 253-2-11-15983	Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not relevant for SL formulation					
Wet sieve test (KCP 2.8.5.1.2)	Not relevant for SL formulation					
Dust content (KCP 2.8.5.2.1)	Not relevant for SL formulation					
Particle size of dust (KCP 2.8.5.2.2)	Not relevant for SL formulation					
Attrition (KCP 2.8.5.3)	Not relevant for SL formulation					
Hardness and integrity (KCP 2.8.5.4)	Not relevant for SL formulation					
Emulsifiability (KCP 2.8.6.1)	Not relevant for SL formulation					
Emulsion stability (KCP 2.8.6.2)	Not relevant for SL formulation					
Re-emulsifiability (KCP 2.8.6.3)	Not relevant for SL formulation					
Flowability (KCP 2.8.7.1)	Not relevant for SL formulation					
Pourability (KCP 2.8.7.2)	Not relevant for SL formulation					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dustability following accelerated storage (KCP 2.8.7.3)	Not relevant for SL formulation					
Physical compatibility of tank mixes (KCP 2.9.1)	Not relevant for SL formulation					
Chemical compatibility of tank mixes (KCP 2.9.2)	Not relevant.					
Adhesion to seeds (KCP 2.10.1)	Not relevant.					
Distribution to seed (KCP 2.10.2)	Not relevant.					
Other/special studies (KCP 2.11)	Not relevant.					

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 1 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 4.1-2: Packaging information for 5 liter bottle

Type	Description
Material:	HDPE
Shape/size:	jerrykan / approx. 131.0 mm x 189.0 mm x 285.0 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 10 liter bottle

Type	Description
Material:	HDPE
Shape/size:	jerrykan / approx. 192.0 mm x 232.0 mm x 313.0 mm
Opening:	47.0 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 20 liter bottle

Type	Description
Material:	HDPE
Shape/size:	jerrykan / approx. 240.0 mm x 285.0 mm x 387.5 mm
Opening:	47.0 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1-5: Packaging information for 200 liter drum

Type	Description
Material:	HDPE
Shape/size:	drum / approx. 940.0 mm x 581.0 mm x 550 mm
Opening:	BCS 56x4
Closure:	PE bung
Seal:	-
Manner of construction	extruded
UN/ADR	compliant

RMS comment:

Based on the accelerated and ambient storage stability data all HDPE packs 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	Hetal K. Desai	2017	Appearance (colour, physical state and odour) of Glyphosate 54% SL Jai Research Foundation (JRF), 201-2-11-15985 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.2.1	H.S. Anand	2017	Determination of explosive properties of Glyphosate 54% SL Advinus, G14423 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.2.2	Hetal K. Desai	2018	Oxidizing properties of Glyphosate 54% SL Jai Research Foundation (JRF), 230-2-11-18940 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.3.1	Hetal K. Desai	2017	Flash point of Glyphosate 54% SL Jai Research Foundation (JRF), 221-2-11-15982 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.3.3	Hetal K. Desai	2017	Auto-ignition point of Glyphosate 54% SL Jai Research Foundation (JRF), 241-2-11-15982 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.4.1 KCP 2.4.2	Hetal K. Desai	2017	pH of Glyphosate 54% SL Jai Research Foundation (JRF), 210-2-11-15989 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.5.1	Hetal K. Desai	2017	Viscosity of Glyphosate 54% SL Jai Research Foundation (JRF), 214-2-11-15987	N	Sharda Cropchem

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
			GLP Unpublished		Limited
KCP 2.6.1	Hetal K. Desai	2017	Specific gravity of Glyphosate 54% SL Jai Research Foundation (JRF), 236-2-11-15992 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.6.1	Hetal K. Desai	2017	Relative density of Glyphosate 54% SL Jai Research Foundation (JRF), 260-2-11-16583 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.5.2 KCP 2.7.1	Hetal K. Desai	2018	Accelerated storage stability and corrosion characteristics of Glyphosate 54% SL Jai Research Foundation (JRF), 234-2-11-18053 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.1	Mercedes Pardo Martinez	2020	Glyphosate 54% w/v SL: Determination of the Accelerated Storage Stability and Corrosion characteristics ChemService S.r.l. Controlli e Ricerche, Report No. CH – 0484/2020 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.4	Hetal K. Desai	2017	Stability of Glyphosate 54% SL at 0°C Jai Research Foundation (JRF), 252-2-11-15991 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.5	Hetal K. Desai	2020	Two years storage stability and corrosion characteristics of Glyphosate 54% SL Jai Research Foundation (JRF), 237-2-11-18054 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.8.2	Hetal K. Desai	2017	Persistent foaming of Glyphosate 54% SL Jai Research Foundation (JRF), 248-2-11-15990 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
			Unpublished		
KCP 2.8.4	Hetal K. Desai	2017	Dilution stability of Glyphosate 54% SL Jai Research Foundation (JRF), 253-2-11-15983 GLP Unpublished	N	Sharda Cropchem Limited

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

A 2.1 Glyphosate

No relevant. There is no additional data on the active substance.