

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 2600 E

Product name: PENSHUI

Chemical active substances:

Pendimethalin 455 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: June 2020

Update date: February 2022

MS Finalisation date: February 2021, **April 2022**

Version history

When	What
February 2021	RMS finalised dRR assessment
February 2022	Applicant update
April 2022	zRMS assessment after commenting period and Applicant's update.

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- Data on the stability of the active substance and the physico-chemical characteristics of the preparation on storage at ambient temperature (shelf-life) (authorisation can be granted for 1 year only)
- Content of relevant impurities after accelerated storage — the Applicant should provide the data on the content of relevant impurities after storage at ambient temperature

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, 12th 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
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 Pendimethalin

Pendimethalin min. 980 g/kg Sharda source (assessment by UK)
 min. 900 g/kg (Commission Implementing Regulation (EU) 2017/1114 (22 June 2017) and SANTE/11656/2016 (18 May 2017 rev. 2))

Relevant impurities:

1,2-dichloroethane ≤ 1 g/kg in the technical
 Total N-Nitroso compounds max 100 mg/kg, of which N-Nitroso-pendimethalin: < 45 mg/kg in the technical

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

Trade name: PENSHUI
 Company code number: SHA 2600 E

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)
Pendimethalin	455 g/L	432.25 - 477.75 g/L ($\pm 5\%$ of declared content)	464.29 g/L	39.67

* Based on the minimum purity of the active substance (98% w/w) declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.1705 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
1,2-dichloroethane	≤ 1 g/kg in the technical
Total N-Nitroso compounds	max 100 mg/kg, of which N-Nitroso-pendimethalin: < 45 mg/kg in the technical

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 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: Capsule Suspension

[Code: CS]

1.6 Function (KCP 1.6)

The product PENSHUI (Pendimethalin 45.5% CS) 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 yellow to brown viscous liquid having non-characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 375°C. In aqueous solution, it has a pH value around 9.53 ± 0.01 at 20 °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. A shelf life of at least 2 years at ambient temperature is on-going and the final report will be provided as soon as available. Its technical characteristics are acceptable for a *capsule suspension* formulation.

The intended concentration of use is ~~0.333% to 1.5%~~ 0.25% to 1.75% (v/v).

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.

Compliance with FAO specifications:

~~The product Pendimethalin 45.5% CS complies with FAO specifications.~~
At the time of evaluation no FAO specification was allocated.

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 OCSPP 830.6303 OCSPP 830.6304	Pendimethalin 455 g/L CS Batch: SCL-40026	Yellow to Brown (7.5 YR 7/12) viscous liquid having non-characteristic odour at 20 °C.	Y	K. XXX, 2017 Report No. 201-2-11-16336	Accepted.
	OCSPP 830.6302 OCSPP 830.6303 OCSPP 830.6304	Pendimethalin 455 g/L CS SCL-32690	Orange suspension liquid with characteristic odor		XXX, 2021 Report No.: 47/2021	As the results of the 2017 study was accepted, this point was not assessed.
Explosive properties (KCP 2.2.1)	EEC A.14	Pendimethalin 455 g/L CS Batch: SCL-40026	The test item was non-explosive when subjected to thermal sensitivity (flame) and mechanical sensitivity (shock) tests.	Y	H.S. XXX, 2017 Report No. G14435	Accepted.
Oxidizing properties (KCP 2.2.2)	EEC A.21	Pendimethalin 455 g/L CS Batch: SCL-40026	Pendimethalin 455 g/L CS is non-oxidizing in nature	Y	K. XXX, 2017 Report No. 230-2-11-18398	Accepted.
Flash point (KCP 2.3.1)	CIPAC MT 12.3 EEC A.9	Pendimethalin 455 g/L CS Batch: SCL-40026	The flash point of Pendimethalin 455 g/L CS > 100 °C, the test item began to boil at 100 °C and spilled out from the sample cup at normal atmospheric pressure (i.e. 760 mm Hg).	Y	K. XXX, 2017 Report No. 221-2-11-16339	The Pensky Martens method was used. The formulation is not flammable. Accepted.
Flammability (KCP 2.3.2)			Please refer to KCP 2.3.1			
Self-heating (KCP 2.3.3)	EEC A.16 A.15	Pendimethalin 455 g/L CS Batch: SCL-40026	Test item Pendimethalin 455 g/L CS has got the auto-ignition temperature 375 °C (1004 ÷ 1006 hPa)	Y	XXX, 2017 Report no. BC-67/17	Accepted.
Acidity or alkalinity			Please refer to KCP 2.4.2			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
and pH (KCP 2.4.1)						
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Pendimethalin 455 g/L CS Batch: SCL-40026	pH (1% (w/v) aqueous solution) = 9.53 ± 0.01 at 20 °C pH (undiluted (as such)) = 8.40 ± 0.005 at 20 °C	Y	K. XXX, 2017 Report No. 210-2-11-16337	Accepted.
	CIPAC MT 75.3	Pendimethalin 455 g/L CS SCL-32690	pH value (1 % w/v aqueous dilution), 20 °C = 9.42 (pH of used water = 6,18) pH value (neat form) , 20 °C = 7.93	Y	XXX, 2021 Report No.: 47/2021	As the results of the 2017 study was accepted, this point was not assessed.
Viscosity (KCP 2.5.1)	OECD 114	Pendimethalin 455 g/L CS Batch: SCL-40026	Dynamic viscosity Mean viscosity at 20 ± 0.2 °C = 768.5 cP (mPa·s) Mean viscosity at 40 ± 0.2 °C = 437.5 cP (mPa·s) The dynamic viscosity: 20 ± 0.2 °C: from 13850 to 768.5 cP (0.3 – 30 rpm) 40 ± 0.2 °C: from 14350 to 437.5 cP (0.3 – 50 rpm) Kinematic viscosity Mean viscosity at 20 ± 0.2 °C = 655 mm ² /s Mean viscosity at 40 ± 0.2 °C = 372.9 mm ² /s The kinematic viscosity: 20 ± 0.2 °C: from 11804.3 to 655 mm ² /s (0.3 – 30 rpm) 40 ± 0.2 °C: from 12230.5 to 372.9 mm ² /s (0.3 – 50 rpm)	Y	K. XXX, 2017 Report No. 214-2-11-16338	The rotational viscometer was used. The formulation is non-Newtonian liquid. The formulation does not pose an aspiration hazard. Accepted.
Surface tension (KCP 2.5.2)	EEC A.5	Pendimethalin 455 g/L CS Batch: SCL-40026	The mean surface tension of 1 g/L aqueous solution of pendimethalin 455 g/L CS measured after 30 min of its preparation was 70.27 ± 0.22 mN/m at 20°C	Y	K. XXX, 2017 Report No. 222-2-11-16340	Surface tension was determined at the concentration lower than the lowest in-use spray concentration. The preparation is not classified as surface-active. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	EEC A.5	Pendimethalin 455 g/L CS SCL-32690	Surface tension (21.5 mL/L aqueous solution), 20 °C = 50.38 mN/m	Y	XXX, 2021 Report No.: 47/2021	Surface tension was determined at a concentration slightly higher than the highest in-use spray concentration (1.75% v/v). The preparation is classified as surface-active. Accepted.
Relative density (KCP 2.6.1)	EEC A.3	Pendimethalin 455 g/L CS Batch: SCL-40026	The mean relative density of Pendimethalin 455 g/L CS was 1.1705 ± 0.0040 at 20 °C.	Y	K. XXX, 2017 Report No. 260-2-11-16335	Accepted.
Bulk density (KCP 2.6.2)			Not relevant for a CS formulation.			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
Storage Stability after 14 days at 54°C (KCP 2.7.1)	CIPAC MT 46.3.1	Pendimethalin 455 g/L CS Batch: SCL-40026	Characteristics		Before storage (0 – Day)	After storage at 54 ± 2 °C for 14 days	Y	K. XXX, 2017 Report No. 234-2-11-16485	The mean storage temperature was 53.51°C. No change in the a.s. content was observed; no change in properties. See KCP 2.8.3.1 comment regarding the suspensibility test. The content of the relevant impurities determined before the storage was below the levels of Commission Implementing Regulation (EU) 2017/1114. The content of the relevant impurities after the storage was not determined. However, as the content of the a.s. was stable during the storage it can be accepted. During storage, the packaging container (HDPE bottle) proved to be resistant to its content Accepted.
			Packaging inspection/ Corrosion characteristics	Perforation	No	No			
				Leaking at the seam	No	No			
				Distortion	No	No			
			Appearance of the container (visual)	Shape	Cylindrical	Cylindrical			
				Colour	White	White			
				Crack	No	No			
			Appearance		7.5YR 7/12 yellow to brown colour, viscous liquid having non-characteristic odour	7.5YR 7/12 yellow to brown colour, viscous liquid having non-characteristic odour			
			pH		9.42	9.21			
			Active ingredient content		39.41% w/w or 462.43 g/L	39.40% w/w or 462.31 g/L			
			Relevant impurities content		1,2-dichloroethane <LOQ (LOQ=0.025 g/kg) N-nitrosopendimethalin <LOQ (LOQ=0.010 g/kg)				
			Wet Sieve test		100% material passed through 75 µm test sieve	100% material passed through 75 µm test sieve			
			Suspensibility	Minimum recommended dose	87.62	88.99			
				Maximum recommended dose	87.99	88.83			
Pourability	Residue (%)	2.49	1.74						
	Rinsed Residue (%)	0.05	0.13						
Spontaneity of Dispersion		97.68	97.35						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																	
	CIPAC MT 46.3 CIPAC MT 46.3 LC-MS/GC-MS	Pendimethalin 455 g/L CS SCL-32690 Pendimethalin 455 g/L CS	<table border="1"> <tr> <td colspan="3">Pendimethalin 45.5 % CS</td> </tr> <tr> <td></td> <td colspan="2">Active substance content test results (HPLC)</td> </tr> <tr> <td></td> <td>0 days</td> <td>54°C, 14 days (CIPAC MT 46.3)</td> </tr> <tr> <td>Pendimethalin Total</td> <td>38.40 %, (w/w) 384.01 g/kg 45.32 %, (w/v) 453.21 g/L</td> <td>40.12 %, (w/w) 401.25 g/kg 47.36 %, (w/v) 473.55 g/L</td> </tr> <tr> <td colspan="3">Free and Encapsulated Active substance content test results (CIPAC MT 189)</td> </tr> <tr> <td>Pendimethalin form</td> <td>0 days</td> <td>54°C, 14 days (CIPAC MT 46.3)</td> </tr> <tr> <td colspan="3">Pendimethalin form relative contents, %</td> </tr> <tr> <td>Relative Free Pendimethalin</td> <td>0.37 % relative active</td> <td>0.35 % relative active</td> </tr> <tr> <td>Relative Encapsulated Pendimethalin</td> <td>99.63 % relative active</td> <td>99.65 % relative active</td> </tr> <tr> <td colspan="3">Pendimethalin form contents, % w/w</td> </tr> <tr> <td>Total Pendimethalin</td> <td>38.40</td> <td>40.13</td> </tr> <tr> <td>Free Pendimethalin</td> <td>0.14</td> <td>0.14</td> </tr> <tr> <td>Encapsulated Pendimethalin</td> <td>38.26</td> <td>39.98</td> </tr> <tr> <td colspan="3">Pendimethalin form contents, g/kg</td> </tr> <tr> <td>Total Pendimethalin</td> <td>384.01</td> <td>401.25</td> </tr> <tr> <td>Free Pendimethalin</td> <td>1.41</td> <td>1.41</td> </tr> <tr> <td>Encapsulated Pendimethalin</td> <td>382.60</td> <td>399.84</td> </tr> <tr> <td colspan="3">Relevant impurities content, ppm</td> </tr> <tr> <td>N-Nitrosopendimethalin</td> <td>6.087</td> <td>5.424</td> </tr> <tr> <td>1,2-Dichloroethane</td> <td>25.613</td> <td>26.117</td> </tr> <tr> <td>N-Nitrosodimethylamine</td> <td><LOD (LOD=0.092)</td> <td><LOD (LOD=0.092)</td> </tr> <tr> <td>N-Nitrosomethylethylamine</td> <td><LOD (LOD=0.015)</td> <td><LOD (LOD=0.015)</td> </tr> <tr> <td>N-Nitrosodiethylamine</td> <td><LOD (LOD=0.004)</td> <td><LOD (LOD=0.004)</td> </tr> <tr> <td>N-Nitrosopyrrolidine</td> <td><LOD (LOD=0.009)</td> <td><LOD (LOD=0.009)</td> </tr> <tr> <td>N-Nitrosodipropylamine</td> <td><LOD (LOD=0.011)</td> <td><LOD (LOD=0.011)</td> </tr> <tr> <td>N-Nitrosopiperidine</td> <td><LOD (LOD=0.005)</td> <td><LOD (LOD=0.005)</td> </tr> <tr> <td>N-Nitrosodibutylamine</td> <td><LOD (LOD=0.216)</td> <td><LOD (LOD=0.216)</td> </tr> </table>	Pendimethalin 45.5 % CS				Active substance content test results (HPLC)			0 days	54°C, 14 days (CIPAC MT 46.3)	Pendimethalin Total	38.40 %, (w/w) 384.01 g/kg 45.32 %, (w/v) 453.21 g/L	40.12 %, (w/w) 401.25 g/kg 47.36 %, (w/v) 473.55 g/L	Free and Encapsulated Active substance content test results (CIPAC MT 189)			Pendimethalin form	0 days	54°C, 14 days (CIPAC MT 46.3)	Pendimethalin form relative contents, %			Relative Free Pendimethalin	0.37 % relative active	0.35 % relative active	Relative Encapsulated Pendimethalin	99.63 % relative active	99.65 % relative active	Pendimethalin form contents, % w/w			Total Pendimethalin	38.40	40.13	Free Pendimethalin	0.14	0.14	Encapsulated Pendimethalin	38.26	39.98	Pendimethalin form contents, g/kg			Total Pendimethalin	384.01	401.25	Free Pendimethalin	1.41	1.41	Encapsulated Pendimethalin	382.60	399.84	Relevant impurities content, ppm			N-Nitrosopendimethalin	6.087	5.424	1,2-Dichloroethane	25.613	26.117	N-Nitrosodimethylamine	<LOD (LOD=0.092)	<LOD (LOD=0.092)	N-Nitrosomethylethylamine	<LOD (LOD=0.015)	<LOD (LOD=0.015)	N-Nitrosodiethylamine	<LOD (LOD=0.004)	<LOD (LOD=0.004)	N-Nitrosopyrrolidine	<LOD (LOD=0.009)	<LOD (LOD=0.009)	N-Nitrosodipropylamine	<LOD (LOD=0.011)	<LOD (LOD=0.011)	N-Nitrosopiperidine	<LOD (LOD=0.005)	<LOD (LOD=0.005)	N-Nitrosodibutylamine	<LOD (LOD=0.216)	<LOD (LOD=0.216)	Y Y	XXX, 2021 Report No.: 47/2021 D. XXX, 2021 Report No.: G21360	The mean storage temperature was 54°C. The change of the a.s. content was 4.5%. The content of the relevant impurities determined before and after the storage was below the levels of Commission Implementing Regulation (EU) 2017/1114. No significant changes in physical-chemical properties after storage were noted. See KCP 2.8.3.1 comment regarding the suspensibility test. Accepted.
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Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			Pendimethalin 45.5 % CS - 54°C, 14 days (CIPAC MT 46.3)						
			STUDY NAME	METHOD	RESULTS 0 days	RESULTS 54 days			
			Appearance (physical state, colour, odour, 20 °C)	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Orange suspension liquid with characteristic odor	Orange suspension liquid with characteristic odor			
			pH value (neat form), 20 °C		7,93	7,73			
			pH value (1 % w/v aqueous dilution), 20 °C	CIPAC MT 75.3	9,42	9.32 (pH of used water = 6,89)			
			Suspensibility (dilution at 21,5 mL/L)	CIPAC MT 184	91,95% w/w	93.27 % w/w			
			Suspensibility (dilution at 3,33 mL/L)	Standard water D	90,81% w/w	91.14 % w/w			
			Spontaneity of dispersion (dilution at 21,5 mL/L)	CIPAC MT 160 Standard water D	101.78% w/w	99.56 % w/w			
			Wet sieve	CIPAC MT 185	0.022% of residue on a 75 µm mesh sieve	0.019 % of residue on a 75 µm mesh sieve			
			Pourability	CIPAC MT 148	Residue = 1.05% w/w Rinsed residue = 0.23 % w/w	Residue = 0.89 % w/w Rinsed residue = 0.22 % w/w			
			Stability of packaging and packaging/preparation interactions	Technical Monograph CropLife	After accelerated storage procedure: - no changes in appearance of sample was observed; - no changes in appearance of packaging was observed; - weight loss of the package with sample was 0,06 % (w/w).				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																									
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)	HPLC	Pendimethalin 455 g/L CS Batch: SCL-40026	<table border="1"> <thead> <tr> <th>Active substance</th> <th>0 days</th> <th>14 d at 54°C</th> </tr> </thead> <tbody> <tr> <td>Pendimethalin</td> <td>39.41% w/w or 462.43 g/L</td> <td>39.40% w/w or 462.31 g/L</td> </tr> </tbody> </table>	Active substance	0 days	14 d at 54°C	Pendimethalin	39.41% w/w or 462.43 g/L	39.40% w/w or 462.31 g/L	Y	K. XXX, 2017 Report No. 234-2-11-16485	Accepted.																			
Active substance	0 days	14 d at 54°C																													
Pendimethalin	39.41% w/w or 462.43 g/L	39.40% w/w or 462.31 g/L																													
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 75.3 CIPAC MT 184 and HPLC CIPAC MT 185 CIPAC MT 148 and 148.1 CIPAC MT 160 and HPLC	Pendimethalin 455 g/L CS Batch: SCL-40026	<table border="1"> <thead> <tr> <th colspan="2">Characteristics</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td colspan="2">pH (1% w/v) at 20°C</td> <td>9.50</td> </tr> <tr> <td colspan="2">pH (at such) at 20°C</td> <td>8.33</td> </tr> <tr> <td rowspan="2">Suspensibility</td> <td>Min. recommended dose</td> <td>92.73%</td> </tr> <tr> <td>Max. recommended dose</td> <td>93.31%</td> </tr> <tr> <td rowspan="2">Pourability</td> <td>Residue (%)</td> <td>1.64</td> </tr> <tr> <td>Rinsed Residue (%)</td> <td>0.17</td> </tr> <tr> <td colspan="2">Spontaneity of Dispersion</td> <td>95.71%</td> </tr> <tr> <td colspan="2">Wet Sive Test</td> <td>100% material passed through 75 µm test sive</td> </tr> </tbody> </table>	Characteristics		Results	pH (1% w/v) at 20°C		9.50	pH (at such) at 20°C		8.33	Suspensibility	Min. recommended dose	92.73%	Max. recommended dose	93.31%	Pourability	Residue (%)	1.64	Rinsed Residue (%)	0.17	Spontaneity of Dispersion		95.71%	Wet Sive Test		100% material passed through 75 µm test sive	Y	K. XXX, 2018 Report No. 277-2-11-16342	The material was stored in HDPE bottle. See KCP 2.8.3.1 comment regarding suspensibility test. Accepted.
Characteristics		Results																													
pH (1% w/v) at 20°C		9.50																													
pH (at such) at 20°C		8.33																													
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Spontaneity of Dispersion		95.71%																													
Wet Sive Test		100% material passed through 75 µm test sive																													
		Pendimethalin 455 g/L CS Batch: SCL-32690	<p>In the freeze/thaw stability test the formulation (1 container with sample 47.1/2021) was cycled between -10 ± 2°C and 20 ± 2°C temperatures on 18-hour-freeze/6-hour-melt cycles for a total of 4 cycles.</p> <table border="1"> <thead> <tr> <th colspan="2">Characteristics</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td colspan="2">a.s. content</td> <td>40.10% (w/w) 401.02 g/kg 47.33 % (w/v) 473.29 g/L</td> </tr> <tr> <td colspan="2">Relative Free Pendimethalin</td> <td>0.36%</td> </tr> <tr> <td colspan="2">Relative Encapsulated Pendimethalin</td> <td>99.64%</td> </tr> <tr> <td colspan="2">pH (1% w/v) at 20°C</td> <td>9.40</td> </tr> <tr> <td colspan="2">pH (neat) at 20°C</td> <td>7.92</td> </tr> <tr> <td>Suspensibility</td> <td>(dilution at 3.33 mL/L)</td> <td>92.46</td> </tr> </tbody> </table>	Characteristics		Results	a.s. content		40.10% (w/w) 401.02 g/kg 47.33 % (w/v) 473.29 g/L	Relative Free Pendimethalin		0.36%	Relative Encapsulated Pendimethalin		99.64%	pH (1% w/v) at 20°C		9.40	pH (neat) at 20°C		7.92	Suspensibility	(dilution at 3.33 mL/L)	92.46			The change of a.s. content was 4.4%. The formulation remained stable. See KCP 2.8.3.1 comment regarding suspensibility test. Accepted.				
Characteristics		Results																													
a.s. content		40.10% (w/w) 401.02 g/kg 47.33 % (w/v) 473.29 g/L																													
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
			<table border="1"> <tr> <td></td> <td>(dilution at 21.5 mL/L)</td> <td>92.35</td> </tr> <tr> <td>Pourability</td> <td>Residue (%)</td> <td>0.92%</td> </tr> <tr> <td></td> <td>Rinsed Residue (%)</td> <td>0.22%</td> </tr> <tr> <td colspan="2">Spontaneity of Dispersion (dilution at 21,5 mL/L)</td> <td>99.63% w/w</td> </tr> <tr> <td>Wet sieve Test</td> <td>0.022%</td> <td></td> </tr> </table>		(dilution at 21.5 mL/L)	92.35	Pourability	Residue (%)	0.92%		Rinsed Residue (%)	0.22%	Spontaneity of Dispersion (dilution at 21,5 mL/L)		99.63% w/w	Wet sieve Test	0.022%				
	(dilution at 21.5 mL/L)	92.35																			
Pourability	Residue (%)	0.92%																			
	Rinsed Residue (%)	0.22%																			
Spontaneity of Dispersion (dilution at 21,5 mL/L)		99.63% w/w																			
Wet sieve Test	0.022%																				
Ambient temperature shelf life (KCP 2.7.5)			On-going																		
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not required																		
Wettability (KCP 2.8.1)			Not relevant for a CS formulation.																		
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2 (Standard Water C)	Pendimethalin 455 g/L CS Batch: SCL-40026	<table border="1"> <thead> <tr> <th>3.7 L/ha in 400 L/ha:</th> <th>3.7 L/ha in 100 L/ha:</th> </tr> </thead> <tbody> <tr> <td>33.6 ml after 10 s</td> <td>36.6 36.3 ml after 10 s</td> </tr> <tr> <td>5.3 ml after 1 min</td> <td>11.9 ml after 1 min</td> </tr> <tr> <td>0.0 ml after 3 min</td> <td>0.0 ml after 3 min</td> </tr> <tr> <td>NA after 12 min</td> <td>NA after 12 min</td> </tr> </tbody> </table>	3.7 L/ha in 400 L/ha:	3.7 L/ha in 100 L/ha:	33.6 ml after 10 s	36.6 36.3 ml after 10 s	5.3 ml after 1 min	11.9 ml after 1 min	0.0 ml after 3 min	0.0 ml after 3 min	NA after 12 min	NA after 12 min	Y	K. XXX, 2017 Report No.248-2-11-16341	The test concentration at low level (0.925% v/v) was higher than the minimum recommended concentration (0.25% v/v) and the concentration at high level (3.7% v/v) was higher than the maximum recommended concentration (1.75% v/v). Accepted.					
3.7 L/ha in 400 L/ha:	3.7 L/ha in 100 L/ha:																				
33.6 ml after 10 s	36.6 36.3 ml after 10 s																				
5.3 ml after 1 min	11.9 ml after 1 min																				
0.0 ml after 3 min	0.0 ml after 3 min																				
NA after 12 min	NA after 12 min																				
	CIPAC MT 47.3 (Standard Water D)	Pendimethalin 455 g/L CS	Persistent foaming (21.5 mL/L aqueous solution) = 1 mL of foam after 1 minute	Y	XXX, 2021 Report No.: 47/2021	The test concentration at low															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		SCL-32690	Persistent foaming (3.33 mL/L aqueous solution) = 0 mL of foam after 1 minute			level (0.33% v/v) was slightly higher than the minimum recommended concentration (0.25% v/v) and the concentration at high level (2.15% v/v) was slightly higher than the maximum recommended concentration (1.75% v/v). Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184 (Standard Water D)	Pendimethalin 455 g/L CS Batch: SCL-40026	3.7 L/ha in 400 L/ha = 86.51 ± 0.50% w/w 3.7 L/ha in 100 L/ha = 88.11 ± 0.27% w/w	Y	K. XXX, 2017 Report No.251-2-11-163432	The test concentration at low level (0.925% v/v) was higher than the minimum recommended concentration (0.25% v/v) and the concentration at high level (3.7% v/v) was higher than the maximum recommended concentration (1.75% v/v). Accepted.
	CIPAC MT 184 (Standard Water D)	Pendimethalin 455 g/L CS SCL-32690	21.5 mL/L = 91.95 % w/w 3.33 mL/L = 90.81 % w/w	Y	XXX, 2021 Report No.: 47/2021	The test concentration at low level (0.33% v/v)

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						was slightly higher than the minimum recommended concentration (0.25% v/v) and the concentration at high level (2.15% v/v) was slightly higher than the maximum recommended concentration (1.75% v/v). Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Pendimethalin 455 g/L CS Batch: SCL-40026	The mean spontaneity of dispersion of pendimethalin 455 g/L CS was 97.98 ± 0.29% w/w	Y	K. XXX, 2017 Report No.242-2-11-18394	The Standard Water C was used. The test was performed at room temp. The gravimetric method was used. Accepted.
	CIPAC MT 160 (Standard water D)	Pendimethalin 455 g/L CS SCL-32690	Spontaneity of dispersion (dilution at 21.5 mL/L) = 101.78 % w/w	Y	XXX, 2021 Report No.: 47/2021	As the results of the 2017 study was accepted, this point was not assessed.
Dispersion stability (KCP 2.8.3.3)			Not relevant for a CS formulation.			
Degree of dissolution and dilution stability (KCP 2.8.4)			Not relevant for a CS formulation.			
Particle size distribution /			Not relevant			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
nominal size range of granules (KCP 2.8.5.1.1)						
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Pendimethalin 455 g/L CS Batch: SCL-40026	Residue in 75 µm sieve 0.00%	Y	K. XXX, 2017 Report No.245-2-11-18393	Accepted.
	CIPAC MT 185	Pendimethalin 455 g/L CS SCL-32690	0.022 % of residue on a 75 µm mesh sieve	Y	XXX, 2021 Report No.: 47/2021	As the results of the 2017 study was accepted, this point was not assessed.
Dry sieve test			Not relevant for a CS formulation.			
Dust content (KCP 2.8.5.2.1)			Not relevant for a CS formulation.			
Particle size of dust (KCP 2.8.5.2.2)			Not relevant for a CS formulation.			
Attrition (KCP 2.8.5.3)			Not relevant for a CS formulation.			
Hardness and integrity (KCP 2.8.5.4)			Not relevant for a CS formulation.			
Emulsifiability (KCP 2.8.6.1)			Not relevant for a CS formulation.			
Emulsion stability (KCP 2.8.6.2)			Not relevant for a CS formulation.			
Re-emulsifiability (KCP 2.8.6.3)			Not relevant for a CS formulation.			
Flowability (KCP 2.8.7.1)			Not relevant for a CS formulation.			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Pourability (KCP 2.8.7.2)	CIPAC MT 148 and 148.1	Pendimethalin 455 g/L CS Batch: SCL-40026	The mean percentage of residue (R) and rinsed residue (R') of the Pendimethalin 455 g/L CS remaining in the test cylinder was 1.74% and 0.14%, respectively.	Y	K. XXX, 2017 Report No.261-2-11-16344	Accepted.
	CIPAC MT 148	Pendimethalin 455 g/L CS SCL-32690	Residue = 1.05 % w/w Rinsed residue = 0.23 % w/w	Y	XXX, 2021 Report No.: 47/2021	As the results of the 2017 study was accepted, this point was not assessed.
Dustability following accelerated storage (KCP 2.8.7.3)			Not relevant for a CS formulation.			
Physical compatibility of tank mixes (KCP 2.9.1)			Not relevant.			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not relevant.			
Adhesion to seeds (KCP 2.10.1)			Not relevant, not used for seed treatment.			
Distribution to seed (KCP 2.10.2)			Not relevant, not used for seed treatment.			
Other/special studies (KCP 2.11)	CIPAC MT 190	Pendimethalin 455 g/L CS SCL-32690	Release rate of Pendimethalin CIPAC MT 190	Y	XXX, 2021 Report No.: 47/2021	Accepted.
			R _t , %			
			Percentage of Pendimethalin released relative to the Pendimethalin content of the formulation			
			Pendimethalin 45.5 % CS Initial sample			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			- extracted at time 15 minutes is 0.659 % - extracted at time 30 minutes is 0.938 0.918 % - extracted at time 180 minutes is 3.399 % Pendimethalin 45.5 % CS 4 storage cycles (-10 ±2 °C, 18 hour / 20 ±2 °C, 6 hour) - extracted at time 15 minutes is 0.594 % - extracted at time 30 minutes is 0.865 % - extracted at time 180 minutes is 3.463 % Pendimethalin 45.5 % CS 54°C, 14 days (CIPAC MT 46.3) - extracted at time 15 minutes is 0.777 % - extracted at time 30 minutes is 1.078 % - extracted at time 180 minutes is 3.144 %			

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)

Comment of zRMS:	In the accelerated stability study the formulation has been tested in HDPE bottles and the packaging remained stable. Therefore, the proposed commercial packs are considered acceptable.
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Table 4.1-1: Packaging information for 100 mL

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 57 mm diameter x 85.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
UN/ADR	compliant

Table 4.1-2: Packaging information for 250 mL

Type	Description
Material:	HDPE
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
UN/ADR	compliant

Table 4.1-3: Packaging information for 500 mL

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 69.5 mm diameter x 188.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
UN/ADR	compliant

Table 4.1-4: Packaging information for 1 L

Type	Description
Material:	HDPE
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
UN/ADR	compliant

Table 4.1-5: Packaging information for 5 L

Type	Description
Material:	HDPE
Shape/size:	Jerrycan; 136 mm x 192 mm x 285 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
UN/ADR	compliant

Table 4.1-6: Packaging information for 10 liter bottle

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 313 mm x 192 mm x 232 mm
Opening:	47 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 20 L

Type	Description
Material:	HDPE
Shape/size:	jerrycan / 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
UN/ADR	compliant

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

Experience in use of plant protection products based on Pendimethalin has not indicated any particular problems. Low levels of residues of PENSHUI (Pendimethalin 455 g/L, CS) in the equipment are not expected to present any particular risk to crops to be treated from a tank that has previously been used for the product.

The efficacy of cleaning of the application equipment with regard to impacts on “other” crops can be estimated on the basis of the PSD Efficacy Guideline 302 (December 2001). As worst case, the following prerequisites were considered:

Application rate: 3.0 L product/ha, (1.365 kg/h of Pendimethalin)
 Tank volume: 2000 L
 Volume remaining in spray lines and pump after spraying: 20 L
 Spray volume: 200 L/ha (lowest spray volume corresponding to the maximum concentration of PENSHUI in diluted spray)

Based on these prerequisites and in consideration of 3 rinses with each 300 – 500 L of water based on good agricultural cleaning procedures, Pendimethalin residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues	
		product [L PPP/L water]	active substance [kg as/L]
Tank filling: Residues after spraying:	2000 20	0.015	0.006825
1 st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	0.0015	0.0006825
2 nd step: 20% of tank volume added: Residues after spraying:	400 20	7.5×10^{-5}	3.4125×10^{-5}
3 rd step: 20% of tank volume added: Residues after spraying:	400 20	3.75×10^{-6}	1.70625×10^{-6}
Addition of fresh spray solution: Residues in the tank filling:	2000	3.75×10^{-8}	1.70625×10^{-8}

PPP = PENSHUI as = Pendimethalin

Residues remaining in the last cleaning solution were calculated to be 1.70625×10^{-6} kg/L of Pendimethalin resulting in residue concentration of 1.70625×10^{-8} g/L Pendimethalin after refilling the tank with

2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 600 L/ha applied to succeeding crops, residues of 3.4125×10^{-6} – 1.02375×10^{-6} g Pendimethalin will be applied per ha.

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	K. XXX	2017	APPEARENCE (COLOUR, PHYSICAL STATE AND ODOUR) OF PENDIMETHALIN 455 g/L CS Report No: 201-2-11-16336 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.2.1	H.S. XXX	2017	DETERMINATION OF EXPLOSIVE PROPERTIES OF PENDIMETHALIN 45.5% 455 g/L CS Report No: G14435 Advinus Therapeutics Limited GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.2.2	K. XXX	2017	OXIDIZING PROPERTIES OF PENDIMETHALIN 455 g/l CS Report No: 230-2-11-18398 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.3.1	K. XXX	2017	FLASH POINT OF PENDIMETHALIN 455 g/L CS Report No: 221-2-11-16339 JAI Research Foundation 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 2.3.3	XXX	2017	Pendimethalin 455 g/L CS: Determination of auto-ignition temperature Study No: BC-67/17 Institute of Industrial Organic Chemistry GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.4.2	K. XXX	2017	pH OF PENDIMETHALIN 455 g/L CS Report No: 210-2-11-16337 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.5.1	K. XXX	2017	VISCOSITY OF PENDIMETHALIN 455 g/L CS Report No: 214-2-11-16338 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.5.2	K. XXX	2017	SURFACE TENSION OF PENDIMETHALIN 455 g/L CS Report No: 222-2-11-16340 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.6.1	K. XXX	2017	RELATIVE DENSITY TENSION OF PENDIMETHALIN 455 g/L CS Report No: 260-2-11-16335 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.7.1 KCP 2.7.3	K. XXX	2017	ACCELERATED STORAGE STABILITY AND CORROSION CHARACTERISTICS OF PENDIMETHALIN 455 g/L CS Report No: 234-2-11-16485 JAI Research Foundation 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 2.7.4	K. XXX	2018	FREEZE-THAW STABILITY TEST OF PENDIMETHALIN 455 g/L CS Report No: 277-2-11-16342 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.8.2	K. XXX	2017	PERSISTENT FOAMING OF PENDIMETHALIN 455 g/L CS Report No: 248-2-11-16341 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.8.3.1	K. XXX	2017	SUSPENSIBILITY OF PENDIMETHALIN 455 g/L CS Report No: 251-2-11-16343 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.8.3.2	K. XXX	2017	SPONTANEITY OF DISPERSION OF PENDIMETHALIN 455 g/L CS Report No: 242-2-11-18394 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.8.5.1.2	K. XXX	2017	WET-SIEVE TEST OF PENDIMETHALIN 455 g/L CS Report No: 245-2-11-18393 JAI Research Foundation GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.8.7.2	K. XXX	2017	POURABILITY OF PENDIMETHALIN 455 g/L CS Report No: 261-2-11-16344 JAI Research Foundation	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
			GLP Unpublished		
KCP 2.4.2 KCP 2.5.2 KCP 2.7.1 KCP 2.7.2 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.11	XXX	2021	Pendimethalin 45.5 % CS: Analysis of active substance content and physicochemical properties of initial preparation and preparation after accelerated and freeze/thaw storage procedures Report No.: 47/2021 Institute of Heavy Organic Synthesis „Blachownia” GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.7.1	D. XXX	2021	Accelerated Storage Stability Test by Heating at elevated Temperature of Pendimethalin 455 g/L CS Report No.: G21360 Eurofins Advinus Limited 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 Pendimethalin

Not relevant. There is no additional data on the active substance Pendimethalin.