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 9700 A

Product name: RULER

Chemical active substance:

Fenazaquin, 200 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: May 2019

Update date: May 2020

MS Finalisation date: 09.2020; 05.2021; 07.2022

Version history

When	What
May 2020	Applicant update
September 2020	Assessment by the expert
May 2021	Final Version
July 2022	Assessment after the source equivalence assessment of active substance (fenazaquin) has been completed.

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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.

Noticed data gaps are:

2-years storage stability study – test on-going

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

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)

1.2.3.1 Fenazaquin

Fenazaquin	min. 985 g/kg (Sharda source, has been completed in Poland:R-76/2022 (11-07-2022)
	min. 975 g/kg (Directive 2011/39/EC; SANTE/11781/2017 rev 1, 23 March 2018)

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

Trade name: RULER

Company code number: SHA 9700 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)
Fenazaquin	200 g/L	188 – 212 g/L (± 6%)	203.05 g/L	19.39 %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 = 1.0467 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
-	-

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

Table 1.4-2: Information on Fenazaquin

Type	Name/Code Number
ISO common name	Fenazaquin
CAS No.	120928-09-8
EC No.	410-580-0
CIPAC No.	693

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: Suspension concentrate [Code: SC]

1.6 Function (KCP 1.6)

The product Fenazaquin 20% SC is an insecticide.

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 product is not explosive. The product is not flammable/has a flash point of 98.8 °C. It has a self ignition temperature of 600.2 ± 0.1 ºC.

The shelf-life of at least 1 year at ambient temperature, according to accelerated storage stability study.

The intended concentration of use is 0.0002%. of a.s.

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 Fenazaquin 20% SC 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)	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Fenazaquin 20% SC batch SCL-22018	~~Study ongoing~~ Colour: 5 Y 9/1 (off white) Odor: Mild Pungent Physical state: Liquid	Y	Deepthi Prakash, 2019, report No. G14035	Accepted
Explosive properties (KCP 2.2.1)	EEC Method A.14	Fenazaquin 20% SC batch SCL-22018	The test item was non-explosive when subjeted to thermal sensitivity (flame) and mechanical sensitivity (shock) tests.	Y	Deepthi Prakash, 2018, report No. G14027	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A. 21	Fenazaquin 200 g/L SC batch SCL-22018	~~Study ongoing~~ The formulation has no oxidizing properties.	Y	Deepthi Prakash, 2019, report No. G14028	Accepted
Flash point (KCP 2.3.1)	EEC Method A.9, CIPAC MT 12	Fenazaquin 20% SC batch SCL-22018	The flash point of the test item was greater than 98.8°C.	Y	Deepthi Prakash, 2018, report No. G14029	Accepted
Flammability (KCP 2.3.2)			Please refer to KCP 2.3.1			Statement accepted
Self-heating (KCP 2.3.3)	EEC A.15	Fenazaquin 20% SC batch SCL-22018	Auto-ignition temperature is 600.2 ± 0.1 ºC (ignition delay time <1 min; volume of test item: 100 µL).	Y	Deepthi Prakash, 2019, report No. G14034	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)			~~Study ongoing~~ Not required. Since the obtained pH value was in the range 4 to 10, the acidity or alkalinity test was not performed.			Statement accepted
pH of a 1% aqueous	CIPAC MT 75.3	Fenazaquin	Study ongoing	Y	Deepthi Prakash, 2019,	Accepted

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td>dilution, emulsion or dispersion
(KCP 2.4.2)</td><td></td><td>20% SC batch SCL-22018</td><td>pH of 1% aqueoues emulsion – 7.25
pH of neat formulation – 6.83</td><td></td><td>report No. G14035</td><td></td></tr>
<tr><td>Viscosity
(KCP 2.5.1)</td><td>CIPAC MT 192</td><td>Fenazaquin 20% SC batch SCL-22018</td><td>
<table>
<tr><th>Rotational spped (rpm)</th><th>Apparent viscosity (cP) at 20 ± 0.5°C</th><th>Apparent viscosity (cP) at 40 ± 0.5°C</th></tr>
<tr><td>20</td><td>1417.70 ± 13.85</td><td>1471.69 ± 19.28</td></tr>
<tr><td>30</td><td>1026.45 ± 14.05</td><td>1069.107 ± 16.65</td></tr>
<tr><td>40</td><td>820.82 ± 7.54</td><td>854.82 ± 12.00</td></tr>
<tr><td>Repeated in 30</td><td>1013.12 ± 16.16</td><td>1059.77 ± 16.00</td></tr>
<tr><td>Repeated in 20</td><td>1367.71 ± 24.00</td><td>1413.70 ± 18.32</td></tr>
</table>
</td><td>Y</td><td>Deepthi Prakash, 2018, report No. G14030</td><td>Accepted

RMS Comments :
<table>
<tr><th>Rotational spped (rpm)</th><th>Kinematict viscosity (mm^2/s) at 20 ± 0.5°C</th><th>Kinematict viscosity (mm^2/s) at 20 ± 0.5°C</th></tr>
<tr><td>20</td><td>1354.5</td><td>1406</td></tr>
<tr><td>30</td><td>980.6</td><td>1021.4</td></tr>
<tr><td>40</td><td>784.2</td><td>816.7</td></tr>
</table>
</td></tr>
<tr><td>Surface tension
(KCP 2.5.2)</td><td>OECD 115, EEC method A.5</td><td>Fenazaquin 20% SC batch SCL-22018</td><td>The surface tension of 1 mL/L aqueous suspension of the test item was determined to be 37.846 dynes/cm at 20.17°C.

Results for neat : 37.846 mN/m
Results for intended concentration: 33.994 mN/m</td><td>Y</td><td>Deepthi Prakash, 2018, report No. G14031</td><td>Accepted

RMS Comment:
Active surface product</td></tr>
<tr><td>Relative density
(KCP 2.6.1)</td><td>OPPTS 830.8300, CIPAC MT 3, EEC Method A.3</td><td>Fenazaquin 20% SC batch SCL-22018</td><td>The density and relative density at 20.0°C were found to be 1.0467 ± 0.0003 g/mL.</td><td>Y</td><td>Deepthi Prakash, 2018, report No. G14032</td><td>Accepted</td></tr>
<tr><td>Bulk density
(KCP 2.6.2)</td><td></td><td></td><td>Not relevant for a liquid.</td><td></td><td></td><td>Statement accepted</td></tr>
<tr><td>Storage Stability after 14 days at 54º C
(KCP 2.7.1)</td><td>OPPTS 830.6313
CIPAC MT 46.3.1</td><td>Fenazaquin 20% SC batch SCL-22018</td><td><s>Study ongoing</s>
Stable in its commercial package under the accelerated storage.
Physical state colour and odour</td><td>Y</td><td>Deepthi Prakash, 2019, report No. G14035</td><td>Accepted

RMS Comment:
Packagings after accelerated</td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Before storage: Colour: 5 Y 9/1 (off white) Odor: Mild Pungent Physical state: Liquid After storage: Colour: 5 Y 9/1 (off white) Odor: Mild Pungent Physical state: Liquid **pH Determination of 1%** Before storage: 7.25 After storage: 7.23 **pH Determination of neat formulation** Before storage: 6.83 After storage: 6.79 **Pourability:** Before storage: 1.85 % After storage: 1.88 % **Active ingredient content:** Before storage: 19.50 ± 0.02% (w/w); 204.07 g/L After storage: 19.55 ± 0.04% (w/w); 204.60 g/L **Spontaneity of dispersion** Before storage: 98.32 % After storage: 98.32 % **Suspensibility** at 2 mL/L Before storage 92.35 % After storage 92.34 % At 4 mL/L Before storage 96.51 %			storage stability study : no change , no stains, any perforation and leakage, after storage HDPE/PA COEX Because storage stability test was started on April 2019 , method development and Validation criteria are within SANCO/3030/99 rev.4 According to accelerated storage stability study (in HDPE/PA COEX packaging) 1-year shelf life is accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After storage 96.43 % **Wet sieve** Before storage: 0.078 % After storage: 0.076 %			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			~~Study ongoing~~ Not relevant			Statement accepted
Minimum content after heat stability testing (KCP 2.7.3)			~~Study ongoing~~ Not relevant			Statement accepted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Fenazaquin 20% SC batch SCL-22018	~~Study ongoing~~ Stable at 0°C as the preparation did not show significant changes in the nature of test item.	Y	Deepthi Prakash, 2019, report No. G14035	Accepted
Ambient temperature shelf life (KCP 2.7.5)			Study ongoing			Statement accepted RMS Comment: According to accelerated storage stability study (HDPE/PA COEX packaging) 1-year shelf life is accepted.
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not relevant.			Statement accepted
Wettability (KCP 2.8.1)			Not relevant for a liquid.			Statement accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Fenazaquin 20% SC	~~Study ongoing~~ Low dose	Y	Deepthi Prakash, 2019, report No. G14035	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		batch SCL-22018	After 1 minute ± 10 sec – 8 mL After 12 minutes ± 10 sec – Nil High dose After 1 minute ± 10 sec – 10 mL After 12 minutes ± 10 sec - Nil			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Fenazaquin 20% SC batch SCL-22018	~~Study ongoing~~ At 2 mL/L 92.35 % At 4 mL/L 96.51 %	Y	Deepthi Prakash, 2019, report No. G14035	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Fenazaquin 20% SC batch SCL-22018	~~Study ongoing~~ 98.32 ± 0.02 %	Y	Deepthi Prakash, 2019, report No. G14035	Accepted
Dispersion stability (KCP 2.8.3.3)			Not relevant for a SC formulation.			Statement accepted
Degree of dissolution and dilution stability (KCP 2.8.4)			Not relevant for a SC formulation.			Statement accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)			Not relevant for a SC formulation.			Statement accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Fenazaquin 20% SC batch SCL-22018	~~Study ongoing~~ % of test item retained on 75 µm sieve – 0.078 %	Y	Deepthi Prakash, 2019, report No. G14035	Accepted
Dust content (KCP 2.8.5.2.1)			Not relevant for a SC formulation.			Statement accepted
Particle size of dust			Not relevant for a SC formulation.			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.2.2)						
Attrition (KCP 2.8.5.3)			Not relevant for a SC formulation.			Statement accepted
Hardness and integrity (KCP 2.8.5.4)			Not relevant for a SC formulation.			Statement accepted
Emulsifiability (KCP 2.8.6.1)			Not relevant for a SC formulation.			Statement accepted
Emulsion stability (KCP 2.8.6.2)			Not relevant for a SC formulation.			Statement accepted
Re-emulsifiability (KCP 2.8.6.3)			Not relevant for a SC formulation.			Statement accepted
Flowability (KCP 2.8.7.1)			Not relevant for a SC formulation.			Statement accepted
Pourability (KCP 2.8.7.2)	CIPAC MT 148	Fenazaquin 20% SC batch SCL-22018	~~Study ongoing~~ 1.85 %	Y	Deepthi Prakash, 2019, report No. G14035	Accepted
Dustability following accelerated storage (KCP 2.8.7.3)			Not relevant for a SC formulation.			Statement accepted
Physical compatibility of tank mixes (KCP 2.9.1)			Not relevant.			Statement accepted
Chemical compatibility of tank mixes (KCP 2.9.2)			Not relevant.			Statement accepted
Adhesion to seeds (KCP 2.10.1)			Not relevant, not used for seed treatment.			Statement accepted
Distribution to seed			Not relevant, not used for seed treatment.			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.10.2)						
Other/special studies (KCP 2.11)			Not relevant.			Statement 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

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information for 100 mL

Type	Description
Material:	PET
Shape/size:	Round bottle / approx. 57 mm diameter x 75 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 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 4.1-3: 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

RMS Comment:
HDPE, PET packaging are accepted although accelerated storage stability has been done in HDPE/PA COEX packagings (suspension concentrate with 65% of water)

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 2.2.1	Deepthi Prakash	2018	Determination of explosive properties of Fenazaquin 20% SC Eurofins report No. G 14027 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.2.2	Deepthi Prakash	2019	Oxidizing properties of fenazaquin 200 g/L SC. Eurofins Advinus Limited Study No. G14028 GLP Unpublished	N	Sharda
KCP 2.3.1	Deepthi Prakash	2018	Determination of flash point of Fenazaquin 20% SC Eurofins report No. G14029 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.3.3	Deepthi Prakash	2019	Determination of auto ignition temperature of Fenazaquin 20% SC Eurofins report No. G14034 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.5.1	Deepthi Prakash	2018	Determination of viscosity of Fenazaquin 20% SC Eurofins report No. G14030 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.5.2	Deepthi Prakash	2018	Determination of surface tension of aqueous solution of Fenazaquin 20% SC Eurofins report No. G 14031 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 2.6.2	Deepthi Prakash	2018	Determination of density and relative density of Fenazaquin 250% SC Eurofin repor tNo. G14032 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.7.1	Deepthi Prakash	2019	Accelerated storage stability test by heating at elevated temperature of fenzaquin 200 g/L EC. Eurofins Advinus Limited Study No. G14035 GLP Unpublished	N	Sharda

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 Fenazaquin

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