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 123000 A

Product name(s): AZA

Chemical active substance:

Azadirachtin, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

Update date: May 2021

MS Finalisation date: July 2021

Version history

When	What
May 2021	Updated by applicant
June 2021	RMS assessment

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

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:

- 2 years storage stability study

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 Azadirachtin

Azadirachtin	min. 111 g Azadirachtin A/kg (Regulation (EU) No. 540/2011) min. 322 g Azadirachtin A /kg (Sharda Source)

Relevant impurities

Sum of aflatoxin B1, B2, G1, G2	max. 300 µg/kg Azadirachtin A (Regulation (EU) No. 540/2011)

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: Azadirachtin 1% EC
AZA

Company code number: SHA123000A

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 1.4.1-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Azadirachtin	10	8.5 – 11.5 (± 15 %)	31.1 g/L	3.24

* Based on the minimum purity of the active substance 32.2% declared for registration in the active substance dossiers.
** Based on the density of the formulation = 0.9608 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4.1-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Aflatoxins (Sum of aflatoxin B1, B2, G1, G2)	3 ug/L

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

Table 1.4-2: Information on Azadirachtin

Type	Name/Code Number
ISO common name	Azadirachtin (no ISO common name allocated)
CAS No.	11141-17-6
EC No.	~~Not available~~ 601-089-4
CIPAC No.	627

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: Emulsifiable concentrate [Code: EC]

1.6 Function (KCP 1.6)

Azadirachtin 1% EC is intended to be used as 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 appearance of the product is that of light brown viscous liquid with mild odor. It is not explosive, has no oxidizing properties, and surface tension 62.35 mN/m. In aqueous solution, it has a pH value around 6 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed Its technical characteristics are acceptable for an *Emulsifiable concentrate* formulation. 2 years Storage stability test is currently on going and results will be provided as soon as possible. Authorization can be granted for 1 year only.
The intended concentration of use is 0.25 % to 0.5 %.

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 Azadirachtin 1% EC 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)	~~Visual~~		~~Brown viscous liquid~~	~~N~~	~~Sreelola Vutpala, M., 2019, Report No G12476~~	Accepted
	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Azadirachtin 1% EC (Batch No SCL-280918)	Light brown liquid with mild basic odor, color 2.5Y 6/10	Y	D. Bangera, 2020 Report No. G12479	
Explosive properties (KCP 2.2.1)	EEC A.14	Azadirachtin 1% EC (Batch No SCL-280918)	The product is not considered as having explosive properties. The test item was non-explosive when subjected to thermal sensitivity (flame) and mechanical sensitivity (shock) tests.	Y	Sreelola Vutpala, M., 2019, Report No G12473	Accepted.
	Software CHETAH (Chemical Thermodynamic And Hazard evaluation), version 7.3 (ASTM 2002).	Azadirachtin 1 % EC	The product does not have explosive properties in accordance with Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria criteria.	N	Mena, B., 2020, report No. SCE-037	
Oxidizing properties (KCP 2.2.2)	Software CHETAH (Chemical Thermodynamic And Hazard evaluation), version 7.3 (ASTM 2002).	Azadirachtin 1 % EC	The product does not have ~~explosive~~ oxidizing properties in accordance with Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria criteria.	~~Y~~ N	Mena, B., 2020, report No. SCE-037	Accepted
	OPPTS 830.6314	Azadirachtin 1% EC (Batch No SCL-280918)	The product is not considered as having ~~explosive~~ oxidising properties. The test item did not show any significant oxidising or reducing properties as well as any chemical incompatibility characteristics when brought in contact with chosen reactants, tap water and	Y	Sreelola Vutpala, M., 2019, Report No G12474	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			turpentine at room temperature.			
Flash point (KCP 2.3.1)	EEC A.9	Azadirachtin 1% EC (Batch No SCL-280919)	~~Ongoing~~ The flash point of the formulation is 151°C.	Y	M. Michalec-Minch, 2021 Report No. 15/2021	Accepted.
Flammability (KCP 2.3.2)	~~EEC A.15~~	-	~~Ongoing~~ Not relevant. Pleease refer to KCP 2.3.1.	-	-	-
Self-heating (KCP 2.3.3)	-	-	Not required.	-	-	-
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ pH = 5.61 Acidity/Alkalinity not performed since pH is in range 4-10.	Y	D. Bangera, 2021 Report No. G21298	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ pH = 6.01	Y	D. Bangera, 2021 Report No. G21298	Accepted
Viscosity (KCP 2.5.1)	CIPAC MT 192	Azadirachtin 1% EC (Batch No SCL-280918)	Apparent viscosity (cP) at 20 ± 0.5°C: At 20 s^{-1}: 46.98 ± 2.03 At 30 s^{-1}: 44.87 ± 2.55 At 40 s^{-1}: 44.11 ± 2.49 At 30 s^{-1}: 44.52 ± 2.18 At 20 s^{-1}: 45.66 ± 2.12 Apparent viscosity (cP) at 40 ± 0.5°C: At 20 s^{-1}: 22.63 ± 1.39 At 30 s^{-1}: 20.68 ± 1.20 At 40 s^{-1}: 19.96 ± 1.25 At 30 s^{-1}: 20.85 ± 1.92 At 20 s^{-1}: 22.96 ± 0.34	Y	Sreelola Vutpala, M., 2019, Report No G12476	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Kinematic viscosity: at 20 ± 0.5°C: At 20 s^{-1}: 48.90 mm^2/s At 30 s^{-1}: 46.71 mm^2/s At 40 s^{-1}: 45.92 mm^2/s at 40 ± 0.5°C: At 20 s^{-1}: 23.56 mm^2/s At 30 s^{-1}: 21.53 mm^2/s At 40 s^{-1}: 20.78 mm^2/s			
Surface tension (KCP 2.5.2)	OECD 115 EEC A.5	Azadirachtin 1% EC (Batch No SCL-280918)	Aqueous solution of test item (0.83% w/v): 66.812 mN/m at 20.2°C Test item as such (neat): 62.350 mN/m at 25.0°C	Y	Sreelola Vutpala, M., 2019, Report No G12477	Accepted.
Relative density (KCP 2.6.1)	OPPTS 830.7300 CIPAC MT 3 EEC A.3	Azadirachtin 1% EC (Batch No SCL-280918) Azadirachtin 1% EC (Batch No SCL-280918)	Mean density: 0.9608 ± 0.0109 g/mL at 20.0°C Specific gravity: 0.9625 ± 0.0109 g/mL at 20.0°C Mean density: 0.9606 ± 0.0105 g/mL Specific gravity: 0.9623± 0.0105	Y	Sreelola Vutpala, M., 2019, Report No G12478 D. Bangera, 2020 Report No. G12479	Accepted
Bulk density (KCP 2.6.2)	-	-	Not required.	-	-	-
Storage Stability after 14 days at 54º C (KCP 2.7.1)	CIPAC MT 46.3 OPPTS 830.6313 SANCO/3030/99 rev. 5 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ Test | Day 0 | After 14 days at 54°C A.s. content | 1.12% w/w | 1.13% w/w Aflatoxins content (G2, | Not detected (Below level | Not detected (Below level	Y	D. Bangera, 2020 Report No. G12479 D. Bangera, 2021 Report No. G21298	Accepted The intended concentrations are 0.25%-0.5% and the investigated are 0.25% and 1.2%, but the study

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	EEC A.3 CIPAC MT 3 CIPAC MT 36.3		<table><tr><td>G1, B2, B1)</td><td>of detection)</td><td>of detection)</td></tr><tr><td>Appearance</td><td>Light brown liquid with mild basic odor color 2.5Y 6/10</td><td>Light brown liquid with mild basic odor color 2.5Y 6/10</td></tr><tr><td>pH neat</td><td>5.61</td><td>5.66</td></tr><tr><td>pH 1% aqueous solution</td><td>6.01</td><td>6.02</td></tr><tr><td>Density</td><td>0.9606 g/mL</td><td>0.9607 g/mL</td></tr><tr><td>Emulsion characterisstics</td><td>0.25% and 1.2% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily</td><td>0.25% and 1.2% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily</td></tr></table>			can be accepted as the intended concentrations are in range of the investigated ones.

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
				layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed.	layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed.			
			~~Emulsion characteristics~~	~~0.25% and 0.6% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of~~	~~0.25% and 0.6% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of~~			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			~~froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed.~~			
			Stability of packaging (HDPE	-	No perforations, leakage,			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			COEX) discolorations and darkening were found.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please, refer the KCP 2.7.1	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ The test item was observed to be homogeneous without any phase separation. Emulsion characteristics: Before and after storage: 0.25% and 0.6% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed	Y	D. Bangera, 2021 Report No. G12481	Accepted. The intended concentrations are 0.25%-0.5% and the investigated are 0.25% and 0.6%, but the study can be accepted as the intended concentrations are in range of the investigated ones.
Ambient temperature shelf life (KCP 2.7.5)	-	-	Study on-going.	-	-	Authorization can be granted for 1 year only.
Shelf life in months	-	-	Not required.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(if less than 2 years) (KCP 2.7.6)						
Wettability (KCP 2.8.1)	-	-	Not required.	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Azadirachtin 1% EC (Batch No SCL-280918)	Foam after 1 minute: 0.6515 % w/v: 0 mL in Standard Water D 0.3297 % w/v: 0 mL in Standard Water D	Y	Sreelola Vutpala, M., 2019, Report No G12480	Accepted. The intended concentrations are 0.25%-0.5% and the investigated are 0.33% and 0.65%, but the study can be accepted as the intended concentrations are very close to the investigated ones and the results did not show any possibility that trigger value could be exceeded.
Suspensibility (KCP 2.8.3.1)	-	-	Not required.	-	-	
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required.	-	-	
Dispersion stability (KCP 2.8.3.3)	-	-	Not required.	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required.	-	-	
Particle size distribution / nominal size range of granules	-	-	Not required.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.1.1)						
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required.	-	-	
Dust content (KCP 2.8.5.2.1)	-	-	Not required.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not required.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required.	-	-	
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ 0.25% and 1.2% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed. 0.25% and 0.6% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream	Y	D. Bangera, 2020 Report No. G12479 D. Bangera, 2021 Report No. G21298	Accepted. The intended concentrations are 0.25%-0.5% and the investigated are 0.25%, 0.6% and 1.2%, but the study can be accepted as the intended concentrations are in range of the investigated ones.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed.			
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ 0.25% and 1.2% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed. 0.25% and 0.6% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed.	Y	D. Bangera, 2020 Report No. G12479 D. Bangera, 2021 Report No. G21298	Accepted The intended concentrations are 0.25%-0.5% and the investigated are 0.25%, 0.6% and 1.2%, but the study can be accepted as the intended concentrations are in range of the investigated ones.
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	Azadirachtin 1% EC (Batch No SCL-280918)	~~Ongoing~~ 0.25% and 1.2% v/v in standard Water A and Standard Water D	Y	D. Bangera, 2020 Report No. G12479	Accepted The intended

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed. 0.25% and 0.6% v/v in standard Water A and Standard Water D 30 sec: no formation of froth on top or bottom of the emulsion 30 min: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion. 2h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h: no formation of froth or oily layer, or cream separation on top or bottom of the emulsion 24h and 30min: no from no free oil or cream or solid matter separation observed.		D. Bangera, 2021 Report No. G21298	concentrations are 0.25%-0.5% and the investigated are 0.25% , 0.6% and 1.2%, but the study can be accepted as the intended concentrations are in range of the investigated ones.
Flowability (KCP 2.8.7.1)	-	-	Not required.	-	-	
Pourability (KCP 2.8.7.2)	-	-	Not required.	-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required.	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not required.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not required.	-	-	
Other/special studies (KCP 2.11)	-	-	Not required.	-	-	

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 0.15 liter bottle

Type	Description
Material:	PA/PE (Coex)
Shape/size:	cylindrical / approx. 63 mm diameter x 92 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	HF-seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.250 liter bottle

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	Round bottle / approx. 61 mm diameter x 138.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 0.500 liter bottle

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	Round bottle / approx. 69 mm diameter x 199.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 1 liter bottle

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	Round bottle / approx. 88.5 mm diameter x 239.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 5 liter bottle

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	jerrycan / approx. 136 mm x 192 mm x 285 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 10 liter bottle

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	jerrycan / approx. 174 mm x 226 mm x 368 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 20 liter bottle

Type	Description
Material:	COEX (HDPE/PA)
Shape/size:	jerrycan / approx. 245 mm x 294 mm x 400 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

The accelerated storage stability study is declared to be conducted in HDPE-COEX commercial packagings. Thus the proposed packagings can be accepted.

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

Experience in use of plant protection products based on Azadirachtin has not indicated any particular problems. Low levels of residues of AZA (Azadirachtin 1% EC) 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: 2.5 L product/ha, (25 g of azadirachtin A)
Tank volume: 2000 L
Volume remaining in spray lines and pump after spraying: 20 L
Spray volume: 500 L/ha (lowest spray volume corresponding to the maximum concentration of AZA in diluted spray)

Based on these prerequisites and in consideration of 3 rinses with each 200 – 400 L of water based on good agricultural cleaning procedures, Azadirachtin 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]	Azadirachtin A [kg as/L]
Tank filling: Residues after spraying:	2000 20	5×10^{-3}	5×10^{-5}
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	5×10^{-4}	5×10^{-6}
2nd step: 20% of tank volume added: Residues after spraying:	400 20	2.5×10^{-5}	2.5×10^{-7}
3rd step: 20% of tank volume added: Residues after spraying:	400 20	1.25×10^{-6}	1.25×10^{-8}
Addition of fresh spray solution: Residues in the tank filling:	2000	1.25×10^{-8}	1.25×10^{-10}

PPP = AZA

Residues remaining in the last cleaning solution were calculated to be 12.5 µg/L of Azadirachtin resulting in residue concentration of 0.0125 µg/L Azadirachtin after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 500 – 1000 L/ha applied to succeeding crops, residues of 6.25 µg – 12.5 µg Azadirachtin A will be applied per ha.
Compared to the effect levels on non-target plants, these residues are clearly below the ER50 > 30.9 g a.s./ha determined for seedling emergence and vigour vegetative in the studies conducted with AZA (Wrobel, A. (2015), KIIIA 10.8.1.2 for seedling emergence; Wroble, A. (2016), KIIIA 10.8.1.3 for vegetative vigour). Thus, any detrimental effect on plants from tank residues can be excluded.

The information presented above should be included in the documentation in form of the report.

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	Sreelola Vutpala, M.	2019	Determination of explosive properties of Azadirachtin 1% EC Company Report No G12473 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.2.2 KCP 2.2.1	Mena B.	2020	Azadirachtin 1 % EC: Determination of the oxidizing properties and explosive properties. Sharda CropChem report No. SCE-037/2020 Non GLP/Unpublished	N	Sharda Cropchem Ltd.
KCP 2.5.1	Sreelola Vutpala, M.	2019	Determination of viscosity of Azadirachtin 1% EC Company Report No G12476 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.5.2	Sreelola Vutpala, M.	2019	Suface tension of aqueous solution/suspension of Azadirachtin 1% EC Company Report No G12477 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.6.1	Sreelola Vutpala, M.	2019	Determination of density of Azadirachtin 1% EC Company Report No G12478 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.

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 2.8.2	Sreelola Vutpala, M.	2019	Determination of persistent foam of Azadirachtin 1% EC. Company Report No G12480 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.2.2	Sreelola Vutpala, M.	2019	Determination of chemical incompatibility (oxidation/reduction properties) of Azadirachtin 1% EC. Company Report No G12474 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.1 KCP 2.7.1 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3	Deepthi Bangera	2020	Accelerated storage stability test by heating et elevated temperature of Azadirachtin 1% EC. Company Report No G12479 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.4.1 KCP 2.4.2 KCP 2.7.1 KCP 2.8.6.1 KCP 2.8.6.2 KCP 2.8.6.3	Deepthi Bangera	2021	Accelerated storage stability test by heating at elevated temperature of Azadirachtin 1% EC. Company Report No G21298 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.7.4	Deepthi Bangera	2021	Low temperature stability of Azadirachtin 1% EC Company Report No G12481 EUROFINS Advinus Limited GLP, Unpublished	N	Sharda Cropchem Ltd.
KCP 2.3.1	M. Michalec-Minch	2021	Azadirachtin 1% EC. Determination of flash point (EEC A.9)	N	Sharda

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
			Institute of Heavy Organic Synthesis "Blachownia" Report No. 15/2021 GLP Unpublished		Cropchem Litd.

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

A 2.1 Azadirachtin

No additional data was submitted on the physical chemical and technical properties on the active substance.