

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 5500 A

Product name(s): ASSET (~~ZUXION~~)

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2020

MS Finalisation date: 10/2020; 07/2021

Version history

When	What
07/2021	Final Version

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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.

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

xxx

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: xxx

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

Name: xxxx

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

1.2.3.1 Acetamiprid

Acetamiprid

min. 990 g/kg (SANTE/10502/2017 Rev 4 13 December 2017)
min. 990 g/kg (Sharda source)

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: ~~ZUXION~~ ASSET

Company code number: SHA 5500 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)
Acetamiprid	200.00 g/kg	188.0 – 212.0 g/kg (± 6%)	202.02 g/kg	20.20 % w/w

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

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

Table 1.4-2: Information on Acetamiprid

Type	Name/Code Number
ISO common name	Acetamiprid
CAS No.	135410-20-7
EC No.	-
CIPAC No.	649

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water soluble granules

[Code: SG]

1.6 Function (KCP 1.6)

~~ZUXION~~ ASSET (SHA 5500 A) 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 appearance of the product is that of light blue solid granules odourless. It is not explosive, has no oxidising properties. The product is not flammable and is not self-ignition. In aqueous solution, it has a pH value around 8.33. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for a water soluble granules formulation.

The intended concentration of use is 0.25 g/l to 1 g/l.

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 ~~ZUXION~~ ASSET (SHA 5500 A) complies with FAO specifications.

Formulation used for tests

The product used to determinate the physical, chemical and technical properties is the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual Visual -	Actamiprid 20% SG, batch No. SWEPL- 10035	Physial state: solid granules Colour: light blue Odour: odorless	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Explosive properties (KCP 2.2.1)	EEC A.14	Actamiprid 20% SG, batch No. SWEPL- 10035	The substance is not explosive to shock, to friction and under conditions of intense heat and defined confinement	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Oxidizing properties (KCP 2.2.2)	EEC A.17	Actamiprid 20% SG, batch No. SWEPL- 10035	The substance is not oxidizing	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Flash point (KCP 2.3.1)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Flammability (KCP 2.3.2)	ECC A.10	Actamiprid 20% SG, batch No. SWEPL- 10035	The substance is not flammable.	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Self-heating (KCP 2.3.3)	EEC A.16	Actamiprid 20% SG, batch No. SWEPL- 10035	The substance is not self-igniting, the substance doesn't melt melts down	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Acidity or alkalinity and pH	CIPAC MT 31.2	Actamiprid 20% SG,	Free acidity: 0.003883% w/w as H ₂ SO ₄	Y	Jose Angel Escudero, 2016, Laboratorios	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.4.1)		batch No. SWEPL-10035			Munera, N°15-4150-03	
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Actamiprid 20% SG, batch No. SWEPL-10035	8.33 ± 0.03	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Viscosity (KCP 2.5.1)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Surface tension (KCP 2.5.2)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Relative density (KCP 2.6.1)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Bulk density (KCP 2.6.2)	CIPAC MT 186	Actamiprid 20% SG, batch No. SWEPL-10035	Pour density: 0.68 ± 0.02 g/ml Tap density: 0.72 ± 0.02 g/ml	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46 Visual OPPTS 830.6320 CIPAC MT 172 CIPAC MT 31.2 CIPAC 75.3 CIPAC MT 179 CIPAC MT 47.2 CIPAC MT 53.3 CIPAC MT 58.2 CIPAC MT 178.2 CIPAC MT 171	Actamiprid 20% SG, batch No. SWEPL-10035	Before Storage: Acetamiprid content: 20.4 ± 0.1 % w/w Physial state: solid granules Colour: light blue Odour: odorless Corrosive properties: - Flowability:- Free acidity: 0.003883% w/w as H ₂ SO ₄ pH (1% v/v dilution): 8.33 ± 0.03 Dilution stability: no insoluble material to the test sieve after 5 min, non undissolved material after 18h Persistent foam: - At 0.05 0.25 g/l: 8 ml after 1 min; 4 ml - 0 ml	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted The intended concentration of use is 0.25 g/l to 1 g/l, so the study does not fully cover the intended concentrations. However, as the obtained result is far from the trigger value, the study may be accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>after 12 min</p> <ul style="list-style-type: none"> - At 0.5 g/l: 4 ml after 1 min; 0 ml after 12 min <p>Wettability: complete wetting of the powder Particle size distribution: 150 µm: 10.7%; 250 µm: 33.8%; 355 µm:16.2%; 400 µm: 31.2%; 500 µm:7.9%; 710 µm: 0%; 850 µm: 0% Attrition resistance : 100% Dust content : nearly dust free</p> <p>After storage (14 days at 54°C): Acetamiprid content: 20.6 ± 0.1 % w/w Physial state: solid granules Colour: light blue Odour: odorless Corrosive properties: unaltered container Flowability: The sample drops through the sieve spontaneously Free acidity: 0.006796 % w/w as H₂SO₄ pH (1% v/v dilution): 8.19 ± 0.01 Dilution stability: no insoluble material to the test sieve after 5 min, non undissolved material after 18h Persistent foam: <ul style="list-style-type: none"> - At 0.25 0.05 g/l: 8 ml after 1 min; 4 ml 0-after 12 min; - At 0.5 g/l: 4 ml after 1 min; 0 ml 6 ml after 12 min <p>Wettability: complete wetting of the powder Particle size distribution: 150 µm: 9.6%; 250 µm: 34.5%; 355 µm:16.3%; 400 µm: 31.6%; 500 µm:7.8%; 710 µm: 0%; 850 µm: 0% Attrition resistance : 100% Dust content : nearly dust free</p> </p>			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Ambient temperature shelf life (KCP 2.7.5)	Visual OPPTS 830.6320 CIPAC MT 172 CIPAC MT 31.2 CIPAC 75.3 CIPAC MT 179 CIPAC MT 47.2 CIPAC MT 53.3 CIPAC MT 58.2 CIPAC MT 178.2 CIPAC MT 171	Actamiprid 20% SG, batch No. SWEPL-10035	<p>Before Storage: Acetamiprid content: 20.4 ± 0.1 % w/w Physial state: solid granules Colour: light blue Odour: odorless Corrosive properties: - Free acidity: 0.003883% w/w as H₂SO₄ pH (1% w/v dilution): 8.33 ± 0.03 Emulsion stability: no insoluble material to the test sieve after 5 min, non undissolved material after 18h Persistent foam: - At 0.25 g/l: 8 ml after 1 min; 4 ml after 12 min - At 0.5 g/l: 4 ml after 1 min; 0 ml after 12 min - Wettability: complete wetting of the powder - Particle size distribution: 150 µm: 10.7%; 250 µm: 33.8%; 355 µm:16.2%; 400 µm: 31.2%; 500 µm:7.9%; 710 µm: 0%; 850 µm: 0% - Attrition resistance : 100% - Dust content : nearly dust free - Wet sieve test : < 0.1% retained in 75 µm sieve</p> <p>After storage (24 months at 25 °C): Acetamiprid content: 20.09 20.1 ± 0.1 % w/w Physial state: solid granules Colour: light blue Odour: odorless Corrosive properties: unaltered container (1L container of HDPE with aluminium seal in the mouth of the bottle and screw cap)</p>	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-04	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Free acidity: 0.007759% w/w as H₂SO₄ pH (1% w/v dilution): 7.97 ± 0.04 Emulsion stability: no insoluble material to the test sieve after 5 min, non undissolved material after 18h Persistent foam:</p> <ul style="list-style-type: none"> - At 0.25 0.05 g/l: 6 ml after 1 min; 2 ml after 12 min - At 0.5 g/l: 12 ml after 1 min; 8 ml after 12 min - Wettability: complete wetting of the powder after 1 second - Particle size distribution: 150 µm: 29.0%; 250 µm: 54.7%; 355 µm: 11.3%; 400 µm: 4.3%; 500 µm: 0.2%; 710 µm: 0%; 850 µm: 0% - Attrition resistance : 100% - Dust content : nearly dust free <p>Wet sieve test : < 0.1% retained in 75 µm sieve</p>			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.	-	-	Statement accepted.
Wettability (KCP 2.8.1)	CIPAC MT 53.3	Actamiprid 20% SG, batch No. SWEPL-10035	Complete wetting of the powder in 0 s.	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Actamiprid 20% SG, batch No. SWEPL-10035	<ul style="list-style-type: none"> - At 0.25 g/l At 0.05 g/l: 8 ml after 1 min; 4 ml after 12 min - At 0.5 g/l: 4 ml after 1 min; 0 ml after 12 min 	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Suspensibility (KCP 2.8.3.1)	-	-	Not relevant for SG formulation.	-	-	
Spontaneity of dispersion	-	-	Not relevant for SG formulation.	-	-	Statement accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.2)						
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 179	Actamiprid 20% SG, batch No. SWEPL-10035	No insoluble material to the test sieve after 5 min. Non undissolved material after 18h.	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 58.2	Actamiprid 20% SG, batch No. SWEPL-10035	150 µm: 10.7%; 250 µm: 33.8%; 355 µm:16.2%; 400 µm: 31.2%; 500 µm:7.9%; 710 µm: 0%; 850 µm: 0%	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Actamiprid 20% SG, batch No. SWEPL-10035	0% retained in 75 µm sieve.	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	Actamiprid 20% SG, batch No. SWEPL-10035	Nearly dust free.	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	Actamiprid 20% SG, batch No. SWEPL-10035	100%	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Hardness and integrity	-	-	Not relevant for SG formulation.	-	-	Statement accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.5.4)						
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Flowability (KCP 2.8.7.1)	CIPAC MT 172	Actamiprid 20% SG, batch No. SWEPL-10035	Flowability after storage stability under pressure: the sample drops through the sieve spontaneously.	Y	Jose Angel Escudero, 2016, Laboratorios Munera, N°15-4150-03	Accepted.
Pourability (KCP 2.8.7.2)	-	-	Not relevant for SG formulation.	-	-	Statement accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for SG 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.	-	-	Statement accepted.
Distribution to seed (KCP 2.10.2)	-	-	Not relevant.	-	-	Statement accepted.
Other/special studies (KCP 2.11)	Efficacy Guideline 302 and 305	Actamiprid 20% SG,	Results of evaluation by removed the acetamiprid in small scale jar are the 99.9%±0.1%.	Y	Jose Angel Escudero, 2016, Laboratorios	Accepted.

Annex point	Method used / deviations	Test ma- terial	Findings	GLP Y/N	Reference	Acceptability / comments
		batch No. SWEPL- 10035			Munera, N°15-4150-27	

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 0.060 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	Round bottle / approx. 40.0 mm diameter x 91.5 mm
Opening:	20.0 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 0.100 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
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 4.1-3: Packaging information for 0.250 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	Round bottle / approx. 62.5 mm diameter x 126.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 0.500 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
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
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 1 liter bottle

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

Table 4.1-6: Packaging information for 5 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	jerry can / approx. 131 mm x 189 mm x 280 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 10 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	jerry can / 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

Type	Description
UN/ADR	compliant

Table 4.1-8: Packaging information for 20 liter bottle

Type	Description
Material:	Fluorinated
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

RMS comment: The 2 years shelf life study was conducted in HDPE bottles, thus the extrapolation for HDPE/COEX is possible. From the physicochemical point of view, presented packagings 0.06,, 0.1, 0.25, 0.5, 1, 5 and 10 L and 20 L have been accepted. ~~The packaging of 20L cannot be extrapolated, thus it cannot be accepted.~~

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.2 KCP 2.3 KCP 2.4 KCP 2.6 KCP 2.7.1 KCP 2.8.1 KCP 2.8.2 KCP 2.8.4 KCP 2.8.5.1 KCP 2.8.5.2 KCP 2.8.5.3 KCP 2.8.7	Jose Angel Escudero	2016	Physico-Chemical Characterization of ACETAMIPRID 20% SG Laboratorios Munuera Report No 15-4150-03 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.5	Jose Angel Escudero	2018	Storage stability for two years at 25 ± 2 °C of ACETAMIPRID 20% SG Laboratorios Munuera Report No 15-4150-04 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.11	Jose Angel Escudero	2016	Cleaning application equipment – Small scale jar test protocol for ACETAMIPRID 20% SG Laboratorios Munuera Report No 15-4150-27	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

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 Acetamiprid

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