

FINAL REGISTRATION REPORT

Part A

Risk Management

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

(authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 03/2022, 07/2022

Version history

When	What
March 2022	ZRMs evaluated dRR submitted by Applicant.
July 2022	ZRMS Assessment after commenting period

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is submitted by SHARDA CROPCHEM ESPAÑA S.L.

This application is for approval of AZA (Azadirachtin 1% EC), an emulsifiable concentrate containing 10 g/L of azadirachtin, as insecticide on strawberry, citrus, tomato, potato and melon in Central Europe.

zRMS: Poland.

1.2 Letters of Access

Not applicable, letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation Azadirachtin 1% EC as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 123000 A
Product name in MS	AZA
Authorization number	First authorisation
Function	Insecticide
Applicant	SHARDA Cropchem España S.L.
Active substance(s) (incl. content)	Azadirachtin; 10 g/L
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	0.15, 0.25, 0.5, 1, 5, 10, 20 L HDPE/PA, professional user
Coformulants of concern for national authorizations	–

Restrictions related to identity	–
Mandatory tank mixtures	–
Recommended tank mixtures	–

2.2 Conclusion

Physical and chemical properties section:
Authorization can be granted for 1 year only.

Efficacy section:

Due to limited data or exceptions from EPPO standards in methodology for some uses, decision about registration each use was left to CMS. For Poland only use against aphids on field tomato and against potato beetle on potato can be accepted. Use against thrips and aleuroides on field tomato and against aphids on ornamentals can be accepted only in line to Article 51. Detailed information's are presented in B3.

Toxicology section:

AZA is unclassified. No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

Ecotoxicology section:

The evaluation of the application for Azadirachtin 1% EC resulted in the decision on the authorization. **for ornamentals <50 cm as the aquatic risk assessment is not finalized.**

Metabolism and residues

Data gaps:

- Freezer storage stability study demonstrating stability of the samples from the new field trials on potatoes.
- Data on the effects on the residue level in pollen and bee products for ornamentals (post-registration requirement)

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aquatic Chronic 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	GHS09
Signal word:	

Hazard statement(s):	H411
Precautionary statement(s):	P101, P102, P391
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
–	–

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>Fruiting Vegetables (Tomato): To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 20m to surface water bodies.</p> <p>Potato: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 20 m to surface water bodies</p> <p>Ornamentals >50cm: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed vegetated buffer zone of 10m to surface water bodies.</p> <p>Fruiting Vegetables (Tomato): To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</p> <p>Potato: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</p> <p>Ornamentals >50cm: To protect aquatic organisms, respect an unsprayed buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 10m to surface water bodies.</p> <p>Ornamentals <50cm: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</p>

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
–	Work wear (but not specialistic protective clothing)
Worker protection:	
–	Work wear (but not specialistic protective clothing)
–	Treated crops should not be re-entered before spray deposits on leaf surface have completely dried.
Integrated pest management (IPM)/sustainable use:	
–	–
Environmental protection	
SPE3	<p>Fruiting Vegetables (Tomato): To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 20m to surface water bodies.</p> <p>Potato: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 20m to surface water bodies</p> <p>Ornamentals >50cm: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed vegetated buffer zone of 10m to surface water bodies.</p> <p>Fruiting Vegetables (Tomato): To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</p> <p>Potato: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</p> <p>Ornamentals >50cm: To protect aquatic organisms, respect an unsprayed buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 10m to surface water bodies.</p> <p>Ornamentals <50cm: To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</p>
Other specific restrictions	
–	–

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
–	–

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:	Relevant for use no.
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—	—	—
Environmental protection:		Relevant for use no.
—	<p>Fruiting Vegetables (Tomato): <i>To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</i></p> <p>Potato: <i>To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</i></p> <p>Ornamentals >50cm: <i>To protect aquatic organisms, respect an unsprayed buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 10m to surface water bodies.</i></p> <p>Ornamentals <50cm: <i>To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.</i></p>	—

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Azadirachtin 1% EC
 Active substance 1: azadirachtin
 Safener: -
 Synergist: -
 Applicant: Sharda Cropchem España S.L.
 Zone(s): Central ^(d)
 Verified by MS: yes/no

GAP rev. 0, date: 2017-September-12th
 Formulation type: EC (Emulsifiable Concentrate) ^(a, b)
 Conc. of as 1: 10 g/L ^(c)
 Conc. of safener: - ^(c)
 Conc. of synergist: - ^(c)
 Professional use:
 Non professional use:

Field of use: Insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Tomato	F	Aleuroids, Thrips, Aphids	Foliar Spray	Apply at pest presence BBCH 12-85	a) 2 b) 2	7-10	a) 3.0 b) 6.0	a) 0.03 b) 0.06	750- 1000	3	DE: Plant height until 50 cm 2 l/ha in 600 l/ha, from 50 to 125 cm 2.5 l/ha in 800 l/ha, over 125 cm 3 l/ha in 1000 l/ha Efficacy section: Thrips and aleuroides can be accepted only in ac- cordance to Artricle 51.
2	CEU	Potato	F	Collorado beetle (<i>Leptino- tarsa decemlineata</i>)	Foliar Spray	Apply at pest presence BBCH 12-91	a) 2 b) 2	7-10	a) 2.5 b) 5.0	a) 0.025 b) 0.05	500- 1000	3 4	Residues section: 1 application PHI=4

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
							1						
3	PL	Ornamentals	F	Aleuroids, Thrips, Aphids	Foliar Spray	Apply at pest presence BBCH 12-89	a) 2 b) 2	7-10	a) 3.0 b) 6.0	a) 0.03 b) 0.06	750- 1000	3	Efficacy section: registration is possible only in line to Article 51 Section Ecotox: The use in ornamentals is considered safe for orna- mentals > 50 cm

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 %.

3.2 Efficacy (Part B, Section 3)

AZADIRACHTIN 1% EC is a emulsifiable concentrate (EC) containing 10 g/L azadirachtin for use in tomato, potato and ornamentals.

In compliance with the GAP, the following dose rates are applied for registration:

- Up to two applications per season (BBCH 12-85) to control aleuroids, thrips and aphids in Tomato, target rate: 3.0 L/ha.
- Up to two applications per season (BBCH 12-91) to control collorado beetle (*Leptinotarsa decemlineata*) in Potato, target rate: 2.5 L/ha.
- Up to two applications per season (BBCH 12-89) to control aleuroids, thrips and aphids in Ornamentals, target rate: 3.0 L/ha.

This document serves the registration of Azadirachtin 1% EC in the Central zone of the EU. The objective of this document is to prove and support the label claims of the fungicidal efficacy Azadirachtin 1% EC in the label claimed crops.

Comprehensive field trials were conducted in Poland, Lithuania, Greece, Italy, Germany, Czech Republic, S-France and Hungary in 2016 and 2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the pest control and safety to the crop of Azadirachtin 1% EC is comparable to that of the reference products registered in the EU Central zone, and the applicant therefore wishes to cite the original registrant's data on azadirachtin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal evaluator extrapolate from those data.

3.3 Efficacy data

Preliminary tests

The activity of azadirachtin is well known, as it has been marketed since 1980's to control a wide range of pests including aphids, thrips, aleuroids and *Leptinotarsa decemlineata* in many crops as well as in other pest control. Based on the knowledge about the active substance and the experiences with azadirachtin in the GAP claimed uses, the necessary application rates to obtain sufficient control of the pest

organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

To determine the minimum effective dose rate, data from 9 trials conducted in tomato, 15 trials conducted in potato and 4 trials conducted in ornamentals are included in this section. In the twenty-eight trials, Azadirachtin 1% EC was applied at 2.0, 2.5 and 3.0 L/ha for the control of aleuroids, thrips, aphids and at 1.75, 2.0 and 2.5 L/ha for the control of collorado beetle. The dose rates tested reflects 70%, 80% and 100% of the recommended rate of Azadirachtin 1% EC, in accordance with the EPPO guideline PP 1/225(2) "Minimum effective dose". The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data is presented from trials conducted in the Maritime EPPO zone (5; i.e. Czech Republic (3) and Germany (2)), the North-east EPPO zone (8, i.e. Poland (7) and Lithuania (1)), the South-east EPPO zone (2; i.e. Hungary), the Mediterranean EPPO zone (6, i.e. Greece (3) and Italy (3)) and greenhouse (7).

Control of aleuroids in tomato: In order to prove and to support the requested dose rate of 3.0 L/ha Azadirachtin 1% EC [30 g azadirachtin per hectare] applied for the control of aleuroids in tomatoes, the assessment results of four efficacy trials performed in the greenhouse in 2016 and 2017 season, are reported. Azadirachtin 1% EC was included in these trials at 3.0 L/ha to demonstrate the recommended dose rate as well as at two lower than recommended dose rates (2.0 L/ha [20 g azadirachtin per hectare] and 2.5 L/ha [25 g azadirachtin/ha]). The rates reflect the proposed label rate as well as 66 and 83% of the full recommended rate of Azadirachtin 1% EC, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

Based on results achieved on aleuroids in 4 tomatoes trials treated with two applications, it can be concluded that to consistently control frequently occurring aleuroids in tomatoes crops, Azadirachtin 1% EC should be applied two times at 3.0 L/ha.

Control of aphids in tomato: In order to prove and to support the requested dose rate of 3.0 L/ha Azadirachtin 1% EC [30 g azadirachtin per hectare] applied for the control of aphids in tomatoes, the assessment results of four efficacy trials performed in the North-east, the Mediterranean EPPO zones and in greenhouse in 2016 and 2017 season, are reported. Azadirachtin 1% EC was included in these trials at 3.0 L/ha to demonstrate the recommended dose rate as well as at two lower than recommended dose rates (2.0 L/ha [20 g azadirachtin per hectare] and 2.5 L/ha [25 g azadirachtin/ha]). The rates reflect the proposed label rate as well as 66 and 83% of the full recommended rate of Azadirachtin 1% EC, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

Based on results achieved on aphids in 4 tomatoes trials treated with two applications, it can be concluded that to consistently control frequently occurring aphids in tomatoes crops, Azadirachtin 1% EC should be applied two times at 3.0 L/ha.

Control of thrips in tomato: In order to prove and to support the requested dose rate of 3.0 L/ha Azadirachtin 1% EC [30 g azadirachtin per hectare] applied for the control of thrips in tomatoes, the assessment results of one efficacy trial performed in the Mediterranean EPPO zone in 2016 season, are reported. Azadirachtin 1% EC was included in these trials at 3.0 L/ha to demonstrate the recommended dose rate as well as at two lower than recommended dose rates (2.0 L/ha [20 g azadirachtin per hectare] and 2.5 L/ha [25 g azadirachtin/ha]). The rates reflect the proposed label rate as well as 66 and 83% of the full recommended rate of Azadirachtin 1% EC, in accordance with the EPPO standard PP 1/225(2) '*Minimum effective dose*' and the Central zone efficacy requirements.

Based on results achieved on thrips in one tomato trial treated with two applications, it can be concluded that to consistently control frequently occurring thrips in tomatoes crops, Azadirachtin 1% EC should be applied two times at 3.0 L/ha.

Control of collorado beetle in potato: In order to prove and to support the requested dose rate of 2.5 L/ha Azadirachtin 1% EC [25 g azadirachtin per hectare] applied for the control of Collorado beetle (*Lepidoptera decemlineata*) in potatoes, the assessment results of fifteen efficacy trials performed in the Maritime, the North-east, the South-east and the Mediterranean EPPO zones in 2016 and 2017 season, are reported. Azadirachtin 1% EC was included in these trials at 2.5 L/ha to demonstrate the recommended dose rate as well as at two lower than recommended dose rates (1.75 L/ha [17.5 g azadirachtin per hectare] and 2.0 L/ha [20 g azadirachtin/ha]). The rates reflect the proposed label rate as well as 70% and 80% of the full recommended rate of Azadirachtin 1% EC, in accordance with the EPPO standard PP 1/225(2) '*Minimum effective dose*' and the Central zone efficacy requirements.

Based on results achieved on collorado beetle in fifteen potato trial treated with two applications, it can be concluded that to consistently control frequently occurring collorado beetle in potato crops, Azadirachtin 1% EC should be applied two times at 2.5 L/ha.

Control of aphids in ornamental: In order to prove and to support the requested dose rate of 3.0 L/ha Azadirachtin 1% EC [30 g azadirachtin per hectare] applied for the control of aphids in ornamentals, the assessment results of four efficacy trials performed in the Maritime EPPO zone and greenhouse in 2016 and 2017 season, are reported. Azadirachtin 1% EC was included in these trials at 3.0 L/ha to demonstrate the recommended dose rate as well as at two lower than recommended dose rates (2.0 L/ha [20 g azadirachtin per hectare] and 2.5 L/ha [25 g azadirachtin/ha]). The rates reflect the proposed label rate as well as 66 and 83% of the full recommended rate of Azadirachtin 1% EC, in accordance with the EPPO standard PP 1/225(2) '*Minimum effective dose*' and the Central zone efficacy requirements.

Based on results achieved on aphids in four ornamentals trials treated with two applications, it can be concluded that to consistently control frequently occurring aphids in ornamentals crops, Azadirachtin 1% EC should be applied two times at 3.0 L/ha.

Conclusion: Azadirachtin 1% EC applied at 3.0 L/ha to control aphids, thrips and aleuroids in tomato and ornamentals and azadirachtin 1% EC applied at 2.5 L/ha to control collorado beetle in potato achieved moderate to excellent control of all target pests. Reducing the application rate of Azadirachtin 1% EC from the proposed dose rate to 60% to 80% of that rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the proposed dose rates of 2.5 L/ha and 3.0 L/ha, it is recommended that Azadirachtin 1% EC is applied under optimal conditions, i.e. early growth stage of the pests and optimal weather conditions.

The same pests are controlled by azadirachtin in the different crops. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

As will be demonstrated in the following section, this document clearly demonstrates that the efficacy and crop safety of Azadirachtin 1% EC is equivalent to that of the standard azadirachtin reference products (i.e. Azatin, Neemazal) to which it was compared. The applicant therefore wishes to cite the original registrant's data on azadirachtin now out of protection in support of those recommendations on the draft label

that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Efficacy tests and conclusions regarding authorization of intended uses

Details of experiment are presented above by Applicant. All used methodology is in accordance to GEP rules (some exceptions will be presented later). Trials were conducted during two growing seasons (2016 and 2017), which is in line to appropriate EPPO standard.

Applicant submitted in total 28 efficacy trials, carried out in the Maritime EPPO zone – 5 trials (DE-2, CZ-3); North-East EPPO zone – 8 trials (PL); South-East EPPO zone – 2 trials (HU) and Mediterranean EPPO zone – 6 trials (GR-3, IT-3), and 7 studies were performed in greenhouse (5-tomato, 2-ornamentals).

Applicant presented 9 efficacy trials carried out on tomato, 15 on potato and 4 trials performed on ornamental plants. Below we present the number of surveys carried out for each crop and pest, divided into climate zones in which they were done.

Tomato:

• aphids:

- ✓ MED EPPO zone – 2 trials were conducted in Grece (2 applications per season were studied).
- ✓ North-East EPPO zone – 1 trial was carried out in Poland (2 applications per season – 2 trials).
- ✓ South-East – lack of trials
- ✓ Mediterranean – lack of trials
- ✓ Greenhouse – 1 trial (performed in PL from N-E).

During MED trials – MYZUPE as pest and during N-E trials (field, greenhouse) – APHIFA as pest was studied. Studied pest are in line to EPPO standard.

AZA (SHA 103000 A) applied at the proposed dose rate of 3,0 L/ha provides a high level of control of aphids found in tomato.

Trials conducted under glasshouse represent a more challenging situation to control studied insects since the controlled conditions inside glasshouses have better humidity and temperature for the development of insects. Thus, it is considered that glasshouse trials are valid to demonstrate efficacy in the field (but in the opinion of Evaluator only for field trials carried out in the same EPPO zone as greenhouse trials). Basis on this statement, **use against aphids on field tomato can be accepted only in Poland (2 trials: 1 field and 1 greenhouse). cMS from MED should decide if 2 field trials can be acceptable** (according to EPPO at least 3 trials should be submitted). Maybe, 2 field trial from MED and 1 greenhouse will sufficient for registration. **In the opinion of Evaluator, registration in MAR and S-E without any trial is not possible. However, final decision is left to each cMS.** Also, field use on tomato against aphids can be acceptable in the situation of not sufficient number of trials according to Article 51 (as tomato is a minor crop).

• thrips:

- ✓ Maritime EPPO zone – lack of trials.
- ✓ North-East EPPO zone – lack of trials.
- ✓ South-East – lack of trials
- ✓ Mediterranean- 1 trial performed in IT (2 applications per seasons were studied). THRITB as pest was studied
- ✓ Greenhouse – lack of trials

AZA applied at the proposed dose rate of 0,3 L/ha provides a high level of control of thrips found in tomato. In the opinion of Evaluator, **thrips should be excluded from GAP table and label project due to not enough number of trials. At least 2-3 efficacy trials for each EPPO zone should be presented. Only cMS, from MED should decide if only one trial can be accepted.**

• aleuroides:

- ✓ MED EPPO zone – lack of trials.
- ✓ North-East EPPO zone – lack of trials.

- ✓ South-East – lack of trials
- ✓ Mediterranean – lack of trials
- ✓ Greenhouse – 4 trials (performed in PL-1, FR-1, IT-2). 2 applications per season were studied.

BEMITA and TRIAVA as pest were studied during trials. AZA (SHA 103000 A) applied at the proposed dose rate of 3,0 L/ha provides a high level of control of aleuroides found in tomato. In the opinion of Evaluator, **registration the plant protection product - AZA for application on tomato can not be accepted for field use (at least 2-3 efficacy trials carried out in each EPPO zone is required)**. From N-E we have only one trial performed in greenhouse. It is not sufficient for support field registration. In the opinion of Evaluator, **according to submitted 4 trials carried out in greenhouse, use against aleuroides on tomato in greenhouse in MED, MAR, S-E and N-E can be accepted. However, use for greenhouse was not presented in GAP table and lable project by Applicant.**

Potato:

- **Colorado beetle:**

- ✓ Maritime EPPO zone – 3 trials (CZ-2, DE-1). 2 applications were studied.
- ✓ North-East EPPO zone – 7 trials (PL-6, LT-1). 2 application were studied.
- ✓ South-East – 2 trials (HU). 2 application were studied.
- ✓ Mediterranean – 3 trials (BR-1, IT-2). 2 application were studied.

AZA applied at 2,5 L/ha provides a high level of control of a colorado beetle commonly found in potato. In all studies LPTNDE as pest was studied. On the basis on presented documentation, **registration in N-E should be possible. CMS from Maritime, S-E and MED EPPO zone should decide if limited number of trials can be acceptable.**

Ornamental plants:

- **aphids:**

- ✓ Maritime EPPO zone – 2 trials carried out in Czech Republic and Germany. NNNZZ was studied during trials.
- ✓ North-East EPPO zone – lack of trials.
- ✓ South-East – lack of trials.
- ✓ Mediterranean – lack of trials
- ✓ Greenhouse – 2 trials (PL).

AZA applied at 3,0 L/ha provides a high level of control of aphids commonly found in ornamentals. On the basis on presented documentation, registration the application 2 times per season should be possible. **In the opinion of Evaluator, field use on ornamental against aphids will be possible only in MAR EPPO zone, if the CMS accepts deviations from the EPPO standards.** During field trials: METODR and DACTJA were studied as pest, which is not in line to appropriate EPPO standard. Tested organisms should be: non-winged stages of aphids such as *Myzus persicae* (MYZUPE), *Aphis fabae* (APHIFA), *Aulacorthum circumflexum* (MYZUCI), *Macrosiphoniella sanborni* (MACRCH), *Brachycaudus helichrysi* (ANURHE), *Macrosiphum rosae* (MACSRO), *Aphis gossypii* (APHIGO). ROSSS and CENIM as ornamental species of platnt were studied in field trials. According to EPPO standard (1/23) – *Aster spp.* (1ASTG), *Chrysanthemum indicum* (CHYIN), *Dahlia hybrids* (DAHBY), *Centaureum erythrea* (CTIER), *Centaurea spp.* (1CENG) should be studied. **Although a sufficient number of studies were presented for Poland (trials from neighbouring countries from MAR), the valid species to EPPO standards were not studied, so only, according to Article 51, this registration would be possible in the opinion of Evaluator.**

In N-E, MED and S-E should be presented at least 2-3 efficacy trials carried out on field on ornamentals against aphids. At this moment, without trials only registration according to Article 51 (without any field trials) is possible.

On the basis on 2 greenhouse trials, ornamentals can be accepted in N-E, S-E, MED and MAR but only for greenhouse use against aphids. During trials APHIFA as pest was studied, which is in line to EPPO 1/23. TOPMA and DAHBY where studied, which is not in line to regulations. According to EPPO 1/23 for greenhouse use following species shuld be studied: *Chrysanthemum indicum* (CHYIN), *Calceo-*

laria herbeohybrida (CAZHY), *Rosa spp.* (1ROSG), *Asparagus spp.* (1ASPG), *Hibiscus spp.* (1HIBG), *Freesia spp.* (1FREG), goździk *Dianthus caryophyllus* or *Dianthus spp.* (DINCA, 1DING), *Pericallis x hybrida* (SENCR). So, each cMS should decide if those deviations from EPPO standards can be acceptable. In Poland, ornamental plants should be excluded from GAP table and label project. Although a sufficient number of studies were presented for N-E, the correct species were not studied in these studies, so only, according to Article 51, this registration would be possible in the opinion of Evaluator.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The following dossier section follows EPPO standard PP 1/213(3) *Resistance risk analysis* in particular point 6. *Registration requirements* of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The insect-resistant population develops because the sensitive population is suppressed and the rare insecticide-resistant individual is allowed to multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the infestation and use pattern of the insecticide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of insect control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, insecticide applications in most cases will provide satisfactory control.

Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant: use alternately insecticides with different modes of action, use as recommended on the label; do not use reduced doses. Recommendation to use only in a programme e.g. before or after an application of an insecticide from a different mode of action group.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

The crop safety of Azadirachtin 1% EC was assessed in 28 efficacy trials (6 MED, 8 N-E, 5 MAR, 2 S-E and 7 greenhouse) where Azadirachtin 1% EC was applied at 1.75 L/ha to 3.0 L/ha, and 14 selectivity trials (2 MED, 5 MAR, 3 N-E, 1 S-E and 1 greenhouse) where Azadirachtin 1% EC was applied at 3.0 L/ha and 6.0 L/ha.

Azadirachtin 1% EC applied at the recommended dose rate was perfectly crop safe and did not cause phytotoxicity in any of the trials conducted on potato, tomato and ornamental.

As the data on potato, tomato and ornamental show, the crop safety and efficacy of Azadirachtin 1% EC is equivalent to that of the Azadirachtin reference product. For recommendations claimed on the draft Azadirachtin 1% EC label not adequately supported by the applicant's trials data, Sharda wishes to cite the original registrant's data on azadirachtin now out of protection and requests that the evaluators extrapolate from those data.

Effects on yield and quality

Seven selectivity trials were conducted with the same formulation currently under registration, i.e. Azadirachtin 1% EC, in the Maritime EPPO zone (2, i.e. Czech Republic), the North-east EPPO zone (2, i.e. Poland and Lithuania) and the Mediterranean EPPO zone (3, i.e. S-France (2) and Italy (1)) to evaluate the effect of Azadirachtin 1% EC on the quality of the harvested crop of tomato, potato and ornamental.

Azadirachtin 1% EC applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, in potato, tomato and ornamental did not affect crop yield nor the quality of the crop yield significantly in any of the 7 trials harvested. In all selectivity trials, Azadirachtin 1% EC applied at dose rates higher than the recommended rate did not significantly affect the crop yield.

Effect on transformation processes

There are no indications that the use of azadirachtin will have influence on possible transformation processes. It is therefore expected that Azadirachtin 1% EC, when applied as recommended in the GAP claimed uses will not cause any unacceptable adverse effects on transformation processes.

Furthermore, the residue data (see Part B Section 7) clearly demonstrate that, at the proposed application rates, no azadirachtin nor its metabolites above the LOQ (= limit of quantification) are found in any of the tested crops. In case of undetectable residues no special studies are required according to the EPPO guideline PP 1/243(1).

Finally, it should be noted that azadirachtin has been used for a long time as a insecticide. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor do azadirachtin containing products have any label restrictions concerning their use on crops destined for processing.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

Based on experiences with the solo active ingredient, the risk that the product Azadirachtin 1% EC has negative impact on succeeding crops, if applied at the proposed GAP for protection against insect feeding, is regarded to be negligible. Thus the recommendation of no restrictions on following crops after sowing seeds treated with Azadirachtin 1% EC is justified.

Impact on other plants including adjacent crops

According to EPPO PP 1/256, no data are normally required for insecticide such as Azadirachtin 1% EC. Furthermore, azadirachtin has been used for several years on e.g. potato and tomato crops, without identifying any issues.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy trials conducted.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Method suitable for the determination of active substances Azadirachtin in plant protection product AZA (SHA 123000 A)

	Azadirachtin
Author(s), year	D. Bagnera, 2020
Principle of method	HPLC
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	5 points 37.42 to 121.61 µg/mL R = 1.000 y=6549.573x-8472.877
Precision – Repeatability Mean n = 5 (%RSD)	%RSD = 0.88% Horrat value = 0.34
Accuracy n = 3 (% Recovery)	90%: 99.51 ± 0.25 100%: 97.54 ± 0.67 110%: 101.03 ± 0.34%
Interference/ Specificity	No interference. The method is specific.
Comment	The analytical method meets the criteria of specificity, linearity, precision and accuracy. The method is acceptable and is suitable for determination of azadirachtin in plant protection product Aza

Method suitable for the determination of relevant impurities Aflatoxin-G2, Aflatoxin-G1, Aflatoxin-B2 and Aflatoxin-B1 in plant protection product AZA (SHA 123000 A)

	Aflatoxin-G2	Aflatoxin-G1	Aflatoxin – B2	Aflatoxin – B1
Author(s), year	D. Bagnera, 2020			
Principle of method	HPLC			
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	5 points 0.0000480 to 0.001920 µg/mL R = 0.996 y=204908421.2x-4080.22	5 points 0.0001920 to 0.00768 µg/mL R = 1.00 y=532302341.28x-13086.65	5 points 0.0000460 to 0.001840 µg/mL R = 0.9998 y=673567983.45x-13337.72	5 points 0.0001910 to 0.007640 µg/mL R = 1.00 y=794845007.86x-19381.19
Precision – Repeatability Mean n = 5 (%RSD)	Method precision: 0% (as analyte <LOD) System precision: 4.414%	Method precision: 0% (as analyte <LOD) System precision: 3.154%	Method precision: 0% (as analyte <LOD) System precision: 4.207%	Method precision: 0.000000037% (as analyte <LOD) System precision: 3.074%
Accuracy n = 3 (% Recovery)	Overall mean accuracy 96.473 ± 11.012	Overall mean accuracy 99.561 ± 5.970	Overall mean accuracy 104.503 ± 5.617	Overall mean accuracy 89.34 ± 11.057
Interference/ Specificity	No interference, the method is specific.			
Comment	LOD =	LOD =	LOD =	LOD =

	Aflatoxin-G2	Aflatoxin-G1	Aflatoxin – B2	Aflatoxin – B1
	0.00000000053% w/w LOQ = 0.00000007 % w/w	0.00000000031% w/w LOQ = 0.00000026 % w/w	0.00000000022% w/w LOQ = 0.0000000506 % w/w	0.00000000025% w/w LOQ = 0.00000026 % w/w

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Commodity/crop	Supported/ Not supported
Tomato	Supported
Potato	Supported
Ornamentals	Not required

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Azadirachtin 1% EC were not evaluated as part of the EU review of Azadirachtin. All relevant data were provided and are considered adequate.

The toxicological classification of AZA was calculated.

Classification: Not classified

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	> 5000 mg/kg bw	Yes	None	Calculated
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	Calculated
LC ₅₀ inhalation, rat (OECD 403)	> 5mg/L air	Yes	None	Calculated
Skin irritation, rabbits (OECD 404)	Non-irritant	Yes	None	Calculated
Eye irritation, rabbits (OECD 405)	Non-irritant	Yes	None	Calculated
Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Yes	None	Calculated
Supplementary studies for combinations	No data – not			

of plant protection products	required			
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3.5.2 Operator exposure

Operator exposure for Azadirachtin 1% EC was not evaluated as part of the EU review of Azadirachtin. Therefore, all relevant data were provided and are considered adequate.

Estimation of potential operator exposure have been undertaken for Azadirachtin 1% EC using EFSA AOEM Model and default dermal absorption values (70% concentrate and 70% dilution).

Conclusion:

According to the AOEM model, calculations, it can be concluded that the risk for the operator using AZA is acceptable without PPE only with standard working clothing (long sleeved shirt and trousers) during mixing/loading and application.

Implication for labelling:

None.

3.5.3 Worker exposure

Worker exposure for Azadirachtin 1% EC was not evaluated as part of the EU review of Azadirachtin. Therefore, all relevant data were provided and are considered adequate.

Conclusion:

It is concluded that there is no unacceptable risk is anticipated for the worker re-entering the treated crops tomato and potato and no unacceptable risk for workers with suitable work wear (arms, body and legs covered) after application on ornamentals.

Implication for labelling:

Treated crops should not be re-entered before spray deposits on leaf surface have completely dried.

3.5.4 Bystander and resident exposure

Bystander and resident exposure for Azadirachtin 1% EC was not evaluated as part of the EU review of Azadirachtin. Therefore, all relevant data were provided and are considered adequate.

Conclusion:

According to the EFSA Model, the calculations show that the risk for bystanders and residents when using Azadirachtin 1% EC is acceptable without specific mitigation measures.

Bufor zone 2-3 m.

Implication for labelling:

None.

3.6 Residues and consumer exposure (Part B, Section 7)

The preparation Azadirachtin 1% EC is composed of Azadirachtin.

Toxicological reference values for the dietary risk assessment of Azadirachtin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Azadirachtin - Parent compound					
ADI	EFSA Journal 2018;16(4):5234	2018	0.1 mg/kg bw/d	Rat, 90-day (Trifolio, Sipcam, Mitsui extracts)	300
ARfD	EFSA Journal 2018;16(4):5234	2018	0.75 mg/kg bw/d	Rat, teratogenicity (Trifolio, Sipcam, Mitsui extract)	300

An acceptable acute and chronic risk for consumer is expected after the use of Azadirachtin 1% EC according to the intended GAPs.

3.6.1 Residues

Stability of Residues

The storage stability study demonstrates that Azadirachtin A is stable in tomato for 24 months and potato in 21 months.

Default conversion factor (CF) from enforcement to risk assessment can be used. Therefore no further data are required to support the proposed uses.

Metabolism in plants

No new data submitted in the framework of this application.

Summary of the nature of residues in commodities of plant origin (confirmatory data: *EFSA Journal 2018;16(9):5234*):

Endpoints	
Plant groups covered	No metabolism study available. Surrogate decline study (no labelling) on known components in the technical neem extract available in lettuce.
Rotational crops covered	No data available on the nature of residues in soil.
Metabolism in rotational crops similar to metabolism in primary crops?	No data available on the nature of residues in soil.
Processed commodities	No data available on the nature of residues in processed commodities.
Residue pattern in processed commodities similar to pattern in raw commodities?	No data available on the nature of residues in processed commodities.
Plant residue definition for monitoring	Azadirachtin A
Plant residue definition for risk assessment	Provisional: Azadirachtin (sum of active components in the extract, determined as Azadirachtin A x CF 9) (default) The nature of the residues which are forming from the degrading neem extract in the field is largely unknown and should be further addressed (data gap)
Conversion factor from enforcement to RA	Default CF: 9

Metabolism in livestock: No data available on the nature of residues in livestock. Currently not triggered.

Magnitude of residues in plants

Based on the available confirmatory data, azadirachtin A may be considered as a relevant analytical marker component to characterize residue levels in field samples.

No new data were submitted in the framework of this application. Applicant refers to unprotected EU data.

Proposed use:

2 applications; interval: 7-10 days; BBCH 12-85 (tomato), BBCH 12-91 (potato), BBCH 12-89 (ornamentals); Application rate per treatment: 0.03 kg as/ha (tomato and ornamentals), 0.025 kg as/ha (potato), PHI: 3 (potato and tomato)

Potatoes

Applicant refers to the unprotected EU data.

EU supported GAP for potato (SANTE/11848/2019, 17 July 2020, Rev.1):

1 application, during the vegetation period (independent from growth stage), 0.025 kg as./ha, PHI: 4 days
EFSA, 2018: *As for the representative use in potatoes, one overdosed residue trial investigated potential transport of azadirachtin A from the leaves to tubers, which was not observed (< LOQ). Only three independent field trials in potato are available, all analysing only for azadirachtin A.*

Residues: 3 x <0.01 mg/kg

RA = 3 x < 0.09 mg/kg (CF= 9 following *EFSA Journal 2018;16(9):5234*)

EFSA, 2018: *Risk assessment is indicative but was conducted for residues of known components in the technical neem extract only, while the nature of the residues which are forming from the degrading neem extract in the field is largely unknown and should be further addressed to finalise the assessment (data gap). The use of a conversion factor to the field trials is adding additional uncertainty.*

Residue input values for risk assessment were generated by use of a conversion factor (CF 9)

GAP on which EU first a.s. assessment was based: 1 x 0.025 – 0.625 kg as/ha, BBCH 41-70, PHI 4d, outdoor (Germany, 2008)

Residues: 5x <0.01 mg/kg (Azadirachtin A according to enforcement residue definition)

RA = 5 x < 0.09 mg/kg (CF= 9 following *EFSA Journal 2018;16(9):5234*)

EU critical GAP includes 1 treatment while the applied GAP includes two treatments. Only one treatment with PHI=4 days can be supported by the available data.

The results from field trials indicated that an exceedance of the current MRL of 1 mg/kg for Azadirachtin in potatoes is not expected (provided that 1 application is used and PHI is 4 days).

According to SANTE/2019/12752 8 trial for major crops per zone is required. However, the number of trials can be reduced to 4 in case of residues below LOQ. Therefore, the number of trials on potatoes is acceptable.

July 2022

Applicant submits new residue trials on potatoes to cover uses with 2 applications 0.025 kg a.s./ha and PHI of 3 days. Field phase and analytical methods used are acceptable.

Residues: 4 x <0.003 mg/kg (<LOD)

Samples were stored more than 21 months (demonstrated stability time for high starch content matrix) (data gap). Therefore, these studies cannot be used to evaluate the proposed use on potatoes.

Tomatoes (F)

Outdoor N-EU study can support the proposed uses

Germany, 2008 (Ruch, B., 2005)	N-EU	GAP on which EU a.s. assessment is based: 1-3 x 0.025 kg a.s./ha, BBCH 82-84, PHI 3 days, outdoor: 4x <0.1 mg/kg
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Indoor studies and studies performed in S-EU are not accepted to cover this application.

The results from field trials indicated that an exceedance of the current MRL of 1 mg/kg for Azadirachtin in tomatoes is not expected.

According to SANTE/2019/12752 8 trial for major crops per zone is required. However, the number of trials can be reduced to 4 in case of residues below LOQ. Therefore, the number of trials on tomatoes is acceptable.

Ornamentals

Residue data are not required

Information about residue level in pollen and bee products should be provided by the applicant (minor data gap).

Magnitude of residues in livestock

No data available on the nature of residues in livestock. Currently not triggered (EFSA Journal 2018;16(9):5234).

Following explanation provided by applicant is accepted:

The use of Azadirachtin A does not generate significant residues in potential feeding stuffs and is not likely to accumulate in animal matrices. Moreover, no metabolism data for livestock animal is available and no residue definition in animal matrices is proposed (Germany, 2007).

Therefore, dietary burden is currently not triggered

Under consideration of the low residues of Azadirachtin A found in supervised residue trials and the absence of residue definition in animal matrices, livestock feeding studies are not required.

Magnitude of residues in processed commodities

On the basis of the results of the residue studies provided in the DAR (Germany, 2007) showing that residues at harvest are below 0.1 mg/kg, studies on the effect of industrial processing or house-hold preparation are not considered as relevant and therefore no further study is required.

No data available on the nature of residues in processed commodities (active substance data gap).

Magnitude of residues in representative succeeding crops

No data available on the nature of residues in soil.

According to the information provided during the EU review of Azadirachtin (Germany, 2007), soil degradation studies show that Azadirachtin A degrades rapidly with a mean DT50 value of 10.7 days (median: 3.5 days) and a mean DT90 values of 35.7 days (median: 11.5 days). Thus, no relevant residues are expected in the soil in cases where succeeding crops are planted or sown after harvest of the treated crops. It can therefore be assumed that residues do not accumulate in the plant and that no significant residues

will occur in the plant material at harvest of succeeding crops. Studies on residues in succeeding crops are therefore not required.

3.6.2 Consumer exposure

Consumer risk assessment

The proposed uses of Azadirachtin in the formulation Azadirachtin 1% EC do not represent unacceptable acute and chronic risks for the consumer (see also Appendix 3).

1. TMDI

The exposure values were calculated by using all MRLs and a very conservative conversion factor of 9 to extrapolate from the residue levels of azadirachtin A to the plant residue definition for risk assessment (zRMS calculation, first tier).

The Highest TMDI was 401% ARfD (NL toodler, highest contribution: 97% apples)

Highest intake of Tomatoes: 32% (GEMS/Food G06)

Highest intake of Potatoes: 48% (PT general)

Refined calculation (TMDI)

STMR values derived from the available trials were considered in the risk assessment. Conservative conversion factor of 9 was used (refined calculation).

The Highest TMDI was 3% ARfD (GEMS/Food G06)

2. IESTI

HR values derived from the available trials were considered in the risk assessment. Conservative conversion factor of 9 was used.

IESTI (%ARfD):

9% Tomatoes

2% Potatoes

2.3% Tomatoes / juice

1.1% Tomatoes / sauce/puree

1.4% Potatoes / fried

0.7% Potatoes / dried (flakes)

3.7 Environmental fate and behaviour (Part B, Section 8)

Concentration of Azadirachtin and its relevant metabolites in various environmental compartments are predicted following the proposed use patterns. The predicted environmental concentration (PEC values) in soil, surface water, sediments and ground water are provided.

Table 3.7-1: Intended use pattern of Azadirachtin 1% EC

Crop	Application rate (kg a.s./ha)	Application method	Max. number of applications	Min. application interval	Application timing
Tomato	Azadirachtin: 0.030	Foliar spray	2	7	BBCH 12-85
Potato	Azadirachtin: 0.025	Foliar spray	2	7	BBCH 12-91
Ornamentals	Azadirachtin: 0.030	Foliar spray	2	7	BBCH 12-89

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Azadirachtin and its relevant metabolites using the EU agreed endpoints (EFSA, 2018).

For these calculations, Onion has been chosen as surrogate crop for all the intended uses since the application is linked to the highest application rate and the lowest crop interception.

Maximum PEC_{soil} obtained are reported below:

- Azadirachtin A: 0.066 mg/kg,
- Azadirachtin H: 0.041 mg/kg
- 1,2 decarbometyazadirachtin: 0.005 mg/kg,
- 11 epi azadirachtin D: 0.011 mg/kg,
- Azadirachtin B: 0.020 mg/kg,
- 3 desacetylsalanin: 0.012 mg/kg,
- 6 desacetylnimbin: 0.015 mg/kg,
- Sub 8 (ohchinolide): 0.008 mg/kg,
- Azadiradione: 0.030 mg/kg,
- Nimbin: 0.020 mg/kg,
- Salannin: 0.057 mg/kg,
- 14,15 epoxyazadiradione: 0.011 mg/kg

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} calculations have been conducted with Azadirachtin and its relevant metabolites using the EU agreed endpoints (EFSA, 2018).

All the crops under consideration have been taken into account. Moreover, to cover the ornamentals use grapevine (for bushed ornamentals) and onion (for herbaceous and ornamental flowers) were chosen as surrogate crops. The FOCUS PELMO and PEARL PEC_{gw} for Azadirachtin A and its metabolite Azadirachtin H were below 0.1 µg/L for all crops and scenarios.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{sw/sed} of Azadirachtin and its relevant metabolites have been assessed with the models FOCUS Steps 1, 2, 3 and 4 (when necessary) using the EU agreed endpoints (EFSA, 2018). Please refer to Part B, Section 8, point 8.9 for more details about the results obtained. According the Polish harmonization guidance the calculations in step 4 using VFSSMOD modelling are acceptable. Therefore the PEC_{sw/sed} calculations performed in step 4 by Applicant in NA were accepted.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance Azadirachtin A is < 10⁻⁵ Pa. Hence the active substance Azadirachtin A is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Azadirachtin A due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

After the FOCUS step 4 calculations and RAC of 0.16 microgram/L for *Chironomus riparius* the following risk mitigation measures is needed:

Fruiting Vegetables (Tomato)

- ~~R1 stream: 20 m no spray buffer and 20 m vegetative filter strip~~

Potato

- ~~R1 stream: 20m no spray buffer and 20 m vegetative filter strip.~~

Ornamentals >50 cm

- ~~D3 ditch, D4 stream, R1 stream; 5 m no spray buffer with 50% of nozzles reduction or 10 m no spray buffer.~~

Ornamentals <50 cm

- ~~D3 ditch 5 m no spray buffer.~~
- ~~R1 stream: risk unacceptable. Therefore, further refinement is needed.~~

3.8.1 Effects on terrestrial vertebrates

Birds:

According to the screening tier assessments, a low acute and chronic risk are expected for birds following the intended uses of AZA for all the intended uses assessed in the framework of this application. No risk for birds was identified via drinking water exposure and secondary poisoning via the food chain can be excluded, following the intended uses of AZA, due to the low log Pow values below 3 of the two major fractions Azadirachtin A and B. Moreover, no risk of biomagnification in terrestrial food chain was identified.

Mammals:

According to the screening and first-tier assessments, a low acute and chronic risk are expected for mammals following the intended uses of AZA for all the intended uses assessed in the framework of this application, except for the uses on Ornamentals and fruiting vegetables (Tomato) for which a chronic risk was identified regarding the small herbivorous mammal "vole". However, according to the higher-tier assessment, a low chronic risk is expected for mammals for the intended uses on ornamentals and fruiting vegetables. No risk for mammals was identified via drinking water exposure and secondary poisoning via the food chain can be excluded following the intended uses of AZA, due to the low log Pow values below 3 of the two major fractions Azadirachtin A and B. Moreover, no risk of biomagnification in terrestrial food chain was identified.

3.8.2 Effects on aquatic species

After the FOCUS step 4 calculations and RAC of 0.16 microgram/L for *Chironomus riparius* the following risk mitigation measures is needed:

Fruiting Vegetables (Tomato)

- ~~R1 stream: 20 m no spray buffer and 20 m vegetative filter strip~~

Potato

- ~~R1 stream: 20 m no spray buffer and 20 m vegetative filter strip.~~

Ornamentals >50 cm

- ~~D3 ditch, D4 stream, R1 stream; 5 m no spray buffer with 50% of nozzles reduction or 10 m no spray buffer.~~

Ornamentals <50 cm

- ~~D3 ditch 5 m no spray buffer.~~
- ~~R1 stream: risk unacceptable. Therefore, further refinement is needed.~~

Fruiting Vegetables (Tomato): Spe3 – To protect aquatic organisms, respect an unsprayed vegetated

buffer zone of 5m to surface water bodies.

Potato: Spe3 – *To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.*

Ornamentals >50 cm: Spe3 – *To protect aquatic organisms, respect an unsprayed buffer zone of 5m to surface water bodies with 50% of nozzles reduction OR an unsprayed buffer zone of 10m to surface water bodies.*

Ornamentals < 50 cm: Spe3 – *To protect aquatic organisms, respect an unsprayed vegetated buffer zone of 5m to surface water bodies.*

3.8.3 Effects on bees

First-tier assessments indicate that no unacceptable risk for bees exposed to the product AZA is expected according to the proposed intended uses. According to EU Reg. 284 /2009, the chronic toxicity test for adult bees and the chronic test for larvae ~~should be~~ are provided for authorization of plant protection product. ~~for Poland when GD for Bees will be applied at EU level.~~

3.8.4 Effects on other arthropod species other than bees

No in-field and off-field risk to non-target arthropods is expected after the application of AZA according to the proposed GAP.

3.8.5 Effects on soil organisms

The TER_{it} value for AZA formulation is higher than the Annex VI trigger value of 5, indicating a low long-term risk to earthworms. The TER calculated is far above the trigger and, therefore, the Applicant considers that an acceptable risk to *Folsomia candida* and *Hypoaspis aculeifer* can be concluded on the basis that low risks to other soil macro-organisms was concluded.

Risk assessments conducted with relevant PEC_{soil} for the active substance Azadirachtin and AZA formulation indicated a low risk to soil microorganisms.

3.8.6 Effects on non-target terrestrial plants

The TER_{LT} values from seedling and vegetative vigor test for non - target plants were achieved the trigger value of 5 indicating an acceptable risk. No mitigation measures are required to non-crop area.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No inhibition of respiration of activated sewage sludge of >10 % was observed up to the highest tested concentration of 1000 mg Neem Azal (34% Azadirachtin A)/L. NOEC is therefore >1000 mg/L for Azadirachtin. It is not expected that Azadirachtin reaches biological sewage treatment plants at higher concentrations. Therefore, the risk to biological methods of sewage treatment is expected to be low from the intended uses.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolite Azadirachtin H is predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR section B8, point 8.8.2.1). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 should therefore not be required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant since Azadirachtin is not classified as Candidate for Substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Skuteczność:

Zastosowanie na roślinach ozdobnych oraz na pomidorze przeciw wciornastkom i aleuroidom może być tylko uwzględnione w etykiecie na podstawie Artykułu 51. Brak możliwości zaakceptowania tych zastosowań w trybie art. 33. Zmiany te wprowadzono do etykiety już podczas oceny środka. W trakcie komentowania uzupełniono tylko tabelę o informacje nt, wprowadzonych zmian.

Pozostałości:

Ziemniak: zaakceptowano maksymalnie 1 zabieg w sezonie. Zaakceptowano PHI =4 dni

Los: bez uwag

Ekotoksykologia: Przekreślono zarządzanie ryzykiem dla organizmów wodnych w przypadku roślin ozdobnych, ze względu na brak zgody na to zastosowanie przez Sekcję Skuteczności.

Załącznik do zezwolenia MRiRW nr R -/..... z dnia2020

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center Carril Condomina n°3, 12th Floor, 30006 Murcia, Hiszpania tel. +34868127589, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail: eu.sales@shardaintl.com.

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: (...)

AZA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Azadyrachtyna A (substancja z grupy limonoidów) - **10 g/l (1,04%)**

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.

	
H411	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P501	Zawartość, pojemnik usuwać do firm posiadających odpowiednie uprawnienia.

OPIS DZIAŁANIA

AZA jest insektycydem w formie koncentratu do sporządzania emulsji wodnej o szerokim spektrum działania. Środek stosuje się do zwalczania owadów ssących, gryzących oraz minujących w formie oprysku nalistnego.

AZA na roślinie wykazuje działa wgłębne, a na zwalczanych organizmach żołądkowe. Aktywność owada ustaje w ciągu kilku godzin po spożyciu. Formy larwalne zaprzestają żerowania i zatrzymuje się ich rozwój, co ostatecznie po kilku dniach prowadzi do ich śmierci. Formy dorosłe zaprzestają żerowania, ograniczona jest ich płodność oraz w mniejszym stopniu śmiertelność.

Zgodnie z klasyfikacją IRAC substancja czynna azadyrachtyna A należy do grupy o nieznanym lub niespecyficznym mechanizmie działania (grupa IRAC UN).

STOSOWANIE ŚRODKA

Pomidor

~~Aleuroidy, wełniarnastki~~, mszyce

Maksymalna dawka dla jednorazowego zastosowania: 3 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3 l/ha

Liczba zabiegów: 2

Termin stosowania środka: stosować po pojawieniu się insektów, od początku fazy drugiego liścia do fazy gdy 50% owoców uzyskuje typową barwę (BBCH 12-85)

Zalecana ilość wody: **750-1000 l/ha**.

Odstęp między zabiegami: 7-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Ziemniak

Stonka ziemniaczana

Maksymalna dawka dla jednorazowego zastosowania: 2,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 2,5 l/ha

Liczba zabiegów: ~~2~~ 1

Termin stosowania środka: stosować po pojawieniu się insektów, od początku fazy drugiego liścia do początku żółknięcia liści (BBCH 12-91)

Zalecana ilość wody: **500-1000 l/ha**.

Odstęp między zabiegami: 7-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~2~~ 1

Rośliny ozdobne

Aleuroidy, wciornastki, mszyce

Maksymalna dawka dla jednorazowego zastosowania: 3 l/ha

Zalecana dawka dla jednorazowego zastosowania: 3 l/ha

Liczba zabiegów: 2

Termin stosowania środka: stosować po pojawieniu się insektów (BBCH 12-89)

Zalecana ilość wody: 750-1000 l/ha.

Odstęp między zabiegami: 7-10 dni

Zalecane opryskiwanie: **średniokropliste**

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

Środka nie stosować:

- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszałem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza nie wyposażonego w mieszało hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ~~ochronną~~ roboczą (kombinezon), ~~zabezpieczającą przed oddziaływaniem środków ochrony roślin~~ w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Pomidor

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie ~~zadarnionej~~ strefy ochronnej o szerokości ~~5~~ **20**m od zbiorników i cieków wodnych.

Ziemniak

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie ~~zadarnionej~~ strefy ochronnej o szerokości ~~5~~ **20**m od zbiorników i cieków wodnych.

Rośliny ozdobne (o wysokości powyżej 50 cm)

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych z jednoczesnym zastosowaniem rozpylaczy redukujących znośzenie cieczy użytkowej podczas zabiegu o 50%

LUB

wyznaczenie strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych

Rośliny ozdobne (o wysokości poniżej 50 cm)

SPe3

W celu ochrony organizmów wodnych konieczne jest wyznaczenie ~~zadarnionej~~ strefy ochronnej o szerokości ~~5 m~~ **20 m** od zbiorników i cieków wodnych

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie dotyczy

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Pomidor, ~~ziemniak~~ – 3 dni

Ziemniak: 4 dni

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,

- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - **1 rok**
Data produkcji -
Zawartość netto -
Nr partii -

Appendix 3 Letter of Access

Not relevant.

Appendix 4 Lists of data considered for national authorization

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	Verte-brate study Y/N	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.1	Sreelola Vutpala, M.	2019	DETERMINATION OF EXPLOSIVE PROPERTIES OF AZADIRACHTIN 1% EC Report No G12473 Eurofins Advinus GLP Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 2.2.2	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	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 2.5.1	Sreelola Vutpala, M.	2019	DETERMINATION OF VISCOSITY OF AZADIRACHTIN 1% EC Report No G12476 Eurofins Advinus GLP Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 2.5.2	Sreelola Vutpala, M.	2019	SURFACE TENSION OF AQUEOUS SOLUTION/SUSPENSION OF AZADIRACHTIN 1% EC Report No G12477 Eurofins Advinus GLP Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 2.6.1	Sreelola Vutpala, M.	2019	DETERMINATION OF DENSITY OF AZADIRACHTIN 1% EC Report No G12478 Eurofins Advinus GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Azadirachtin 1% EC (10 g/kg azadirachtin) – EU Central zone Sharda Cropchem España -, - Unpublished			Data/study report never submitted before on Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 8.3.1.1	G. Wagner	2021	Determination of the residues of Azadirachtin in/on potato after two applications of Azadirachtin 1% EC in Northern Europe – Hungary in 2019. Report No. 034SRHU19R08 GLP	N	Y	Data/study report never submitted before on Poland	Sharda Cropchem Ltd.
KCP 8.3.1.2	S. Niewelt	2021	Determination of the residues of Azadirachtin in/on potato, after application of Azadirachtin 1% EC in Northern Europe – Hungary in 2019, Report No. DPL/60/2020 GLP	N	Y	Data/study report never submitted before on Poland	Sharda Cropchem Ltd.
KCP 8.3.1.3	T. Peda	2021	Magnitude of the residue of azadirachtin in potato Raw Agricultural Commodity after two applications of Azadirachtin 1% EC – one decline curve trial in Poland, Report No. 19SGS05 GLP	N	Y	Data/study report never submitted before on Poland	Sharda Cropchem Ltd.
KCP 8.3.1.4	K. Rump	2021	Determination of residues at harvest of Azadirachtin in Potato, following two broadcast applications of Azadirachtin 1% EC, under open field conditions. Germany – Season 2019, Report No. FRS 012/19	N	Y	Data/study report never submitted before on Poland	Sharda Cropchem Ltd.
KCP 8.3.1.5	S. Niewelt	2021	Determination of residues at harvest of Azadirachtin in Potato following broadcast application of Azadirachtin 1% EC, under open field conditions. Germany – season 2019. Report No. DPL/58/2020 GLP	N	Y	Data/study report never submitted before on Poland	Sharda Cropchem Ltd.
KCP 10.3.1.1.2	Parma, P.	2018	Azadirachtin 1% EC Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Study No. B/53/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.3.1.2	Prabha, K.L.	2022	Chronic Oral Toxicity Study of Azadirachtin 1% EC on adult honey bee (<i>Apis mellifera</i>), Study No. 9036/2021 Bioscience Research Foundation GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.3.1.3	Prabha, K.L.	2022	Effect of Azadirachtin 1% EC on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Study No. 9035/2021 Bioscience Research Foundation GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2-01	Lemańska, N.	2019	An extended laboratory test for evaluating the effects of Azadirachtin 1% EC on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) Study No. B/54/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.4.1.1	Wróbel, A.	2020	Azadirachtin 1% EC Earthworm Reproduction Test (<i>Eisenia andrei</i>) Study No. G/03/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.5.1	Dec, W.	2018	Azadirachtin 1% EC Soil Microorganisms: Nitrogen Transformation Test Study No. G/02/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.5.2	Dec, W.	2018	Azadirachtin 1% EC Soil Microorganisms: Carbon Transformation Test Study No. G/01/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.6.2-01	Wróbel, A.	2020	Azadirachtin 1% EC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study No. G/06/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	SHARDA Cropchem Limited
KCP 10.6.2-02	Wróbel, A.	2020	Azadirachtin 1% EC Terrestrial Plant Test: Vegetative Vigour Test Study No. G/07/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP, Unpublished	N	Y	Data/study report never submitted before on Poland	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS : Data protection started with: <insert authorization number of first authorization>	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS : Data protection started with: <insert authorization number of first authorization>	Owner