

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: SHA 123000 A

Product name: AZA

Chemical active substance:

Azadirachtin, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 03/2022

## Version history

When	What
March 2022	Assessment by expert

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

This application is submitted by SHARDA Cropchem España S.L. for approval of Azadirachtin 1% EC, an emulsifiable concentrate formulation containing 10 g/L of Azadirachtin for use as insecticide on strawberry, citrus, tomato, potato and melon in southern Europe.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
<b>Central zone</b>	Poland AZA	–
<b>Southern zone</b>	Malta AZA	–

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Azadirachtin

**Table 0.1-2: Summary of regulatory history of CAS No: 11141-17-6**

<b>Status</b>	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Directive 2011/44/EU or Commission Implementing Regulation (EU) 2018/1266 and Commission Implementing Regulation (EU) No 540/2011 Reg. (EU) 2020/2007 Reg. (EU) 2020/1293
RMS	Germany (Spain as co-RMS)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2011

<b>Status</b>	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.11.2011
Date of final Commission (re-registration) deadline (Step 2)	31.05.2015
Current expiration of approval	<del>31.05.2021</del> 31.08.2024
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the dietary exposure of consumers in view of future revisions of Maximum Residue Levels;
- the protection of non-target arthropods and aquatic organism. Risk mitigation measures should be applied where appropriate.

The SANCO report for Azadirachtin (SANCO/10311/2011 final – 11/03/2011) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 15/03/2018 (EFSA Journal 2018;16(9):5234).

**Table 0.1-3: Information on minimum purity of Azadirachtin**

<b>EU agreed minimum purity from Inclusion Directive or Implementing regulation</b>	<b>(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **</b>
minimum purity of Azadirachtin A (TK) ≥ 111 g/kg	minimum purity of Azadirachtin A 322 g/kg Equivalence report available: Y/N RMS: Germany

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\* If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The information on the equivalence of the active substances sources has been provided by the Applicant to the Polish Ministry of Agriculture and Rural Development and assessed and approved by the Ministry during the completeness check.

The endpoints used in the evaluation are in line with EU endpoints.

#### **0.1.4 Regulatory history of the product**

Not relevant as the product has not yet been authorised

#### **0.2 zRMS conclusion**

Uses to be considered safe on the basis of EU methodology:

Efficacy section: 1-3 Mammalian toxicology section: Residues section: 1-3 Environmental fate and behavior section: 1-3 Ecotoxicology section: 1-3 with restriction for some scenarios for aquatic organism
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Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none  
Mammalian toxicology section:  
Residues section: none  
Environmental fate and behavior section: none  
Ecotoxicology section: Fruiting vegetables (tomato) R3 and R4 scenarios should be further refined for aquatic organism.  
Ornamentals<50 cm: D6 ditch, R1 stream and R4 stream scenarios should be further refined for aquatic organism.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

Further refinement should be considered for some scenarios for aquatic organism ( risk for Chironomus riparius). The final risk mitigation measures should be provided at MSs level.

The following text is to be shortened or to be amended as necessary.

**Metabolism and residue:**

All uses/ GAPs are covered by established MRLs

Conclusions:

**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.

**Mammalian 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

**Metabolism and residues section:**

Potatoes: Max 1 application

PHI=4

**Fate section:**

There is no risk to groundwater after the application of the product.

**Ecotox section:**

The risk for non-target organisms is considered acceptable with restriction for some scenarios for aquatic organisms.

## **Appendix 1 ALL intended uses**

GAP rev. 0, date: 2017-September-12<sup>th</sup>

PPP (product name/code): Azadirachtin 1% EC  
Active substance 1: Azadirachtin  
Safener: -  
Synergist: -  
Applicant: Sharda Cropchem España S.L.  
Zone(s): Central <sup>(d)</sup>  
Verified by MS: **yes**

Formulation type: EC (Emulsifiable Concentrate) <sup>(a, b)</sup>  
Conc. of as 1: 10 g/L <sup>(c)</sup>  
Conc. of safener: - <sup>(c)</sup>  
Conc. of synergist: - <sup>(c)</sup>  
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. <sup>(e)</sup>	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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					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		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	CEU	<b>Tomato</b>	F	<i>Aleuroids, Thrips, Aphids</i>	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
2	CEU	<b>Potato</b>	F	Collorado beetle ( <i>Leptinotarsa decem- lineata</i> )	Foliar Spray	Apply at pest presence BBCH 12-91	<del>a) 2</del> <del>b) 2</del>  I	<del>7-10</del>	a) 2.5 <del>b) 5.0</del>	a) 0.025 <del>b) 0.05</del>	500- 1000	<del>3</del>  4	Residues section: 1 application PHI=4
3	CEU	<b>Ornamentals</b>	F	<i>Aleuroids, Thrips, Aphids</i>	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	

**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.

<b>Remarks</b>	1	Numeration necessary to allow references	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
<b>columns:</b>	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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