FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

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; May 2021

MS Finalisation date: 12/2020; 07/2021; 03/2023

Version history

When	What
12/2020	Finalisation of the assessment by zRMS
May 2021	The product name was corrected (ASSET instead of Zuxion)
July 2021	ZRMS made changes according to commenting period.
March 2023	Assessment in relation to updated Section B7

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of ASSET ~~ZUXION~~, a water-soluble granule formulation (SG) containing 200 g/kg acetamiprid, for use as insecticide in oilseed rape and pome fruits.

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)**
Northern zone	-	-
Central zone	Poland, ASSET ~~ZUXION~~	Romania, Hungary ASSET ~~ZUXION~~
Southern zone		
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Acetamiprid

Table 0.1-2: Summary of regulatory history of CAS No: 160430-64-8

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Original inclusion: Commission Directive 04/99/EC Renewal: Commission Implementing Regulation (EU) No 2018/113
RMS	RMS: Netherland, Co-RMS: Spain
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/03/2018

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01/06/2018
Date of final Commission (re-registration) deadline (Step 2)	01/06/2019
Current expiration of approval	28/02/2033
Low risk substance or Candidate for Substitution?	N/A

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

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

- the risk to aquatic organisms, bees and other non-target arthropods,
- the risk to birds and mammals,
- the risk to consumers,
- the risk to operators.

Conditions of use shall include risk mitigation measures, where appropriate.

The renewal report (SANTE/10502/2017 Rev 4 13 December 2017) for acetamiprid is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is available for the renewal of the approval (EFSA Journal 2016;14(11):4610).

Table 0.1-3: Information on minimum purity of Acetamiprid

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
990 g/kg	minimum purity of active substance: 990 g/kg Equivalence report available: Y RMS: UK

* 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 following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Acetamiprid**	
	EU agreed endpoint from EFSA Journal 2016;14(11):4610	**Endpoint used***
Dermal absorption	Concentrate: 0.6% Field dilution: 8% (Determinated on Acetamiprid 20 SG, 200 g/kg, in an *in vitro* dermal penetration study in human skin)	Concentrate (250 g/kg): 0.83% Spray dilution (0.05 g/L): 35% (Determinated on ASSET ~~ZUXION~~, *in vitro* human skin study)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

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: 1-2
Residues section: 1- 2
Environmental Fate section: 1-2
Ecotoxicology section: 1- 2(~~with restrictions~~)

Uses to be considered non-safe on the basis of EU methodology:
Efficacy section: none
Residues section: none
Environmental Fate section: none
Ecotoxicology section~~: 1~~ 2 with restrictions*

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with identified risk.

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:

Metabolism and Residues section: ~~1~~ none
~~Metabolism and Residues section: Registration in the protection of oil seed rape will be possible after completing the equivalent studies to the following protected studies (see Data matching, The Netherlands, 2018):~~
~~Raufer, B., 2013, 2014 and Hobbs, G., Inns, L., 2012~~

Ecotoxicology section: The risk mitigation measures for aquatic organism and for non - target arthropods should be considered at MS level. *Further refinement is required for long-term risk assessment for frugivorous mammals if DF is not applied for 2 application x 36 g a.s./ha in late orchards. ~~mammals (vole) and for aquatic organism for max application rate: 2x 50 g a.s./ha for orchards. *~~The final decision should be considered at MSs level.

Metabolism and Residues section:
All uses/ GAPs are covered by established MRLs.

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Physical and chemical properties section:
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

Efficacy section:

The Applicant applied for Zuxion, so dRR is with the name Zuxion. But since there is already a complex plant protection product with this name (Zuxion) he had to change the name of product. So, the new one is Asset.

cMS from N-E, Maritime and S-E EPPO zone should decide if extrapolation results from another climatic zone (MED) can be accepted for pear. For Poland is not possible. At least 1-2 efficacy trials carried out on perry against aphids in Poland or neighbouring country is needed. Only according to Article 51 pear without trials can be accepted in Poland as a minor crop. Regarding the use on pome fruits against aphids applicant would like to refer to EPPO extrapolation tables PP 1/257 IEET 3 (2) Extrapolation table for effectiveness of insecticides, Pest on pome fruit where on the use against aphids is presented Apple as Indicator crop and extrapolation to the whole group of pome fruits is permitted. According to this, applicant would like to request evaluator to consider extrapolation from apple to the whole group of pome fruits as acceptable. Possibility of extrapolation should be consider by each cMS, in the opinion of Evaluator. On the basis of evaluation performed by section of Ecotox, only dose 0,18 kg/ha once or twice a season in pome fruits can be accepted. As a result, we believe that a dose of 0.18 kg/ha should be appropriate (observed sufficient effectiveness) and at the same time capable of being acceptable.

Toxicology section:
Classification and labelling of SHA5500A is acceptable (Acute Tox. 4/H302, Repr.2/H361d). No risk for operator, worker, resident/bystander.

Metabolism and Residues section:
Registration in the protection of oil seed rape will be possible after completing the equivalent studies to the following protected studies (see Data matching, The Netherlands, 2018):
Raufer, B., 2013, 2014 and Hobbs, G., Inns, L., 2012
Alternative studies have been provided.
According to the current requirements (SANTE/11956/2016 rev. 9), information on residues in honey is required. Such information can be provided after authorization is obtained.
~~Ecotoxicology Section:~~
~~Further refinement is required for long-term risk assessment for mammals (vole) and for aquatic organism for max application rate: 2x 50 g a.s./ha for orchards.~~

Appendix 1 ALL intended uses

PPP (product name/code):	ASSET (ZUXION)/SHA 5500 A	Formulation type:	SG (Water Soluble Granules)
Active substance 1:	Acetamiprid	Conc. of as 1:	200 g/kg
Active substance 2:	-	Conc. of as 2:	-
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem España S.L	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/~~no~~		
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: developmental 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	**Oilseed Rape**	F	Pollen Beetle (*Meligethes aeneus)*	Foliar spray	At pest presence. Before BBCH 69	a) 1 b) 1	NA	a) 0.2 b) 0.2	a) 0.04 b) 0.04	200-600	28	Metabolism and Residues Use is accepted
~~2~~	~~CEU~~	~~**Pome fruits**~~	~~F~~	~~Aphids~~	~~Foliar spray~~	~~At pest presence, Before BBCH 59 and from BBCH 69~~	~~a) 2~~ ~~b) 2~~	~~14~~	~~a) 0.25~~ ~~b) 0.5~~	~~a) 0.05~~ ~~b) 0.10~~	~~900-1000~~	~~14~~	~~Further refinement required for long-term risk for frugivorous mammals. Ecotoxicology section.~~

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		
2	CEU	**Pome fruits**	F	Aphids	Foliar spray	~~At pest presence,~~ ~~Before BBCH 59~~ and from BBCH 69	a) 1-2 b) 1-2	14	a) 0.18***- ~~0.25~~ b) 0.36***-~~0.5~~	a)0.036-~~0.05~~ b) 0.072***-~~0.10~~	900-1000	14	~~For max application dose 2 x 50 g a.s./ha further refinement of long-term risk for mammals (vole) and further refinement for Chironomus riparius is required~~ Section Ecotoxicology~~:~~ The max acceptable rates for orchards is 1-2 36 g a.s./ha with BBCH>69