

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 0**

Product Background, Regulatory Context and  
GAP information

Product code: SHA 9700 A

Product name: RULER

Chemical active substance:

Fenazaquin, 200 g/L

Interzonal

Zonal Rapporteur Member State: Poland

### **CORE ASSESSMENT**

Applicant: Sharda Cropchem España S.L.

Submission date: May 2019

Update date: May 2020

MS Finalisation date: 10/2020; 05/2021; 07.2022

## Version history

When	What
May 2020	Update by Applicant
October 2020	Assessment by the experts
May 2021	Final Version
July 2022	Assessment after the source equivalence assessment of active substance (fenazaquin) has been completed.

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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 CROP CHEM ESPAÑA S.L. for approval of RULER, a suspension concentrate formulation containing 200 g/l fenazaquin for use as an acaricide on melon, ornamentals, tomato and strawberry in 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)
Interzonal	Poland RULER	Poland, Greece, Spain RULER

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

**Table 0.1-2: Summary of regulatory history of CAS No: 20427-59-2**

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Original inclusion: Commission Directive 2011/39/EU Commission Implementing Regulation (EU) Reg. (EU) No 2018/1266
RMS	RMS: Germany, Co-RMS: Poland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/06/2011
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	
Current expiration of approval	31/05/2023
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:

- (a) the protection of aquatic organisms;
- (b) the protection of operators, also ensuring that the conditions of the use include the application of adequate personal protective equipment;
- (c) the protection of bees;
- (d) the risk to bees and bumble bees released for pollination, when the substance is applied in glass-houses;
- (e) the risk to consumers, in particular from the residues generated during processing;
- (f) the conditions of use to avoid exposure to residues of fenazaquin with respect to crops for human and animal consumption.

The SANCO report for fenazaquin (SANCO/10324/2011–11/03/2011) 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 2013 (EFSA Journal 2013;11(4):3166).

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

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 *, **
975 g/kg (Regulation EU 2018/1266)	minimum purity of active substance: 985 g/kg Equivalence report available: Y RMS: Poland

\* 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 endpoints used in the evaluation are in line with EU endpoints.

#### **0.1.4 Regulatory history of the product (if relevant)**

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: 1-4

Residues section: 2

Environmental Fate section: 1-4

Ecotoxicology section: 1-4

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

Efficacy section: none

Residues section: 1, 3, 4

Environmental Fate section: none

Ecotoxicology section: none

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:

Section Ecotoxicology:

The product Ruler cannot be used in IPM program in glasshouse.

Residues section:

Uses on Melons, Tomato, Strawberry are not covered by established MRLs.

More details of the overall summary of the assessment:

### Physical and chemical properties section:

The evaluation of the application for RULER resulted in the decision to grant the authorization.

Shelf life – 1 year.

Recommended packaging: HDPE and PET are accepted.

### Efficacy section:

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product (a.s. fenazaquin) in their own Member State. Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.

### Residues section:

Noticed data gaps are:

- Additional information on TBPE stability in the high water content matrix.
- Residue trials on melons, tomato and strawberry.
- Additional information on processed commodities to cover proposed uses.
- Consumer risk assessment for fenazaquin and TBPE.

### Toxicology section:

Classification and labelling of RULER is acceptable (Acute Tox. 4/H302).

No risk for operator, worker in relation to RULER (SHA9700 A) indicates that there is no unacceptable risk when the product is used in accordance with the specified PPE for the label.

## Appendix 1 ALL intended uses

GAP rev. 0, date: 2018-January-10th

PPP (product name/code): Fenazaquin 20% SC  
Active substance 1: fenazaquin  
Active substance 2:  
Safener: -  
Synergist: -  
Applicant: SHARDA Cropchem España  
Zone(s): CEU/SEU/NEU  
Verified by MS: yes/no

Formulation type: SC (Suspension Concentrate)  
Conc. of as 1: 200 g/L  
Conc. of as 2:  
Conc. of safener: -  
Conc. of synergist: -  
Professional use: ☒  
Non professional use: ☐

Field of use: only glasshouse Insecticide  
uses\*:

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: develop- mental 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		



Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU/SEU/NEU	Melon	G	Spider mites	Foliar Spray	Pest presence BBCH 70-79	a) 1 b) 1	NA	a) 1 b) 1	a) 0.2 b) 0.2	1000	7	
2	CEU/SEU/NEU	Ornamentals	G	Spider mites	Foliar Spray	Pest presence BBCH 35-67	a) 2 b) 2	7-10	a) 1 b) 2	a) 0.2 b) 0.4	1000		
3	CEU/SEU/NEU	Tomato	G	Spider mites	Foliar Spray	Pest presence BBCH 51-89	a) 2 b) 2	7-10	a) 1 b) 2	a) 0.2 b) 0.4	1000	3	
4	CEU/SEU/NEU	Strawberry	G	Spider mites	Foliar Spray	Pest presence BBCH 15-91	a) 2 b) 2	7-10	a) 1 b) 2	a) 0.2 b) 0.4	1000	3	
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

**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 columns:</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
	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	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

\*Permament covered crops were only considered in the risk assessment on area on Ecotoxicology and fate and behaviour