

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 9700 B

Product name: RULER 10 EC

Chemical active substance:

Fenazaquin, 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: July 2019

Update date: May 2020; Update date: December 2021;

February 2022; March 2023

Version history

When	What
May 2020	Update by Applicant
November 2021	Assessment by expert
December 2021	Applicant update
February 2022	RMS Assessment
March 2022	Reassessment after applicant's additions

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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 10 EC, a emulsifiable concentrate formulation containing 100 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 10 EC	Poland RULER 10 EC

0.1.3 Regulatory history of the active(s)

0.1.3.1 Fenazaquin

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

Status	
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: 985 984 g/kg Equivalence report available: No. Evaluation ongoing Yes RMS: Spain 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: 2-4
Residues section: 2, 4
Environmental fate and behavior section: 1-4

Ecotoxicology section: 1-4

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

Efficacy section: 1 (open-field trials carried only in MED EPPO zone are not representative for glass-house use in all EPPO zones)
Residues section: 1,3,
Environmental fate and behavior section: none
Ecotoxicology section: none

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

zRMS conclusions.

Mammalian toxicology section:

Classification and labelling of RULER is acceptable (H302, H304). No risk for operator, worker in relation to RULER 10 EC indicates that there is no unacceptable risk when the product is used in accordance with the specified PPE for the label.

Phys-chem section:

The evaluation of the application for Ruler 10 EC resulted in the decision to grant the authorization.

Shelf life – 2 years.

Classification from the physicochemical point of view: H 304. Repeated exposure may cause skin dryness or cracking. [EUH066].

Mixture contains a total of 10% or more of substance of substances classified in Aspiration toxicity Category 1 and has kinematic viscosity of 20.5 mm²/s or less, the product / RULER 10 EC has to be classified as **Aspiration toxicity (Category 1) – H304**

Recommended packaging: HDPE/EVOH COEX are accepted.

Efficacy Section:

use 1 should not be registered in the opinion of Evaluator, open-field trials carried out only in MED EPPO zone are not relevant for glasshouse use in different EPPO zones (N-E, S-E or Maritime). However final decision is left to each cMS. In the opinion of Evaluator only open-field use on melon in MED EPPO zone can be accepted.

Metabolism and 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.
- **Melon:** Application rate per treatment in the residue trials is too low to cover the proposed in GAP. Acceptable application rate per treatment is 0.15 kg.a.s./ha. Additional information on TBPE stability in the high water content matrix is required.
- **Tomato:** Application rate per treatment in the residue is too low to cover the proposed in GAP. Acceptable application rate per treatment is 0.15 kg.a.s./ha. Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1. Additional information on TBPE stability in the high water content matrix is required.
- **Strawberry:** Number of applications in the residue trials is too low to cover the proposed in GAP. Acceptable number of applications is 1.

Appendix 1 ALL intended uses

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

PPP (product name/code): Fenazaquin 10% EC
Active substance 1: fenazaquin
Active substance 2:
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España
Zone(s): CEU/SEU/NEU
Verified by MS: yes

Formulation type: EC (Emulsifiable Concentrate)
Conc. of as 1: 100 g/L
Conc. of as 2:
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

Field of use: Glasshouse only*

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: develop- mental 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/SEU/NEU	Melon	G	Spider mites	Foliar Spray	Pest presence BBCH 70-79	a) 1 b) 1	NA	a) 2 b) 2	a) 0.2 b) 0.2	1000	7	Not accepted (section B7)
2	CEU/SEU/NEU	Ornamentals	G	Spider mites	Foliar Spray	Pest presence BBCH 35-67	a) 2 b) 2	7-10	a) 2 b) 4	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) 2 b) 4	a) 0.2 b) 0.4	1000	3	Not accepted (section B7)
4	CEU/SEU/NEU	Strawberry	G	Spider mites	Foliar Spray	Pest presence BBCH 15-91	a) 2 1 b) 2 1	7-10	a) 2 b) 4 2	a) 0.2 b) 0.4 0.2	1000	3	Not accepted accepted (section B7) Acceptable number of applications is 1.
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													

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

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	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/m³ 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