

FINAL REGISTRATION REPORT

Part A

Risk Management

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: June 2019

MS Finalisation date: 11/2020; 05/2021

Version history

When	What
November 2020	Corrected efficacy section and label project
May 2021	Final Version

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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 Fenazaquin 20% SC, a suspension concentrate containing 200 g/L of Fenazaquin, as acaricide on melon, ornamentals, tomato and strawberry in greenhouse.

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 Fenazaquin 20% SC 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 9700 A
Product name in MS	RULER
Authorization number	First authorisation
Function	Acaricide
Applicant	SHARDA Cropchem España S.L.
Active substance(s) (incl. content)	Fenazaquin, 200 g/L
Formulation type	Suspension concentrate [Code: SC]
Packaging	100 mL PET; 500 mL and 1L HDPE, professional user
Coformulants of concern for	-

national authorizations	
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for Fenazaquin 20% SC resulted in the decision to grant the authorization **on ornamentals only.**

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:	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1
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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:	GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	H302, H400, H410
Precautionary statement(s):	P273, P280, P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazolin-3-one (2634-33-5). May produce an allergic Reaction [EUH208]

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:	
e.g. EUH 208	Contains 1,2-benzisothiazolin-3-one (2634-33-5). May produce an allergic Reaction

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). Dangerous to bees. Do not use where bumble bees are pollinators.
SP8	

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:	
P280	Work wear (arms, body and legs covered) M/L+ gloves M/L and A +RPE (filtertype 2)
Worker protection:	
P280	Toamto, melon, strawberry - Work wear (arms, body and legs covered) and gloves Ornamentals - Work wear (arms, body and legs covered) and gloves – time period of 4 days after application
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-
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.
-	-	-

Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Fenazaquin 20% SC
Active substance 1: Fenazaquin
Active substance 2: -
Safener: -
Synergist: -
Applicant: Sharda Cropchem España S.L.
Zone(s): Interzonal
Verified by MS: yes

GAP rev. 0, date: 2018-January-10th
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: Insecticide
only glasshouse uses:

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		
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)													
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	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) 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	Not accepted (section B7)
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	Not accepted (section B7)

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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/m ³ 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

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 product is not explosive. The product is not flammable/has a flash point of 98.8 °C. It has a self ignition temperature of 600.2 ± 0.1 °C.

According to accelerated storage stability study in HDPE/PA COEX packagings 1-year shelf life is accepted.

The intended concentration of use is 0.0002% of active substance.

3.2 Efficacy (Part B, Section 3)

Fenazaquin 20% SC is a Suspension Concentrate (SC) containing 200 g/L fenazaquin for use in melon, strawberry, tomato and ornamentals. It is used to control spider mites.

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

- One application in melon to control spider mites, target rate: 0.2 L/ha
- Two applications in Ornamentals to spider mites, target rate: 0.2-0.4 L/ha
- Two application in Tomato to control spider mites, target rate: 0.2-0.4 L/ha
- Two application in Strawberry to control spider mites, target rate: 0.2-0.4 L/ha

This document serves the registration of Fenazaquin 20% SC in the Central, Northern and Southern zone of the EU. The objective of this document is to prove and support the label claims of the pesticide efficacy and crop safety of Fenazaquin 20% SC in melon, strawberry, tomato and ornamentals, as claimed in the GAP table.

Comprehensive field trials were conducted in 2017 season in a range of European countries in the Mediterranean (i.e. Spain, Italy and Greece), South-East (i.e. Romania), North-east (i.e. Poland) and Maritime (i.e. Germany) EPPO zones. The trials followed the corresponding EPPO guidelines, in exception of EPPO 1/181 (4). However, Applicant has made the appropriate explanation for carrying out the survey only in one growing season, which was accepted by Evaluator.

3.3 Efficacy data

Preliminary tests

The activity of fenazaquin is well known, as it has been marketed since 2011 to control mites in many crops. Based on the knowledge about the active substance and the experiences with Fenazaquin 20% SC in the GAP claimed crops at the proposed dose rates, 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

Field trials were established in order to determine the minimum effective dose for the control of the key target claimed in this dossier. In the following, summaries of the performance of Fenazaquin 20% SC on key pests in melon, strawberry, tomato and ornamentals are presented. It is not necessary to demonstrate

the minimum effective dose on all target pests but only those that are considered key and therefore drive the overall dose rate when a product such as Fenazaquin 20% SC is used.

Fenazaquin was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Fenazaquin 20% SC applied at different dose rates was evaluated in 6 melon trials, 11 strawberry trials, 14 tomato trials and 18 ornamentals trials. In all trials, Fenazaquin 20% SC was applied at 0.5, 0.75 and 1.0 L/ha. These ranges reflect 50%, 75% and 100% of the full recommended rate of Fenazaquin, in accordance with the EPPO guideline PP 1/225(1) "Minimum effective dose". The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product.

Data are presented across the EU South zone, EU Central zone and EU North zone, i.e. trials were conducted in the Mediterranean (i.e. Spain, Greece and Italy), South-East (i.e. Romania), North-east (i.e. Poland) and Maritime (Germany) EPPO zones. Studies from the four climatic zones are used in this document to support the registration of Fenazaquin 20% SC. However, most of the studies are performed in a glasshouse, all of them have been grouped in the same tables, without specifying the climatic zone where they were performed.

Conclusion: Fenazaquin 20% SC applied at 1.0 L/ha to control spider mites achieved moderate to excellent control of spider mites. Reducing the application rate of Fenazaquin 20% SC from the proposed dose rate (1.0 L/ha) to 50% or 75% of that rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the proposed dose rate of 1.0 L/ha, it is recommended that Fenazaquin 20% SC is applied under optimal conditions, i.e. optimal weather conditions.

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, in exception of EPPO 1/181 (4). However, Applicant has made the appropriate explanation for carrying out the survey only in one growing season, which was accepted by Evaluator.

Applicant submitted in total 49 trials (34 – greenhouse, 11 – under plastic tunnel and 4 – open field) showing the results in research into product efficacy carried out during one growing season in melon (6 trials), strawberries (11 trials), tomato (14 trials) and ornamentals (18 trials). Those efficacy trials were performed in MED (melon, strawberries, tomato, ornamentals), Maritime (ornamentals), S-E EPPO zone (tomato) and N-E EPPO zone (tomato, ornamentals). The number of trials is sufficient and fulfil EPPO requirements for melon, tomato, strawberries and ornamentals. Trials were carried out in a glasshouse or/and under plastic tunnel, so all EPPO zones can be assessed together. For ornamentals in Maritime EPPO zone, Applicant presented only open field trials. In the opinion of Evaluator, those trials are acceptable only for Maritime EPPO zone and open-field use, not a glasshouse (at least 2-3 trials carried out in a glasshouse should be done). However, final decision is left to each cMS.

To demonstrate the effectiveness of the tested plant protection product at the recommended dose rate against spider mites application in studied crops is compare to the reference product included in the trials.

Submitted trials:

- melon – 6 trials from MED EPPO zone (SP-3, GR-3). Those trials were carried out in glasshouse. Lack of trials for Maritime, N-E and S-E EPPO zone. According to carried studies in greenhouse, results from MED EPPO zone are considered valid for all intended EPPO zones countries.
- strawberry – 11 trials from MED EPPO zone (SP-6, GR-2, IT-3). Those trials were carried out in glasshouse. Lack of trials for Maritime, N-E and S-E EPPO zone. According to carried studies in greenhouse, results from MED EPPO zone are considered valid for all in-tended EPPO zones countries.
- tomato – 6 trials from MED EPPO zone (SP), 2 trials from S-E EPPO zone (HU) and 6 trials from N-E EPPO zone (PL). Lack of trials from Maritime EPPO zone. In MED 6 trails were carried out in greenhouse (SP) and in S-E (2 trials-RO) and N-E EPPO zone (6 trials -PL) were performed under plastic tunnel. According to carried studies in greenhouse, results from MED EPPO zone are considered valid for all intended EPPO zones countries. Also results from S-E and N-E consider the efficacy of RULER under plastic tunnel.

- ornamentals – 9 trials from MED EPPO zone (SP-5, GR-4), 5 trials from N-E (PL) and 4 trials from Maritime (DE). In MED EPPO zone all trials were carried out in greenhouse. In N-E EPPO zone 2 trials were performed in greenhouse and 3 trials under plastic tunnel. In Maritime EPPO zone trials were carried out only as open-field trials. According to carried studies in greenhouse, results from MED EPPO and 2 trials from N-E zone are considered valid for all intended EPPO zones countries. Also results from N-E consider the efficacy of RULER under plastic tunnel. Results from Maritime can only support registration for use in greenhouse.

Studies pests:

- melon – *Tetranychus urticae* in Spanish and Greek trials
- strawberry – *Tetranychus urticae* in Greek, Italian and 3 Spanish trials. During three other Spanish trials *Tetranychus evansi* was studied.
- tomato – *Tetranychus urticae* was studied during Romanian, Spanish and 5 Polish trials. During one Polish study red spiders (*Tetranychus sp.*) was studied.
- ornamentals – *Tetranychus urticae* in Greek trials, Spanish and Polish trials. In field open trials from Germany – *Panonychus ulmi* was studied.

So, in accordance with the prescriptions, the applicant conducted research on suitable agrophages on strawberries, melons and tomatoes. The guideline for testing the efficacy of plant protection products against ornamental plant mites (1/168) indicates that tests should be carried out on pests of the rosewood mite family, including the strawberry mite and *Polyphagotarsonemus latus*. The object of the study should be a plant/variant susceptible to interference in greenhouse conditions, e.g. alpine violet, santpaulia, hedge or gloxinia. The extrapolation table EPPO 1/257 indicates that research on ornamental plants under greenhouse conditions should be conducted on chrysanthemum (indicator plant). Moreover, it indicates that the appropriate bioindicators here are mainly hop spinner, and in the second place the species of mites of the genus *Eotetranychus* and *Tetranychus*. In view of the above, the Applicant has also conducted tests on ornamental plants in an acceptable manner.

List of studied ornamental plants species during trials:

- MED – *Helianthus debilis* (2 GR trials), *Gerbera jameosii* (GR-1), *Mandevilla senderi* (GR-1, SP-2), *Dianthus caryophyllus* (3 Spanish trials)
- Maritime – *Callistephus chinensis* (1-DE), *Ajuga reptans* (DE-1), *Zinnia elegans* (DE-1), *Dahlia hybrids* (DE-1)
- N-E – *Dendranthema indicum* (PL-2 trials), *Fuchsia magellanica* (PL-1), *Rosa sp.* (PL-2).

According to Polish rules we can accepted following ornamental species: *Dendranthema indicum*; *Rosa sp.*, *Helianthus debilis*, *Mandevilla senderi* and *Dianthus caryophyllus*. Extrapolation results from *Dendranthema indicum* is possible according to 2-3 selectivity/phytotoxicity trials submitted on other ornamental species. Unfortunately, the following species did not meet this requirement: *Gerbera jameosii* (only one trial in which *Tarsonemidae* was not studied) and species studied in open-field trials in Germany: *Callistephus chinensis*, *Ajuga reptans*, *Zinnia elegans* and *Dahlia hybrids*. cMS should accept ornamental plants according to EPPO 1/257 and their national guidelines.

In our opinion spider mites can be accepted in GAP table. Spider mites are members of the *Acari* (mite) family *Tetranychidae*, which includes about 1,200 species. The applicant conducted research on only one mite family – *Tetranychidae* (*Tetranychus sp.* – red spiders, *Tetranychus urticae*, *Tetranychus evansi* and *Panonychus ulmi* were studied during trials). Such a general entry in the GAP table is indicated, as it applies not only to Poland but also to the Member States to which the final decision on the acceptance of applications is left. The narrowing of the application took place at national level in the label.

In Polish label we can accepted spider mites, however we proposed following entry: *Tetranychus urticae* (przędziorek chmielowiec) and other pests from the family of the *Tetranychidae*. cMS should decide which entries on the label can be accept.

RULER (SHA 9700 A) applied at the proposed dose rate of 1.0 L/ha provides a very high level of control of spider mites, in all EPPO zones. Compared to the fenazaquin reference product, the efficacy obtained with Fenazaquin 20% SC is comparable against all pest species

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.

It is recommended to authorize the product Ruler (SHA 9700 A) in the extent of the authorization of the reference product (a.s. fenazaquin) at the equivalent dose rate.

Conclusion: Based on the results of 49 field efficacy trials carried out in 2017, the following can be concluded for the intended use to control spider mites with Fenazaquin 20% SC applied at the rate of 1.0 L/ha in melon, strawberry, tomato and ornamentals:

- Fenazaquin 20% SC applied at the proposed dose rate of 1.0 L/ha provides a very high level of control of spider mites, in all EPPO zones.
- Compared to the fenazaquin reference product, the efficacy obtained with Fenazaquin 20% SC is comparable against all pest species.
- The trial results are considered valid for all intended EPPO zones countries.

Fenazaquin 20% SC applied is suitable for the control of spider mites in melon, strawberry, tomato and ornamentals.

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

Fenazaquin 20% SC contains fenazaquin.

Fenazaquin belongs to the quinonazole class of chemicals and is a pesticide intended to control mites and insects (especially whiteflies). Its route of exposure is ingestion and dermal, and its mode of action is the disruption of the biochemistry of insect mitochondria, inhibiting mitochondrial electron transport at Site 1, similar to the Pyridazinones.

The quinazolines offer a unique chemical configuration, consists only of one miticide, fenazaquin.

As the unmodified use pattern is considered unacceptable a number of modifiers are proposed which are entirely in accordance with the general recommendations.

- Use in alternation with insecticides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Fenazaquin 20% SC should only be applied when the pest population reaches the recommended threshold in the region/crop.
- Use other measures such as crop rotation, good agronomic practice

The Registration of Fenazaquin 20% SC is endorsed.

The two-spotted spider mite, *Tetranychus urticae* Koch (*Acari: Tetranychidae*) is an important agricultural pest in a wide range of outdoor and protected crops worldwide. Fenazaquin is mitochondrial electron transport inhibition (METI)-acaricide and its extensive and frequent use for control of this mite has facilitated resistance development.

Resistance mechanisms to fenazaquin were surveyed in Iranian populations of the two-spotted spider mite, *Tetranychus urticae* Koch (Mahdavi Moghadam et al. 2012).

Tetranychus urticae is known to have a high tendency to develop resistance to acaricides among the mite species. It has been heavily exposed to acaricides among the acari and had developed resistance to dicofol, amitraz, organotins, propargite, pyrethroids, fenbutatin oxide, hexythiazox, clofentezine, abamectin and METI (Mitochondrial Electron Transport Inhibitors) acaricides fenazaquin, fenpyroximate, pyridaben and tebufenpyrad around the globe.

An EPPO conform analysis of the resistance risk was carried out. Evaluator accepted strategy against

resistance developing.

The resistance management for fenazaquin is coordinated by IRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

The proposed resistance risk management strategy is acceptable. Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

The crop safety of Fenazaquin 20% SC was assessed in melon, strawberry, tomato and ornamentals in 48 efficacy trials where Fenazaquin 20% SC was applied at 0.5 L/ha, 0.75 L/ha and 1.0 L/ha.

These trials were conducted in the Mediterranean (30, i.e. Spain (18), Greece (9) and Italy (3)), the South-East (1, i.e. Romania (1)), North-east (11, i.e. Poland (11)) and the Maritime EPPO zone (4, i.e. Germany (4)) in 2017 and 2018, to evaluate the crop safety of Fenazaquin 20% SC in melon, strawberry, tomato and ornamentals.

Studies from the four climatic zones are used in this document to support the registration of Fenazaquin 20% SC. However, since all the studies are performed in a glasshouse, all of them have been grouped in the same tables, without specifying the climatic zone where they were performed.

Fenazaquin 20% SC applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on melon, strawberry, tomato nor ornamentals when applied as recommended.

Effects on yield and quality

No studies of yield and quality of the crops had been recorded.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on treated plants or plant products to be used for propagations

Special tests to investigate this purpose are not required.

The product complies with the Uniform Principles.

Impact on other plants including adjacent crops

During the conduct of efficacy trials, no observations about negative or positive effects on other plants or neighbouring crops were reported. Furthermore, Fenazaquin is not phytotoxic.

The data presented within this Annex Point justifies the recommendation of no restrictions on adjacent crops regarding the application of Fenazaquin 20% SC.

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 and crop safety trial conducted.

3.4 Methods of analysis (Part B, Section 5)

Analytical method to determine active substance: fenazaquin has been developed.

Validation criteria for acceptance of the analytical method were based on SANCO /3030/99 rev 4, be-

cause of the starting experimental phase on April 2019.

Analytical method for Fenazaquin 20% SC SC in food, feed of plant and animal origin, water , soil and air are available.

3.4.1 Analytical method for the formulation

3.4.2 Analytical methods for residues

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

Noticed data gaps are:

- none

Commodity/crop	Supported/ Not supported
Melon	Supported
Ornamentals	Supported
Tomato	Supported
Strawberry	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Fenazaquin 20% SC were not evaluated as part of the EU review of Fenazaquin. All relevant data were provided and are considered adequate. The assessment of all acute toxicological properties of Fenazaquin 20% SC was derived from the calculation method based on the classification of the active compound and co-formulants.

Classification: H302 Harmful if swallowed.

[EUH208] Contains 1,2-benzisothiazol-3(2H)-one (2634-33-5). May produce an allergic reaction

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Skin irritation, RHE (OECD 439 and 431)	Non-irritant	Yes	None	B. K. Indrani, 2019, report G13250

3.5.2 Operator exposure

Operator exposure to Fenazaquin 20% SC was not evaluated as part of the EU review of Fenazaquin for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure have been undertaken for Fena-

zaquin using Dutch greenhouse model.

Operator exposure in glasshouse applications to tomato, melon, strawberry and ornamentals is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) and respiratory protections during mixing/loading and application

Implication for labelling: P280: Wear protective gloves, protective clothing, face protection.

3.5.3 Worker exposure

Worker exposure to Fenazaquin 20% SC was not evaluated as part of the EU review of Fenazaquin for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential worker exposure have been undertaken for Fenazaquin using EFSA AOEM Model).

Conclusions:

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated tomato, melon and strawberry with suitable protective clothing (gloves).

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves), for maintenance activities when for re-entering ornamentals treated with RULER a time period of 4 days after application is respected.

Implication for labelling: P280: Wear protective gloves

3.5.4 Bystander and resident exposure

For use in greenhouse, the risk for residents and bystanders is considered as negligible.

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

3.6.1 Residues

Storage stability

Fenazaquin residues in high acid and in high water content are stable for at least 12 months. TBPE is stable in grapes, raisins and orange pulp for at least 18 months, and in orange peel for at least 12 months under frozen conditions. 4-OHQ residues in fortified matrices of grapes, raisins, and citrus (orange peel and pulp) are stable under frozen conditions for at least 18 months.

Additional information on TBPE stability in the high water content matrix is required.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion of the active substance are sufficient to describe the behavior of the formulated product, and no further studies are required.

Plant residue definition for monitoring: Fenazaquin (Regulation No. 2019/50)

Plant residue definition for risk assessment (EFSA Journal 2020;18(1):5955):

Fruits: 1) fenazaquin and 2) TBPE

Leafy vegetables(tentative): 1) fenazaquin and 2) TBPE

Magnitude of residues in plants

Melon, Tomato, Strawberry

No new data are submitted in the framework of this application.

Residue studies are on-going.

Uses are not accepted

Residue trials on melons, tomato and strawberry are required.

Ornamentals

Uses are accepted

Magnitude of residues in livestock

Uses on melon, ornamentals, tomato and strawberry are not edible for European livestock, therefore, dietary burden calculations are not necessary.

Processing studies

No new data were submitted in the framework of this application.

Additional information on processed commodities to cover proposed uses is required.

Magnitude of residues in representative succeeding crops

Not relevant as the intended uses consider only glasshouses.

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.

3.6.2 Consumer exposure

Consumer risk assessment for fenazaquin and TBPE is required..

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

Concentration of Fenazaquin in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentration (PEC values) in soil, surface water, sediments and ground water are provided.

Intended use pattern of Fenazaquin 20% SC

Crop	Application rate (kg a.s./ha)	Application method	Max. number of applications	Min. application interval	Application timing
Melon	Fenazaquin: 0.2	Foliar spray	1	-	BBCH 70-79
Ornamentals	Fenazaquin: 0.2	Foliar spray	2	7	BBCH 35-67
Tomato	Fenazaquin: 0.2	Foliar spray	2	7	BBCH 51-89
Strawberry	Fenazaquin: 0.2	Foliar spray	2	7	BBCH 15-91

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

PEC_{soil} calculations have been conducted with Fenazaquin and its relevant metabolites using the EU agreed endpoints (EFSA Journal 2013;11(4):3166).

Maximum PEC_{soil} for Fenazaquin was 0.366 mg/kg, 0.035 mg/kg for 2-oxy-fenazaquin, 0.033 mg/kg for 4-OHQ and 0.019 mg/kg for TBPE.

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

PEC_{gw} calculations have been realised for Fenazaquin and its relevant metabolites 2-oxy-fenazaquin, 4-OHQ and TBPE by FOCUS PELMO v5.5.3 and PEARL v4.4.4 programs.

PEC_{gw} values were all below 0.001 µg/L for Fenazaquin and its metabolites.

Due to the very low concentrations PEC_{gw} obtained as a result of calculations and the proposed use plant protection product in greenhouse, no additional calculations for scenarios important for Poland for surrogate plants are necessary.

No risk of groundwater contamination with fenazaquin and its metabolites are expected when the product Ruler 10 EC is applied in permanent greenhouses.

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

The PEC_{sw/sed} of Fenazaquin and its relevant metabolites, 4-OHQ and TBPE have been assessed with the model GEM v3.3.2 for soilless crops due to our GAP is only for greenhouse permanent crops. However, no accepted calculations PEC_{sw} assessed by GEM v3.3.2 in Poland.

Due to this the evaluator has been calculated PEC_{sw} for applications in permanent glasshouses.

Since no FOCUS scenario currently exists for greenhouse uses, an emission to surface water of 0.1 % of applied amount was assumed according to the recommendations of the PL national authorities.

The calculations made by the evaluator taking into account 0.1% emissions from the greenhouse.

An emission to surface water of 0.1 % of applied amount (0.20 kg ai/ha) was assumed to a standard water body of 100 m length, 1 m width and 30 cm depth, resulting in a water volume of 30.000 L:

$$[\{200 \text{ g} \times 0.001 \text{ (drift)}\} : 100 \text{ (m}^2\text{)}] : 30000 \text{ (L)} = 6.66 \times 10^{-8} \text{ g} \\ (= 0.066 \text{ µg/L}).$$

This results in an initial PEC_{sw} of 0.066 µg a.s./L for a standard water body of 30 cm depth.

Property	Fenazaquin	4-(2-(4-(1,1-dimethyl ethanoic acid) phenyl) ethoxyl) quinazoline	2-Oxy-fenazaquin	4-OHQ (4-hydroxy-quinazoline)	TBPE (2-(4-tert-Butylphenyl) ethanol)
Molar mass [g/mol]	306.4	336.39	322.4	146.15	178.28
Max occurrence in water/sediment study [%]	-	11.5	21.2	79.3	82.2
PEC _{sw} µg/L	0.066	0.0084	0.007	0.025	0.038

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

The vapour pressure at 20°C of the active substance Fenazaquin is between $< 10^{-5}$ Pa. Hence the active substance Fenazaquin is regarded as non-volatile. Therefore, exposure of adjacent surface waters and

terrestrial ecosystems by the active substance Fenazaquin due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

- Birds

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “*the acute oral toxicity of the plant protection product shall be investigated if toxicity cannot be predicted on the basis of the data for the active substance, or where results from mammalian testing give evidence of higher toxicity of the plant protection product compared to the active substance, unless the applicant shows that it is not likely that birds are exposed to the plant protection product itself*” and “*possible risks to birds shall be investigated if the toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance, except, for example, where the plant protection product is used in enclosed spaces or for wound-healing treatments where birds will experience neither direct nor secondary exposure.*”

The detailed risk assessment is not required due to the negligible exposure (see above). Moreover, the EFSA Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438 does not propose scenarios relevant to the indoor uses.

According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 20% SC presents no unacceptable acute and long-term risk to birds according to the intended uses.

- Mammals

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “*possible risks to vertebrate species other than birds shall be investigated except when the test substance is included in plant protection products used, for example, in enclosed spaces and wound-healing treatments where vertebrate species other than birds will experience neither direct nor secondary exposure*”.

The detailed risk assessment is not required due to the negligible exposure. Moreover, the EFSA Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438 does not propose scenarios relevant to the indoor uses.

According to the GAP, the intended uses are control of spider mites in permanent greenhouses, therefore negligible exposure of birds is considered. Fenazaquin 20% SC presents no unacceptable acute and long-term risk to mammals according to the intended uses.

3.8.2 Effects on aquatic species

For the intended uses on melon, tomato, strawberry and ornamentals, calculated PEC/RAC ratios did not indicate an unacceptable risk for the most sensitive group of aquatic organisms.

Metabolites of Fenazaquin: for all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

3.8.3 Effects on bees

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “*the possible effects on bees shall be investigated except where the plant protection product is for exclusive use in situations where bees are not likely to be exposed such as: [...] (f) use in greenhouses without bees as pollinators*”.

According to the EFSA GD, 2013 (EFSA Journal 2013;11(7):3295), is not mandatory: “*examples when*

exposure of bees [/ bumble bees/ solitary bees] is negligible: food storage in enclosed spaces, wound sealing and healing treatments and use in glasshouses without bumble bees as pollinators”.

According to the GAP, the product is to be used only in glasshouse. The intended uses covers self- or hand- pollinating tomato, self- pollinating strawberries, where presence of pollinating insects is not required. The pollination is not desired and avoided in case of flowering ornamentals and not relevant in case of non-flowering ornamentals. Melon is pollinated and attractive to bees, however in permanent greenhouses the hand- pollination is performed.

Since the product is to be used only in glasshouse and the intended uses do not require presence of pollinating insects, the risk assessment is low due to the negligible exposure.

In case when bumble bees are used as a pollinators the following phrase should be applied

SPe8 Dangerous to bees. Do not use where bumble bees are pollinators.

3.8.4 Effects on other arthropod species other than bees

The only non target arthropod species are these used as biological control agents. Therefore, integrated pest management (IPM) is not recommended during the production cycle when fenazaquin was applied.

The exposure to NTAs invading the greenhouse (e.g. through the open widows) is not a point of concern in the available guidance documents on the safety of chemical pesticides, but may be considered as non-relevant when crossreading with the OECD Guidance to the environmental safety evaluation of microbial biocontrol agents (OECD Environment, Safety and Health Publications, Series on Pesticides, No 67, 2012, ENV/JM/MONO/2012(1))

According to the EFSA PPR Panel (EFSA Journal 2015;13(2): 3996), “*in some cases off-field exposure is considered to be negligible and not further assessed, e.g. in the case of rodenticides, substances used for wound protection or in the case of substances used in stored products or in greenhouses*”.

The in-field and off-field HQ values were not calculated for the product Fenazaquin 20% SC due to the negligible exposure following application according to the proposed use pattern .

However, integrated pest management (IPM) with the introduction of parasitoid/ predatory arthropods cannot be conducted during the production season.

3.8.5 Effects on soil organisms

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “*the possible impact on earthworms shall be reported unless the applicant shows that it is not likely that earthworms are exposed, directly or indirectly*”.

The emission of pesticides and their metabolites to soil is to be assessed “*for all structures that can be considered non-permanent*” (EFSA Journal 2014;12(3):3615).

For permanent structures a risk assessment is only necessary for persistent substances (DT₉₀ >1 year, according to the Uniform principles (Regulation (EU) no 546/2011), which is not relevant for fenazaquin (DT_{90lab} 184.3- 402.4 days (not normalized), geomean DT_{90lab} 256.7 days).

The intended uses in the permanent glasshouses, where additionally artificial or natural substrates (mineral wool, coconut fibres) are used rather than soil, do not require a specific risk assessment due to the negligible risk.

Since the intended uses do not cause release of the product to the environment it is concluded that active substance Fenazaquin does not pose an acute and long-term to earthworms and other soil macro- and mesofauna when applied according to the proposed uses and rates.

3.8.6 Effects on non-target terrestrial plants

According to the Commission Regulation (EU) No 284/2013 of 1 March 2013, “*data are not required, where exposure is negligible, for example in the case of rodenticides, active substances used for wound protection or seed treatment, or in the case of active substances used on stored products or in glass-houses where exposure is precluded*”.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant due to the negligible exposure.

Effect on the sewage treatment: Fenazaquin has no effect on respiration inhibition up at least 100 mg a.s./L.

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites 2-oxy-fenazaquin, 4-OHQ and TBPE are predicted to occur in groundwater at concentrations below 0.001 µg/L (see dRR Part B8, Chapter 8.9). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

Not relevant, the active substance Fenazaquin is not 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

Sekcja Ekotoksykologii: Środek nie może być stosowany w programie IPM w szklarniach.

Sekcja Toksykologii: Środek został oceniony pozytywnie na wszystkie proponowane uprawy w szklarniach (operator i pracownik sprawdzający jakość zabiegu)

Sekcja pozostałości: Zgoda tylko na rośliny ozdobne

Załącznik do zezwolenia MRiRW nr R- / z dnia r.

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina nº 3, 12th Floor, 30006 Murcia, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, 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. (22) 886 9328 lub (17) 240 13 07, e-mail: eu.sales@shardaintl.com


RULER

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

fenazachina (związek z grupy chinazolin) - **200 g/l (18,28 %)**

Zezwolenie MRiRW nr R- z dnia r.

	
Uwaga	
H302 H304 H410	Działa szkodliwie po połknięciu. Połykanie i dostanie się przez drogi oddechowe może grozić śmiercią. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208 EUH401	Zawiera 1,2-benzoizotiazolin-3-on. Może powodować wystąpienie reakcji alergicznej. W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.

P273 P391 P501	Unikać uwolnienia do środowiska. Zebrać wyciek Zawartość/pojemnik usuwać do specjalny punkt zbioru niebezpiecznych lub specjalnych odpadów, zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i/lub międzynarodowymi
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OPIS DZIAŁANIA

Środek przedziorkobójczy w formie koncentratu stężonej zawiesiny do rozcieńczania wodą. Środek o działaniu kontaktowym, przeznaczony do zwalczania przedziorków. Zwalcza wszystkie stadia rozwojowe przedziorków. Na roślinie działa powierzchniowo.

Środek do stosowania wyłącznie pod osłonami typu szklarnia, tj. w szklarniach izolowanych od środowiska i zabezpieczających przed niekontrolowanym uwalnianiem się środków ochrony roślin do środowiska.

Środek przeznaczony do stosowania przy użyciu opryskiwaczy ciśnieniowych przystosowanych do pracy w szklarni (ręczne opryskiwacze hydrauliczne, opryskiwacze plecakowe, taczkowe lub szynowe).

STOSOWANIE ŚRODKA

Rośliny ozdobne

~~Przedziorkowate~~ *Przedziorek chmielowiec i inne szkodniki z rodziny przedziorkowatych*

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, stosować w fazie BBCH 35-67

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 1000 l/ha

Truskawka

~~przedziorkowate~~

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, stosować w fazie BBCH 15-91

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 1000 l/ha

Pomidor

~~przedziorkowate~~

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, stosować w fazie BBCH 51-89

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 1000 l/ha

Melon

przędziorkowate

Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1 l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, stosować w fazie BBCH 70-79

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 1000 l/ha

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ:

Środek stosować przemienne z innym środkami przedziorkobójczymi zawierającymi substancje czynne o odmiennym mechanizmie działania.

Należy unikać stosowania środka w rejonach, gdzie notowana jest stabilna odporność szkodnika na substancję czynną środka lub inne substancje czynne o takim samym mechanizmie działania

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową i uzupełnić wodą do potrzebnej ilości.

Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz mechanicznie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu oraz z wodą użytą do mycia aparatury 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.

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:

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

Stosować rękawice ochronne/odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie 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.

SP8 Niebezpieczny dla pszczoł. Nie stosować w szklarniach w czasie, kiedy są wprowadzane owady zapylające.

OKRES OD ZASTOSOWANIA ŚRODKA DO DNIA, W KTÓRYM NA OBSZAR, NA KTÓRYM ZASTOSOWANO ŚRODEK MOGĄ WEJŚĆ LUDZIE ORAZ ZOSTAĆ WPROWADZONE ZWIERZĘTA:

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin

Nie dotyczy.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA DO DNIA ZBIORU ROŚLINY UPRAWNEJ (okres karencji):

~~Pomidor, truskawka – 3 dni~~

~~Melon – 7 dni~~

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY DO DNIA, W KTÓRYM MOŻNA SIAĆ LUB SADZIĆ ROŚLINY UPRAWIANE NASTĘPCZO:

Nie dotyczy.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY PRZEZNACZONE NA PASZĘ DO DNIA, W KTÓRYM ZWIERZĘTA MOGĄ BYĆ KARMIONE TYMI ROŚLINAMI (okres karencji dla pasz):

Nie dotyczy.

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 lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradzić się sprzedawcy środków ochrony roślin.

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

No Letter of Access to protected data is required.

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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.1	Deepthi Prakash	2018	Determination of explosive properties of Fenazaquin 20% SC Eurofins report No. G 14027 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.3.1	Deepthi Prakash	2018	Determination of flash point of Fenazaquin 20% SC Eurofins report No. G14029 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.3.3	Deepthi Prakash	2019	Determination of auto ignition temperature of Fenazaquin 20% SC Eurofins report No. G14034 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.5.1	Deepthi Prakash	2018	Determination of viscosity of Fenazaquin 20% SC Eurofins report No. G14030 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.5.2	Deepthi Prakash	2018	Determination of surface tension of aqueous solution of Fenazaquin 20% SC Eurofins report No. G 14031 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 2.6.2	Deepthi Prakash	2018	Determination of density and relative density of Fenazaquin 250% SC Eurofin repor tNo. G14032 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 6.0-	Anonymous	2019	Biological Assessment Dossier: Fenazaquin 20% SC – EU	N	Y	Data/study report never submitted before to 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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
001			Interzonal Sharda Cropchem España -, - Unpublished				
KCP 7.1.4-01	B. K. Indrani	2019	Fenazaquin 20% SC: <i>in vitro</i> skin irritation: reconstructed human epidermis test method Eurofins report No. G13250 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 7.1.4-02			On-going: Fenazaquin 20% SC: <i>in vitro</i> corrosion: reconstructed human epidermis (RHE) test method Eurofins report No. G13249 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited
KCP 10.3.1.1.1	Likith N.G	2019	Fenazaquin 200 g/L SC: acute oral toxicity test in honey bees Eurofins report No. G13474 GLP, unpublished	N	Y	Data/study report never submitted before to 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	Vertebrate 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

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